Manufactured Crisis:

By Discontinuing Asthma Inhaler, GSK Profited While Children Suffered

Ranking Member Maggie Hassan | Minority Report

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Executive Summary

GlaxoSmithKline (GSK) discontinued the Flovent HFA inhaler — formerly one of the most prescribed controller inhalers for young children with asthma and one of the only inhalers suitable for these patients because of its effectiveness, safety, and ease of use — in January 2024.[1] GSK had jacked up prices for Flovent HFA for years, and because of this, would have owed millions to Medicaid starting in 2024. GSK used a loophole to evade these penalties and continue reaping profits: GSK entered an exclusive agreement with Prasco Laboratories (Prasco) to launch a copycat version of Flovent HFA — the only available identical alternative to the medication at the time. As this report details, GSK's actions led to life-threatening medical challenges and cost and access issues for families across the United States. This month, following years of scrutiny from Ranking Member Hassan regarding GSK's actions, FDA approved the first true generic version of Flovent HFA, which will finally enable more children to get the asthma treatment that they need.

In January 2024, GSK's discontinuation of Flovent HFA in favor of a new "authorized generic" version created significant hardships for many families who could not afford the new product. Previous rebates and discounts from GSK for Flovent HFA significantly reduced its list price and out-of-pocket costs for patients.[2] GSK and Prasco, however, have not offered these same discounts and rebates for the authorized generic — meaning that in practice, the authorized generic is more costly than Flovent HFA.[3] This greater expense has led major insurers and pharmacy benefit managers (PBMs) to delay or deny coverage of the authorized generic, which has limited patient access.[4] According to a study published in October 2024, patients who had been prescribed fluticasone propionate — the active ingredient in Flovent HFA — saw a 17.5 percent increase in asthma-related hospitalizations in the three months after the discontinuation of Flovent products and a 24.1 percent increase in the next three months, compared to the average rates for the corresponding quarters in 2022 and 2023.[5]

Discontinuing the Flovent HFA inhaler also enabled GSK to rake in profits and evade payments that it would have owed Medicaid in 2024 and ensuing years for raising prices for the inhaler higher than the rate of inflation, as established under the American Rescue Plan Act of 2021.[6] As of January 2024, this law lifted the cap on rebates that Medicaid could collect from pharmaceutical companies that raise drug prices significantly over time.[7] These rebates are

calculated as the difference between the current price of a drug and the price of the drug at its launch date as adjusted for inflation over time.[8] According to one study, because of GSK's price increases for Flovent HFA — the price increased by nearly 50 percent between 2014 and 2023 — the company could have owed an estimated $367.6 million in rebates to Medicaid in 2024 alone if not for the discontinuation of the drug.[9] (For comparison, between December 2014 and December 2023, prices in general rose nearly 31 percent.[10]) Instead of receiving these rebates, Medicaid spent on net an estimated $551.8 million on the authorized generic version of Flovent HFA in 2024.[11] For 2024, GSK reported total sales of approximately $40.1 billion dollars.[12] GSK also appears to continue to receive significant revenue from the authorized generic version under its agreement with Prasco.

Given the immediate consequences of the discontinuation for patients, as well as GSK's apparent maneuver to avoid rebates it owed to the federal government, Ranking Member Hassan requested in May 2024 that GSK restore Flovent HFA to the market and work with its business partner Prasco to lower the price for the copycat version.[13] After GSK declined this request, and amid ongoing inhaler access challenges as described by doctors and families, Ranking Member Hassan launched a new investigation, issuing requests to GSK and Prasco in June 2025 that sought detailed information on the ongoing contractual financial relationship between these companies, revenue that the parties received through this relationship, and analyses of the market for the branded and authorized generic drugs, among other materials.[14]

Both GSK and Prasco provided limited written responses on July 31, 2025, and GSK provided a briefing to staff for Ranking Member Hassan on December 9, 2025. GSK specifically acknowledged to Subcommittee staff the role of the American Rescue Plan Act in its decision to discontinue Flovent products. The company also touted that it prioritized ongoing patient access to the authorized generic and that it was "encouraged by the broad coverage and affordability of the [authorized generic]."[15] However, the company did acknowledge that only around half of commercially-insured patients receive coverage for the authorized generic without prior authorization, compared to the roughly 75 percent of commercially-insured patients who had received coverage for Flovent prior to the discontinuation.[16] Notably, GSK and Prasco both declined to produce materials that would have clarified their contractual financial relationship regarding the authorized generic version of Flovent HFA and related revenue the companies have received.

To evaluate the impact of GSK's actions, staff for Ranking Member Hassan also obtained data on Flovent HFA, the authorized generic version, and other similar inhaler products from three major pharmacy benefit managers (PBMs). The information that these PBMs provided, on the condition of anonymity, showed significant declines in patient use of inhaled corticosteroids — the drug category that includes Flovent, the authorized generic, and other inhalers — after the discontinuation of Flovent products.[17] For example:

- Data from one PBM showed inhaled corticosteroid use by beneficiaries dropped *almost 20 percent* from the first half of 2023 through the first half of 2025.[18]
- Data from another PBM also showed that the rate of chronic inhaler users who discontinued asthma therapy altogether *more than doubled* from 8.6 percent in 2023 to 19 percent in 2024.[19]

Information that the three PBMs provided to the Subcommittee also showed significant rising costs for health plans covering the authorized generic version of Flovent HFA. For instance, one PBM reported that the net cost to plan sponsors for an average beneficiary using the authorized generic versions of Flovent was nearly *five times higher* than the cost for the branded Flovent products, comparing the first half of 2024 to the first half of 2023.[20]

Staff for Ranking Member Hassan also obtained survey results regarding the discontinuation of Flovent products that Massachusetts physicians, including Dr. Ashley L. Saint-Fleur of Boston Children's Hospital, received from pediatric clinicians and parents (or other caregivers) for children who had used Flovent. These results are published for the first time in the report below. In interpreting results from their initial survey of 43 parents or other caregivers, the physicians concluded that a subset of families "experienced significant challenges, including higher costs, worsening symptoms, and increased acute healthcare utilization for asthma exacerbations," including ER visits and hospitalizations.[21] For example:

- More than 78 percent of parents reported that their child switched to another medication following the discontinuation of Flovent, and "[r]eported impacts included increased out-of-pocket costs (27.3%), worsening day-to-day symptoms (18.2%), missed school days (18.2%), and greater asthma flare-ups (9.1%)."[22]
- At the time of the survey in the second half of 2025, around 12 percent of parents "continued to face barriers such as cost, insurance coverage, or pharmacy availability."[23]
- Around 18 percent of parents also reported one or more urgent care or ER visits in the past year, and around 12 percent reported one or more hospitalizations in the past year.[24]

In response to these surveys, parents also recounted significant, ongoing medical and financial disruptions associated with the Flovent discontinuation:

- "It has had a big impact on my child's asthma control, especially in cold [and] flu season. No other medications work as well as Flovent for control. It has impacted my child's life, she has missed many days of school because of it and her grades suffered and it caused her to have anxiety attacks about school."[25]

- "This was a major life disruption which still impacts my family today. My child's quality of life hasn't been the same since switching to the new medication. This happened abruptly with no real notice and left my family scrambling. Appalling move by the manufacturer."[26]
- "It was terrible. Originally my child was too young…for any other medication than Flovent. We paid out of pocket, $300 a month until she was old enough for Symbicort. We started Symbicort earlier than really indicated due to this issue."[27]

According to the results of the clinician survey, "[p]ediatric clinicians who care for children with asthma reported significant disruptions to patient care following the discontinuation of brand-name Flovent."[28] These disruptions provide further evidence of the negative impacts of the discontinuation on patients and their families. For example:

- More than 90 percent of respondents stated that the discontinuation of Flovent had a moderate (37 percent) or severe impact (56 percent) on their practices.[29]
- In terms of the most frequent challenges that clinicians experienced "often" or "always," 80 percent reported pharmacy shortages, and 77 percent reported difficulty in finding an age-appropriate alternative.[30]

The data the Subcommittee obtained from PBMs and from surveys of clinicians and parents illustrates that GSK's discontinuation of Flovent products caused significant medical and financial harm to patients and made it more difficult for clinicians to provide critical health care. As a result, in seeking to evade future payments that it would have owed to Medicaid for raising prices higher than the rate of inflation, GSK appears to have jeopardized the same "patient access to needed medicines" that it claims to have provided.[31] Indeed, as this report shows, parents have faced challenges getting life-saving asthma care for their children over the last two years as GSK has continued to avoid the Medicaid payments that it owed and reap additional financial benefits from the authorized generic. Encouragingly, following years of pressure from Ranking Member Hassan, a true generic alternative will be available soon. Without further action from Congress, however, other companies could also attempt to use "authorized generics" to evade Medicaid rebate payments as GSK did, resulting in similar health and cost challenges for patients.

FLOVENT DISCONTINUATION BY THE NUMBERS

- **$367.6 million**: The estimated amount GSK could have owed in rebates to Medicaid in 2024 alone if not for the discontinuation of Flovent HFA.[32]
- **$551.8 million**: The estimated amount, on net, that Medicaid spent on the authorized generic version of Flovent HFA in 2024.[33]
- **20 percent**: The approximate decline in inhaled corticosteroid use by beneficiaries at one PBM from the first half of 2023 through the first half of 2025.[34]
- **36 percent:** The percentage of parents who reported difficulty in paying for alternative medication for their children after the discontinuation, according to a recent survey.[35]
- **93 percent:** The percentage of clinicians who reported that the discontinuation of Flovent had a moderate (37 percent) or severe impact (56 percent) on their clinical practice, according to a recent survey.[36]

KEY FLOVENT DATES

- **April 2004:** Flovent HFA receives U.S. Food and Drug Administration (FDA) approval[37]
- **March 2021:** President Biden signs the American Rescue Plan Act into law[38]
- **May 2022:** Introduction of Prasco's authorized generic for Flovent HFA[39]
- **June 2023:** GSK notifies FDA regarding the discontinuation of branded Flovent products[40]
- **January 2024:** Provisions in the American Rescue Plan Act ending the cap on rebates in the Medicaid Drug Rebate Program go into effect[41]
- **January 2024:** Discontinuation of branded Flovent products[42]
- **May 2024:** Ranking Member Hassan sends her first request to GSK[43]
- **June 2025:** Ranking Member Hassan sends updated requests to GSK and requests to Prasco[44]
- **March 2026:** FDA approves the first true generic of Flovent HFA.[45]

Introduction, Background, and Methodology

In January 2024, GlaxoSmithKline (GSK) discontinued the Flovent HFA inhaler — formerly one of the most prescribed controller inhalers for young children with asthma — leading to life-threatening medical challenges and cost and access issues for families across the United States.[46] Importantly, Flovent HFA was one of the only inhaled corticosteroids (ICS) suitable for young children because of its effectiveness, safety, and ease of use.[47] In a statement to the Asthma and Allergy Foundation of America, however, GSK stated that it "expect[ed] minimal disruption for patients" due to the discontinuation.[48] Previously, GSK partnered with Prasco Laboratories (Prasco) to distribute an authorized generic version of Flovent HFA, which launched in May 2022.[49]

Nearly four years later, following years of scrutiny from Ranking Member Hassan regarding GSK's actions, FDA approved the first true generic version of Flovent HFA, manufactured by Glenmark Specialty SA, in March 2026. For decades, GSK tweaked its product and gained new patents, thereby ensuring that no low-cost generic competition could receive FDA approval and reach patients.[50] Over the last decade, a generic company has tried and failed to compete with GSK twice.[51] As a result of the patent wall that it built around its Flovent products, GSK enjoyed more than 30 years of uninterrupted exclusivity for its inhaler.[52]

This report details the serious consequences for parents and families that occurred between the discontinuation of Flovent HFA in January 2024 and the approval of the generic version in March 2026. Many families in New Hampshire and across the country could not afford the new authorized generic product due to significant insurance coverage barriers. Notably, according to an April 2025 study published in a leading medical journal, the withdrawal of Flovent HFA "was associated with increased discontinuation of inhaled steroid therapy among children using this drug," especially among young children and Medicaid patients.[53] Although GSK has noted that the "wholesale acquisition cost for the [authorized generic] represents a 35 percent reduction from the branded Flovent,"[54] previous rebates and discounts for Flovent HFA significantly reduced its list price and out-of-pocket costs for patients.[55] 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.[56] In fact, new prior authorization requirements from PBMs and a lack of coverage from large insurers has limited patient access to the authorized generic.[57] Compounding these issues, the caps on out-of-pocket costs for patients that GSK imposed in 2024 did not apply to the authorized generic version of Flovent.[58]

Major PBMs have been clear that they based their coverage decisions on concerns regarding the cost of the authorized generic. 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 for its clients than a brand name drug.[59] 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."[60]

In addition, families have faced substantial obstacles when seeking alternatives to the Flovent authorized generic. As the New England Pediatric Pulmonary Consortium has explained, "Flovent HAD been THE #1 go-to preventive inhaler for asthma, prescribed by pediatric providers to millions of children for decades."[61] In addition, certain alternative inhalers may not effectively treat eosinophilic esophagitis, a chronic allergic inflammatory condition for which Flovent HFA was the standard of care.[62] Even if patients could benefit from alternatives, shortages and coverage issues have limited access. One common alternative, Asmanex HFA, experienced substantial shortages throughout 2024, and Alvesco, an alternative only available to older children, has lacked broad insurance coverage.[63]

After the discontinuation of Flovent, asthma-related hospitalizations and ICU admissions for patients also significantly increased. According to a study published in October 2024, patients that had been prescribed fluticasone propionate — the active ingredient in Flovent HFA — saw a 17.5 percent increase in asthma-related hospitalizations in the three months after the discontinuation of Flovent products and a 24.1 percent increase in the next three months, compared to the average rates for the corresponding quarters in 2022 and 2023.[64] Asthma-related intensive care unit admission rates increased by similar amounts, with dramatic increases in some areas.[65] For example, in the Philadelphia region, 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.[66]

GSK's decision to discontinue Flovent HFA has also had far-reaching financial consequences for patients, the health care system, and the government. In taking this action, GSK appears to have evaded payments in 2024 and beyond that the company would have owed Medicaid under the American Rescue Plan Act of 2021 (ARPA) for raising prices faster than the rate of inflation.[67] These inflation-linked rebates are calculated as the difference between the current price of a drug and the price of the drug at its launch date as adjusted for inflation over time.[68] Effective January 1, 2024, ARPA lifted caps that had previously limited how much drugmakers had to pay in total rebates.[69] This change had significant implications for drugs with price increases much faster than inflation over time.[70] According to one study, because of GSK's price increases for Flovent HFA — the price increased by nearly 50 percent between 2014 and 2023, for example — the company could have owed an estimated $367.6 million in rebates to Medicaid in 2024 alone if not for the discontinuation of the drug.[71] (For comparison, between December 2014 and December 2023, prices in general rose nearly 31 percent.[72]) Instead of receiving these rebates, Medicaid spent on net an estimated $551.8 million on the authorized generic version of Flovent HFA in 2024.[73] For 2024, GSK reported total sales of approximately $40.1 billion dollars.[74] GSK also appears to have continued to receive significant revenue from the authorized generic version under its agreement with Prasco. In its 2024 annual report, for example, GSK stated that

although Medicaid changes impacted sales performance due, in part, to "the decision to discontinue branded Flovent," this impact "has been fully offset by the increased use of authorised generic versions of [another drug] and Flovent."[75]

At the patient level, physicians have also stated publicly that even individuals with insurance coverage for the authorized generic have paid as much as $150 for a single inhaler.[76] More broadly, childhood asthma is a major cause of missed school days for patients and missed workdays for parents; the overall burden of childhood asthma costs the U.S. health care system an estimated $6 billion per year.[77]

As this report illustrates, medical and financial consequences for patients have persisted since the discontinuation of Flovent. Given these significant consequences, Ranking Member Hassan requested in May 2024 that GSK restore Flovent HFA to the market and work with Prasco to lower the price for the authorized generic version.[78] Following the request, GSK did not restore Flovent HFA or lower the price of the authorized generic. Staff for Ranking Member Hassan also continued to hear reports of serious consequences for asthma patients and the Medicaid program. In June 2025, Ranking Member Hassan supplemented her May 2024 requests with requests to GSK and Prasco for the licensing agreement between GSK and Prasco for the authorized generic; detailed cost, volume, and payment information for the branded and authorized generic drugs; and internal analyses regarding the market, pricing, and competition for these drugs, among other materials.[79] GSK and Prasco each provided limited written responses on July 31, 2025, and GSK provided a briefing to staff for Ranking Member Hassan on December 9, 2025, as described below.[80]

Separately, staff requested data regarding use and cost for Flovent HFA, the authorized generic, and other inhaled corticosteroid products from three major pharmacy benefit managers (PBMs). All three PBMs provided relevant information on the condition of anonymity. Staff also received results from surveys that Massachusetts physicians distributed to pediatric clinicians and parents or other caregivers of children who had used Flovent products. These results are published for the first time in this report.

GSK Downplayed Patient Access Issues with the Authorized Generic, and GSK and Prasco Declined to Answer Requests About Their Financial Relationship

In response to the requests that Ranking Member Hassan sent in June 2025, GSK and Prasco each provided limited written responses that largely failed to address the specific requests for documents and data from the Subcommittee. Importantly, GSK and Prasco both declined to produce materials that would have clarified their contractual financial relationship regarding the authorized generic version of Flovent HFA. In its response, GSK also claimed that it was "deeply committed to patient access to needed medicines" and had prioritized a transition process to the

authorized generic version of Flovent "that would not jeopardize patient access to fluticasone propionate [the active ingredient in Flovent]."[81] In addition, GSK also stated that it was "encouraged by the broad coverage and affordability of the [authorized generic]" and that "patient access has increased over time."[82] In its response, Prasco also emphasized its efforts to promote access to the authorized generic through its patient assistance program and discounts to customers like wholesalers, retail chains, and hospitals.[83] As described below, however, data from PBMs, parents, and clinicians suggest that the discontinuation of Flovent products caused medical and financial harm to patients and made it more difficult for clinicians to provide critical health care.

GSK Continued to Downplay Disruptions to Patients While Acknowledging Role of American Rescue Plan Act and Declines in Insurance Coverage Following Flovent Discontinuation

On July 31, 2025, GSK responded to the request Ranking Member Hassan sent to the company in June 2025.[84] Importantly, the company acknowledged that the "passage of the American Rescue Plan Act…made the continued sales of Flovent economically unsustainable."[85] In the substance of its response, the company failed to provide the specific materials that Ranking Member Hassan had requested, including documents and data on cost, volume of goods sold, net revenue, prices, Medicaid payments, patient assistance, and settlement agreements.[86] In particular, GSK declined to produce the licensing agreement between the company and Prasco for the authorized generic version of Flovent HFA, which could have clarified the contractual financial relationship between these parties.

GSK claimed that it was "deeply committed to patient access to needed medicines" and discussed measures it had taken to make the authorized generic version of Flovent "more accessible, including providing advanced notice of our discontinuation and helping to jump start the [authorized generic], and providing free product for the launch of a patient assistance program for the [authorized generic]."[87] GSK stated, for example, that it had "prioritized a transition process to the [authorized generic] that would not jeopardize patient access to fluticasone propionate" — in part by implementing a year-and-a-half overlap period between the introduction of the authorized generic in May 2022 and the discontinuation of Flovent, during which branded Flovent remained on the market.[88] The company also cited efforts to notify Flovent prescribers of the transition and execute a communications plan targeting wholesalers, distributors, pharmacists, and patients starting in early 2023.[89]

Regarding cost and access issues related to the authorized generic, GSK stated that it "fully supported the inclusion of the AG on PBM and insurer formularies, which currently provide broad coverage for the [authorized generic]."[90] The company also explained that "[m]ore than half of commercially-insured patients are covered by the [authorized generic], without requiring a prior authorization, most of whom pay less than $25."[91] This is especially noteworthy given that in a follow-up briefing to staff for Ranking Member Hassan, GSK stated that around 75 percent

of commercially-insured patients had received coverage for Flovent prior to the discontinuation.[92] GSK also stated that after the overlap period mentioned above, "most of the prescription volume from branded Flovent was replaced by the [authorized generic] in the [relevant inhaler] market. […] As an update, that is still true for the first half of 2025. It is reassuring to know that patients have been able to access the [authorized generic] in 2024 and thereafter."[93] The company further stated that it was "encouraged by the broad coverage and affordability of the [authorized generic]," "that there is an adequate supply of the [authorized generic] on the market at pharmacies across the country," and that "patient access has increased over time."[94]

Regarding the broader asthma treatment market, GSK stated in a briefing to Subcommittee staff that the share of this market for the inhaled corticosteroid category (including Flovent products and their authorized generic versions) has declined in recent years.[95] According to GSK, this decline has occurred alongside an increase in patient use of dual therapy and triple therapy, in which a single inhaler combines an inhaled corticosteroid with other medications to treat asthma.[96] Additionally, GSK stated that in 2023 it had formally requested that FDA remove patents for all doses of Flovent from the Orange Book, the official FDA drug patent list.[97] In March 2026, FDA approved the first traditional generic of Flovent HFA, 44 micrograms per actuation, manufactured by Glenmark Specialty SA.[98]

Prasco Provided Minimal Information in Response to Requests

Prasco responded to Ranking Member Hassan on July 31, 2025.[99] As with GSK, Prasco failed to provide the specific documents and data Ranking Member Hassan had requested, including any versions of the licensing agreement between Prasco and GSK regarding the authorized generic version of Flovent HFA. Instead, Prasco emphasized its efforts to provide "broad access to its generic products through up-front discounted customer pricing and wide distribution."[100] Regarding the authorized generic version of Flovent, specifically, Prasco explained that its commercial list price or wholesale acquisition cost "is 35% below the brand product commercial list price as of the launch date" of the drug in 2022.[101] Prasco also stated that it offers the authorized generic at a further discount to customers like wholesalers, retail chains, and hospitals.[102] Moreover, the company explained that it had not raised the price of the authorized generic since the launch of the drug.[103] In general, Prasco noted that it does not set the price that a patient ultimately pays for the authorized generic and that "PBM and health plan decisions about formulary designs directly impact" access and cost for insured Americans.[104] Finally, Prasco also highlighted its patient support program, beginning in December 2024, to provide eligible patients with free monthly supplies of the authorized generic.[105]

Data From Major PBMs Undercuts GSK Efforts to Downplay Disruptions by Showing Declining Use of Inhaler Products and Increasing Costs After Flovent Discontinuation

Staff for Ranking Member Hassan requested data regarding use and cost for Flovent products, the authorized generic versions, and other inhaled corticosteroid products from three major pharmacy benefit managers (PBMs). On behalf of their clients — including commercial health plan sponsors — PBMs manage relationships across the health care sector to administer prescription drug benefits for around 275 million American beneficiaries.[106] Due to consolidation in the health care marketplace, three PBMs — Express Scripts, CVS Caremark, and Optum Rx — processed around 80 percent of prescriptions that U.S. pharmacies dispensed in 2023.[107]

The information that PBMs provided to the Subcommittee — explained in more detail below — consistently shows declining use across the category of all inhaled corticosteroids following the discontinuation of Flovent products. PBM A, for example, provided data showing that use among its beneficiaries dropped by almost 20 percent from the first half of 2023 through the first half of 2025, and PBM B showed a 25 percent decline between 2023 and 2024. Data from PBM C showed that the rate of chronic inhaler users who discontinued asthma therapy altogether more than doubled from 8.6% in 2023 to 19% in 2024. Based on this trend, one PBM stated that "it is reasonable to conclude utilization overall was affected by Flovent's removal from sale" — potentially due, in part, to beneficiaries who may have "stopped treating their condition altogether."[108]

The three PBMs also reported cost increases for plan sponsors and beneficiaries following the Flovent discontinuation. PBM A explained that the net cost to its clients for an average beneficiary using the authorized generic versions of Flovent was nearly *five times higher* than the cost of the branded Flovent products, comparing the first half of 2024 to the first half of 2023. PBM B reported that switching to the authorized generic versions of Flovent products resulted in *more than a doubling of average plan costs*. PBM C also stated that costs for plan sponsors rose due to the transition; under one plan, for example, costs increased from $58 for Flovent HFA in 2023 to $144 for the authorized generic version in 2024. In contrast to statements from GSK downplaying cost and access disruptions following the withdrawal of Flovent, this data — in the words of one PBM — suggests that the discontinuation "was disruptive to patients and costly to … plan sponsors."[109]

PBM A

According to PBM A, use among its beneficiaries across the inhaled corticosteroid category, including Flovent products, dropped by almost 20 percent from the first half of 2023 through the first half of 2025.[110] This decline equated to around 115,000 fewer 30-day prescriptions for inhalers and around 58,000 fewer distinct users of these products.[111] While acknowledging the mix of factors likely responsible for these declines, PBM A noted that "it is reasonable to

conclude utilization overall was affected by Flovent's removal from sale if all other market conditions remained largely the same before and after withdrawal."[112] PBM A also explained that around 17 percent of the decline in use occurred in the second half of 2023, which correlated with changes in formularies to exclude Flovent products.[113] (GSK notified FDA regarding the discontinuation of branded Flovent products on June 2, 2023.[114]) Based on its data, PBM A concluded that while certain prescriptions shifted to inhaler alternatives, use of the overall class of inhalers at issue "did not come back to the 2023 level, indicating members may have chosen: to pay cash prices to obtain the non-covered authorized generic (AG), opted against adopting alternative medications *and/or stopped treating their condition altogether*."[115]

Regarding cost, PBM A reported to the Subcommittee that its clients have paid more for the authorized generic versions of Flovent compared to branded Flovent products because the net cost of the authorized generics is higher than the cost of the branded products (with rebates included).[116] PBM A also explained that, accounting for rebates, the net cost to its clients for an average beneficiary using the authorized generic versions of Flovent was nearly *five times higher* than the cost of the branded products, based on a comparison of costs in the first half of 2024 versus the first half of 2023.[117] Finally, PBM A stated that for clients dropping coverage of the authorized generics, it anticipates that patients (or their parents) will "either pay cash on the authorized drugs at ~$170 per 30-day script, adopt covered alternative medications, or stop treatment altogether. All of these outcomes result in disruption to patients previously stabilized on brand Flovent products, impact medication adherence overall along with potentially reducing effectiveness of treatment and may increase member out-of-pocket spending."[118]

PBM B

In correspondence with the Subcommittee, PBM B noted that "GlaxoSmithKline's (GSK) withdrawal of the brand Flovent® HFA inhaler from the market and its replacement with an authorized generic (AG) was disruptive to patients and costly to our plan sponsors."[119] In fact, data from PBM B on commercial coverage prescriptions for inhaled corticosteroids shows a 25 percent decline — or around 128,000 prescriptions — in 2024 (after the Flovent withdrawal) compared to 2023 (before the Flovent withdrawal).[120]

In general, PBM B explained that the data it provided to the Subcommittee "demonstrates the effect of manufacturer tactics to maintain the competitive landscape tilted towards what are effectively brand products and maintain high prices."[121] PBM B provided data to the Subcommittee showing increased costs for patients and plan sponsors due to the change to the authorized generic versions of Flovent products. According to PBM B, patients who received prescriptions for the authorized generic in 2024 saw a slight increase in average out-of-pocket costs compared to costs for Flovent HFA in 2023.[122] In terms of costs for commercial plan sponsors, transitioning to the authorized generic versions of Flovent products *more than doubled average plan costs*.[123] Specifically, the average plan net cost for branded Flovent products was $65-$75 in 2023 compared to $155.61-$171.15 for the authorized generic versions in 2024.[124]

In contrast, average plan net cost per prescription for alternative inhaled corticosteroids declined from $68.21 to $61.92 over the same period.[125]

Because "the list price of the authorized generic versions of Flovent® exceeded the prior net price of the branded versions," PBM B recommended that "clients transition patients to lower cost, preferred alternatives and added several lower cost alternatives to standard formularies."[126] PBM also informed patients about the discontinuation of Flovent products and encouraged transitioning to preferred alternatives.[127] On average, patients switching to alternative inhaler products from the authorized generic saved $6 per fill.[128]

PBM C

PBM C reported to the Subcommittee that the discontinuation of Flovent "correlated with a notable increased rate of individuals who were no longer processing claims for respiratory therapy, rising from 8.6% in 2023 to 19% in 2024."[129] The company characterized this *doubling* of the rate of chronic inhaler users who discontinued therapy as "adherence challenges in asthma management."[130]

Utilization data from PBM C also shows that significantly more inhaler users pursued options other than the authorized generic versions of Flovent following the Flovent discontinuation. In 2023, for example, 77 percent of inhaler users at PBM C used Flovent HFA, 4.4 percent used the authorized generic, 4 percent used Flovent Diskus, and 14.6 percent relied on other inhaled corticosteroids.[131] Following the Flovent withdrawal, less than 0.5 percent of inhaler users remained on Flovent HFA, 23.5 percent used the authorized generic, and 76 percent used other inhaled corticosteroids, including Flovent Diskus (less than 0.5 percent) and the authorized generic of Flovent Diskus (less than 0.05 percent).[132]

Information from PBM C also shows that the transition from Flovent HFA to the authorized generic increased average cost for patients. PBM C noted that it had arranged a "tiering exception" to ensure patients had a cost share for the authorized generic versions of Flovent that was similar to their payment for branded Flovent products in 2023.[133] Members of one plan, for example, paid $29 on average for Flovent HFA in 2023 and $39 on average for the authorized generic version in 2024.[134] Under another plan, however, members paid $42 on average for Flovent HFA in 2023 and $62 on average for the authorized generic in 2024 — an increase of almost 50 percent.[135] In contrast, average member costs for other inhaled corticosteroids products remained the same or declined slightly during the same period.[136]

According to PBM C, costs for plan sponsors increased significantly after the Flovent discontinuation. PBM C explained that based on an average of net cost across all its plans, the net cost for the most common strength of the Flovent HFA inhaler *more than doubled* — from around $70 to $161 — after the transition to the authorized generic.[137] Cost for plan sponsors under one plan rose from $144 for Flovent HFA in 2023 to $174 for the authorized generic in 2024.[138] Cost for plan sponsors under another plan rose even more significantly during the same

period — from $58 for Flovent HFA in 2023 to $144 for the authorized generic in 2024.[139] During the same period, the cost for plan sponsors for other inhaled corticosteroid products either declined or rose modestly, depending on the plan.[140]

Patient and Clinician Surveys Also Undercut GSK Claims by Showing That Flovent Discontinuation Caused Significant Disruptions to Patient Care and Hardships for Families

To understand the real-life impact of the Flovent discontinuation, physicians in Massachusetts, including Dr. Ashley L. Saint-Fleur of Boston Children's Hospital, conducted national surveys in 2025 that questioned pediatric clinicians and parents (or other caregivers) of children who had used Flovent products. The results from these surveys, disclosed publicly for the first time in this report, show that the discontinuation led to significant disruptions to patient care and hardships for families. Regarding the impact on parents, the Massachusetts physicians concluded based on initial survey results that a subset of families "experienced significant challenges, including higher costs, worsening symptoms, and increased acute healthcare utilization [including ER, hospital, and ICU visits] for asthma exacerbations."[141] Both the initial survey results and results from an expanded survey included firsthand accounts from parents concerning a variety of cost, access, and medical impacts.

For clinicians, disruptions included "inadequate preparation for an abrupt and substantial change in practice" and "reduced patient access" to asthma medications.[142] Moreover, the difficulties clinicians have experienced in finding age-appropriate alternatives to Flovent could "result in suboptimal medication delivery and greater risk of poor asthma control and increased exacerbations."[143] These findings provide further evidence of the consequences of the Flovent discontinuation for patients and their families. Both sets of survey results — for clinicians and parents — undercut claims that the discontinuation did not negatively impact costs, medication access, and health outcomes for vulnerable patients.

Patients Reported Financial, Medication Access, and Medical Challenges

In the second half of 2025, Dr. Ashley Saint-Fleur and Dr. Gregory S. Sawicki of Boston Children's Hospital conducted a survey of parents (or other caregivers) of children who had used Flovent to assess the impact of the discontinuation on pediatric asthma control and treatment access.[144] Reviewing an initial set of these survey results for 43 parents or other caregivers, the physicians concluded that a subset of families "experienced significant challenges, including higher costs, worsening symptoms, and increased acute healthcare utilization [including ER, hospital, and ICU visits] for asthma exacerbations."[145] Regarding impacts on medication access, for example:

- Around 42 percent of parents reported at least some difficulty in obtaining information about the Flovent withdrawal.[146]

- Around 30 percent of parents experienced at least some difficulty in obtaining insurance coverage for alternatives medication.[147]
- Around 12 percent of parents reported that cost issues had led to skipped doses or delayed refills.[148]
- In terms of current challenges in the second half of 2025, around 12 percent of parents "continued to face barriers such as cost, insurance coverage, or pharmacy availability."[149]

Regarding increased costs, around 36 percent of parents reported at least some difficulty in paying for alternative medication for their children, and more than 30 percent experienced at least some difficulty in getting insurance to cover the new medication.[150] Importantly, parents also reported the following health consequences and related challenges after the Flovent discontinuation:

- More than 78 percent of parents reported that their child switched to another medication following the discontinuation of Flovent, and "[r]eported impacts included increased out-of-pocket costs (27.3%), worsening day-to-day symptoms (18.2%), missed school days (18.2%), and greater asthma flare-ups (9.1%)."[151]
- Around 30 percent of parents reported one or more instances of their children taking oral steroids.[152] Long-term use of this medication or use at higher doses can result in high blood pressure or increased blood sugar levels, among other side effects.[153]
- Around 18 percent of parents reported one or more urgent care or ER visits in the past year.[154]
- Around 12 percent of parents reported one or more hospitalizations in the past year.[155]

These initial survey results and results from an expanded set of 145 parents also included firsthand accounts from parents concerning a variety of cost, access, and medical impacts due to the Flovent HFA discontinuation. One New Hampshire parent, for example, stated:

> We've had to travel up to 3 hours round trip to find a pharmacy that could fill [a replacement medication] and a few of those times there has been a gap between the last dose of the previous and when we can get the new one. Most recently we were told by several pharmacies that they wouldn't be able to fill it for a month. Thankfully we did find one left at a pharmacy 45 minutes away.[156]

Another New Hampshire parent noted that "[t]he whole thing was a giant mess trying to get … the new medication covered by insurance. We finally got it sorted out this summer and now we recently got a notice from insurance that they will no longer cover [an alternative medication] so

my children will have to switch again which I am very mad about."[157] Many other parents expressed similar frustration and disappointment concerning the discontinuation of Flovent HFA:

- "We dealt with a lot of frustration with insurance trying to find safe and covered alternatives to Flovent, and then still dealt with stock issues with the new medication and monitoring your child on a new/different medication when the one they were on was already working well for them."
- "We had to add a [pulmonologist] to our care team which was very expensive. We have also learned about the fluticasone generic but it wasn't clear that that even existed when we heard about the discontinuation ... it would have helped to know about that."
- "It was really disappointing for us as a family to finally have a medication and an action plan for our son's asthma's symptoms to turn around in less than 6 months and his prescription was discontinued."
- "It has had a big impact on my child's asthma control, especially in cold [and] flu season. No other medications work as well as Flovent for control. It has impacted my child's life, she has missed many days of school because of it and her grades suffered and it caused her to have anxiety attacks about school."
- "In a year [and] a half we are onto our second controller med after being able to access and use [F]lovent for 8 years. I can't help but think back to [F]lovent being discontinued precipitating the beginning of these changes."
- "This was a major life disruption which still impacts my family today. My child's quality of life hasn't been the same since switching to the new medication. This happened abruptly with no real notice and left my family scrambling. Appalling move by the manufacturer."
- "[W]e now pay for generic [F]lovent out of pocket, as our insurance refuses to pay for the generic version."
- "We ended up seeing a pulmonologist because of the lack of control over asthma."
- "My daughter was switched to QVAR in December of 2023 and a month after (late Jan. 2024) she was admitted to the Intermediate Care Unit at Children's hospital due to asthma complications with Flu A."
- "Switching to generic was problematic in needing prior authorization and a lot of resale. Other options were on back order and I didn't want to switch controller meds in a well controlled child midway through winter/respiratory virus season!"

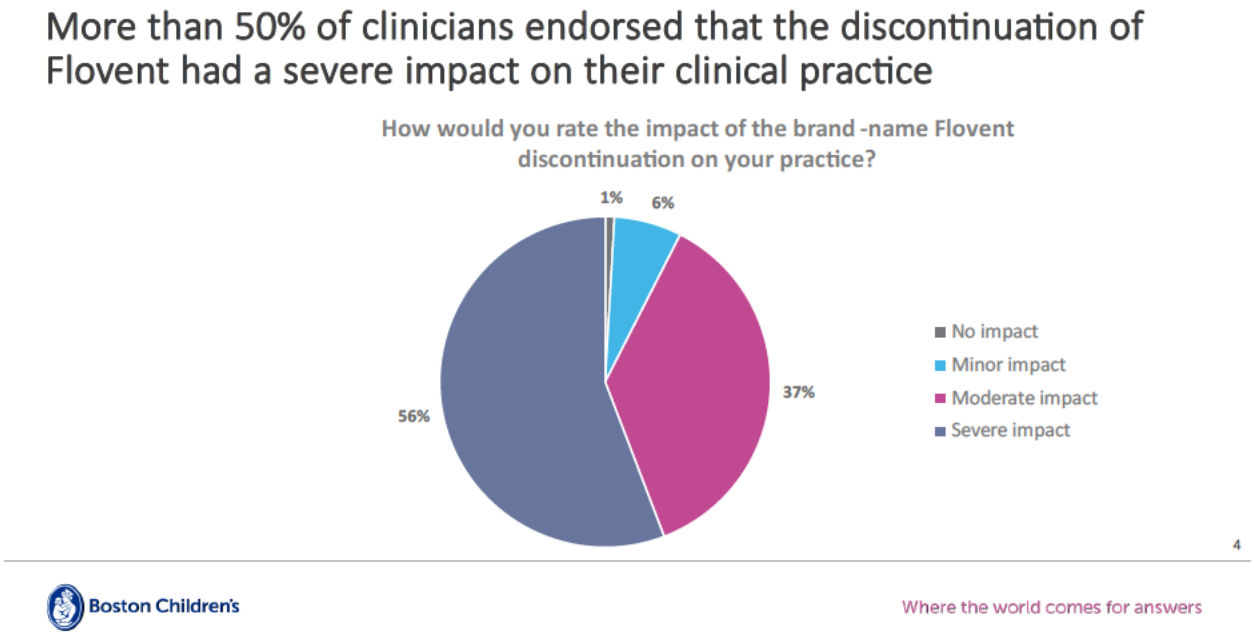
- "The other medications were distractingly poorer at asthma control and larger side effects. We have tried 3 different medications."
- "[E]xperience was horrible. [M]issed school, multiple dr or urgent care visits. [H]ad to go on prednisone. [P]ediatrician couldn't get it right. Just multiple misses."
- "[G]eneric fluticasone is still EXTREMELY expensive for being such a common medication - we haven't been able to find it for less than $150 even with good rx. Why would insurances cover the brand name but not the generic???"
- "It was terrible. Originally my child was too young … for any other medication than Flovent. We paid out of pocket, $300 a month until she was old enough for Symbicort. We started Symbicort earlier than really indicated due to this issue."[158]

Importantly, Dr. Saint-Fleur noted to staff for Ranking Member Hassan that all children covered in the survey were receiving care in a pediatric pulmonology clinic, and access to specialty care, proactive medication adjustments, and treatment escalation may have mitigated the worst impacts of the Flovent discontinuation.[159] As a result, outcomes observed in this population of patients might underestimate the impact of the discontinuation in general pediatric populations, particularly for patients receiving treatment solely through primary care or facing greater barriers to timely medication substitution.[160] Dr. Saint-Fleur also explained that the timing of the survey may have influenced reporting, as parents were reflecting on outcomes over the prior year — meaning that acute events immediately following the discontinuation of Flovent HFA may be underreported.[161]

Clinicians Reported Significant Disruptions to Patient Care

Prior to the parent surveys mentioned above, Massachusetts physicians, including Dr. Saint-Fleur and Dr. Sawicki, distributed a national survey to clinicians — mostly pediatric pulmonologists or primary care providers — between February and May 2025. (Of the 226 survey participants, 75 percent practiced in the Northeast.[162]) According to an analysis of the results, "[p]ediatric clinicians who care for children with asthma reported significant disruptions to patient care following the discontinuation of brand-name Flovent."[163] These disruptions included "inadequate preparation for an abrupt and substantial change in practice," challenges with the administration of their practices, and "reduced patient access to controller medications."[164] Specifically, although "71% of clinicians were aware of the discontinuation of brand-name Flovent in advance, 79% felt unprepared or very unprepared."[165] In addition, 93 percent of respondents stated that the discontinuation of Flovent had a moderate (37 percent) or severe impact (56 percent) on their clinical practice.[166] *See* Figure 1 below.

Figure 1: Impact of Flovent Discontinuation on Clinical Practice



In terms of the most frequent challenges clinicians experienced "often" or "always," 87 percent mentioned the need for insurance prior authorization (which can result in care delays); 80 percent reported pharmacy shortages; and 77 percent reported difficulty in finding an age-appropriate alternative.[167] In addition, clinicians described these same obstacles as placing a moderate or severe strain on time, resources, or patient care.[168] The survey authors noted that difficulty in finding age-appropriate alternatives, specifically, "can result in suboptimal medication delivery and greater risk of poor asthma control and increased exacerbations."[169] *See* Figure 2 and Figure 3 below.

Figure 2: Frequency of Challenges that Pediatric Clinicians Experienced

Frequency of Challenges Experienced

Pharmacy shortages, Need for insurance prior authorization, and Patient calls/EMR messages were the most frequently experienced challenges with **over 80% of respondents** endorsing these challenges "often" or "always."

Patient visits to discuss medications was the least frequently experienced challenge.

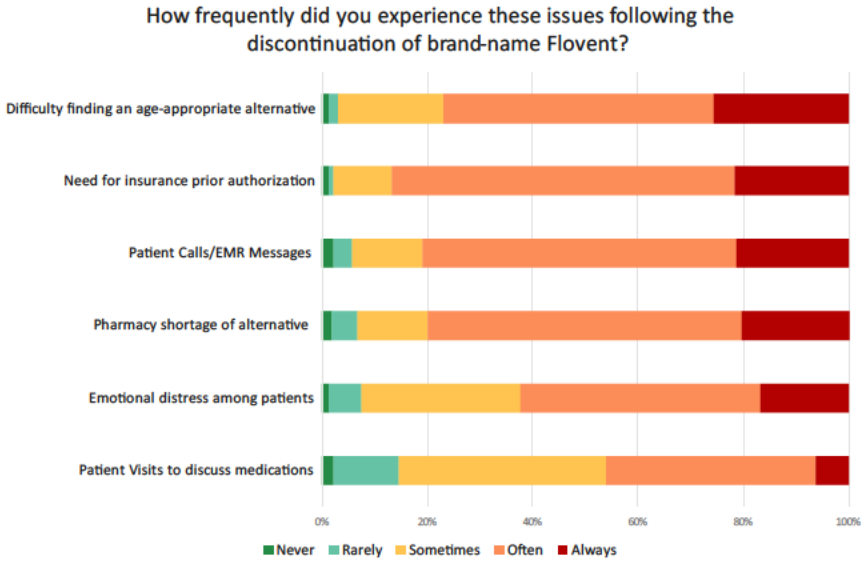


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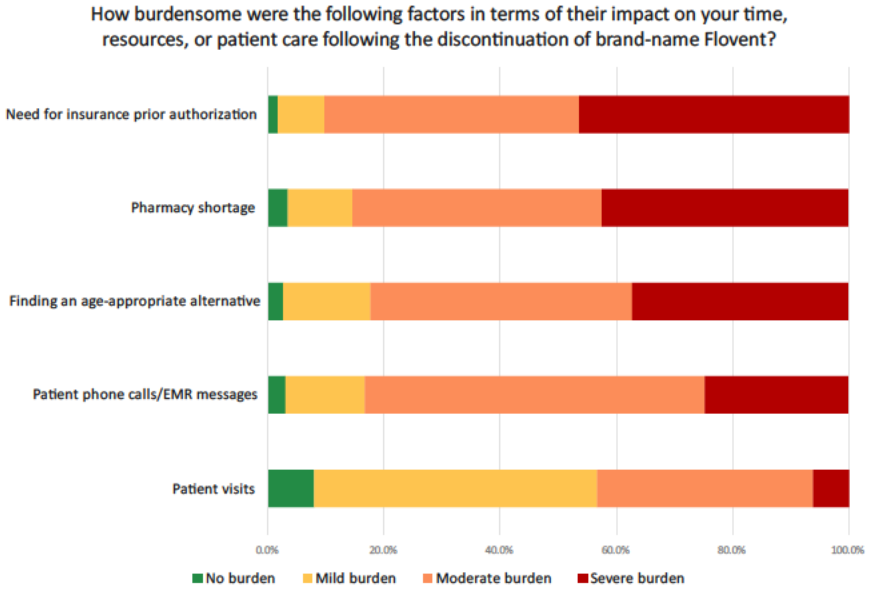
Figure 3: Burden of Challenges Pediatric Clinicians Experienced

Burden on Healthcare clinicians

Need for insurance authorization was the most burdensome (90.6%), followed by pharmacy shortages (85.5%), and finding an age-appropriate alternative (82.5%)

*based on respondents endorsing a moderate burden (*Noticeable impact; required significant effort or resources*) and severe burden (*Major impact; extremely difficult to manage*)



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Interpreting these results, the Massachusetts physicians concluded that "clinicians both in specialty and primary care experienced significant disruptions in their clinical management of patients with asthma."[170] Clinicians reported that they were unprepared to navigate these disruptions "due to inadequate information about alternative options available to patients and lack of structural supports for clinician workflows and care delivery."[171] Consequently, "the majority of clinicians indicated that the [Flovent] discontinuation had a severe impact on their clinical practice."[172] These findings provide further evidence of the negative impacts of the discontinuation for asthma patients and their families.

DIRECT QUOTES FROM CLINICIANS

- "This discontinuation was incredibly disruptive and challenging, particularly for children and families who experienced poor access to care, low health literacy."
- "Even if patients were approved for generic fluticasone propionate, patients were having to pay hundreds of dollars out of pocket for a 30-day supply."
- "I had several patients in the ED with exacerbations due to coming off of their inhaler. Also had several children in the PICU with increased exacerbation rates."
- "This debacle created a danger for our patients—particularly our youngest who are unable to use a breath-activated inhaler."
- "This has had a huge adverse effect on the health of children with asthma resulting in more ER visits, hospitalizations and oral steroids."
- "This change put our most vulnerable children/patients with asthma at significant risk of morbidity and mortality."
- "No one seemed to be prepared for how disruptive this would be for young children who could not use a breath actuated inhaler."
- "It was severely disruptive… and directly led to worse outcomes in our youngest patients with asthma."
- "I feel this was a disservice to pediatric patients who cannot use powder inhalers."[173]

Conclusion

In public statements and correspondence with the Subcommittee, GSK has attempted to downplay the disruptions involved with the discontinuation of Flovent, including impacts on patient access to asthma treatment. However, the data above from PBMs, parents, and clinicians suggest that the Flovent discontinuation caused access and affordability issues that led to medical and financial harm for patients and obstacles for clinicians. As a result, in seeking to evade future payments it would have owed to Medicaid under the American Rescue Plan Act, GSK appears to have jeopardized the same "patient access to needed medicines" that it claims to have provided.[174] Encouragingly, following years of pressure from Ranking Member Hassan, a true generic alternative will be available soon. Without further action from Congress, however, other companies could also attempt to use "authorized generics" to evade Medicaid rebate payments as GSK did, resulting in similar health and cost challenges for patients.

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[15] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).

[16] *Id*.; GlaxoSmithKline, Briefing with Staff for Ranking Member Hassan (Dec. 9, 2025).

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[19] Email from PBM C to Staff for Ranking Member Hassan (Nov. 13, 2025).

[20] Email from PBM A to Staff for Ranking Member Hassan (July 30, 2025).

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[22] *Id*.

[23] *Id*.

[24] *Id*.

[25] *Id*.

[26] *Id*.

[27] *Id*.

[28] Ashley L. Saint-Fleur et al., *Clinician Perspectives on the Discontinuation of Brand Name Flovent in Pediatric Asthma Care* (pre-print copy on file with the Subcommittee).

[29] *Id*.

[30] *Id*.

[31] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).

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[44] Letter from Ranking Member Hassan to Emma Walmsley, Chief Executive Officer, GlaxoSmithKline (June 27, 2025); Letter from Ranking Member Hassan to Christopher Arington, Chief Executive Officer, Prasco Laboratories (June 27, 2025).

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[46] *See* Erin D. Parker and Joseph M. Collaco, *Inhaled Corticosteroid Alternatives for Young Children After Flovent Withdrawal*, Contemporary Pediatrics Journal (Apr. 2, 2025) (www.contemporarypediatrics.com/view/inhaled-corticosteroid-alternatives-for-young-children-after-flovent-withdrawal). Unlike rescue inhalers, which can immediately address symptoms during an asthma attack, controller inhalers help patients manage their asthma through routine use, even when symptoms are not present. Express Scripts Pharmacy, *Understanding the Difference Between Rescue Inhalers and Controller Inhalers* (Sept. 3, 2023) (www.express-

scripts.com/pharmacy/blog/difference-between-rescue-and-controller-inhalers). At the same time as GSK discontinued Flovent HFA, the company also discontinued Flovent Diskus. Asthma and Allergy Network, *Flovent Asthma Inhalers Discontinued: What You Need to Know* (Oct. 21, 2024) (allergyasthmanetwork.org/news/flovent-asthma-inhalers-discontinued/). Both the Flovent HFA inhaler and Flovent Diskus products contained the active ingredient fluticasone propionate, but Flovent HFA was a metered-dose inhaler and Diskus was a dry powder inhaler. *Id.* Unless otherwise specified, this report uses "Flovent" to refer to Flovent HFA and Flovent Diskus.

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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").

[56] *Discontinuation of Popular Asthma Medication, Flovent, Linked with Increased Hospitalization*, ABC News (Oct. 29, 2024) (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. 8, 2024) (www.forbes.com/sites/joshuacohen/2024/01/03/new-medicaid-rebate-rule-causes-problems-for-asthma-patients-on-flovent/).

[57] *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/).

[58] *'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).

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

[62] 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).

[63] *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/); *'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). *See also* Mayo Clinic, Ciclesonide (Inhalation Route) (Dec. 1. 2025) (www.mayoclinic.org/drugs-supplements/ciclesonide-inhalation-route/description/drg-20071477).

[64] Christopher Alban 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).

[65] *Id.*; Chén Kenyon, Bianca Nfonoyim Bernhard, and Tyra Bryant-Stephens, *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/). According to the American Thoracic Society, "[p]atients who require care in the intensive care unit (ICU) have the most serious illnesses, often requiring multiple forms of life support." American Thoracic Society, *Managing the Intensive Care Unit (ICU) Experience: A Proactive Guide for Patients and Families* (May 2020) (www.thoracic.org/patients/patient-resources/resources/managing-the-icu-experience.pdf).

[66] Chén Kenyon, Bianca Nfonoyim Bernhard, and Tyra Bryant-Stephens, *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/).

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[72] Calculation using the Consumer Price Index for All Urban Consumers. *See* U.S. Bureau of Labor Statistics, *Consumer Price Index for All Urban Consumers: All Items in U.S. City Average [CPIAUCSL]*, retrieved from FRED, Federal Reserve Bank of St. Louis (last accessed Dec. 3, 2025) (fred.stlouisfed.org/series/CPIAUCSL).

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[74] GlaxoSmithKline: *Strong Sales and Core EPS Growth Reflecting Accelerating Momentum in Specialty Medicines Offsetting Lower Vaccine Sales* (Feb. 5, 2025) (www.gsk.com/en-gb/media/press-releases/gsk-delivers-strong-2024-performance-with-further-improvement-to-long-term-growth-outlook/).

[75] GlaxoSmithKline, Annual Report 2024 (Feb. 27, 2025) (www.gsk.com/media/wrvfwob1/annual-report-2024.pdf).

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

[77] P.W. Sullivan et al., *The National Burden of Poorly Controlled Asthma, School Absence and Parental Work Loss Among School-Aged Children in the United States*, Journal of Asthma (June 2018) (pubmed.ncbi.nlm.nih.gov/28981368/); Richard Perry et al., *The Economic Burden of Pediatric Asthma in the United States: Literature Review of Current Evidence*, Pharmacoeconomics (Oct. 13, 2018) (pmc.ncbi.nlm.nih.gov/articles/PMC6386052/).

[78] Letter from Ranking Member Hassan to Emma Walmsley, Chief Executive Officer, GlaxoSmithKline (May 1, 2024).

[79] Letter from Ranking Member Hassan to Emma Walmsley, Chief Executive Officer, GlaxoSmithKline (June 27, 2025); Letter from Ranking Member Hassan to Christopher Arington, Chief Executive Officer, Prasco Laboratories (June 27, 2025).

[80] Prior to the June 2025 requests, GSK provided a written response to Ranking Member Hassan on May 14, 2024, and a briefing to staff for Ranking Member Hassan on July 23, 2024. *See* Letter from Amy Efantis, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Senator Hassan (May 14, 2024); GlaxoSmithKline, Briefing with Staff for Senator Hassan (July 23, 2024).

[81] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).

[82] *Id*.

[83] Letter from Christopher H. Arington, Chief Executive Officer, Prasco Laboratories, to Ranking Member Hassan (July 31, 2025).

[84] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).

[85] *Id*.

[86] Letter from Ranking Member Hassan to Emma Walmsley, Chief Executive Officer, GlaxoSmithKline (June 27, 2025).

[87] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).

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[91] *Id*.

[92] GlaxoSmithKline, Briefing with Staff for Ranking Member Hassan (Dec. 9, 2025).

[93] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).

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[95] GlaxoSmithKline, Briefing with Staff for Ranking Member Hassan (Dec. 9, 2025).

[96] *Id*. *See also* Asthma and Allergy Network, Asthma Medication and Treatment (allergyasthmanetwork.org/what-is-asthma/how-is-asthma-treated/) (accessed Dec. 10, 2025). One 2024 study examining patients who initiated triple therapy between 2017 and 2019 concluded that this therapy "may have been initiated as a step up from previous controller medications, as recommended by the Global Initiative for Asthma, instead of as an initial therapy option." Nadia N. Hansel et al., *Real-World Users of Triple Therapy for Asthma in the US*, The American Journal of Managed Care (Feb. 9, 2024) (www.ajmc.com/view/real-world-users-of-triple-therapy-for-asthma-in-the-us). The study noted that more than 80 percent of the patients examined had used controller therapy — like Flovent — in the 12 months before initiating triple therapy. *Id.*

[97] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).

[98] U.S. Food and Drug Administration: *FDA Approves First Generic of Flovent HFA for Treatment of Asthma* (Mar. 3, 2026) (www.fda.gov/drugs/drug-safety-and-availability/fda-approves-first-generic-flovent-hfa-treatment-asthma); Glenmark Specialty SA: *Glenmark Specialty SA Receives U.S. FDA Approval for Fluticasone Propionate Inhalation Aerosol USP, 44 mcg per actuation, with 180-Day Competitive Generic Therapy Exclusivity* (Mar. 4, 2026). Teva Pharmaceuticals previously filed two applications with FDA seeking approval for a generic competitor to Flovent, but no generic reached the market. *See* U.S. Food and Drug Administration, *Paragraph IV Patent Certifications* (Mar. 2, 2026) (www.fda.gov/media/166048/download). In response to one of these applications, GSK filed suit against Teva in March 2017. *See* Complaint, ECF No. 1, *Glaxo Group Ltd. v. Teva Pharmaceuticals USA, Inc.*, No. 1:17-cv00357-UNA (D. Del. Mar. 31, 2017).

[99] Letter from Christopher H. Arington, Chief Executive Officer, Prasco Laboratories, to Ranking Member Hassan (July 31, 2025).

[100] *Id*.

[101] *Id*.

[102] *Id*.

[103] *Id*.

[104] *Id*.

[105] *Id*.

[106] BRG, *Pharmacy Benefit Manager Overview* (Apr. 2025) (www.thinkbrg.com/insights/publications/pharmacy-benefit-manager-overview/); Statista, *Number of People in the U.S. Served by Pharmacy Benefit Managers (PBMs) As of 2023, By Insurance Type* (July 7, 2025) (www.statista.com/statistics/1172652/pbms-number-of-served-us-persons/).

[107] Federal Trade Commission: *FTC Releases Interim Staff Report on Prescription Drug Middlemen* (July 9, 2024) (www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen); Drug Channels, *The Top Pharmacy Benefit Managers of 2023: Market Share and Trends for the Biggest Companies—And What's Ahead* (Apr. 9, 2024) (www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html).

[108] Email from PBM A to Staff for Ranking Member Hassan (July 30, 2025).

[109] Email from PBM B to Staff for Ranking Member Hassan (Oct. 14, 2025).

[110] Email from PBM A to Staff for Ranking Member Hassan (July 30, 2025). PBM A examined data from January 2023 to June 2025 concerning 30-day scripts, distinct utilizers, and member and pre-rebate client costs for Flovent, authorized generics, and other inhaled corticosteroids. PBM A focused its analysis on its commercial book of business, excluding all restricted clients. *Id*.

[111] *Id*.

[112] *Id*.

[113] *Id*. PBM A noted that formulary changes to exclude Flovent HFA mostly drove this decline. Email from PBM A to Staff for Ranking Member Hassan (Dec. 8, 2025).

[114] MassHealth Pharmacy Program, *The Prescriber E-Letter: Discontinuation of Brand© Flovent Products* (Sept. 2023) (www.mass.gov/doc/issue-3-september-2023-0/download).

[115] Email from PBM A to Staff for Ranking Member Hassan (July 30, 2025) (emphasis added).

[116] *Id*.

[117] *Id*.

[118] *Id*.

[119] Email from PBM B to Staff for Ranking Member Hassan (Oct. 14, 2025).

[120] *Id*. PBM B provided data to the Subcommittee on adjusted commercial coverage prescriptions in 2023 and 2024 and commercial coverage patient and plan sponsor costs over the same period. "Adjusted" prescriptions refers to 90-day prescription fills that have been appropriately adjusted to reflect the equivalent number of 30-day prescriptions. According to PBM B, its calculations for net costs are "reflective of ingredient cost discounts, rebate[s] available in 2023 and member average copay/coinsurance." *Id*.

[121] *Id*.

[122] *Id*.

[123] *Id*.

[124] *Id*.

[125] *Id*.

[126] *Id*.

[127] Email from PBM B to Staff for Ranking Member Hassan (Jan. 29, 2026).

[128] *Id*.

[129] Email from PBM C to Staff for Ranking Member Hassan (Nov. 13, 2025).

[130] *Id*.

[131] *Id*.

[132] *Id*.; Email from PBM C to Staff for Ranking Member Hassan (Dec. 10, 2025).

[133] Email from PBM C to Staff for Ranking Member Hassan (Nov. 13, 2025).

[134] *Id*.

[135] *Id*.

[136] *Id*.

[137] *Id*.; Email from PBM C to Staff for Ranking Member Hassan (Dec. 18, 2025).

[138] Email from PBM C to Staff for Ranking Member Hassan (Nov. 13, 2025).

[139] *Id*.

[140] *Id*.

[141] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Patient/Family Reported Impact of Brand-name Flovent Discontinuation* (pre-print copy on file with the Subcommittee).

[142] Ashley L. Saint-Fleur et al., *Clinician Perspectives on the Discontinuation of Brand Name Flovent in Pediatric Asthma Care* (pre-print copy on file with the Subcommittee).

[143] *Id*.

[144] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Updated Summary of Data on Patient Experiences with Flovent Discontinuation* (pre-print copy on file with the Subcommittee). The survey "aimed to gather insights into the experiences of parents managing their child's asthma" and focused on patients 18 years old or younger who were prescribed Flovent at the time of discontinuation. *Id.* The survey did not distinguish between experiences with Flovent HFA and Flovent Diskus. Dr. Saint-Fleur indicated to staff for Ranking Member Hassan, however, that most, if not, all responses likely applied to Flovent HFA because providers rarely prescribed Flovent Diskus for pediatric use. Email from Dr. Ashley Saint-Fleur to Staff for Ranking Member Hassan (Nov. 21, 2025).

[145] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Patient/Family Reported Impact of Brand-name Flovent Discontinuation* (pre-print copy on file with the Subcommittee).

[146] *Id*.

[147] Email from Dr. Ashley Saint-Fleur to Staff for Ranking Member Hassan (Oct. 28, 2025).

[148] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Patient/Family Reported Impact of Brand-name Flovent Discontinuation* (pre-print copy on file with the Subcommittee).

[149] *Id*.

[150] Email from Dr. Ashley Saint-Fleur to Staff for Ranking Member Hassan (Oct. 28, 2025).

[151] Ashley L. Saint-Fleur et al., *Patient/Family Reported Impact of Brand-name Flovent Discontinuation* (pre-print copy on file with the Subcommittee). Relatedly, a 2017 study found that school absenteeism due to asthma (an additional 2.3 missed school days per person per year) during 2008-2013 caused an economic loss of $1.1 billion in the United States. Tursynbek Nurmagambetov, Robin Kuwahara, and Paul Garbe, *The Economic Burden of Asthma in the United States, 2008-2013*, Annals of the American Thoracic Society (Mar. 2018) (pubmed.ncbi.nlm.nih.gov/29323930/). An earlier study from 2004 calculated $719.1 million in lost productivity for parents due to asthma-related school absence days (2.48 days per child with asthma). Li Yan Wang, Yuna Zhong, and Lani Wheeler, *Direct and Indirect Costs of Asthma in School-age Children*, Preventing Chronic Disease (Dec. 15, 2004) (pmc.ncbi.nlm.nih.gov/articles/PMC1323314/).

[152] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Patient/Family Reported Impact of Brand-name Flovent Discontinuation* (pre-print copy on file with the Subcommittee).

[153] American Lung Association, *The Potential Risks of Repeated Corticosteroid Use* (Sept. 10, 2024) (www.lung.org/blog/corticosteroid-use-risks).

[154] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Patient/Family Reported Impact of Brand-name Flovent Discontinuation* (pre-print copy on file with the Subcommittee).

[155] *Id*.

[156] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Data for New Hampshire Residents* (pre-print copy on file with the Subcommittee).

[157] *Id*.

[158] Ashley L. Saint-Fleur and Gregory S. Sawicki, *Updated Summary of Data on Patient Experiences with Flovent Discontinuation* (pre-print copy on file with the Subcommittee); Ashley L. Saint-Fleur and Gregory S. Sawicki, *Patient/Family Reported Impact of Brand-name Flovent Discontinuation* (pre-print copy on file with the Subcommittee).

[159] Email from Dr. Ashley Saint-Fleur to Staff for Ranking Member Hassan (Dec. 18, 2025).

[160] *Id*.

[161] *Id*.

[162] Ashley L. Saint-Fleur et al., *Clinician Perspectives on the Discontinuation of Brand Name Flovent in Pediatric Asthma Care* (pre-print copy on file with the Subcommittee).

[163] *Id*. According to the authors of the study, "[a] cross-sectional web-based survey was disseminated via pediatric and pediatric pulmonary networks both regionally and nationally to pediatric clinicians (i.e., physicians and advanced practice practitioners). The survey assessed clinician awareness, preparedness, and the clinical impact of brand-name Flovent discontinuation." *Id.* The survey did not distinguish between experiences with Flovent HFA and Flovent Diskus. Dr. Saint-Fleur indicated to staff for Ranking Member Hassan, however, that most, if not, all responses likely applied to Flovent HFA because providers rarely prescribed Flovent Diskus for pediatric use. Email from Dr. Ashley Saint-Fleur to Staff for Ranking Member Hassan (Nov. 21, 2025).

[164] Ashley L. Saint-Fleur et al., *Clinician Perspectives on the Discontinuation of Brand Name Flovent in Pediatric Asthma Care* (pre-print copy on file with the Subcommittee).

[165] *Id*.

[166] *Id*.

[167] *Id*. *See also* Jacob Murphy et al., *Adverse Effects of Health Plan Prior Authorization on Clinical Effectiveness and Patient Outcomes: A Systematic Review*, The American Journal of Medicine (Sept. 3, 2025) (www.amjmed.com/article/S0002-9343(25)00553-4/fulltext).

[168] Ashley L. Saint-Fleur et al., *Clinician Perspectives on the Discontinuation of Brand Name Flovent in Pediatric Asthma Care* (pre-print copy on file with the Subcommittee).

[169] *Id*.

[170] *Id*.

[171] *Id*.

[172] *Id*.

[173] *Id*.

[174] Letter from Harmeet Dhillon, VP, Government Affairs, Public Policy & Patient Advocacy, GlaxoSmithKline, to Ranking Member Hassan (July 31, 2025).