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IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, *ex rel.* KRISTIN K. MAYES, ATTORNEY GENERAL Plaintiff, v. GLAXOSMITHKLINE LLC Defendant.	Case No.: **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff, the State of Arizona, *ex rel.* Kristin K. Mayes, the Attorney General (the "State") brings this action against Defendant GlaxoSmithKline LLC ("GSK"). Through the conduct alleged herein, Defendant violated the Arizona Consumer Fraud Act, A.R.S. § 44-1521, *et seq.* In support of its Complaint, the State alleges as follows:

INTRODUCTION

1. On January 1, 2024, Defendant GSK suddenly discontinued one of the most prescribed asthma medications in the country, Flovent, and replaced it with a materially identical authorized generic (the "Authorized Generic").

2. As GSK writes on the Flovent website: "Other than the fact that it does not have the brand name on its label, [an authorized generic] is the exact same drug product as the branded product."

3. GSK essentially just renamed Flovent.

4. GSK did so to avoid the obligation to pay rebates to Medicaid under the Medicaid Prescription Drug Rebate Program (MDRP).

5. In order to sell drugs to Medicaid, drug manufacturers must agree to pay rebates that are based, in part, on the degree to which the drug manufacturer has increased the price of a drug since its launch. This is intended to discourage drug manufacturers from extreme price inflation.

6. Prior to January 1, 2024, the rebate amount was capped at the price of a given drug; but, on that date, the cap was removed. The cap's removal was intended to further discourage extreme price inflation.

7. Since its introduction into the market, GSK aggressively raised the price of Flovent. It raised the price so much that, with the removal of the rebate cap, GSK was faced with the prospect of having to pay more to Medicaid in rebates than it would earn from sales of the drug to Medicaid.

8. GSK could have avoided such significant rebates by reducing Flovent's price, and thus reducing the amount of price inflation since Flovent's introduction.

9. But GSK chose not to reduce Flovent's price. Rather, GSK simply dropped the Flovent name, reintroduced the drug as the Authorized Generic, and continued to sell at a heavily inflated price (the "Flovent Renaming Scheme").

10. Apart from maintaining an inflated price for the drug, the Flovent Renaming Scheme has had significant, and predictable, negative consequences.

11. By formally discontinuing Flovent, GSK caused thousands of patients, including thousands of Arizonans, to suddenly lose insurance coverage for the drug.

12. For many patients, and especially young children, there was not a readily available alternative for the drug.

13. Children whose families could not afford the list price of the Authorized Generic (well over $100 a month) have been forced to go without this critical medication.

14. There has been a resultant increase in emergency room visits, and even deaths, from asthma.

15. In July, NPR reported on a nine-year-old boy who had an asthma attack when he was unable to get asthma medication after GSK discontinued Flovent.[1] "You could see his ribs because he was struggling so hard to breathe," his mother said. The boy spent two days in an intensive care unit while his doctors attempted to locate a Flovent alternative that the family's insurance would cover.

16. Defendant's sale of the Authorized Generic at its current prices is unfair within the meaning of the Arizona Consumer Fraud Act. It is only possible for Defendant to sell the Authorized Generic at these prices because GSK, after profiting immensely from public Medicaid funds, contrived to avoid its rebate obligations in callous disregard for the health of child asthmatics throughout the United States, including in Arizona.

[1] Alan Yu, *A discontinued asthma medication has patients scrambling, some to the ER*, NPR, 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.

PARTIES

I. PLAINTIFF

17. The State of Arizona is authorized to bring this action pursuant to the Arizona Consumer Fraud Act, A.R.S. §§ 44-1521 to 44-1534, to obtain injunctive relief to permanently enjoin and prevent the unlawful acts and practices alleged in this Complaint, and to obtain other relief, including restitution, disgorgement of profits, gains, gross receipts, or other benefits, civil penalties, and costs and attorneys' fees.

18. Plaintiff seeks relief for the harm suffered by consumers and payors in Arizona because of Defendant's unfair Flovent Renaming Scheme, as well as civil penalties and injunctive relief to prevent future harm.

II. DEFENDANT

19. Defendant GlaxoSmithKline LLC ("GSK") is a Delaware LLC with its principal place of business at 2929 Walnut Street, Suite 1700, Philadelphia, Pennsylvania.

20. GSK has been registered to do business in the State of Arizona since 2009.

21. GSK transacts business in Arizona, targeting this market for its products, including Flovent and the Authorized Generic.

JURISDICTION AND VENUE

22. Jurisdiction is appropriate in this Court pursuant to A.R.S. § 12-123.

23. This Court has personal jurisdiction over Defendant because Defendant: (1) transacts business within Arizona, (2) maintains substantial contacts in Arizona, and (3) committed violations of the Arizona Consumer Fraud Act within the State of Arizona. This action arises out of and relates to Defendant's contacts within Arizona.

24. The Flovent Renaming Scheme has been directed at and has had the foreseeable and intended effect of harming consumers residing in Arizona. At-issue transactions occurred in the State of Arizona.

25. Defendant purposefully availed itself of the privilege of doing business within Arizona, and derived substantial financial gain from doing so.

26. Defendant systematically targeted the Arizona market in connection with the Flovent Renaming Scheme such that there is a strong relationship among Defendant, this forum, and the litigation.

27. Venue is appropriate pursuant A.R.S. § 12-401 as Maricopa County is the seat of the State government and the Office of the Attorney General.

FACTUAL ALLEGATIONS

I. ASTHMA IN ARIZONA.

28. Asthma is a long-term, chronic disease of the airways of the lungs characterized by a narrowing of the airways, which results in symptoms such as wheezing and shortness of breath.

29. It is one of the most common diseases in the United States, affecting more than 27 million people in the United States, including approximately 4.5 million children under the age of 18.[2]

30. Approximately 10 people in the United States die from asthma each day, with deaths due to asthma recently rising for the first time in 20 years.[3]

31. It is estimated that more than 1 million Arizona residents have asthma.[4]

32. In 2021, the most recent year for which the Arizona Department of Health Services has published data, asthma was mentioned as a condition in approximately 100,000

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[2] Rhoda Oja, *et al.*, *Epidemiology of Current Asthma in Children Under 18*, Cureus, Nov. 22, 2023, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10739102/#:~:text=Asthma%20prevalence%20increased%20globally%2C%20affecting,18%20%5B3%2D4%5D.

[3] Asthma Facts, Asthma and Allergy Foundation of America, https://aafa.org/asthma/asthma-facts/#:~:text=On%20average%2C%2010%20people%20in,the%20right%20treatment%20and%20care.&text=In%202020%2C%20deaths%20due%20to,first%20time%20in%2020%20years.

[4] Arizona Asthma Coalition, https://www.azasthma.org/.

emergency room visits, and was the first listed diagnosis in over 18,000 of these visits.[5]

33. Almost 100 Arizona residents die every year due to asthma.[6]

34. Compared to all U.S. residents, Arizonans, and Arizona youth, are disproportionately affected by asthma.[7]

35. There is no cure for asthma, but asthma can be managed with proper prevention and treatment.

II. FLOVENT BEFORE ITS DISCONTINUATION.

36. Flovent was a brand name asthma drug manufactured and sold by GSK.

37. Flovent was sold as both a prescription metered-dose inhaler (Flovent HFA) and a dry powder inhaler (Flovent Diskus).

38. Flovent Diskus entered the market in 2000, and Flovent HFA entered the market in 2004.

39. Flovent was a maintenance inhaler, as opposed to a rescue inhaler.

40. Whereas a rescue inhaler is intended to relieve an asthma attack that has already started, a maintenance inhaler is used regularly for the purpose of preventing, or decreasing the number and severity of, asthma attacks.

41. The active ingredient in Flovent was fluticasone propionate, a steroid that helps reduce inflammation and swelling in airways, and which is used to prevent asthma attacks.

42. For people with persistent asthma, Flovent was the most commonly used daily preventive anti-inflammatory medication for decades.[8] Indeed, it was the most commonly

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[5] Arizona Department of Health Services, *Hospital Inpatient Discharges & Emergency Room Visits Statistics*, https://pub.azdhs.gov/health-stats/hip/index.php?pg=asthma.

[6] *Id.*

[7] Ariona Asthma Coalition, https://www.azasthma.org/Public-Resources.

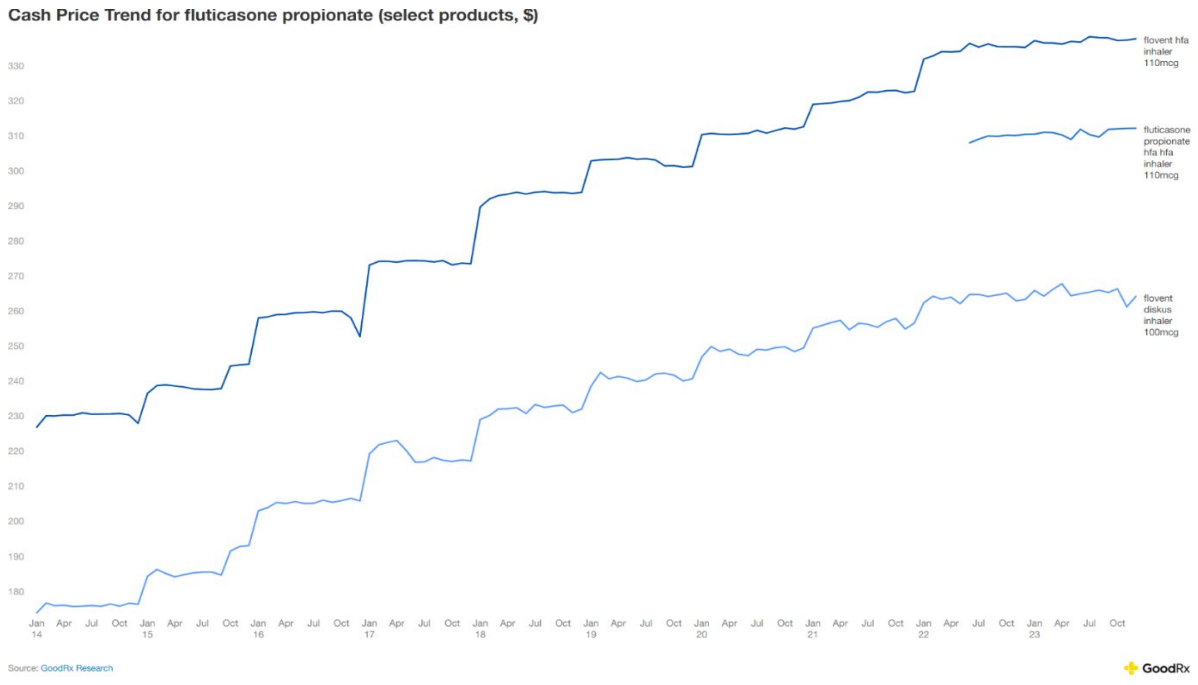
[8] Meg Tirrell, *"A Huge Shock to the System:" Doctors Warn About Asthma Inhaler Switch Coming in January*, CNN, Dec. 28, 2023, https://www.cnn.com/2023/12/28/health/asthma-inhaler-generic-switch/index.html.

used inhaled medication for the past 25-30 years.[9]

43. In 2021, for example, fluticasone was prescribed approximately 25.3 million times.[10]

44. According to Dr. Robyn Cohen, a pediatric pulmonologist at Boston Medical Cener, Flovent is the medication that "overwhelmingly, pediatricians reach for when they decide that their patient needs a daily preventive medication."[11]

45. Over the course of, at least, the last ten years, GSK consistently raised prices on Flovent grossly in excess of the annual US inflation rate. The chart below[12] shows the Flovent cash price increase for the last ten years:



[9] Jay Croft, *Switch to Generic Version of Asthma Inhaler Could Be Problematic*, WebMD, Dec. 28, 2023, https://www.webmd.com/asthma/news/20231228/switch-to-generic-version-asthma-inhaler-problematic.

[10] Matej Mikulic, *Number of Fluticasone Prescriptions in the US: 2004-2021*, https://www.statista.com/statistics/781803/fluticasone-prescriptions-number-in-the-us/.

[11] Croft, *Switch to Generic Version of Asthma Inhaler Could Be Problematic.*

[12] Tori Marsh, https://www.goodrx.com/healthcare-access/research/cash-price-trend-for-fluticasone-propionate.

46. In a January 8, 2024 letter to Emma Walsley, GSK's CEO, Senators Bernie Sanders, Tammy Baldwin, Ben Ray Luján, and Edward Markey addressed GSK's price increases for its asthma inhaler products in the context of GSK's alleged manipulation of the patent system.[13] The Senators noted that GSK sells its inhaler products for "often 10 times the prices it charges for the exact same products in Germany, Japan, Canada, France, and the U.K."[14]

47. Flovent's price increases can be attributed, in part, to the absence of generic alternatives; which, in turn, is attributable, in part, to GSK's manipulation of the patent system.

48. Part of the reason that GSK was able to raise prices on Flovent so dramatically is because it also manipulated the patent system to prevent the introduction of generics.

49. GSK used tactics referred to as patent thicket and device hopping to effectively prevent generic competition for Flovent.

50. In the pharmaceutical context, the term patent thicket refers to a brand-name manufacturer (like GSK) claiming that a brand-name pharmaceutical is protected by multiple patents, most of which do not cover the active pharmaceutical compounds, but instead are directed to peripheral features such as methods of use and deliver devices.[15]

51. Brand-name drug manufacturers list the patents associated with their brand-name products in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). The FDA cannot approve generic drugs for marketing until patents in the Orange Book on the brand-name drugs expire or are successfully challenged. Thus, the more patents that are associated with a brand-name product, the longer the product can be patent

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[13] Letter to Emma Walmsley, January 8, 2024, available at https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-GSK.pdf.

[14] *Id.*

[15] *Patent Thickets and Product Hops: How Congress Could Reward Legitimate Innovation While Facilitating More Timely Generic Competition*, *Before the United States Senate Judiciary Committee* (2024) (William B. Feldman, Harvard Medical School).

protected and the more difficult it is for a generic manufacturer to introduce a generic alternative.[16]

52. Device hopping refers to the practice of placing the same active ingredient (e.g. fluticasone) into a new device with new patents and exclusivities.[17]

53. When it launched Flovent HFA in 2004, GSK listed six patents in the Orange Book. After 2004, GSK listed an additional 16 patents associated with the product, including 13 that were added in 2009 or later, including patents on dose counters.[18]

54. Under United States patent law, the term of a patent is 20 years from the filing of the patent application to which priority is claimed.

55. GSK filed its first patent on a fluticasone inhaler (Flovent) in 1981 and introduced follow-on fluticasone inhalers with patents running through 2030, or 49 years after the first filing with no gaps between products.[19]

56. GSK made billions of dollars through the sale of Flovent, long after the patent on the active ingredient, fluticasone propionate, had expired.[20]

57. As Senators Sanders, Baldwin, Luján, and Markey recognized, GSK's exorbitant prices have the effect of forcing people, especially the uninsured and underinsured, "to ration doses or abandon their prescriptions altogether," which predictably leads to more

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[16] *Id.*

[17] William B. Feldman, *Patents and regulatory exclusivities on inhalers for asthma and COPD*, *1986-2020*, Health Affairs, May 17, 2022, https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01874.

[18] Letter from Senator Sanders to Emma Walmsley, Jan. 8, 2024, available at https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-GSK.pdf.

[19] William B. Feldman, *Patents and regulatory exclusivities on inhalers for asthma and COPD*, *1986-2020*, Health Affairs, May 17, 2022, https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01874.

[20] *Patent Thickets and Product Hops: How Congress Could Reward Legitimate Innovation While Facilitating More Timely Generic Competition*, *Before the United States Senate Judiciary Committee* (2024) (William B. Feldman, Harvard Medical School).

people "likely to get sick, to be hospitalized or to die."[21] The Senators referenced Dr. Michael Joffe, a primary care doctor in Virginia who polled his patients to see which drugs they had the most difficulty affording. The answer was asthma inhalers, and particularly, maintenance inhalers like Flovent.[22]

58. The people most likely to suffer from asthma are the people least likely to be able to afford inhalers—people living in poor and underserved communities who are exposed to allergens and pollutants at high rates due to low-quality housing or exposure to major sources of pollution, such as factories and roadways.[23]

59. From 2014 to 2023, during which time GSK increased the price of Flovent by 47%, GSK made approximately $71 billion in profit.[24]

III. GSK PROFITS FROM MEDICAID, BUT DOES NOT PLAY BY ITS RULES.

60. As of January 2024, approximately 84 million Americans were enrolled in Medicaid and Children's Health Insurance Programs (CHIP).[25] Of these, approximately 38 million were children.[26]

61. Over 2.2 million Arizonans have full or partial health coverage through Medicaid or CHIP.

62. In response to rising drug prices and projected increased Medicaid spending, the Medicaid Prescription Drug Rebate Program (MDRP) was created in 1990 by the

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[21] Letter to Emma Walmsley, January 8, 2024, available at https://www.sanders.senate.gov/wp-content/uploads/2024.01.08-HELP-Committee-Letter-to-GSK.pdf.

[22] *Id.*

[23] *Id.*

[24] GSK corporate reports, available at https://www.gsk.com/en-gb/investors/financial-reports/corporate-reports-archive/.

[25] https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.

[26] https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.

Omnibus Reconciliation Act.[27]

63. Under the program, a manufacturer who wants its drug covered under Medicaid must enter into a rebate agreement with the Secretary of Health and Human Services stating that it will rebate a specified portion of the Medicaid payment for the drug to the states, who in turn share the rebates with the federal government.[28] In exchange, Medicaid programs cover nearly all of the manufacturer's FDA-approved drugs, and the drugs are eligible for federal matching funds.[29]

64. The Medicaid rebate amount is set in statute and, generally, is intended to ensure that the program gets the lowest price.[30]

65. The rebate amount includes two main components: (1) a component based on a percentage of average manufacturer price (AMP), or the difference between AMP and "best price," whichever is greater; and (2) an inflationary component to account for price increases.[31]

66. The inflationary component of the rebate is calculated as the difference between the drug's current quarter AMP and its baseline AMP (the AMP of a drug during the first full quarter after launch) adjusted to the current period by the Consumer Price Index for All Urban Consumers.[32] Essentially, if a drug's price increases faster than inflation, the manufacturer has to rebate the difference to Medicaid.

67. Because of the inflationary component, the calculated rebate on a drug whose price increases quickly over time could be greater than the AMP for that drug.

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[27] Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF. November 12, 2019, https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.

[28] *Id.*

[29] *Id.*

[30] 42 U.S.C. § 1396r-8.

[31] *Id.*

[32] *Id.*

68. In prior years, the amount of the rebate was capped at 100% of a drug's AMP.[33]

69. However, a provision in the American Rescue Plan Act removed that cap, effective January 1, 2024.[34]

70. GSK sells to Medicaid and is obligated to provide rebates under the MDRP.

71. Because GSK raised Flovent's prices so aggressively from the date of its launch through 2023, if GSK continued to sell Flovent at its most recent prices, it would have had to pay a rebate that was greater than the drug's AMP.

72. It was only because of GSK's price gouging—increasing the price of Flovent, a medication that families relied on to keep their children safe, at a rate that was far greater than the Consumer Price Index—that GSK would have had to pay such significant rebates.

73. As GSK explained in its second quarter 2023 earnings call, it could have avoided paying rebates greater than Flovent's AMP by reducing the price of the drug.

74. GSK chose not to reduce Flovent's price or pay the rebates.

75. Rather, on January 1, 2024, the exact date that the removal of the rebate cap went into effect, GSK discontinued Flovent and started selling an authorized generic version of the drug through its distributor, Prasco LLC.

76. Prasco states that its "priority" is the success of brand pharmaceutical companies, like GSK.[35]

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[33] Elizabeth Williams, *What Are the Implications of the Recent Elimination of the Medicaid Prescription Drug Rebate Cap*, KFF, Jan. 16, 2024, https://www.kff.org/policy-watch/what-are-the-implications-of-the-recent-elimination-of-the-medicaid-prescription-drug-rebate-cap/#:~:text=As%20of%20January%201%2C%202024,drug%20prices%20substantially%20over%20time.

[34] KFF, https://www.kff.org/policy-watch/what-are-the-implications-of-the-recent-elimination-of-the-medicaid-prescription-drug-rebate-cap/#:~:text=As%20of%20January%201%2C%202024,drug%20prices%20substantially%20over%20time.

[35] https://prasco.com/what-we-do/business-development/.

77. In 2009, Prasco announced that it had entered into an agreement with GSK to serve "as GSK's agent" in the distribution of another of GSK's fluticasone propionate product's Flonase.[36]

78. Prasco serves as GSK's agent with respect to the distribution and sale of the Authorized Generic in Arizona.

79. As GSK states: "According to the FDA, an Authorized Generic is 'an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product."[37]

80. The Authorized Generic is the exact same drug, without the "Flovent" brand name.

81. The Authorized Generic is priced slightly lower than Flovent's most recent price, but still grossly in excess of the price at which Flovent was introduced into the market.

82. GSK is able to sell the Authorized Generic at this inflated rate due to the absence of generic alternatives in the marketplace; which is attributable, at least in part, to GSK's manipulation of the patent system.

83. Because of what is essentially just a name change, GSK has been able to continue to sell its Flovent inhalers at inflated prices, while avoiding the required Medicaid inflationary rebates.

84. Thus, while the Authorized Generic is priced slightly lower than Flovent's most recent price, the scheme in no way benefits consumers because the purpose and result of the scheme is the continued sale of Flovent (now renamed as the Authorized Generic) at inflated prices, with GSK avoiding the significant reduction in Flovent's price that would otherwise have been compelled by removal of the rebate cap.

85. In its Q2 and Q3 2024 earnings announcements, GSK stated that the impact

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[36] Prasco press release, March 11, 2009, https://prasco.com/news/news-archive/2009/prasco-selected-as-gsk%E2%80%99s-generics-marketing-and-distribution-agent.html.

[37] https://www.flovent.com/.

from the removal of the AMP cap on earnings from Flovent "fully offset by the increased use of authorised generic" Flovent.

86. In its Q2 2024 earnings call, a GSK executive explained that the switch to the authorized generic allowed GSK to avoid a "price hit" on Flovent.

87. GSK profited for years from Flovent price increases.

88. During that time, GSK received billions of dollars in public money from selling its drugs through Medicaid.

89. When the time came to either pay more significant rebates or significantly reduce the price of Flovent, GSK unfairly chose a third path.

IV. GSK's SCHEME PREDICTABLY CAUSES PATIENTS AND FAMILES TO SUFFER.

90. GSK's decision to suddenly discontinue Flovent and replace it with the identical Authorized Generic to evade the payment of rebates to Medicaid was unfair because it had predictable monetary and adverse health consequences for consumers.

91. The Flovent Renaming Scheme has caused families to forego the medication needed to control their children's asthma.

92. As three pediatricians recently wrote in an article for STAT, "[a]t least seven children have died due to uncontrolled asthma this year in the Philadelphia region, a dramatic increase from prior years."[38]

93. They wrote further, regarding their institution: "[A]dmissions for intensive care to support children with asthma have nearly doubled from the pre-pandemic baseline, and admissions for asthma are up 50% in March and April compared to last year."[39]

94. This increase in child asthma acuity and deaths is related to access to basic medications.

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[38] Drs. Chén Kenyon, Bianca Nfonoyim Bernhard, and Tyra Bryant-Stephens, *As Childhood Asthma Worsens, Insurers Restrict Access to an Essential Medication*, STAT, May 16, 2024, https://www.statnews.com/2024/05/16/asthma-medicine-discontinuation-flovent-children/.

[39] *Id.*

95. Specifically, the increase in child asthma acuity and deaths is related in significant part to the discontinuation of Flovent.

96. The vast majority of asthmatics pay for their medication through insurance, and the "seemingly simple transition" to the Authorized Generic has "led to a tremendous disruption in the care of children with asthma" because of lack of insurance coverage of the Authorized Generic.[40]

97. Whereas Flovent had been widely covered on insurance company formularies, the same has not been true, at least initially, of the Authorized Generic.

98. OptumRX, one of the largest pharmacy benefit managers ("PBMs"), stated that GSK introduced the generic version of Flovent at a "much higher net price" to insurers than brand name Flovent.[41] In other words, GSK was not paying rebates on the authorized generic.

99. OptumRX described GSK's scheme as "one that puts profits before patients."[42]

100. Instead of introducing the Authorized Generic at the same price to PBMs and payors as Flovent, GSK chose to risk children's lives and inflict tremendous stress on families, as it sought to negotiate a more favorable deal for itself on the Authorized Generic.

101. Because the cost of the Authorized Generic was significantly greater for insurers (despite the cash price being slightly lower), insurers and PBMs approved alternative inhaled corticosteroids rather than cover the Authorized Generic.

102. This practice, known as non-medical formulary switching, typically occurs when a PBM changes coverage to an alternative drug for which it can negotiate a better price, but which is not necessarily better for patients.

103. The decisions not to cover the Authorized Generic, and to instead cover alternative inhaled corticosteroids, proved extremely problematic in the case of Flovent and

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[40] *Id.*

[41] Dr. Edith Bracho-Sanchez, *Doctors, Parents Scrambling After Asthma Inhaler Switch Takes Popular Medication Off the Market*, ABC News, Feb.13, 2024, https://abc7chicago.com/medication-for-asthma-what-is-flovent-inhaler-in-children/14418736/.

[42] *Id.*

the Authorized Generic because these were and are the only readily available metered-dose inhaled corticosteroid.

104. Small children typically require a metered-dose form of the inhaler, as they are not able to take breath-actuated or dry powder inhalers.

105. Small children, and others with poor lung function, need a metered-dose inhaler because it is able to deliver the medication without demanding deep breaths from the patient.

106. The only viable metered-dose alternative to Flovent for young children, Asmanex, has been in short supply. Indeed, "[n]early five months after Flovent's discontinuation, it remain[ed] nearly impossible nationally to find Asmanex."[43]

107. In the STAT article, the pediatricians noted that they are "now regularly seeing children who require repeat hospitalizations and ER visits because their needed controller medicine is not covered by insurance and therefore the asthma gets out of control."

108. The article also quoted the mother of young asthma patient who had been forced to go without a maintenance inhaler because the Authorized Generic was not covered by insurance: "I don't understand. My son needs this medication. How can the insurance company not cover it? What are we supposed to do?"

109. Likewise, in Arizona, Dr. Rahal Chawla, a pediatric emergency room doctor at Banner Health's Thunderbird Medical Center said that he has seen in uptick in asthma patients in the emergency room.

110. Dr. Chawla stated: "We've had patients coming into the ER that are coming in from asthma attacks because they're not taking their controller medication . . . [b]ecause . . . either pharmacies don't have it or the parents can't afford it."[44]

111. As Dr. Chawla stated, "[T]he powder is a much harder way for young children

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[43] Kenyon et al., *As Childhood Asthma Worsens, Insurers Restrict Access to an Essential Medication.*

[44] Alaina Kwan, *Families Scramble After Lifesaving Asthma Inhaler Taken Off the Market*, Arizona Family, Feb. 26, 2024, https://www.azfamily.com/2024/02/26/families-scramble-after-lifesaving-asthma-inhaler-taken-off-market/.

. . . who have lung restraint problems to take the drug . . . . Kids can try taking the powder form of it but it's not going to work . . . ."

112. Dr. Christoper Oerman, a pediatric pulmonologist and director of the Division of Allergy, Immunology, and Pulmonology at Children's Mercy Kansas City stated: "The discontinuation of Flovent has been an unmitigated disaster."[45]

113. Dr. Ben Nelson, a pediatric pulmonologist at Mass General for Children, explained that even when his team is able to identify an alternative and file the appropriate paperwork, the medications are labeled as "tier 3 drugs" by insurance formularies, which require a higher copay.[46]

114. Dr. Christy Sadreameli, a pediatric pulmonologist and assistant professor of pediatrics at Johns Hopkins in Baltimore, Maryland, said "many kids" are falling through the gaps.[47]

115. Data from over 3 million people who had been using Flovent showed a 17.5% increase in asthma-related hospitalization in the three months after Flovent was discontinued, and a 24.1% increase in the following three to six months.[48]

116. ICU admissions for asthma in those previously using Flovent increased 17.4% three months after discontinuation, and 23.1% three to six months after discontinuation.

117. On March 1, 2024 Senator Elizabeth Warren wrote a letter to GSK CEO Walmsley criticizing GSK for its decision to discontinue Flovent, calling it a "shameful money grab."[49]

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[45] *Id.*

[46] *Id.*

[47] *Id.*

[48] Dr. Sejal Parekh, Sara Avery, *Discontinuation of Popular Asthma Medication, Flovent, Linked With Increased Hospitalization*, Oct. 29, 2024, https://abcnews.go.com/Health/discontinuation-popular-asthma-medication-flovent-linked-increased-hospitalization/story?id=115267150.

[49] Letter from Senator Warren to Emma Walmsley, March 1, 2024, available at https://www.warren.senate.gov/newsroom/press-releases/warren-slams-inhaler-

118. Senator Warren wrote: "[GSK's] move is not consistent with GSK's mission of 'uniting science, technology and talent to get ahead of disease together.' It does none of these things. Instead, the company has made a life-saving drug inaccessible for millions of children just months before allergy season – all to pad the profits of GSK's executives and shareholders."[50]

119. On May 1, 2024, Senator Maggie Hassan sent her own letter to Ms. Walmsley, also harshly criticizing GSK's Flovent Discontinuation Scheme.[51]

120. Senator Hassan wrote: "Since GSK's switch in January 2024, parents of children with asthma have faced a worse-case scenario: they cannot afford the new authorized generic product, which is not covered by most insurers and pharmacy benefit managers. Countless children no longer have a single age appropriate inhaler covered by their insurance plan."[52]

121. She also wrote: "[GSK] appears to be exploiting a licensing agreement with Prasco Laboratories in order to circumvent [its] public commitments and price-gouge families without access to affordable alternatives to Flovent."[53]

122. In response to these Senators' criticisms, and the outcry amongst pediatricians, GSK has made it clear that it does not intend to change its course of conduct.[54]

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manufacturer-glaxosmithkline-for-price-gouging-patients-and-making-inhalers-inaccessible-for-children.

[50] *Id.*

[51] Letter from Senator Hassan to Emma Walmsley, May 1, 2024, available at https://www.hassan.senate.gov/news/press-releases/senator-hassan-presses-big-pharma-company-to-restore-access-to-low-cost-asthma-inhalers-for-children.

[52] *Id.*

[53] *Id.*

[54] Kansteiner, Fraiser, "Senator Claims GSK Pulled Popular Asthma Med to Dodge Price Caps," *Fierce Pharma*, May 3, 2024, https://www.fiercepharma.com/pharma/gsk-defends-itself-again-after-senator-argues-it-withdrew-popular-asthma-med-dodge-price.

CLAIMS FOR RELIEF

COUNT ONE
VIOLATION OF THE ARIZONA CONSUMER FRAUD ACT
A.R.S. §§ 44-1521 – 1534

123. Plaintiff repeats and realleges paragraphs 1-122, as if fully set forth herein.

124. Arizona's Consumer Fraud Act states that the "act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby" is an "unlawful practice." A.R.S. § 44-1522(A).

125. Defendant is a "person" within the meaning of, and subject to, the provisions of the Consumer Fraud Act. A.R.S. § 44-1521(6).

126. Each at-issue drug is an object or good and thus constitutes "merchandise" under the Consumer Fraud Act. A.R.S. § 44-1521(5); *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 28, ¶ 33, 365 P.3d 944, 953 (2016) (prescription drugs are "merchandise" under Arizona's Consumer Fraud Act).

127. The Arizona Attorney General is authorized by statute to enforce the Consumer Fraud Act whenever the Attorney General "has reasonable cause to believe that a person has engaged in, is engaging in or is about to engage in any" practice that violates the Consumer Fraud Act. A.R.S. § 44-1524. The Attorney General may seek injunctive relief, restitution, and disgorgement. A.R.S. §44-1528(A).

128. The Attorney General may also recover a civil penalty of not more than $10,000 per violation, if the violation was willful. A.R.S. § 44-1531(A). A willful violation "occurs when the party committing the violation knew or should have known that his conduct was of the nature prohibited" by the Consumer Fraud Act. A.R.S. § 44-1531(B).

129. The Attorney General is further "entitled to recover costs, which in the discretion of the court may include a sum representing reasonable attorney's fees for the services rendered, for the use of the state." A.R.S. § 44-1534.

130. Defendant, through the conduct described in this Complaint, has engaged in unlaw practices prohibited by the Consumer Fraud Act.

131. The Defendant's conduct, including each sale of the Authorized Generic into the State, was an unfair act or practice under the Consumer Fraud Act, because it violated established public policy and substantially injured consumers.

132. The Flovent Renaming Scheme, including the sales of the Authorized Generic, has substantially injured, and will continue to substantially injure, Arizona consumers and payors by forcing them to pay inflated prices for critical medication.

133. The Flovent Renaming Scheme further injured Arizona consumers by preventing them from being able to obtain, or easily obtain, appropriate asthma medication.

134. The injury to Arizona consumers and payors is not an injury that they could have reasonably avoided, and it is not outweighed by any countervailing benefit to consumers or competition.

135. It is public policy, as set forth in the Medicaid Prescription Drug Rebate Program at 42 U.S.C. §1396r-8, that drug manufacturers shall not be able to both profit from selling to Medicaid and grossly inflate the prices of their prescription drugs.

136. Through the Flovent Renaming Scheme, Defendant violated that public policy by selling Flovent and the Authorized Generic at a grossly inflated price, while evading the *quid pro quo* of paying the inflationary rebate.

137. Defendant's actions demonstrate callous disregard for not only the rule of law, but also public health, safety, and well-being.

138. While engaging in the unlawful practices alleged herein, Defendant has, at all times, acted willfully.

139. Defendant knew or should have known that its actions were of the nature prohibited by the Arizona Consumer Fraud Act.

140. As a direct and proximate result of Defendant's unfair acts and practices, payors and consumers in Arizona sustained actual damages, including, but not limited to, paying excessive and inflated prices for the Authorized Generic.

141. As a direct and proximate result of Defendant's unfair acts and practices, Defendant has received, and will continue to receive, income, profits, and other benefits, which it would not have received if it had not engaged in violations of the Arizona Consumer Fraud Act.

142. The State seeks all legal and equitable relief as allowed by law, including injunctive relief, restitution, disgorgement, and civil penalties.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for entry of judgment against the Defendant for all the relief requested herein and to which the Plaintiff may otherwise be entitled, including, without limitation, as follows:

a. A determination that Defendant has violated the Arizona Consumer Fraud Act;

b. Injunctive relief in accordance with the Arizona Consumer Fraud Act to the effect that Defendant, its affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with it, be enjoined and restrained from continuing to sell the Authorized Generic at artificially inflated prices;

c. An award of the maximum amount of statutory civil penalties available under A.R.S. § 1531 against each Defendant for each willful violation of the Arizona Consumer Fraud Act;

d. An award of restitution, disgorgement, and all other legal and equitable relief to which Plaintiff, and other Arizona consumers and Arizona payors may be entitled;

e. An award of pre- and post-judgment interest as provided by such law;

f. An award to the State of the costs incurred in connection with this action, including reasonable attorneys' fees; and

g. Such other further relief as the case may require and the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

DATED: February 6, 2025

Respectfully submitted,

/s/ Mitchell Allee
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