United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

January 8, 2024

Emma Walmsley
Chief Executive Officer
GSK
980 Great West Road
Brentford
Middlesex
TW8 9GS
United Kingdom

Dear Ms. Walmsley,

We write to initiate an investigation into GSK's inhaler products and the company's extensive efforts to keep prices high for patients. In the United States, more than 20 million adults and over 4.5 million children have asthma,[1] and nearly 16 million adults have chronic obstructive pulmonary disease (COPD).[2] Almost all of these people need inhalers to help them breathe. But GSK sets the price of each life-saving device as high as $650 a month.[3]

There is no reason for inhalers to be so expensive. Inhaler devices and the medicine in them are not new. Indeed, the devices have been available since the 1950s and most of the active ingredients they use have been on the market for more than 25 years. Yet GSK charges unbelievable amounts for these products in the United States—often 10 times the prices it charges for the exact same products in Germany, Japan, Canada, France, and the U.K.

These prices are only possible because GSK has manipulated the regulatory system to extend its monopolies over its inhaler products. The company does this by ensuring its inhalers do not face competition from generics, which play a critical role in driving down costs for patients. Where there are multiple generics, inhaler prices can drop to as low as $30.[4] But where there are none, companies can set prices as high as they want—which for GSK means between $150 and $650

[1] *Most Recent National Asthma Data*, CTRS. FOR DISEASE CONTROL AND PREVENTION (CDC) (May 10, 2023), https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm.
[2] *What Do Chronic Obstructive Pulmonary Disease Rates Look Like in Your State*, NAT'L HEART, LUNG, AND BLOOD INST., https://www.nhlbi.nih.gov/health-topics/education-and-awareness/copd-learn-more-breathe-better/state-prevalence (last visited Jan. 4, 2024).
[3] Navlin Int'l Pharm. Pricing Database, https://www.navlin.com/ (last visited Jan. 4, 2024).
[4] Albuterol, GoodRx Inc., https://www.goodrx.com/albuterol (last visited Jan. 4, 2024).

for products that have to be replaced monthly. Of the company's nine inhaler products, only one faces direct generic competition.[5]

GSK's efforts to block generic competition have allowed it to make billions of dollars in revenue on its inhaler products while the people whose lives depend on these products struggle to afford them. Over the past five years, the company has made over $18 billion in revenue from inhalers alone in large part because of these anti-competitive practices.[6] This is not uncommon in the industry. The major brand-name pharmaceutical companies brought in more than $178 billion between 2000 and 2021 on inhaler products, revenues that are a direct result of the outrageous prices the companies charge.[7] These prices force patients, especially the uninsured and underinsured, to ration doses or abandon their prescriptions altogether. The results are predictable and devastating. Without consistent access to inhalers, people with asthma and COPD are more likely to get sick, to be hospitalized, and to die. Asthma alone kills 3,500 people every year, and nearly all of these deaths are preventable with regular treatment and affordable care.[8] This cannot be allowed to continue.

**The people most likely to need inhalers are the people least likely to be able to afford them.**

Asthma and COPD are chronic diseases that make it difficult to breathe. Asthma is one of the most common respiratory diseases in the country and the most common chronic disease among children—about one in every 13 Americans have it.[9] COPD is almost as prevalent, though it is concentrated among adults.[10] Both diseases can be fatal: asthma kills about 10 people every day,[11] while COPD kills about 390 people every day and is the sixth-leading cause of death in the United States.[12]

Although there is no cure for asthma or COPD, inhalers help people who have these diseases manage their symptoms. They can be used daily as "maintenance inhalers" or in response to

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[5] *See* Press Release, Hikma, Hikma Launches Generic Advair Diskus Following FDA Approval (Dec. 17, 2020), https://www.hikma.com/newsroom/article-i4952-hikma-launches-generic-advair-diskus-following-fda-approval/.
[6] Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) majority staff analysis based on GSK, *Annual Report 2022*, *Annual Report 2021*, *Annual Report 2020*, *Annual Report 2019*, *Annual Report 2018*.
[7] William B. Feldman et al., *Manufacturer Revenue on Inhalers After Expiration of Primary Patents, 2000-2021*, 329 JAMA 87 (2022), https://jamanetwork.com/journals/jama/article-abstract/2800037.
[8] Sarah Goff, *Asthma Facts and Figures*, ASTHMA AND ALLERGY FOUND. OF AM. (Sep. 2023), https://aafa.org/asthma/asthma-facts/.
[9] Michelle Trivedi & Eve Denton, *Asthma in Children and Adults – What Are the Differences and What Can They Tell us About Asthma?*, 7 FRONTIERS IN PEDIATRICS 256, 1 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6603154/pdf/fped-07-00256.pdf; CDC, *supra* note 1.
[10] Div. of Population Health, Nat'l Ctr. For Chronic Disease Prevention and Health Promotion, *Chronic Obstructive Pulmonary Disease (COPD)*, CDC (June 30, 2023), https://www.cdc.gov/copd/basics-about.html.
[11] CDC, *supra* note 1.
[12] *Chronic Obstructive Pulmonary Disease (COPD) Includes: Chronic Bronchitis and Emphysema*, CDC (Nov. 13, 2023), https://www.cdc.gov/nchs/fastats/copd.htm.

symptoms as "rescue inhalers."[13] Many people with asthma and COPD rely on both types of inhalers to help them breathe—which adds to their financial burden.[14]

Critically, the people most likely to suffer from asthma and COPD are the people least likely to be able to afford inhalers. People who live in poor and underserved communities are exposed to allergens and pollutants at high rates: mold and pests are common in low-quality housing and major sources of pollution, such as factories and roadways, are often nearby.[15] These allergens and pollutants increase the likelihood that the people who live in these communities—particularly children—will develop asthma and experience severe symptoms as part of the disease.[16] Because of decades of discriminatory housing practices, people from racial and ethnic minority groups are especially vulnerable.[17]

In addition to being exposed to unhealthy environments, people who live in poor and underserved communities have limited access to primary care providers and specialists who can diagnose their asthma and treat their symptoms.[18] As a result, not only are they more likely to have asthma, they are also more likely to need costly emergency care.[19] Because of the inequitable healthcare system in the United States, the burdens of asthma fall disproportionately on Black Americans, who are three times more likely to die from the disease.[20] Black children are at especially high risk: they are nearly eight times more likely to die from the disease.[21]

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[13] *See, e.g.*, *Global Strategy for Asthma Management and Prevention* 56, GLOB. INITIATIVE FOR ASTHMA (July 2023), https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf.

[14] *See id.* at 58-88 (describing standard of care for asthma pharmacotherapy); *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease* 117-20, GLOB. INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE (2023), https://goldcopd.org/wp-content/uploads/2023/03/GOLD-2023-ver-1.3-17Feb2023_WMV.pdf (describing standard of care for COPD pharmacotherapy).

[15] Tyra C. Bryant-Stephens et al., *Housing and Asthma Disparities*, 148 J. ALLERGY & CLINICAL IMMUNOLOGY 1121, 1121-23 (2021), https://www.jacionline.org/action/showPdf?pii=S0091-6749%2821%2901453-6; Mario F. Perez & Maria Teresa Coutinho, *An Overview of Health Disparities in Asthma*, 94 YALE J. BIOLOGY AND MED. 497, 502 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8461584/.

[16] Bryant-Stephens, *supra* note 15, at 1122.

[17] Perez & Coutinho, *supra* note 15, at 502; *see also* Kat Stafford, FROM BIRTH TO DEATH, CHAPTER 2: CHILDHOOD (2023), https://projects.apnews.com/features/2023/from-birth-to-death/black-children-asthma-investigation.html#.

[18] Cynthia A. Pate et al., *Cost Barriers to Asthma Care by Health Insurance Type Among Children with Asthma*, 57 J. ASTHMA 1103, 1107-08 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7291943/pdf/nihms-1571591.pdf.

[19] Margee Louisias & Wanda Phipatanakul, *Managing Asthma in Low-Income, Underrepresented Minority, and Other Disadvantaged Pediatric Populations: Closing the Gap*, 17 CURRENT ALLERGY ASTHMA REP. 68, 70 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5611876/.

[20] Perez & Coutinho, *supra* note 15, at 501; Neeta Thakur et al., *Perceived Discrimination Associated with Asthma and Related Outcomes in Minority Youth – The GALA II and SAGE II Studies*, 151 CHEST 804, 809-11 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5472516/pdf/main.pdf; Melanie Carver et al., *Asthma Disparities in America – A Roadmap to Reducing Burden on Racial and Ethnic Minorities* 11-12, 51-63, ASTHMA AND ALLERGY FOUND. OF AM. (2020), https://aafa.org/wp-content/uploads/2022/08/asthma-disparities-in-america-burden-on-racial-ethnic-minorities.pdf.

[21] *Asthma and African Americans*, U.S DEP'T OF HEALTH AND HUMAN SERVS. OFFICE OF MINORITY HEALTH (Nov. 29, 2022), https://minorityhealth.hhs.gov/asthma-and-african-americans.

COPD also disproportionately affects people in low-income communities. The primary risk factors for COPD are exposure to tobacco smoke and a history of asthma—both of which are common in these communities.[22] Indeed, smoking rates in low-income communities are nearly double what they are in affluent communities.[23] People who live in rural areas are particularly vulnerable: with especially high smoking rates, only half as many primary care providers per resident, and severely limited access to medical specialists, they are far more likely to develop COPD, suffer complications, and die from the disease.[24]

Because inhalers are so expensive, people who have asthma and COPD are often forced to ration their use—if they are able to afford the devices at all.[25] Jenaya Moore had to choose between using her asthma inhaler and keeping her lights on while studying for her graduate degree in Virginia.[26] In 2020, the cost of Ms. Moore's prescription for her inhaler tripled to about $300 a month, which was the same as her electricity bill.[27] As Ms. Moore explained, "I basically called my physician and said, 'Just cut off my refill for right now until I'm able to actually afford it.'" In 2021, Ms. Moore got another part-time job to help pay for her inhaler—working between 60–65 hours a week on top of school. Even with the extra income, she could still only afford to pay for her inhaler occasionally.

Ms. Moore is not alone. Dr. Micha Joffee, a primary care doctor in Virginia, polled his patients to see which drugs they had the most difficulty affording.[28] The answer was asthma inhalers—particularly maintenance inhalers. As Dr. Joffee explained, because maintenance inhalers are so expensive and there are so few generic options, "a lot of times patients will do without them and just kind of put up with not breathing well." But the risk is significant. People with asthma who do not use inhalers as prescribed or do not use them at all are more likely to go to the emergency room, to be hospitalized, and to die.[29]

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[22] *See* Monica E Cornelius et al., *Tobacco Product Use Among Adults – 2021*, 72 MORBIDITY MORTALITY WKLY. REP. 475, 479 (2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7218a1.htm; Roy A. Pleasants, *Defining and Targeting Health Disparities in Chronic Obstructive Pulmonary Disease*, 11 INT'L J. CHRONIC OBSTRUCTIVE PULMONARY DISEASE 2475, 2477-91 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5065167/pdf/copd-11-2475.pdf.

[23] *See* Cornelius, *supra* note 22, at 479.

[24] Pleasants, *supra* note 22, at 2484-88; *About Rural Health*, Nat'l Rural Health Ass'n, https://www.ruralhealth.us/about-nrha/about-rural-health-care (last visited Jan. 4, 2024).

[25] Peter Castaldi et al., *Inhaler Costs and Medication Nonadherence Among Seniors with Chronic Pulmonary Disease*, 138 CHEST 614, 616-19 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2940068/pdf/093031.pdf; Bhavin Patel et al., *Out-of-Pocket Costs and Prescription Filling Behavior of Commercially Insured Individuals with Chronic Obstructive Pulmonary Disease*, 3 JAMA HEALTH FORUM 1167 (2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2792764.

[26] Megan Pauly, *Virginians Struggle with Rising Prescription Drug Prices*, VA. PUB. MEDIA (Feb. 23, 2023), https://www.vpm.org/news/2023-02-23/general-assembly-medication-drug-prices-affordability.

[27] *Id.*

[28] *Id.*

[29] Marjolein Engelkes et al., *Medication Adherence and the Risk of Severe Asthma Exacerbations: A Systematic Review*, 45 EUR. RESPIRATORY J. 396, 404-05 (2015), https://erj.ersjournals.com/content/erj/45/2/396.full.pdf; L. Keoki Williams et al., *Quantifying the Proportion of Severe Asthma Exacerbations Attributable to Inhaled Corticosteroid Nonadherence*, 128 J. ALLERGY CLINICAL IMMUNOLOGY 1185, 1188-90 (2011), https://www.jacionline.org/action/showPdf?pii=S0091-6749%2811%2901481-3.

People with COPD are also forced to choose between paying for their inhalers and paying their bills. Juanita Milton uses two different inhalers every day, including GSK's Breo Ellipta, to manage her COPD.[30] She is also on a fixed income: she has $2,000 a month to cover her mortgage, car payment, Medicare premiums, and other expenses in a small city in Texas. Even with Medicare, Ms. Milton cannot afford the out-of-pocket costs for her two inhalers. Instead, she relies on free samples of one of the inhalers from her doctor—although his supply is limited so she regularly skips doses. She gets the other inhaler from a patient assistance program that has no guarantee of continued supply: when she spoke with a reporter, she had only two doses left. Without consistent access to these critical medications, Ms. Milton struggles to manage her shortness of breath, which she says "feels like drowning." She is also at significantly higher risk for worse health outcomes. As Ms. Milton's doctor explained, without inhalers, patients with COPD are more likely to require emergency care and hospitalization. And studies have shown that skipping doses or not using inhalers at all can lead to premature deaths.[31]

Not surprisingly, both asthma and COPD put significant strain on the healthcare system. Each year, asthma is responsible for more than 1.7 million emergency department visits and over $50 billion in healthcare costs.[32] Similarly, COPD accounts for nearly one million emergency department visits and $24 billion in healthcare costs.[33] The steep price of inhalers—and the resulting lack of consistent use—contributes to these needless expenses.[34]

**Pharmaceutical companies charge exorbitant prices for inhalers.**

The medications Americans rely on to help them breathe are unnecessarily expensive. Modern inhalers have been available since the 1950s, and most of the active ingredients they use have been approved for over 25 years.[35] But despite this decades-old technology, there are very few generic inhalers on the market. Of the 35 brand-name inhalers currently sold in the United States, only five have independent generic competitors.[36] And of the nine inhalers GSK manufactures,

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[30] Sarah Jane Tribble, *Many COPD Patients Struggle to Pay for Each Breath*, KFF HEALTH NEWS (June 5, 2017), https://kffhealthnews.org/news/many-copd-patients-struggle-to-pay-for-each-medicinal-breath/.

[31] Job F.M. van Boven et al., *Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review*, 108 RESPIRATORY MED. 103, 109 (2014), https://www.resmedjournal.com/action/showPdf?pii=S0954-6111%2813%2900364-8.

[32] *CDC's 6│18 Initiative: Accelerating Evidence into Action*, CDC (Mar. 9, 2022), https://www.cdc.gov/sixeighteen/asthma/index.htm.

[33] *COPD Trends Brief: Burden*, AM. LUNG ASS'N, https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-burden (last visited Jan. 4, 2024).

[34] Christopher M. Blanchette et al., *Rising Costs of COPD and the Potential for Maintenance Therapy to Slow the Trend*, 7 AM. HEALTH DRUG BENEFITS 98, 102-05 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4049119/.

[35] William B. Feldman et al., *Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020*, 41 HEALTH AFFAIRS 787, 789 (2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01874; Stephen W. Stein & Charles G. Thiel, *The History of Therapeutic Aerosols: A Chronological Review*, 30 J. AEROSOL MED. PULMONOLOGY DRUG DELIVERY 20, 28-35 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/; Carson Vaughan, *The History of the Asthma Inhaler*, SMITHSONIAN MAG. (Sep. 2020), https://www.smithsonianmag.com/innovation/history-asthma-inhaler-180975511/.

[36] Proventil HFA, ProAir HFA, Advair Diskus, Spiriva HandiHaler, and Symbicort.

only one faces direct generic competition.[37] This lack of generic competition is especially egregious given that many of the active ingredients in GSK's products have been on the market for decades: albuterol since 1981, fluticasone since 1990, and salmeterol since 1994.[38]

In a market with so few generics, manufacturers can charge exorbitant prices. And although there are a number of factors that can influence what patients end up paying, these exorbitant prices are at the heart of the problem. GSK sets the wholesale acquisition cost—the price at which wholesalers can purchase the company's inhalers—at hundreds of dollars each. For example, GSK lists Advair HFA, which treats asthma and COPD, at over $300.[39] After supply-chain markups, the retail cost for patients is nearly $500.[40] Similarly, GSK lists Trelegy Ellipta, which also treats asthma and COPD, at around $650.[41] After markups, the retail cost for patients is close to $800—a staggering amount.[42] In contrast, the generic version of a popular rescue inhaler typically retails at around $45.[43] In other countries, patients can access the same products for dramatically lower prices. The list price of Advair HFA ranges from $22 to $69 in Canada, Germany (sold as Viani), France (Seretide), the U.K. (Seretide), and Japan (Adoair); the list price of Trelegy Ellipta ranges from $49 to $104 in those same countries.[44]

Patients in the United States, on the other hand, can end up spending thousands of dollars a year on inhaler prescriptions that must be filled each month. A person using Advair HFA as prescribed could spend nearly $6,000 a year on the product.[45] A person using Trelegy Ellipta as prescribed could spend nearly $9,500 a year on the product.[46] That is more than the average American spends on food in a year—an incredible sum for a single prescription drug.[47] The cost is even higher for patients who need more than one inhaler a month, as many asthma and COPD patients do.[48]

Of course, most patients without insurance cannot afford those prices, and so are forced to put their lives at risk by either skipping doses or not using inhalers at all. But insurance alone does not solve the problem, as many patients with commercial insurance still face high out-of-pocket costs as a result of exorbitant list prices.[49] Joseph Fabian, a public-school teacher in Texas with

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[37] Press Release, Hikma, *supra* note 5.
[38] Feldman, *supra* note 35, at 790.
[39] Navlin Int'l Pharm. Pricing Database, https://www.navlin.com/ (last visited Jan. 4, 2024).
[40] Advair HFA, GoodRx Inc., https://www.goodrx.com/advair?label_override=advair&form=hfa-inhaler&dosage=115mcg-21mcg&quantity=1&slug=advair (last visited Jan. 4, 2024).
[41] Navlin Int'l Pharm. Pricing Database, https://www.navlin.com/ (last visited Jan. 4, 2024).
[42] Trelegy Ellipta, GoodRx Inc., https://www.goodrx.com/trelegy-ellipta (last visited Jan. 4, 2024).
[43] Albuterol, GoodRx Inc., https://www.goodrx.com/albuterol (last visited Jan. 4, 2024).
[44] Navlin Int'l Pharm. Pricing Database, https://www.navlin.com/ (last visited Jan. 4, 2024).
[45] *See* Advair HFA, GoodRx Inc., https://www.goodrx.com/advair?label_override=advair&form=hfa-inhaler&dosage=115mcg-21mcg&quantity=1&slug=advair (last visited Jan. 4, 2024).
[46] *See* Trelegy Ellipta, GoodRx Inc., https://www.goodrx.com/trelegy-ellipta (last visited Jan. 4, 2024).
[47] Press Release, Bureau of Labor Stat., U.S. Dep't of Labor, Consumer Expenditures 2022 at 7 (Sep. 8, 2023), https://www.bls.gov/news.release/pdf/cesan.pdf.
[48] *See* GLOB. INITIATIVE FOR ASTHMA, *supra* note 13, at 58-88; GLOB. INITIATIVE FOR CHRONIC OBSTRUCTIVE LUNG DISEASE, *supra* note 14, at 117-20.
[49] Patel, *supra* note 25.

health insurance through his job, had to pay almost $350 every six weeks for a single inhaler.[50] As Mr. Fabian told a reporter, "There's no way I can keep working out $350 every month and a half."[51]

Although insurance companies and pharmacy benefit managers typically negotiate with brand-name manufacturers for lower prices through rebates and other discounts, patients rarely see a meaningful difference in the prices they pay at the pharmacy counter. Patients' copays and out-of-pocket costs are usually tied to a drug's list price, not the lower "net price" that accounts for rebates and other discounts. As a result, people like Mr. Fabian still face extremely high costs. Meanwhile, brand-name manufacturers continue increasing list prices. Indeed, GSK has raised the wholesale acquisition cost of one of its inhalers, Serevent, 34 times since 1997 and now lists the product for $423, almost eight times as much as it did when the product was introduced.[52]

While patients struggle to afford these life-saving devices, GSK made almost $4 billion in revenue in 2022 from its inhalers.[53] This is typical in the industry. And a significant portion of this revenue was made through anti-competitive practices.

**Pharmaceutical companies have engaged in decades of anti-competitive practices to prevent generics from competing with their products.**

Pharmaceutical companies are able to keep generics off the market—and keep prices high—by manipulating the regulations that govern how these companies introduce products.[54] When a brand-name manufacturer launches a new inhaler, the manufacturer enjoys a period of exclusivity because of patents the manufacturer has on the product. During this period, the brand-name manufacturer does not face direct competition and so can set as high a price as it wants for the inhaler. Once the patents expire or are successfully challenged, generics are able to enter the market, dramatically lowering the price.[55] These generics must be nearly indistinguishable from the brand-name inhaler to receive FDA approval, which is why they cannot enter the market sooner absent a successful challenge to the patents; if the brand-name manufacturer has a patent on part of its inhaler, it is extremely difficult for other manufacturers to make products similar enough to be granted generic status.[56]

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[50] Rachana Pradhan, *It's Not Just Insulin: Lawmakers Focus on Price of One Drug, While Others Rise Too*, KFF HEALTH NEWS (Sep. 22, 2020), https://kffhealthnews.org/news/its-not-just-insulin-lawmakers-focus-on-price-of-one-drug-while-others-rise-too/.
[51] *Id.*
[52] Navlin Int'l Pharm. Pricing Database, https://www.navlin.com/ (last visited Jan. 4, 2024).
[53] HELP Committee majority staff analysis based on GSK, *Annual Report 2022*.
[54] *See generally* Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 355(b), (j) (2018); Applications for FDA Approval to Market a New Drug, 21 CFR Part 314 (2023).
[55] Chintan V. Dave et al., *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 NEW ENG. J. MED. 2597, 2597-98 (2017), https://www.nejm.org/doi/10.1056/NEJMc1711899.
[56] Bryan Newman et al., *Scientific and Regulatory Activities Initiated by the U.S. Food and Drug Administration to Foster Approvals of Generic Dry Powder Inhalers: Bioequivalence Perspective*, 190 ADVANCED DRUG DELIVERY REVS. 114526 (2022), https://www.sciencedirect.com/science/article/abs/pii/S0169409X22004161; Bryan Newman & Kimberly Witzmann, *Addressing the Regulatory and Scientific Challenges with Generic Orally Inhaled Drug Products*, 34 PHARM. MED. 93, 94-96 (2020), https://pubmed.ncbi.nlm.nih.gov/32112304/; Sanjay Reddy et al.,

Brand-name manufacturers have engaged in a number of tactics to keep generics from competing with their products. For example, when inhalers are nearing the end of the period of exclusivity, brand-name manufacturers have obtained additional patents on the products—further insulating themselves from competition.[57] And when brand-name manufacturers cannot extend their monopolies further, they have shifted patients onto newer, patent-protected versions of their inhalers with the same active ingredients as older versions. The effect is to create a new period of exclusivity that enables them to continue setting prices without direct competition.[58] Brand-name manufacturers have even gone so far as to enter into agreements with generic manufacturers to delay or completely forego the entry of the generic manufacturer's product onto the market—effectively paying the generic manufacturer a portion of the brand-name manufacturer's earnings and enriching both companies at patients' expense.[59]

Although generic manufacturers can introduce competing products before a brand-name manufacturer's patents expire by challenging those patents, brand-name manufacturers have made that process difficult and expensive. A common tactic involves the manipulation of the FDA's Orange Book: a list of information on all FDA-approved drugs that includes the key patents that brand-name manufacturers believe cover their products.[60] If a generic manufacturer wants to introduce a competing product before those patents expire—which is often a decade or more after the inhaler was approved—the generic manufacturer must notify the brand-name manufacturer that it is contesting the patents listed in the Orange Book.[61] Under current law, if the brand-name manufacturer sues the generic manufacturer in response to this notification, approval of the generic is automatically delayed by two and a half years or until the resolution of litigation over the patents.[62]

The problem arises when brand-name manufacturers list patents so disconnected from the inhaler's life-saving medicine that their only effect is to prevent generic manufacturers from introducing competing products. Examples include a patent on a dose-counter, which measures how many times a patient has used the inhaler, and a patent on a cap strap, a small piece of plastic that connects a mouthpiece cap to the rest of the device so that it does not fall off. Brand-name manufacturers use patents like these to delay generics from entering the market. The

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*Patent Challenges and Litigation on Inhalers for Asthma and COPD*, 42 HEALTH AFFAIRS 398, 404 (2023), https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00873.

[57] Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECHNOLOGY 142, 143 (2018), https://pubmed.ncbi.nlm.nih.gov/29406508/; Feldman, *supra* note 7, at 89; Feldman, *supra* note 35, at 790, 794.

[58] Feldman, *supra* note 35, at 792-94; William B. Feldman et al., *Brand-name Market Exclusivity for Nebulizer Therapy to Treat Asthma and COPD,* 40 NATURE BIOTECHNOLOGY 1319, 1321-22 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10591455/; Feldman, *supra* note 7, at 89.

[59] Reddy, *supra* note 56, at 402.

[60] FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (ORANGE BOOK) AD 2 (43d ed. 2023), https://www.fda.gov/media/71474/download?attachment.

[61] Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2018); FDA, *Patent Certifications and Suitability Petitions* (Oct. 31, 2023), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions.

[62] 21 U.S.C. § 355(j)(4)(B)(iii); FDA, *Patent Certifications and Suitability Petitions*, *supra* note 61.

effects on competition are so significant that the Federal Trade Commission (FTC) issued a policy statement warning companies that improper listing of patents could be "an unfair method of competition in violation of the FTC Act."[63] The FTC expressed concern that this practice "may have played a role in distorting pharmaceutical markets for decades."[64] Recently, the FTC challenged more than 100 patents as improperly listed in the Orange Book, including five of GSK's patents: four on Arnuity Ellipta and one on Ventolin HFA, Advair HFA, and Flovent HFA.[65] In response, GSK has de-listed some of these patents.

GSK has also engaged in other potentially anti-competitive practices. In 1996, GSK introduced Flovent, which delivers a steroid in the form of an aerosol.[66] The following year, GSK introduced Flovent Rotadisk, which delivers the same steroid in the form of a dry powder.[67] Since then, GSK has engaged in a number of tactics that have allowed it to sell these products without competition.

In 2004, GSK introduced Flovent HFA as part of the transition from aerosolized inhalers that use CFCs (chlorofluorocarbons) to aerosolized inhalers that use HFAs (hydrofluoroalkanes).[68] When it launched Flovent HFA, GSK listed six patents in the Orange Book.[69] But since 2004, GSK has listed an additional 16 patents in the Orange Book, 13 of which it added in 2009 or later.[70] These include patents on dose counters, one of which does not expire until 2026—22 years after Flovent HFA's entry onto the market.[71] The FTC challenged this patent as improperly listed.[72]

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[63] Statement, Fed. Trade Comm'n (FTC), Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sep. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

[64] *Id*.

[65] Press Release, FTC, FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book; Letter to GSK, FTC, Improper Orange Book-Listed Patents for Advair HFA and Flovent HFA (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxo-group-orange-book.pdf (FTC Letter to GSK regarding Advair HFA et al.); Letter to GSK, FTC, Improper Orange Book-Listed Patents for Arnuity Ellipta and Ventolin HFA (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxosmithkline-orange-book.pdf.

[66] *Drugs@FDA: FDA-Approved Drugs*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020548 (last visited Jan. 4, 2024) (indicating Flovent was approved March 27, 1996).

[67] Approval Package, FDA, Approval Package for NDA 20549 and 20770 (Nov. 7, 1997), https://www.accessdata.fda.gov/drugsatfda_docs/nda/97/020549ap.pdf (approving Flovent Rotadisk).

[68] Letter to GSK, FDA, NDA 21-443 (May 14, 2004), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21433ltr.pdf (approving Flovent HFA).

[69] FDA, ORANGE BOOK ADA 50 (25th ed. 2005) (N 021433, all listed patents), https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-2005-25th-Ed.pdf.

[70] FDA, ORANGE BOOK ADA 58 (27th ed. 2007), https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-2007-27th-Ed.pdf (N 021433, U.S. Patents 5,658,549; 5,674,472; 6,251,368); FDA, ORANGE BOOK ADA 76 (30th ed. 2010), https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-2010-30th-Ed.pdf (N 021433, U.S. Patents 6,161,724; 6,251,368; 6,431,168; 6,435,372; 6,596,260; 6,938,796; 6,966,467; 6,997,349; 7,107,986; 7,143,908; 7,350,676; 7,500,444); FDA, ORANGE BOOK ADA 86 (33d ed. 2013), https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-2013-33rd-Ed.pdf (N 021433, U.S. Patent 7,832,351).

[71] FDA, ORANGE BOOK ADA 167 (43d ed. 2023), https://www.fda.gov/media/71474/download?attachment (N 021433, U.S. Patent 7,500,444).

[72] FTC Letter to GSK regarding Advair HFA et al., *supra* note 65.

GSK has also taken steps to shield its dry-powder inhalers from competition. The company introduced Flovent Rotadisk in 1997, Flovent Diskus in 2000, and Arnuity Ellipta in 2014.[73] All three inhalers use the same steroid, fluticasone, in the same dry powder form (though the company modified the steroid in Arnuity Ellipta to release more slowly). The only meaningful differences between the products are to the physical devices that deliver the steroid. The timing of the second two inhalers suggests GSK intended to use them to extend its monopoly over the product line: GSK introduced Flovent Diskus three years before the remaining patents on Flovent Rotadisk were set to expire[74] and introduced Arnuity Ellipta just two years before the last patent on Flovent Diskus was set to expire.[75] There are currently six unexpired patents listed in the Orange Book for Arnuity Ellipta, four of which the FTC challenged as improperly listed.[76]

At the end of 2023, GSK discontinued all of these products except Arnuity Ellipta, which is patent-protected until 2030.[77] As a result of these efforts, GSK had a 27-year monopoly on the aerosolized product line and, assuming no generic manufacturer successfully challenges the patents on Arnuity Ellipta, GSK will have a 33-year monopoly on the dry-powder line. Not surprisingly, these tactics have proven extremely lucrative for the company: GSK made over $5 billion on these inhalers in the past 10 years alone.[78]

These anti-competitive practices harm patients. With so few generics on the market, brand-name manufacturers are able to charge exorbitant prices for inhalers. These prices place the inhalers out of reach for many Americans—especially the uninsured and underinsured. And in a terrible indictment of the extent to which our country has failed poor and underserved communities, the people who struggle the most to afford inhalers are the people most likely to need them. We cannot accept a world where individuals forced to live in environments that make them sick are

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[73] Letter to GSK, FDA, NDA 20-833 (Sep. 29, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20833ltr.pdf (approving Flovent Diskus); Letter to GSK, FDA, NDA 21-433 (May 14, 2004), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21433ltr.pdf (approving Flovent HFA); Letter to GSK, FDA, NDA 205625 (Aug. 20, 2014), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205625Orig1s000ltr.pdf (approving Arnuity Ellipta).

[74] FDA, ORANGE BOOK ADA 32 (23d ed. 2003), https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-2003-23rd-Ed.pdf (N 020549, U.S. Patent 4,335,121).

[75] FDA, ORANGE BOOK ADA 88 (36th ed. 2016), https://thefdalawblog.com/wp-content/uploads/2020/06/OB-Annual-2016-36th-Ed.pdf (N 020833, U.S. Patent 5,873,360).

[76] FDA, ORANGE BOOK ADA 165 (43d ed. 2023), https://www.fda.gov/media/71474/download?attachment (N 205625); Letter to GSK, FTC, Improper Orange Book-listed patents for Arnuity Ellipta and Ventolin HFA (Nov. 7, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/glaxosmithkline-orange-book.pdf.

[77] *FDA Drug Shortages*, FDA, https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Fluticasone%20Propionate%20Aerosol,%20Metered&st=d (last visited Jan. 4, 2024); *FDA Drug Shortages*, FDA, https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Fluticasone%20 Propionate%20Powder,%20Metered&st=d (last visited Jan. 4, 2024); FDA, ORANGE BOOK ADA 165-66 (43d ed. 2023), https://www.fda.gov/media/71474/download?attachment (patents listed for N 205625).

[78] HELP Committee majority staff analysis based on GSK, *Annual Report 2022*, *Annual Report 2021*, *Annual Report 2020*, *Annual Report 2019*, *Annual Report 2018*, *Annual Report 2017*, *Annual Report 2016*, *Annual Report 2015*, *Annual Report 2014*, *Annual Report 2013*.

denied the medications they need to treat those diseases. The American people deserve access to affordable inhalers.

The Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) has jurisdiction over matters related to biomedical research and development and public health.[79] As members of the HELP Committee, we intend to ensure that pharmaceutical companies like GSK can no longer use anti-competitive practices to force patients to choose between putting food on the table and affording life-saving medicine. Accordingly, we request the following information by January 22, 2024:

1) For each inhaler GSK has sold in the United States since January 1, 2018, please provide, in table format, the following information for each calendar year:
    a. The costs of goods sold;
    b. The volume sold;
    c. The revenue generated, broken out by payer type; and
    d. The prices paid by each of the 10 largest commercial health plans (defined by the number of covered lives) and the five largest pharmacy benefit managers that GSK contracts with.

2) For GSK's patient assistance program, please provide, in table format, the following information for each calendar year since January 1, 2018:
    a. The number of unique patients who received assistance through the program;
    b. The number of inhaler products provided to patients at no or reduced cost, including the average number of inhaler products provided to each patient;
    c. The total amount of financial assistance provided to patients, including the average amount of financial assistance provided to each patient; and
    d. The amount of any federal corporate tax deduction the company claimed in connection with the program.

3) Please provide the following information for U.S. Patents 8,113,199 (Counter for use with a medicament dispenser), 8,161,968 (Medicament dispenser), 8,534,281 (Manifold for use in medicament dispenser), 8,746,242 (Medicament dispenser), and 9,333,310 (Medicament dispenser), which GSK listed in the Orange Book as claiming Anoro Ellipta, Arnuity Ellipta, Breo Ellipta, Incruse Ellipta, and Trelegy Ellipta; U.S. Patent 8,511,304 (Medicament dispenser), which GSK listed in the Orange Book as claiming Anoro Ellipta, Breo Ellipta, and Trelegy Ellipta; U.S. Patent 8,201,556 (Medicament dispenser), which GSK listed in the Orange Book as claiming Arnuity Ellipta and Incruse Ellipta; and U.S. Patent 7,500,444 (Actuation indicator for a dispensing device), which GSK listed in the Orange Book as claiming Advair HFA, Flovent HFA, and Ventolin HFA:
    a. An explanation of the value, including any clinical benefit, that the patented invention adds for patients; and
    b. All memoranda, analyses, forecasts, and presentations related to the development, acquisition, or licensing of the patented invention, the incorporation of the

[79] Standing Rules of the Senate XXV(m)(1).

patented invention into an inhaler product, or the listing of the patent in the Orange Book.

4) For each of the inhaler products described in Request 1, please provide all communications, including but not limited to emails and internal messages, such as those exchanged on channel-based platforms (herein, collectively, "communications"), and documents, including but not limited to memoranda, presentations, spreadsheets, reports, studies, analyses, and forecasts (herein, collectively, "documents"), provided to the Board of Directors; Chief Executive Officer; Chief Financial Officer; Chief Commercial Officer; Chief Scientific Officer; Chief Strategy Officer; Chief Executive Officer, GSK Consumer Healthcare; Group General Counsel; President, Global Pharmaceuticals; President, R&D; President, Corporate Development; President, GSK Global Health; Senior Vice President and Group General Counsel, Legal and Compliance; Senior Vice President, Global Ethics and Compliance; or any Senior Vice Presidents, Vice Presidents, or other employees in supervisory or decision-making roles within the Global Pharmaceuticals, Corporate Development, Strategy, Global Health, Consumer Healthcare, or Ethics and Compliance groups (herein, collectively, "GSK executives") since January 1, 2016 that relate to any of the following:
    a. The lifecycle management of the product or product line;
    b. Any strategy to protect or extend the product or product line's exclusivity, including through efforts to modify the delivery device and efforts to move patients from one product to another;
    c. The potential or actual generic competition for the product;
    d. Any agreement regarding an authorized generic for the product; and
    e. Any agreement with another company concerning a potential or actual competitor product, including any agreement relating to the market entry, marketing, promotion, labeling, conditions of use, or approval pathway of the competitor product.

5) Concerning the switch from Flovent Diskus to Arnuity Ellipta, please provide all communications and documents that were provided to any GSK executives that relate to:
    a. The decision to develop and seek FDA approval of Arnuity Ellipta;
    b. The expiration of any patent or regulatory exclusivity on Flovent Diskus;
    c. The potential generic competition for Flovent Diskus;
    d. The decision to remove Flovent Diskus from the market; and
    e. Access to Flovent Diskus by firms seeking to develop a generic version of the product.

6) Please provide the following:
    a. Any memoranda, analyses, studies, trials, reports, or publications comparing health outcomes associated with the use of any of the company's inhaler products with the use of any other inhaler product, including GSK products; and
    b. Any non-public representations, statements, or claims made to any regulatory body, including any non-U.S. regulatory body, as well as any insurer, pharmacy benefit manager, or other payer, regarding advantages or benefits associated with

any of the company's inhaler products relative to any other inhaler products, including GSK products.

7) Please provide all memoranda, analyses, studies, reports, or publications related to the relationship between product cost and patient medical non-adherence for any of the products responsive to Request 1.

8) Please provide the following information in table form:
   a. The company's spending on research and development in each year since January 1, 2018 directly related to asthma and COPD therapeutics, broken out by product type.
   b. The company's spending on research and development directly related to the Ellipta platform, broken out by product and calendar year, showing how much was spent on preclinical research, clinical testing by phase, acquisition or licensing of intellectual property, manufacturing process development, activities related to regulatory submissions, and all other spending.

Thank you for your prompt attention to these requests.

Sincerely,

Bernard Sanders
Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions

Tammy Baldwin
United States Senator

Ben Ray Luján
United States Senator

Edward J. Markey
United States Senator