



2019 REPORT  
**THE TRUTH  
ABOUT  
GLAXOSMITHKLINE**

*How one of the world's top-5 pharmaceutical  
corporations rips off America*

An analysis by

PATIENTS FOR **AFFORDABLE DRUGS™**

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[www.patientsforaffordabledrugs.org](http://www.patientsforaffordabledrugs.org)

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# INTRODUCTION



Credit: Nick Leyva

Azmia Magane is a social worker, advocate, and writer who was diagnosed with lupus in 2018. After she did not respond to initial therapy, her doctor told her about a new drug called Benlysta.

"He warned me it was a very expensive drug — about \$35,000 a year. I was shocked, and joked with my friends that my new medication cost as much as a new Mercedes Benz, and called it Benz-lysta. He started me on the auto-injectors, and within a few months, my symptoms improved and so did my blood work."

Lupus is an autoimmune disease where the body cannot tell foreign invaders — like bacteria and viruses — from healthy tissue.<sup>1</sup> The result of the body's war on itself is inflammation that damages a person's skin, joints, brain, blood vessels, and other parts of the body.<sup>2</sup> Nine out of 10 patients diagnosed are women, and the condition is lifelong.

Prior treatments for lupus focused on suppressing a patient's entire immune system.<sup>3</sup> But Benlysta targets specific immune cells and offers patients an improved quality of life since it can be administered at home. However, due to the \$35,000 price tag, the auto-injector is not accessible to many patients, including Azmia.

"In January of 2019, my prescription plan changed. It now costs me \$1,700 a month for the auto-injectors. Needless to say, I couldn't afford that. I'm a social worker and bring home about \$3,000 a month. The medication copay cost more than my rent, electricity, cell phone bill, and car payment combined."

As a result of the cost, Azmia went without Benlysta for three months. During that time, her lupus progressed and her symptoms worsened. Now she is forced to get the Benlysta infusion — instead of the self-administered injection — which means she has to take off work to get treatment at her doctor's office. Azmia recently found out that she must get a permanent port for her infusion, which will require a dangerous surgical procedure and put her at ongoing risk of infection since she is immunocompromised due to her treatment. She attributes all these obstacles to the high price of Benlysta.

"The worst part is I'm not the only person I know who this has happened too. My friend was also unable to get the auto-injectors due to cost, and also had to be placed on the infusions. Not only are there very few treatment options for lupus patients, the ones that are available are priced out of range for the average American. Who can afford \$800 to \$1,700 a month for medication?"

The price gouging of Benlysta is business as usual for GSK. The major drug corporation has a long history of prioritizing profit over patients.

GSK rang in the new year by raising prices on three dozen medications, despite ongoing public outcry and political scrutiny over skyrocketing prices.<sup>4</sup> The corporation's first-quarter revenues of \$10 billion came at the expense of taxpayers and patients footing the bill for unfounded hikes.<sup>5</sup>

An analysis by Patients For Affordable Drugs found a pattern of GSK abusing the system in order to maintain monopolies on their products and keep prices high for patients.

## **GSK's track record of corrupt practices includes:**

1. Filing frivolous lawsuits that delay the approval of generic drugs.
2. Submitting sham citizen petitions, a tactic that delays generic competition
3. Cutting pay-for-delay deals
4. Touting false safety information
5. Pricing needed drugs out of reach of the patients who need them to survive.

# PART 1: HURTING PATIENTS BY BLOCKING GENERIC COMPETITION

In 1984, the Hatch-Waxman Act incentivized and accelerated generic entry into the prescription drug market. Since the early 2000s, GSK has routinely exploited loopholes in this law in order to block cheaper, generic versions of their drugs from hitting the market.

## GSK's frivolous lawsuits to delay generics

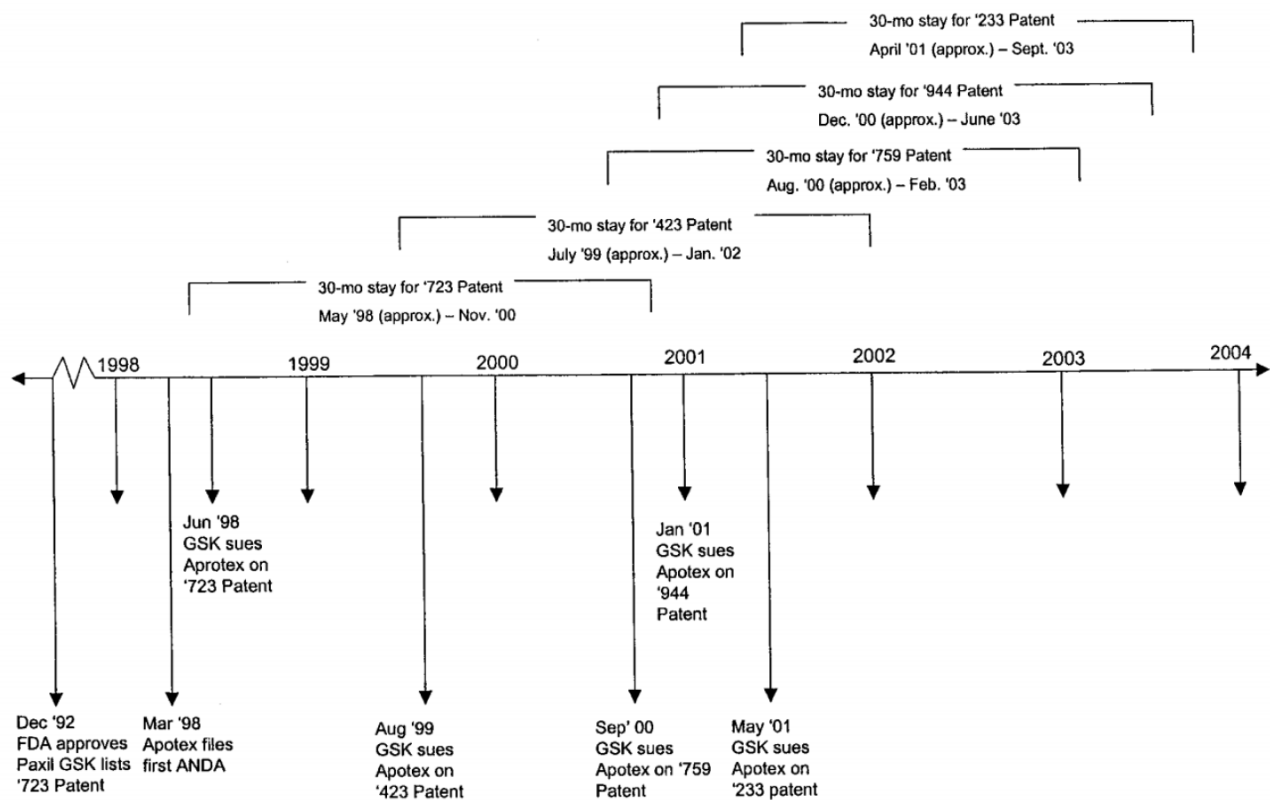
In 2002, a study by the Federal Trade Commission (FTC) found that GSK abused a provision in the Hatch-Waxman Act to delay generic competition for their blockbuster antidepressant, Paxil. By filing frivolous patent infringement lawsuits to trigger an automatic pause on FDA approval of generics, GSK delayed the entry of a generic version of Paxil by 65 months.<sup>6</sup> This period of time was the longest loophole-exploiting delay achieved by any company in the study and led to the FTC's recommendation that the automatic pause provision be limited.

While patients suffering from depression waited more than five years for a lower-price alternative, GSK made \$1 billion a year on Paxil.

"GSK delayed entry  
of generic Paxil by  
65 months."

Figure 4-1 30-Month Stays Obtained for Paxil

FTC Study on Generic Drug Entry Prior to Patent Expiration



GlaxoSmithKline exploited a loophole in federal law to delay generic competition for their blockbuster antidepressant Paxil by 65 months.

As a result of this action, the attorneys general of 49 states and Washington, DC sued GSK for charging state Medicaid programs high prices while blocking competition. In 2006, GSK settled the lawsuit for \$14 million.<sup>7</sup>

## Patient Perspective

For patients on Paxil, these delays must have felt like an eternity. Patricia Brunson lives in Florida and takes Paxil for anxiety.

"I suffer from anxiety, and the stress of paying for prescription drugs is a constant burden on me and my husband. Due to the high cost, I had to go off of Paxil, which has made my anxiety even worse. It's a vicious cycle, and it's not fair that drug companies can charge whatever they want while patients risk their livelihoods in order to manage lifelong conditions." - Patricia Brunson

## GSK's pay-for-delay deals

GSK's tactics to preserve its Paxil monopoly did not end at frivolous lawsuits. In 2016, the United Kingdom fined the drug giant \$54.5 million for entering into anti-competitive agreements with generic companies.<sup>8</sup> The UK's Competition and Markets Authority found that GSK entered into several "pay-for-delay" deals with generic companies — paying them to not bring a generic Paxil to market until an agreed-upon later date.

GSK's efforts to eliminate competitors hurt people like Sue Kenney, a single mom and registered nurse from Georgia.

"It was difficult for me to find an antidepressant that worked. After trying many different drugs, Paxil was the first one to make a real impact on my symptoms. I have been on it now for more than 10 years. However, it's so expensive that my insurance company tries to get me to switch to a cheaper option. I worked so hard to find something that worked for me, and now I constantly worry that I will have to stop taking my medication." - Sue Kenney

## GSK's sham citizen petitions

The FDA citizen petition program exists so average Americans can submit concerns to the FDA about products or medications undergoing the agency's approval process. While each petition is investigated, FDA's approval process is paused — a loophole that GSK manipulates for its own gain. A 2017 study showed that brand-name drug companies submitted 92 percent of petitions about generic drugs, and that 91 percent of those petitions were thrown out after investigation.<sup>9</sup> GSK abused this system between 2004 and 2005 by submitting a series of sham citizen petitions to the FDA right before Flonase was expected to go off patent.<sup>10</sup> At the time, Flonase was a cash cow for GSK — it generated over \$750 million in sales in 2004. In the 23 months that GSK managed to delay generic competition, Flonase made the company approximately \$2.5 billion.<sup>11</sup> Eventually the FDA rejected GSK's petitions as illegitimate and approved a generic version of Flonase on the same day in 2006.

# GSK Disregards Patient Safety

Since 1993, GSK has bribed doctors, lied to patients, and defrauded the health care system in order to increase profits and line the pockets of its executives. In 2012, the Department of Justice reached the largest healthcare fraud settlement in US history with GSK.

## GSK pled guilty to reckless tactics like<sup>12</sup>:

- Falsely advertising safety and efficacy of medications to consumers and providers
- Misbranding drugs for off-label use
- Bribing doctors to promote and prescribe medications
- Omitting alarming safety data in reports to the FDA
- Submitting inflated price reports in order to underpay Medicaid programs

"GSK has bribed doctors, lied to patients, and defrauded the health care system in order to increase profits"

The Department of Justice was so appalled by GSK's pattern of behavior, it required the company to follow a five-year Corporate Integrity Agreement — a plan that included accountability measures and requirements that GSK "implement and/or maintain major changes to the way it does business."<sup>13</sup>

# PART 2: PRICE GOUGING

GlaxoSmithKline has the potential to improve lives and decrease health disparities with breakthrough drugs. Instead, its prices on three important drugs have left the drugs out of the reach of patients who need them.

"...prices on three important drugs have left the drugs out of the reach of patients who need them."

## Lupus and the Advent of Benlysta

Systemic lupus erythematosus, the most common form of lupus, is an autoimmune disease that disproportionately affects women of African, Asian, Hispanic/Latina, and Native descent.<sup>14</sup> Effective treatment of lupus has the potential to decrease negative health disparities, since minority women have higher rates of disease severity and mortality than caucasian women.<sup>15</sup>

The Benlysta breakthrough presented a unique opportunity to improve the lives of patients and make a positive public health impact. Instead, GSK set the list price of Benlysta at \$36,285.<sup>16</sup> This groundbreaking medication can cost patients between \$3,000 and \$5,000 a month. For lupus patients, this causes constant financial distress and worry over how they will treat their disease.

"Benlysta has completely changed my life. I can now get out of bed and spend time with my teenage girls without becoming completely drained. But the cost is ridiculous — my monthly prescription costs are more than a car payment! I worry what will happen if I ever have to go off Benlysta because of cost." - Kennedy R.\*

\* Name has been changed at patient's request to protect patient's privacy.

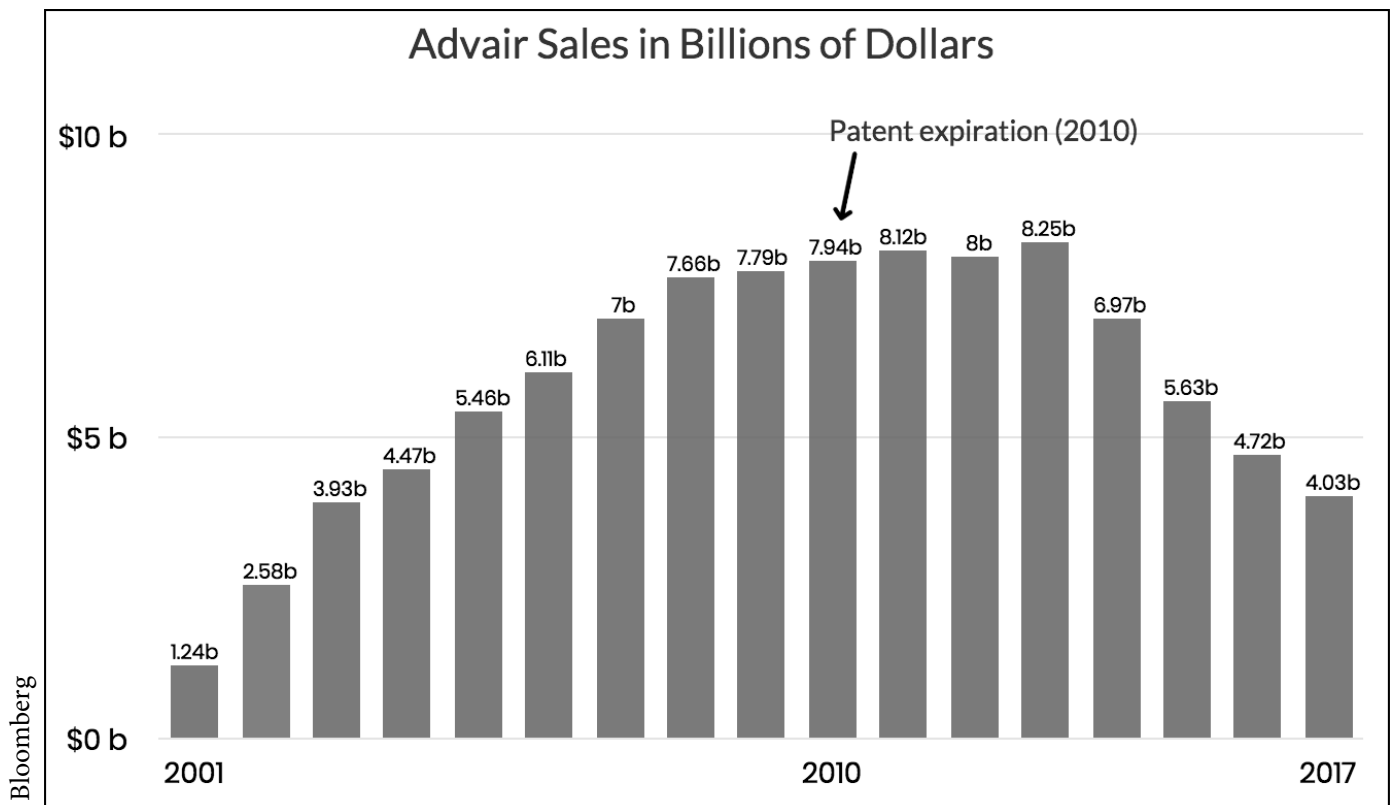
## Advair, Asthma, and a leaked memo

Asthma impacts more than 20 million adults and 6 million children in the United States.<sup>17</sup> For Brenda Gallagher, an asthma patient from California, the disease makes her too short of breath to complete even the most simple tasks. But thanks to her inhalers, Brenda can live a normal life and even participate in her favorite aerobics classes.

GSK's blockbuster drug, Advair, is a long-term inhaler prescribed for daily use by millions of Americans with asthma. Since its arrival on the market in 2001, Advair has surpassed \$100 billion in sales for GSK.<sup>18</sup> Even after 15 consecutive years of sales over a billion dollars, GSK chose to raise Advair's price in 2017 by 17.7%.<sup>19</sup> The price — often more than \$300 a month for patients — means that patients like Brenda cannot afford the medications they need.<sup>20</sup>



"I had to go off of Advair due to the cost. I am now on Flovent, which is also made by GlaxoSmithKline, but I still struggle to pay the \$130 a month for it. Due to the overwhelming costs of prescriptions and medical expenses, my husband and I can't visit family or travel. Our budget is so tight we barely keep our heads above water and all we want to focus on is our bodies healing from the ailments that have plagued us both." - Brenda Gallagher



Despite patent expiration of Advair's active ingredient in 2010, the price of Advair remained outrageously high for eight years due to lack of competition. Potential competitors attempted to bring generic versions of Advair to market, but failed repeatedly. Though the medication's patent had expired, the company also protected its blockbuster drug by obtaining patents on the diskus delivery system.<sup>21</sup> Generic entry was so slow that the FDA issued guidance to generic companies on how to demonstrate equivalence with Advair.<sup>22-23</sup>

# Memo to cheat the system

In early 2019, the FDA approved the first generic for Advair, but GSK refused to let go of its blockbuster's profits. A memo leaked in March showed that GSK was paying rebates to the pharmacy benefit manager Express Scripts so the company would steer patients towards Advair — instead of the new generic that was 70 percent cheaper.<sup>24</sup>

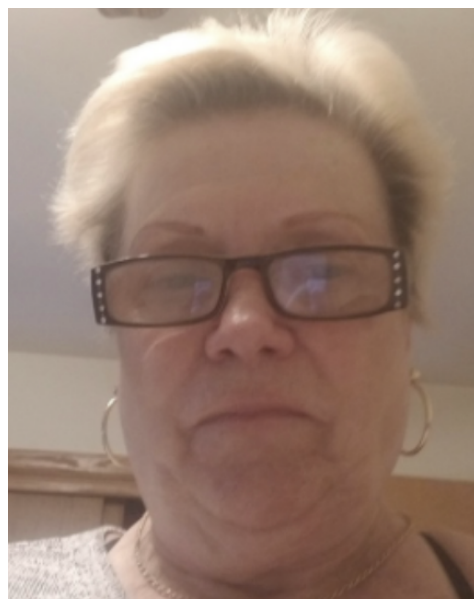
**Vivica Jasson is frustrated because she cannot enjoy being outside in her beautiful state of Hawaii due to her asthma. Vivica cannot afford her Advair and had to switch to a less effective inhaler.**

"I have to be cautious of my breathing and activity levels because I'm no longer on Advair. On pollution alert days, it's even worse. The cost for Advair Diskus is simply too high and is detrimental to my health. GlaxoSmithKline, the corporation that makes Advair, needs to lower the price now. Patients deserve to be able to breathe, and I'm not able to because of GlaxoSmithKline's greed."

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**Mary-Kay Murawski's retirement has been negatively affected by her prohibitively expensive drug costs. She takes Advair for her asthma.**

"Even with my insurance, Advair Diskus, a GlaxoSmithKline drug, still costs me \$139 out of pocket. This is for only a months dose! I have to take this drug two times daily... but I'm forced to use it every other day because it's so expensive that I have to ration it..."



**"...GlaxoSmithKline is pricing breathing out of our reach."**

# GSK rips off taxpayers

In 2017, GSK raked in \$40 billion in sales — including \$7.6 billion attributable to its new products: Nucala, Ellipta inhalers, and HIV medications.<sup>25</sup> American taxpayers paid for more than a third of the sales of these products through Medicare Part D. In 2017, these medications accounted for \$2.78 billion in Medicare spending.<sup>26</sup> GSK is charging Americans exorbitant prices twice — once as a taxpayer and then again at the pharmacy counter.

Drug	Cost	Impact on Patients
<b>NUCALA</b> A monthly injection for severe asthma	<p>The Institute for Clinical and Economic Review (ICER) analyzed Nucala and said it should cost 76% less than its current price tag of \$32,500 a year.<sup>27</sup></p> <p>Medicare spent almost \$19 million on Nucala in 2017 — for just over 1,000 beneficiaries.<sup>28</sup></p>	<p>Azmia, from Florida:</p> <p>"My doctor placed me on Nucala, which acts similar to chemo, except it targets eosinophils. While the medication works great — my hospitalizations for asthma have greatly decreased — the costs of the medication are astronomical. Even with health insurance, my copays were \$1,000 a month. My doctor helped me to get in a patient assistance program, and I don't know what I'd do if I were to lose that program. \$1,000 a month is literally a whole month of rent for me, to put that in perspective. I'd be in the position of choosing between rent and medication to breathe. No one should ever be in that position."</p>
<b>THE ELLIPTA FAMILY</b> Inhalers for asthma and COPD	<p>Medicare spent \$812 million on Breo Ellipta alone in 2017. The same year, GSK made over \$1 billion on the drug.<sup>28-29</sup></p> <p>Between 2013 and 2017, Breo Ellipta's price rose by 20% to \$321.74 a month.<sup>30</sup></p>	<p>Ramona, from Oklahoma:</p> <p>"I found out that Trelegy Ellipta would be \$350, even with my insurance. I can't pay that."</p> <p>Larry, from Tennessee:</p> <p>"When I went to fill my Breo Ellipta prescription, I was told that it would be \$300 for a pack of two inhalers. Who can afford that?"</p>
<b>HIV MEDICATIONS</b> Tivicay and Triumeq	<p>Triumeq sales exceeded \$2.4 billion in 2017; more than \$650 million was Medicare spending (\$23,618 per beneficiary).<sup>28-29</sup></p> <p>GSK made \$1.4 billion on Tivicay in 2017; \$518 million of that was Medicare spending (spending per beneficiary is \$14,161).<sup>28-29</sup></p>	<p>A 2017 letter signed by a coalition of HIV/AIDS advocates and patients called on drug makers — including GSK — to stop "upwardly spiraling drug prices are already beyond the limit of any conceivable justification, are unsustainable, and will further prevent HIV (patients) from accessing life-saving (antiretroviral medications)."<sup>31</sup></p>

## Additional patient perspectives

### Breath-Taking Prices

#### Drenda & Eddie Lawton



Drenda Lawton and her family have made many sacrifices in order to afford her husband Eddie's medications. Eddie takes Flovent, a GSK inhaler.

"Flovent is the most expensive drug Eddie takes. In order to make ends meet, he rations it due to its high cost, which is of course not helpful to his condition."

#### Sammie Eikel

Sammie Eikel takes Trelegy Ellipta.

"I'm suddenly being asked to pay almost \$500 for the Trelegy Ellipta. This is a shocking amount, and one I simply cannot afford. Trelegy Ellipta is a medicine that is the difference between living or dying for me. It opens up my airways so that I can breathe better, and GlaxoSmithKline threatens that by charging such high prices."

#### Angela Gonzales

Angela Gonzales, a COPD patient, takes Breo Ellipta.

"Because of the high price of my Breo, I skip doses, which makes it harder for me to breathe. Sometimes, my whole body starts hurting."

# PART III: CONCLUSION

Going forward, GSK must promise to stop using the anti-patient tactics outlined in this report. GSK calls itself “a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer.” But for decades, the corporation has been employing legal maneuvers that undermine that mission and increase its profits. The tactics outlined in this report keep drugs out of the hands of patients leading to worse health outcomes, shorter lives, and financial instability.

GSK has a chance to turn over a new leaf. The company must publicly denounce the steps it took in the past to keep drug prices high and commit to being a profitable company by inventing new, innovative drugs.

Stop frivolous lawsuits, stop cutting pay-for-delay deals, stop disregarding patient safety in the name of profits, and stop setting prices out of reach for patients. Take an opportunity to have a positive impact public health and decrease health disparities in earnest.

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