Statement of Juliana Keeping, Mother of child living with cystic fibrosis

before the

U.S. House of Representatives
Ways & Means Committee
Subcommittee on Health

More Cures for More Patients: Overcoming Pharmaceutical Barriers

Wednesday, February 5, 2020

Good afternoon. Thank you to Chairman Doggett, Ranking Member Nunes, and members of the committee. I am honored to be here today.

My name is Juliana Keeping, and I'm a patient advocate and mom to two children, including a 7-year-old boy and 9-year-old girl.[1]

I want to start by telling you about my son, Eli. The *least* interesting thing about Eli but what brings me here today is the fact that he has a life-threatening genetic illness called cystic fibrosis. What I really want to talk about is that he loves turning our entire living room into a complex Hot Wheels race course. And he is fascinated by books about exotic travels, the earth and its mysterious inner workings, and distant solar systems and stars. I could talk about Eli and his sister Laila — and their joyous curiosity and endearing spirits — all day; they are the lights of my life. But I've been invited today to speak about my family's experiences with cystic fibrosis and patient assistance programs.

Eli alerted us almost right away that we'd be leading a different kind of life with him. Fourteen hours after he was born it became clear he would require a lifesaving emergency surgery to correct a digestive issue. Two weeks later we learned he had cystic fibrosis. Eli is not his illness. Just an incredible little boy whose life requires a different level of elbow grease, the type most people don't understand, because they don't have to. We were then as we are now, honored to have Eli in our world and to be partners in his journey through it.

But knowing all of this means we like to make the most out of our time together.

Cystic fibrosis is a rare disease that impacts about 30,000 people in the United States and an estimated 100,000 worldwide.[2,3] There is no cure.

---

[1] I currently serve as the Communications Director for Patients For Affordable Drugs, a 501c3 nonprofit in Washington, DC.
[2] https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/
[3] https://www.cfww.org/

When cystic fibrosis was identified in 1938, life expectancies were just six months.[4] Thanks to decades of scientific work and thousands of experts who wake up every day to improve the lives of CFers, our outlook today is much brighter. People born between 2014 and 2018 have a life expectancy of 44 years. Half of babies born in 2018 can expect to live past 47.[5] Eli was born in 2012.

Despite the advances, so much of this illness remains a mystery.

A key component of the care Eli receives to live a life filled with Hot Wheels, books, and family are the drugs he takes every day.

Over his lifetime, Eli has taken a wide range of drugs that have changed as he has grown, based on the ever evolving nature of his illness. The thing his prescriptions have almost all had in common, however, is this: extraordinary expense.

We faced the high cost of Eli's medication almost immediately after his birth. Babies are particularly vulnerable to a severe type of cold called RSV, and for babies with compromised immune systems, like Eli, it can be life-threatening.

So we were relieved to find a drug called Synagis to protect him from RSV for his first cold and flu season.[6] At that time, to help cover our co-pay costs, we were enrolled in the drug maker's patient assistance program. It was such a relief to have a program that assured Eli got the medication he needed.

The following winter, I tried to get him the drug. We faced devastating barriers to our access I had not anticipated. We waged a five-month battle and ultimately lost. Insurance did not cover the drug, and so, we were ultimately denied access to the patient assistance program. We simply couldn't afford the $5,000 drug regimen.[7]

Without Synagis, Eli was hospitalized with RSV. Not only was it a significant setback to his health, but the hospitalization traumatized Eli. It took a SWAT team of nurses to hold him down for blood and urine samples.

It was a special type of torture knowing a drug that would protect my son's young, fragile lungs was held just out of reach. We couldn't afford it, and a patient assistance program that I thought would help us wasn't there when we needed it.

---

[4] https://www.atsjournals.org/doi/full/10.1164/rccm.200505-840OE

[5] https://www.cff.org/Research/Researcher-Resources/Patient-Registry/Understanding-Changes-in-Life-Expectancy/

[6] https://www.synagis.com/patients/rsv-resources.html

[7] Source: AnalySource® as reprinted with permission by First DataBank Inc. All rights reserved. © (2020)

Currently, my son is on a $307,000 per year medication called Symdeko.[8] It is one of the cystic fibrosis community's biggest success stories and is working well to help Eli's condition. But $307,000 is out of the reach of the vast majority of families — including mine. With insurance, my family must meet our $4,000 deductible each January before coverage kicks in. We just can't swing that. So in order to afford it, we are enrolled in a co-pay assistance program through the drugmaker, Vertex. Every year, we receive a coupon worth $4,000, which applies toward our deductible. Trust me, we are grateful.

But from our past experiences, we know we can't rely on patient assistance to always be there for Eli. Changes made by drug companies, patient assistance programs, or insurance companies can all impact the availability of these funds and my family's ability to afford the medication my son needs to breathe.

It is deeply upsetting to be so reliant on a marketing scheme that makes Big Pharma look charitable, but at the end of the day, simply increases drugmaker revenues and profits.

After another hospitalization this past October, I told Eli he was very brave. His response? "Mommy, do you even know how hard it is to be brave?"

"Eli — it's okay not to be brave," I told him. "I take it back. You don't have to be brave. I'll make sure you're safe," I promised.

It's not fair that I can't keep that promise to my child. Whether he'll get the drugs he needs to stay alive is up to a drug company and its patient assistance program.

The feeling of looking your child in the eye and promising to keep him safe, all the while knowing that he's at the drug company's mercy is a feeling I wish upon no one.

What are patient assistance programs?

To understand how a pharmaceutical company uses patient assistance to pad its bottom line, first we must understand what these programs are and how they are funded.

Patient assistance programs are non-profit organizations; in fact, these programs have the same tax designation as advocacy, charity, and religious organizations. These organizations cover expenses for patients associated with prescription drugs such as cost-sharing obligations like copays and coinsurances or they may donate the drug directly to a patient.

[8] Source: AnalySource® as reprinted with permission by First DataBank Inc. All rights reserved. © (2020)

While there are two types of patient assistance programs — independent charitable foundations or those programs run directly by a drug manufacturer — the majority of patient assistance programs are in some way linked to a pharmaceutical company. Last year a study of these programs showed that half of our country's 20 largest charities are associated with pharmaceutical companies.[9]

Impact on Patients

Typically the way patient assistance programs work for families like mine is through a yearly application. Patients or families apply to the programs through often lengthy and deliberately cumbersome application processes. The programs require real knowledge of the health care system and the time and resources to navigate the application.

For individuals in the midst of serious health emergencies, the processes may be too time consuming to complete.

Even when patients or their families successfully apply, the selection process is convoluted, opaque, and ever-changing.

You don't have to tell that to Lora Moser. The 42-year-old Texan, who lives with cystic fibrosis, was suddenly denied her grant funding when her husband got a new job — his new wages rose just $650 outside of the program's wage requirements. And she was denied the $15,000 that helped pay for her medication costs. As a result, she stopped taking her most important medications, fell into a deep depression, and was hospitalized after she lost lung function. Lora's grant was restored after she began speaking out in multiple media reports, but, she shared with me that, each year, "I'm a nervous wreck. My life is in pharma's hands. They literally hold my ability to access the drugs in their hands."

What drug companies look for in these applications is not how much a family *needs* the assistance. Drug companies and patient assistance programs are trying to figure out how much your insurance will *pay* for the drug. Of course a drug company will gladly cover my $100 copay or $4,000 deductible if my insurance company will pay them more than $300,000 for my son's drug.

It's simple math. And a great investment if you're a drug manufacturer.

---

9 https://www.economist.com/united-states/2019/08/15/why-americas-biggest-charities-are-owned-by-pharmaceutical-companies

And even if our application is accepted, we often live in fear that this year funding will run out or the requirements will change, making us no longer eligible for the program. Each year, my family makes the best attempt we can to save at least $4,000 to cover our medications in case we are denied access to our patient assistance program. Other CF families I know have experienced sudden changes to eligibility criteria, leading them to sell anything not nailed down in their homes just to get the drugs keeping their kids alive.

Pharmaceutical companies try to convince patients that their contributions to patient assistance programs are simply benevolent charity, but in reality their reach is calculated and deeply limited.

First, 97 percent of all patient assistance programs require patients to be on insurance in order to participate.[10] That means patients without health insurance, the ones who often have the highest drug costs have virtually no access to programs to offer them relief. And it means the patient assistance programs I utilize to afford my son's medications are tied to my health insurance. If I lost my job or changed insurance, I would once again be at risk of not being able to afford the medications at all.

Additionally, programs often limit the amount of time patients are permitted to receive assistance. This means patients may rely on a program for years but suddenly have the rug yanked out from under them, leaving them without the financial support they need.

I recently spoke to Robert Davis, a 50-year-old living with cystic fibrosis who has experienced exactly the types of crises that result from relying on patient assistance. For the last three years, Robert has taken our newest drugs that are priced at $307,000 per year.

Robert has owed more than $17,500 for his medications. He can rely on patient assistance programs to cover some of the cost, but it's never enough. The list prices are too high. So in August 2018, Robert began rationing his medication, taking one pill instead of two. Within weeks, he experienced breathlessness more severe than what he was used to and over the ensuing days, he felt a gurgle in his lungs.

It was a familiar warning, followed shortly by coughing up palmsful of blood, a terrifying complication to CF called hemoptysis. He drove himself to the doctor and was admitted to the hospital for a week while being treated with antibiotics before being sent home for another week of IV antibiotics to recover.

The fact that patient assistance programs are an inconsistent source of relief is dangerous for people like Robert and my son. It is infuriating that we are held hostage by patient assistance programs and high drug prices.

[10] https://jamanetwork.com/journals/jama/article-abstract/2740721

Impact on Medicare

The situation becomes even more complicated for patients on Medicare. There are many adult CFers on disability, like Lora and Robert, allowing them to qualify for Medicare coverage.

Medicare prohibits its beneficiaries from receiving direct patient assistance from pharmaceutical companies under the anti-kickback statute.[11] However, beneficiaries are permitted to receive assistance from "independent" patient assistance programs. Pharmaceutical companies parlay these regulations into fatter profit margins.

When people on a drug corporation's patient assistance program become eligible for Medicare, the company often funnels these patients from the company program (so as to follow federal law) into independent patient assistance programs — funded in part by the *same* company. That way the "charity" program enables the Medicare beneficiary to stay on the drug by covering their out-of-pocket costs, while simultaneously enabling the drug company to be reimbursed by Medicare.

It's a scam, cloaked in benevolence.

Stunningly, drug companies are exploiting this arrangement to rip off taxpayers in more ways than one. The companies reap massive tax breaks for their so-called "charitable" donations to patient assistance programs — and then turn around and bill the taxpayers who foot the bill for Medicare.

Impact on Drug Company Profits

I am deeply grateful for the relief we have received as a family thanks to patient assistance programs, but it is hard for me to stomach that these very programs actually increase pharma's profits.

According to a study by Citi Research, for every $1 million drug companies donate to assistance charities, they make $21 million in sales.[12]

Beyond tactics that allow pharma to capitalize on Medicare beneficiaries, pharmaceutical companies also develop systems to maximize profits. Drug companies prioritize patient assistance programs not only for the most expensive drugs but also for insured patients. Subsidizing the cost of a patient's copay or coinsurance each month is well worth it when the company will be paid for the entire cost of the drug by the insurance company.

[11] https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf
[12] https://www.wsj.com/articles/u-s-probe-sheds-light-on-charities-role-in-boosting-drug-sales-1497000601

An average copay for a drug is about 10 percent of what a manufacturer charges the insurance company. This means if a company covers $7.4 billion in copay assistance it could earn $74 billion in revenue.[13]

Patient assistance programs reward companies for increasing drug prices in two distinct ways. First, when a drug company covers a patient's copay and deductible, the patient no longer has an incentive to choose a cheaper alternative, like a generic equivalent. Secondly, patients are insulated from the financial impact of price increases, so drug manufacturers can relentlessly raise prices and extract more money from insurance companies and Medicare. As a result of the rigged system, drug prices keep rising. One study shows that drugs associated with cost assistance programs like coupons experience annual price growth of 12-13% in comparison to other drugs that saw price growth of only 7-8%.[14]

Solutions

The undercurrent in all of this is that families like mine are fighting every day not just to keep our children healthy but to keep them alive. Big pharma has manipulated my family, placing us in an unfair situation when it comes to paying for our drugs with patient assistance programs. We are dependent on these programs to ensure my son gets the medication he needs to stay healthy and alive. We live each day at their mercy as drug companies get richer off of their games to keep prices high and patients in limbo.

As Congress begins to examine these patient assistance programs in earnest and with real attention to their functionality, it must do so in an incredibly thoughtful manner.

I'm deeply frustrated with the current system, but for families like mine, patient assistance programs are also vital to our financial security and the lives of our loved ones. The solution cannot be to simply eliminate such programs or take away the incentives that encourage pharmaceutical companies to run them.

Instead, Congress must address the issue at the heart of the conversation — the drug prices themselves. Drug prices are astronomically high and rising unabated. The solution is not more patient assistance to cover higher and higher drug prices, it is lower drug prices.

Congress must work to enact legislative solutions that eliminate the need for patient assistance programs by making drug costs affordable and cost-sharing manageable.

---

[13] https://www.economist.com/united-states/2019/08/15/why-americas-biggest-charities-are-owned-by-pharmaceutical-companies

[14] https://www.nber.org/papers/w22745.pdf

I was encouraged when the House of Representatives passed the bipartisan *H.R. 3, the Elijah Cummings Lower Drug Prices Now Act.* The bill would finally allow Medicare to negotiate with drug companies for fair and affordable drug prices. It would also extend those negotiated prices to private insurance to drive down the cost of the most expensive drugs for about 170 million Americans like Eli.[15]

H.R. 3 would also end pharmaceutical price gouging that drives already high drug prices even higher. According to the CBO, under *H.R. 3* Americans would pay, on average, 14% more than other developed nations, down from the 200-300% we pay today.[16]

I am grateful to members of this committee and the House who supported this legislation and hope the Senate will follow your lead.

The Senate has its own legislation that would help to drive down prices, the bipartisan *Prescription Drug Pricing Reduction Act* (*S. 2543*), which would cap out-of-pocket drug costs for Medicare beneficiaries like Robert and Lora, dropping their cost for their drugs each year to a maximum of $3,100.

The bill would also address price gouging behavior of pharmaceutical companies by penalizing companies for increasing prices beyond the rate of inflation.

I urge the House to introduce a companion bill to help move the bill toward enactment.

We don't need to fix the broken patient assistance program; instead, we need to fix the entire broken drug pricing system.

Conclusion

In many ways it comes down to this question: what kind of country do we want to live in?

One where global drug conglomerates that set prices for lifesaving drugs far beyond what the average patient can afford? One where we accept lotteries called patient assistance programs that currently determine who can afford a drug and who can't?

Or do we, as a nation, decide that everyone deserves a chance to get the drugs they need, because every human life has value?

---

[15] https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&selectedDistributions=employer--non-group&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[16] https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf

Do we say “enough” to our medications being held hostage by pharma-run patient assistance programs?

The drug lobby has spent billions to convince you that this problem is too big, too complicated to fix. But it’s not.

We can start with *H.R. 3* to give taxpayers the power to negotiate prices. We can pass the Senate Finance Committee bill, a bipartisan solution that improves the current path we’re on. We can look at what other countries pay and finally determine that Americans will not be forced to pay 4 times the amount of citizens in other nations.

I don’t want to end patient assistance programs because they’re giant tax loopholes — which they are. I don’t want to end patient assistance programs because they increase drug company profits, hold patients hostage, and cost taxpayers money — they do.

I want to make patient assistance programs *unnecessary.* I want drug prices to be affordable. I want brilliant doctors, hard working nurses, and my loving family to control my son’s health — not a patient assistance program.

That’s the power you hold. Congress can fix this problem. Start by passing legislation to lower drug prices. Then, move to reforming patient assistance programs. You’ll improve patient’s health and our lives.