

# PATIENTS FOR AFFORDABLE DRUGS™

## Statement of David E. Mitchell

Founder, Patients For Affordable Drugs

*before the*

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

*on*

*The Cost of Prescription Drugs: An Examination of the National Academies of Sciences, Engineering, and Medicine Report “Making Medicines Affordable: A National Imperative”*

December 12, 2017

Chairman Alexander, Ranking Member Murray, Members of the Committee: I am honored to be here today.

### ***Section I. Background and Introduction***

My name is David Mitchell. I am the Founder of Patients For Affordable Drugs. We are a bipartisan, national patient organization focused on policies to lower drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

More importantly to today's hearing, I have an incurable blood cancer, and prescription drugs are keeping me alive. Several days ago, I received five hours of drug infusions that carry a price tag of more than \$20,000 every time I get them. I've had them 22 times over the course of the year. So, \$450,000 worth of drugs are keeping me upright.

I am very grateful to the science and research communities in our country for these drugs. And because my disease is incurable, I need innovation and new drugs if I am going to live as long as I hope to. This is not theoretical for me—it is life and death.

But my experience as a cancer patient has taught me one irrefutable fact: **Drugs don't work if people can't afford them.**

Since our launch in February, we have built a community of almost 20,000 Americans across every state.

Piper Peltz of Clinton, Tennessee wrote, "I have a pacemaker and suffer from other conditions as well. I have to resort to taking my expensive heart medicines every other day."

Angel Porche of Montegut, Louisiana was diagnosed with Rheumatoid Arthritis at age 39. Her doctor prescribed Humira to put it in remission, but the drug cost more than she could afford. “So, needless to say, I went without this prescription,” she writes. “I was in so much pain because I could literally feel my feet crippling.”

There are thousands more stories like Piper and Angel.

People are scared and angry, and they need help.

A September Harvard poll showed that [4 in 10](#) Americans want lowering prescription drug prices to be Congress’ top priority.

Sixty four percent of Americans, including a majority of Democrats, Independents, and Republicans, listed lowering drug prices as their top health care priority, according to a [Kaiser Health poll](#).

The message we hear from patients is simple. They understand that drug corporations have monopoly pricing power. Patients and taxpayers know the prescription drug pricing system in the U.S. is rigged against them. They want leaders in Washington to fight to lower the price of drugs, and to get something done.

This is a central health care issue that impacts millions of people every day. We agree with [President Trump](#): “Drug companies frankly are getting away with murder.” And drug companies are not the only ones who take advantage of patients’ pocketbooks.

When prices rise, drug manufacturers, PBMs, doctors, and hospitals all make more money. The people our system hurts are patients, consumers, taxpayers, and employers who foot the bill.

## ***Section II. Reflections on the 2017 National Academies of Sciences Report***

Last week’s National Academies of Sciences, Engineering and Medicine (NASEM) report included a number of excellent recommendations which we support. Here is a patient perspective on some of the most promising recommendations and one potential pitfall.

### *Recommendations Patients For Affordable Drugs Supports:*

- **Limit out-of-pocket costs for Medicare Part D.** We believe beneficiaries should not be charged out-of-pocket costs based on retail prices of drugs when everyone else in the system – employers, insurers, the government – pay based on rebated prices. The Trump Administration requested feedback on implementing this reform, and we encourage Congress to support such a change. We should also cap patient exposure at the catastrophic level of Part D. When drugs cost \$20,000 a month, the current system can be crushing for patients.
- **End patent abuses that circumvent the bipartisan Hatch-Waxman framework.** Examples of patent abuse include: pay for delay, exploitation of restricted distribution

systems, product hopping, evergreening, and rental of sovereign immunity from an independent entity.

FDA Commissioner Scott Gottlieb recently told drug manufacturers, “Stop the shenanigans.” We agree with him. The Hatch-Waxman Act provides five, seven, or 12 years of exclusivity to ensure drug corporations recoup their investments and earn handsome returns. But too many drug companies game the system to block free-market competition far beyond the stated legal time frames.

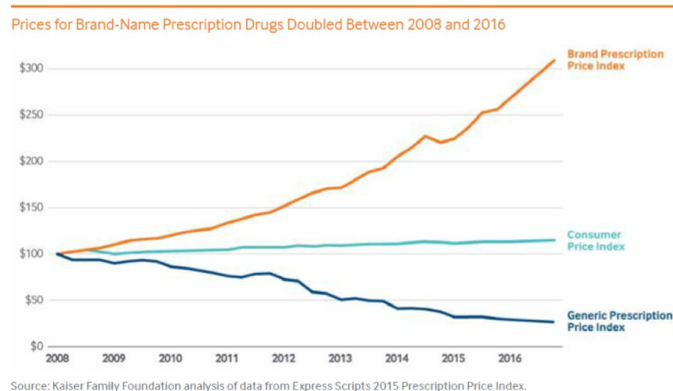
Here’s one example. I took a drug called Revlimid for five years to keep my cancer at bay. Over the course of my treatment, Revlimid’s manufacturer, Celgene, refused to provide samples to generic manufacturers looking to create a competitor. At the same time, the price of Revlimid increased by 34 percent and my co-payments rose by 600 percent. In fact, Revlimid became the most expensive drug for Medicare Part D beneficiaries with a median annual out-of-pocket cost of \$11,500.

Pam Holt of Granger, Indiana is a widowed, retired schoolteacher with multiple myeloma. She wants to spend her remaining years spoiling her grandchildren. But she can’t. Her Revlimid copay is \$577 per month.

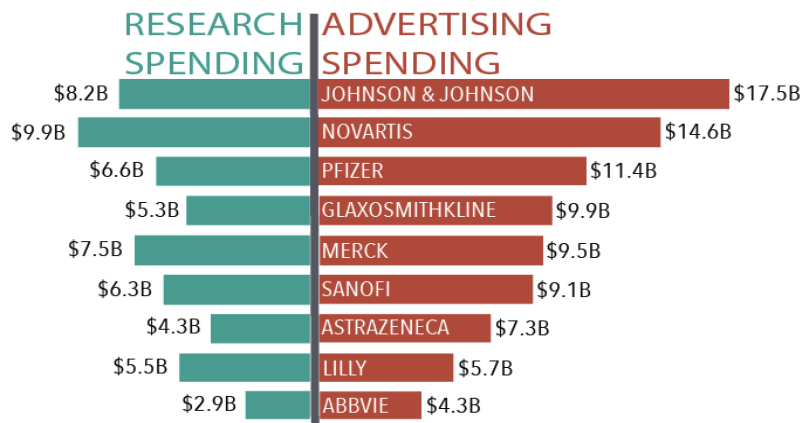
Patients like Pam also forgo their medications altogether or spend their retirement funds and empty their kids’ college savings to afford drugs. This occurs while a generic competitor sits just out of reach.

Bipartisan legislation has been reintroduced in both the House and Senate to fix this particular abuse of our system while maintaining safety for patients. The bipartisan CREATES Act (S. 974, H.R. 2212) will help speed generics to market, increase competition, and provide patients access to more affordable drugs. It is supported by experts across the ideological spectrum – from scholars at the Heritage Foundation to academic experts at Harvard University.

- **Allow Medicare to negotiate lower costs for patients.** The government grants drug manufacturers a pricing monopoly during a period of exclusivity. Medicare negotiations would help balance that monopoly pricing power. Below is a chart that demonstrates why we need negotiations – especially for brand drugs – the fastest growing sector of health spending.



- **End tax breaks for drug companies that spend millions of dollars advertising.** As NASEM noted, drug companies spend significantly more on advertising and marketing than on research and development. It is generally recognized that the drug industry spends [20-40 percent](#) of its overall budget on advertisements and related activities. Only one other country in the world permits direct to consumer advertising for drugs. We don't need to step on a drug company's First Amendment right to advertise, but we don't believe taxpayers should subsidize their TV ads.



*The Washington Post, Big Pharmaceutical Companies are Spending Far More on Marketing than Research; February 11, 2015*

- **Increase transparency throughout the drug supply chain.** Three pharmacy benefit managers control about [75 percent](#) of the drug market. PBMs negotiate deals in secret, leaving consumers and policymakers in the dark. Americans can't tell if these corporations provide value in the form of rebates for patients or if they keep rebates to increase profits. We do know the combined operating profit of the three largest PBMs was \$10.1 billion in 2015, up 30% from 2013. The NASEM recommendations aim to pull back the curtains so consumers and policymakers can better understand drug prices by requiring disclosure on all discounts and rebates. The recommendation avoids specific disclosures that PBMs claim would inhibit their negotiating success by recommending disclosures be made quarterly at the national drug code level.

*We Urge Caution:*

- **We urge caution against so-called outcomes-based pricing arrangements.** First, it is important to distinguish between value-pricing and outcomes-pricing. Value-pricing is conducted by organizations like the Institute for Clinical and Economic Review, the American Society of Clinical Oncology, and the National Comprehensive Cancer Network. They examine the value of a new drug to patients and can serve as one input for negotiations by—for example—the Veterans Administration. Value-pricing can be a useful tool.

On the other hand, outcomes-based pricing is different. It ties reimbursement of a drug to its effectiveness. While this sounds attractive, it's a disaster for patients. Outcomes-pricing in general stipulates that if a drug fails, the drug company will provide a refund. But that system contains a major flaw. It does not lower drug prices; it allows drug companies to keep prices

high. Drug companies have the clinical data that tell them exactly how many patients react positively to a drug and how many will fail. Rather than lower prices, drug companies will simply raise the price of a drug to compensate for failures. Furthermore, it is not clear any refunds will make their way to patients. It is also not clear how to use such a process for drugs like insulin where patients react differently as individuals and drug companies may want to claim user error if the patient doesn't do everything right to manage their disease.

### ***Section III: Not Paying Twice For Taxpayer Investment***

On August 30, 2017, America crossed into new territory. The drug company, Novartis, chose to price a breakthrough cancer drug called CAR-T at \$475,000 per treatment. As NIH Director Francis Collins wrote at the time, the drug is “grounded in initial basic research supported by NIH.”

To be specific, taxpayers invested more than [\\$200 million](#) in CAR-T's discovery. We believe drug corporations should disclose how they set prices if a drug is invented using taxpayer funding.

In October, taxpayers unknowingly entered into a partnership with drug corporations to speed new immunotherapies to market. Under this scheme, taxpayers will fund 75 percent of the research – a total of \$160 million—and 11 drug corporations will contribute the remaining 25 percent or \$55 million.

As a cancer patient, the potential of new drugs is exciting. But in an era of drugs priced at over half a million dollars per treatment, it is no longer appropriate for NIH to conduct basic research and turn that science over to commercializers with no strings attached. Frankly, NIH is helping invent drugs that will bankrupt families and cause our system to buckle under the weight.

We urge Congress to consider ways to require or incentivize price transparency and reasonable pricing when a drug is invented through NIH research. If a drug is built on science and innovation financed by American taxpayers, we have a right know how a drug company chose to price the drug.

### ***Section IV. Immediate bipartisan steps to lower drug prices.***

We recognize that many of the suggestions contained in this testimony may be out of reach in the near future. So, we conclude by highlighting five bipartisan ideas we believe could be implemented immediately and would meaningfully lower drug prices for patients.

- **Pass the CREATES Act.** This bipartisan legislation would save taxpayers \$3.3 billion, according to CBO, and it would address a loophole that delays generic drug competition.
- **Follow the Trump Administration's lead** to allow Part D Medicare beneficiaries to pay out-of-pocket costs based on rebated – not retail – drug prices.
- **Support FDA in its efforts to eliminate the generic backlog**—especially for off-patent

drugs where there is no generic competitor. This could mean additional resources or an increased focus on the problem.

- **Investigate the insulin market.** Three insulin manufacturers command 80 percent of the market for this lifesaving drug. Together, the companies raised prices more than 300 percent in the past ten years – for a drug invented in 1923 and for which the patents were sold for \$3. The prices move in lockstep and people with diabetes suffer at the hands of what can only be called an insulin cartel. Democratic and Republican members in the House are already looking into the insulin market. We encourage Congress to conduct an investigation into anti-competitive behavior and possible price-fixing by Eli Lilly, Novo Nordisk, and Sanofi.
- **Outlaw rental of sovereign immunity.** Recently, the Irish drug company, Allergan, transferred patent rights to its blockbuster drug Restasis to the St. Regis Mohawk Tribe. The drug company explicitly acknowledged the move was intended to prevent vulnerability from *inter partes review* under the America Invents Act. A federal judge correctly characterized this as a rental of sovereign immunity designed to dodge our patent laws. Such rental from any sovereign entity should be outlawed.

In conclusion, we believe our health care system should maximize affordability and accessibility of drugs while ensuring a robust R&D pipeline and fair profits for companies. We believe that balance has been lost. The current system encourages companies to take advantage of patent loopholes, thwart competition, and put profits over patients. The system encourages high prices that only benefit big players. We hope to work with Congress to lower drug prices and let Americans focus on living healthy and productive lives rather than struggling with the rising cost of medicines they depend on.

I am extremely encouraged that members on both sides of the aisle are focused on drug prices. In my experience, the most enduring legislative successes in our country have come with bipartisan action.