

# PATIENTS FOR AFFORDABLE DRUGS™

**Statement of David E. Mitchell  
Founder, Patients For Affordable Drugs**

*before the*

**U.S. House of Representatives Committee on Oversight and Reform**

*for a hearing on*

**The Patient Perspective: The Devastating Impacts of Skyrocketing Drug Prices  
on American Families**

**July 26, 2019**

Chairman Cummings, Ranking Member Jordan, and 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 organization focused on policies to lower prescription drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs.

In a little over two years since we launched, we have collected over 20,000 stories of patients struggling to pay high drug prices. And we have built a community of more than 150,000 patients and allies that mobilize in support of policies to lower drug prices.

More importantly for today, I have an incurable blood cancer, and prescription drugs are keeping me alive.

My story starts a little over eight years ago. I woke up with excruciating back pain, which I chalked up to activities and, of course, my age. On this particular morning, however, it was worse than ever before. Standing in my bedroom alone, I suddenly collapsed on the floor and couldn't move.

After visits to the ER and various doctors, I found out why I couldn't move — a crushed T-11 vertebra.

Cancer had literally broken my back.

Multiple myeloma attacks my bones. It also broke my ribs and ate holes in my pelvis, arm bones, and skull. Doctors repaired my spine, and the fact that I can stand is a miracle of modern medicine.

Unfortunately, I will never be a cancer survivor. Multiple Myeloma is incurable. But with expensive medication, I can keep it at bay for some period of time. Unless we invent a durable cure, I will be in continuous treatment until I die.

So every two weeks, I spend several hours at a local clinic getting an infusion of drugs that costs around \$650,000 per year.

I have already relapsed twice. In fact, I am failing now on my current drug regimen. So the importance of innovation is not theoretical for me — it is literally life and death.

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

## ***Section II. The Cost of Drugs***

From 2011-2016, prescription drug spending in the U.S. grew by 28 percent, which was more than 2.5 times inflation during that period.<sup>1</sup> Forty-two percent of cancer patients deplete their entire net worth within the first 2 years of treatment, in part due to high drug prices.<sup>2</sup> And drug spending growth is projected to accelerate by 31 percent by 2023.<sup>3</sup>

Telling Congress that drugs are too expensive feels a little absurd. This is the one issue just about everyone agrees on.

In fact, a recent Harvard/Politico poll found that 80 percent of Americans say Congress's top priority should be action to lower drug prices. Respondents were given 21 choices to rank, and this issue was ranked higher than every other concern.<sup>4</sup>

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<sup>1</sup>Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11 and BLS data on CPI-U 2011-2016.

<sup>2</sup>Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer. Gilligan, Adrienne M. et al. The American Journal of Medicine, Volume 131, Issue 10, 1187 - 1199.e5

<sup>3</sup>Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11.

<sup>4</sup><https://www.politico.com/f/?id=00000168-1450-da94-ad6d-1ffa86630001>

This makes my story far from unique.

When I first got sick, doctors put me on a drug called Revlimid. I could afford my prescription. But for Medicare patients on Revlimid, the median out-of-pocket cost is \$14,461 per year — that's over half their annual income.<sup>5,6</sup> Pam Holt has traveled from Indiana and will tell the Committee what happened in her life when she needed Revlimid.

Another patient we heard from, Kuzeyde Turan from New Jersey, depends on Revlimid for her survival, but her family cannot afford the monthly out-of-pocket costs. So they've sold their furniture, maxed out their credit cards, and she's skipping doses of the medication she needs to stay alive.

Revlimid is an old drug — it was approved by the FDA in 2005 — and the principal reason it is so expensive is because its maker, Celgene, has gamed the system and refused to sell samples to generic companies trying to bring a competitor to market.<sup>7,8</sup>

Robin Cressman is a patient advocate from California. She lives with Type 1 Diabetes, and over a recent three year period, she spent \$7,000 a year on diabetes supplies. She took on debt, and when it became too much for her and her husband, Robin went to Tijuana, Mexico where a box of Lantus pens costs \$52 compared to the \$700 per box in the U.S. She paid \$13 a piece for half a dozen Humalog pens that would have cost her over \$2,000 in the U.S.

But it's not just insulin and cancer drugs. Take Humira, the world's best selling anti-inflammatory drug. Patent thickets and pay-for-delay deals will keep a competitor off the market in the U.S. until 2023.<sup>9</sup> Ashley Krege has come from Texas to tell the Committee her story struggling to pay for Humira.

Drug prices are bankrupting us. And as people are rationing drugs and skipping them altogether, high prices can literally kill us.

### ***Section III. It's Not About Innovation***

The good news is, we can fix this. Despite what drug companies tell us, sky-high drug prices are not about innovation.

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<sup>5</sup> <https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-tables/>

<sup>6</sup> <https://www.kff.org/report-section/medicare-beneficiaries-out-of-pocket-health-care-spending-as-a-share-of-income-now-and-projections-for-the-future-report/>

<sup>7</sup> <https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/889/revlimid-lenalidomide>

<sup>8</sup> <https://www.bloomberg.com/news/articles/2018-05-17/u-s-names-drugmakers-gaming-safety-system-to-shield-profits>

<sup>9</sup> <https://www.biospace.com/article/dissimilar-to-u-s-market-humira-biosimilar-competition-launches-in-europe/>

Their argument seems to make sense on its face: research and development are expensive.

But their claims mangle the facts.

There is no direct relationship between R&D costs and the price of a drug. As noted policy expert Avik Roy has written about at length: “Proponents of high U.S. drug prices argue that high prices are necessary to support pharmaceutical innovation. But, with a modicum of scrutiny, the fatal flaws in this argument become immediately apparent.”<sup>10</sup>

Dr. Peter Bach, Memorial Sloan Kettering Cancer Center, and his colleagues also examined this issue in depth. Their findings “counter the claim that the higher prices paid by U.S. patients and taxpayers are necessary to fund research and development.”<sup>11</sup>

Right now, drug companies make enormous profits — roughly two to three times the average of the S&P 500.<sup>12</sup> They spend most of it on expenses outside of R&D — nine out of 10 big pharmaceutical companies spend more on marketing, sales, and overhead than they do on research.<sup>13</sup>

From 2013 to 2017, the five largest U.S.-based drug companies spent less than a fifth of their revenue on research and development on average.<sup>14</sup> The same companies — Johnson and Johnson, Pfizer, Merck, AbbVie, and Amgen — spent about 70 percent more on sales, marketing, and administrative expenses than R&D in this same timeframe.<sup>15</sup>

Innovation is a matter of life and death for me. And yet, I can also tell you that the risk companies cite is not the reality. That money invested in research isn’t coming from companies alone; it’s coming from the American people.

U.S. taxpayers foot a huge and critical portion of the bill to develop new drugs. Based on a survey of PhRMA’s own member companies, one out of every three dollars spent on drug research comes from American taxpayers.<sup>16,17</sup> Every single drug approved by the FDA from 2010-2016 was based on science funded by taxpayers through the NIH.<sup>18</sup>

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<sup>10</sup> <https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08>

<sup>11</sup> <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full/>

<sup>12</sup> <https://www.gao.gov/products/GAO-18-40>

<sup>13</sup> [https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm\\_term=.dc7e820c4172](https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172)

<sup>14</sup> Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

<sup>15</sup> Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).

<sup>16</sup> <https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill>

<sup>17</sup> <https://www.phrma.org/advocacy/research-development>

<sup>18</sup> <https://www.pnas.org/content/115/10/2329>

Let me give you an example. There's the imminent cure for sickle cell disease that Francis Collins is excited about.

We know that American taxpayers invested \$300 million into one specific upcoming treatment called LentiGlobin BB305. Right now, clinical trials are being run on that drug inside the walls of NIH. NIH is even recruiting patients to participate in the trials.

Step back from this one specific sickle cell drug, and we know that NIH reports spending \$100 million per year in general to find a cure for sickle cell.

This could be a cure for a disease that is devastating and disproportionately impacts marginalized communities. Currently, potentially curative treatments like this are being priced at \$500,000 to more than \$2 million. Are we going to have a price set at the million dollar benchmark developed with taxpayer support? That would cost \$100 billion for our nation to treat the 100,000 Americans suffering from sickle cell disease.

As a cancer patient, I'm thrilled that the FDA gave the drugmaker Novartis approval for a promising new CAR-T cancer drug called Kymriah. American taxpayers invested more than \$200 million<sup>19</sup> in CAR-T's discovery and development. But Novartis priced its CAR-T drug at \$475,000 per treatment, and to date, it has refused to acknowledge the significance of taxpayers' investment.<sup>20</sup>

Since the introduction of CAR-T drugs, we have seen other gene therapies gain approval: Luxturna for blindness at \$850,000. Zolgensma for Spinal Muscular Atrophy (SMA) at more than \$2.1 million. Both these drugs were developed with taxpayer support.<sup>21, 22</sup>

These early gene therapies will be used in small populations and we are still struggling with how to pay for them. The larger challenge looming is that there are around 400 clinical trials underway for gene therapies that will be used to treat much larger populations.<sup>23,24</sup> It is a tsunami that will crash over us.

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<sup>19</sup> Analysis of NIH funding by Diane Singhroy, PhD. Knowledge Ecology International. NIH data accessed July 25, 2017.

<sup>20</sup> <https://www.forbes.com/sites/matthewherper/2018/02/08/patient-advocate-says-novartis-475000-breakthrough-should-cost-just-160000/#51fb1a195152>

<sup>21</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5738963/>

<sup>22</sup> <https://www.keionline.org/charity-nih-funding-related-to-zolgensma>

<sup>23</sup>

<https://www.healio.com/pediatrics/practice-management/news/print/infectious-diseases-in-children/%7Bcbdc9c6d-2367-4569-8f40-43d331052714%7D/gene-therapies-up-and-coming--and-expensive>

<sup>24</sup> <https://alliancerm.org/publication/q1-2019-data-report/>

Under our current system, taxpayers are forced to pay three times for these breakthrough treatments. First as taxpayers investing in research at the NIH, second as patients at the pharmacy counter, and a third time through tax dollars that support America's largest health insurance programs — Medicare and Medicaid.

The National Academies of Sciences, Engineering, and Medicine recently hosted a workshop on this topic where multiple ways for us to rectify this challenge and ensure our investment in NIH balances critical innovation with essential access and affordability.

- NIH could reinstate its reasonable pricing provision in Cooperative Research and Development Agreements (CRADA) and Exclusive Licensing Agreements. This provision was removed by NIH in 1995.<sup>25</sup>
- Congress could create an outside entity to support NIH and ensure price is addressed when technology is transferred from the NIH to the private sector.

Finally, the drug industry operates without competition and without guardrails to protect Americans from predatory pricing. They have an armament of tricks to maintain monopoly pricing power, and they tell us that if their monopolies aren't enforced, they won't give us the life-saving drugs we need.

Yes, drug companies should make money when they create innovative drugs. But we are way out of balance, and it's costing us all — in bankruptcies, health outcomes, and lives.

Right now, nearly 1 in 3 adults report not taking their medicines as prescribed because of the cost.<sup>26</sup>

The fact is, there is one key reason drug companies charge such high prices: Because they can.

#### ***Section IV. Solutions***

Fortunately, there are three steps our nation could take today to rebalance the actual risk of innovation with a fair price for patients: reform patent law, end the days of monopoly pricing power without taxpayer negotiations, and force transparency from drug middlemen.

Let's start with patent law.

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<sup>25</sup> <https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html>

<sup>26</sup> <https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

When a company brings an innovative drug to market, they should receive a fair return for their risk and investment. But drug manufacturers are abusing America's patent and exclusivity system to prevent free-market competition and block affordable generic and biosimilar drugs from coming to market.

Between 2005 and 2015, at least 74 percent of the new drug patents issued were for drugs already on the market.<sup>27</sup>

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.<sup>28</sup>

These tactics have led to longer exclusivity than our laws intended. The median length of post-approval market exclusivity for small-molecule drugs was not in fact five years or even the seven years allowed for orphan drugs. It was 12.5 years.<sup>29</sup>

Members of this committee are supportive of numerous bipartisan bills to address those abuses. I thank Committee members for their work. We are supportive of the following bipartisan bills making their way through the House and Senate to address these abuses:

- **Deals-For-Delay:** Brand name drug companies pay off generic companies that plan to bring a competitor to market. In exchange for this payment (or something of value that could be another commercial consideration), the generic manufacturer delays its product's entry into the market.
  - *Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2375):* This bill, sponsored by Representatives Nadler (NY-10) and Collins (GA-09), would limit deals in which brand and generic drug manufacturers use anti-competitive pay-off agreements to delay cheaper generic and biosimilar drugs from reaching patients.
  
- **REMS abuses:** Brand drug companies use a safety program called Risk Evaluation and Mitigation Strategies (REMS) as a pretext for not selling drug samples to generic companies, which need the brand product in order to develop an equivalent and lower-priced competitor. The U.S. government could save \$3.9 billion<sup>30</sup> by stopping this abuse, which the FDA has called “unfair and exploitive.”<sup>31</sup>

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<sup>27</sup> <https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows>

<sup>28</sup> [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3061567](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567)

<sup>29</sup> FN-Wang B, Liu J, Kesselheim AS. Variations in time of market exclusivity among top-selling prescription drugs in the United States. *JAMA Internal Medicine* 2015;175(4):635-637.

<sup>30</sup> <https://www.cbo.gov/publication/54479>

<sup>31</sup> <https://www.fda.gov/news-events/speeches-fda-officials/remarks-ftc-workshop-understanding-competition-prescription-drug-markets-entry-and-supply-chain>

- *CREATES Act (H.R. 965)*: The *CREATES Act*, led by Representatives Cicilline (RI-01) and Sensenbrenner (WI-05), addresses delay tactics that are used by brand drug manufacturers to block lower-priced generic drugs.
- **Evergreening**: Drug corporations change drugs incrementally and patent the “new” product, which extends a corporations’ monopoly pricing power. For example, a company might move from a tablet to a capsule and apply for a new patent. This gaming of the system should not be permitted.
  - *REMEDY Act (S. 1209)*: This bill is led by Senators Durbin (D-IL) and Cassidy (R-LA) and allows generic manufacturers to enter the market once the substance patent and all exclusivities have expired and gives generics the ability to assess whether secondary patents are valid and subject to legal action. This will allow generic manufacturers to bring drugs to market sooner.
- **Patent-thickets**: Brand drug companies often file dozens of new patents on old drugs in order to force a generic company to file suit against each of them, delaying a generic competitor from coming to market. For example, AbbVie secured more than 100 patents on Humira and is currently blocking a competitor in the U.S.<sup>32</sup>
  - *Affordable Prescriptions for Patients Act (S.1416)*: This bill sponsored by Senators Cornyn (R-TX) and Blumenthal (D-CT) gives the Federal Trade Commission (FTC) the authority to challenge patent thicketing behavior as anti-competitive.
- **Sham citizen petitions**: Brand-name drug makers were behind 92 percent of all citizen petitions filed between 2011 and 2015 — all aimed at blocking cheaper generic drugs. The FDA threw out nine of every 10 of those petitions.<sup>33</sup> Congress should stop the use of sham citizen petitions.
  - *Ensuring Timely Access to Generics Act of 2019 (H.R. 2455)*: This bill, sponsored by Representatives Joyce (PA-13) and Brindisi (NY-22), allows the FDA to reject citizen petitions that they deem to be designed primarily to delay the entry of a generic drug onto the market.
  - *Stop STALLING Act (H.R. 2374)*: This bill gives the FTC the authority to fine pharmaceutical companies that submit citizen petitions designed primarily to delay the entry of a generic drug onto the market. The bill was introduced by Representative Jeffries (NY-08) and cosponsored by half a dozen bipartisan members.

<sup>32</sup> <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug>

<sup>33</sup> <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1956&context=aulr>



- **Transparency and price hikes:** Drug prices cannot be properly addressed without achieving transparency on the part of pharmaceutical manufacturers.
  - *Fair Drug Pricing Act (H.R. 2296):* This bill, sponsored by Representatives Schakowsky (IL-09) and Rooney (FL-19), requires manufacturers to report and justify certain price hikes. The bill passed out of House Energy and Commerce Committee as part of the More Efficient Tools to Realize Information for Consumers Act (METRIC) Act.

Next, we need Medicare price negotiations.

Over the past five years, AbbVie, the company that makes the top selling drug in the world, Humira, has more than doubled the price here in the United States. But in Europe, Abbvie sells the exact same drug for 80 percent less.<sup>34</sup> On average, Americans pay twice as much for prescription drugs as other nations.<sup>35</sup>

Why does the rest of the world get affordable drugs while Americans pay outrageous prices?

One big reason is that other countries negotiate directly with drug companies. We could do that too. Given the prices we pay, it is clear that relying on pharmacy benefit managers to negotiate is not working. We know that not only from the experience of other nations, but also from the Veterans Administration. The VA negotiates and Medicare Part D could have saved \$14.4 billion in 2016 alone by negotiating as the VA did.<sup>36</sup>

Medicare negotiations can take several approaches; the VA approach is just one. Another approach under consideration is international reference pricing. The International Pricing Index Model proposed by HHS would lower the price of drugs in Medicare Part B and ensure Americans don't pay outrageous prices compared to people in other countries. Inflation indexing is also under discussion, and it would be an important step forward to curb drug price increases. We prefer direct negotiations, but reference pricing and/or inflation indexing can move us toward fairer prices and greater security for the American people.

We must also restructure Medicare Part D to cap annual out of pocket costs. The current structure does not work for people unlucky enough to get a disease that requires very expensive drugs. We should cap patient's out-of-pocket, and shift the risk in Part D to minimize premium impact. For example, we believe drug manufacturers should pick up a greater portion of the cost as the government's responsibility is reduced. We recommend that manufacturers cover 40

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<sup>34</sup> <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>

<sup>35</sup> <https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/>

<sup>36</sup> <https://www.statnews.com/pharmalot/2019/01/14/medicare-drug-prices-veterans-affairs/>

percent of the price of a drug (which they alone set), insurers cover 40 percent, and the government pays 20 percent. The set of proposals offered recently in the Senate Finance Committee move us in this direction, and we think represent an important step in the right direction.

And finally, we need more transparency around Pharmacy Benefit Managers — PBMs. They are the middlemen between insurance companies and manufacturers. These groups cut secret deals that determine how much insured patients pay — but there’s no transparency in this process.

As a patient, I cannot know if the preferred drug on a formulary is the most effective drug, the least expensive among equally effective options, or the drug for which the PBM received the biggest rebate. That is unacceptable.

Moreover, rebates are sometimes used to stymie competition. Professor Robin Feldman explains “the system contains odd and perverse incentives, with the result that higher-priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs.”<sup>37</sup> Lower priced alternatives may be unable to gain traction in the market because of a huge, legal kickback given for use of the more expensive brand, costing patients, consumers and taxpayers.

Secret rebates are bad policy. This is economics 101: Competition — the free market — can’t work effectively without transparency.

### ***Section V. Conclusion***

Right now, Big Pharma wants us to ask this question: What are we willing to pay to save a life?

And that’s easy. When it’s your child’s lungs on the line, when it’s your wife’s diabetes, your husband’s cancer, the answer is “anything.” Yes, we will empty our 401ks; yes, we will take out another mortgage on our home; yes, we will give every precious thing we have, every cent, for one more year. One more day.

The chance to walk my daughter down the aisle? The chance to meet my grandkids — to watch them grow up? There is no amount I wouldn’t give for that.

But that’s the wrong question. We should be asking: *What is the right amount of money that drug companies should make on these drugs?*

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<sup>37</sup>[https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm\\_term=.f9e74687f9af](https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm_term=.f9e74687f9af)

With hundreds of clinical trials underway for new gene therapies that are currently priced from a half-million to more than two million dollars, we cannot agree to any price a drug company wants to charge. Neither American families nor our health care system can afford that.

Through our organization, I met a woman named Ruth Rinehart. Ruth has primary immune deficiency, and her treatments cost around \$52,000 per year. After working as a nurse for 30 years, she retired; and when her husband lost his job, they could no longer afford her treatments. They were forced to file for bankruptcy and eventually lost their home. Today, Ruth and her husband are in debt, living paycheck to paycheck, and she's back at work.

I feel incredibly grateful to spend my retirement fighting so that people like Ruth can one day enjoy theirs.

Because no one should have to choose between their health and their home.

All of you hold the power to fix this broken system. My request to you deliver for the American people. Stop talking and enact legislation. There are bipartisan solutions in play. And keep a focus on patients.

Cancer broke my back, but it stiffened my spine. I believe this is a problem that we can solve. That we must solve. And with bipartisan support, we will solve.

Thank you for your time.