PATIENTS FOR AFFORDABLE DRUGS™

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

before the

U.S. Senate Committee on the Judiciary

for a hearing on

Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition

Tuesday, May 7, 2019

Chairman Graham, Ranking Member Feinstein, 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 the 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 four weeks, I spend several hours at a local clinic getting an infusion of drugs that costs around $325,000 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.[1] 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.[2] And drug spending growth is projected to accelerate by 31 percent by 2023.[3]

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.[4]

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[1] 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.
[2] 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
[3] Analysis of Centers for Medicare & Medicaid Services, Office of the Actuary prescription drug spending data, Table 11.
[4] 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 half their annual income.[5,6]

One patient we heard from, Kuzeyde Turan, 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[7] — 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.[8]

Or take Humira, the world's best selling drug. Patent thickets and pay-for-delay deals will keep a competitor off the market in the U.S. until 2023.[9] Ashley Krege is from Texas. She needs Humira to treat her psoriasis. But it's too expensive. So instead of focusing full time on growing her small business, she's spent years grappling with the price and trying less effective medications.

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.

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

[5] https://www.kff.org/report-section/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019-tables/
[6] 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/
[7] https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/889/revlimid-lenalidomide
[8] https://www.bloomberg.com/news/articles/2018-05-17/u-s-names-drugmakers-gaming-safety-system-to-shield-profits
[9] https://www.biospace.com/article/dissimilar-to-u-s-market-humira-biosimilar-competition-launches-in-europe/

high prices are necessary to support pharmaceutical innovation. But, with a modicum of scrutiny, the fatal flaws in this argument become immediately apparent."[10]

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."[11]

Right now, drug companies make enormous profits — roughly three times the average of the S&P 500.[12] 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 on they do on research.[13]

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.[14] 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.[15]

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.[16,17] Every single drug approved by the FDA from 2010-2016 was based on science funded by taxpayers through the NIH.[18]

Recently, the FDA gave the drugmaker Novartis approval for a promising new CAR-T cancer drug called Kymriah. American taxpayers invested more than $200 million[19] 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.[20]

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[10] https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08
[11] https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/
[12] https://www.gao.gov/products/GAO-18-40
[13] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172
[14] Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).
[15] Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).
[16] https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill
[17] https://www.phrma.org/advocacy/research-development
[18] https://www.pnas.org/content/115/10/2329
[19] Analysis of NIH funding by Diane Singhroy, PhD. Knowledge Ecology International. NIH data accessed July 25, 2017.
[20] https://www.forbes.com/sites/matthewherper/2018/02/08/patient-advocate-says-novartis-475000-breakthrough-should-cost-just-160000/#51fb1a195152

Taxpayers should not have to pay exorbitant amounts for drugs that they've already invested millions of dollars in.

Finally, the drug industry operates without competition. 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.[21]

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.

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 existing drugs already on the market.[22]

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.[23]

[21] https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/
[22] https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows
[23] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567

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.[24]

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 legislation 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 (S.64):* Originally sponsored by Senators Grassley (R-IA) and Klobuchar (D-MN), this legislation would allow the FTC to investigate any deals between brand name and generic manufacturers and biologic and biosimilar manufacturers for anti-competitive practices. The bill is referred to the Judiciary Committee.

- **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[25] by stopping this abuse, which the FDA has called "unfair and exploitive."[26]
    - *Recent legislation: S.340/H.R.965 CREATES Act:* These bills address delay tactics that are used by brand drug manufacturers to block lower-priced generic drugs. The bill has support from Senators Leahy (D-VT), Grassley (R-IA), Blumenthal (D-CT), Booker (D-NJ), Cruz (R-TX), Durbin (D-CA), Ernst (R-IA), Feinstein (D-CA), Kennedy (R-LA), Klobuchar (D-MN), Lee (R-UT), and Whitehouse (D-RI). It passed out of the Judiciary committee in the 115th Congress.

- **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.

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[24] 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.*

[25] https://www.cbo.gov/publication/54479

[26]https://www.fda.gov/news-events/speeches-fda-officials/remarks-ftc-workshop-understanding-competition-prescription-drug-markets-entry-and-supply-chain

    - *Recent legislation: S.1209 REMEDY Act:* 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.[27]

- **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.[28] Congress should stop the use of sham citizen petitions.
    - *S. 1169 Ensuring Timely Access to Generics Act of 2019:* This bill 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. The bill is led by Senators Cassidy (R-LA), Shaheen (D-NH), Gardner (R-CO), and Bennett (D-CO).
    - *S. 1224/H.R.2374 Stop STALLING Act:* This bill is lead by Senators Klobuchar (D-MN) and Grassley (R-IA) and 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 has been referred to the Senate Judiciary Committee and has passed the House Judiciary Committee.

- **Fixing Inter Partes Review**: We urge the Committee to protect and strengthen the inter partes review (IPR) that Congress put in place with the America Invents Act. We hope this Committee and Congress will review the process for granting patents to ensure the procedures and practices at the PTO result in patents granted for drugs that are in fact new and not obvious.

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.[29] On average, Americans pay twice as much for prescription drugs as other nations.[30]

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[27] https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug
[28] https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1956&context=aulr
[29] https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html
[30] https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

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

One example is that AbbVie's patent thicket is currently blocking a competitor in the U.S. until 2023, which represents a 21 year monopoly for the drug first approved in 2002.[31]

The second 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.[32]

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. While we prefer direct negotiations, reference pricing can work to achieve fairer prices.

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."[33] 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?

[31] https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf
[32] https://www.statnews.com/pharmalot/2019/01/14/medicare-drug-prices-veterans-affairs/
[33] https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm_term=.f9e74687f9af

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?*

With hundreds of clinical trials underway for new gene therapies that are currently priced north of $500,000, 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 is to continue that work on this issue. Keep talking about it. Keep reaching across the aisle to find solutions. 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.

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