PATIENTS FOR AFFORDABLE DRUGS™

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

before the

U.S. House of Representatives Subcommittee on Health, Employment, Labor and Pensions of the

House Committee on Education and Labor
for a hearing on

Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency

September 26, 2019

Chairwoman Wilson, Ranking Member Walberg, 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 almost nine 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 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 currently cost around $650,000 per year. That doesn't include my non-infused drugs. Once those are factored in, the total list price for my treatment right now is more than $875,000 per year.

I am very grateful for these drugs; they are keeping me alive. I have already relapsed twice. 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%, 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 two years of treatment — in part due to high drug prices.[2] And drug spending growth is projected to accelerate by 31% by 2023.[3]

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

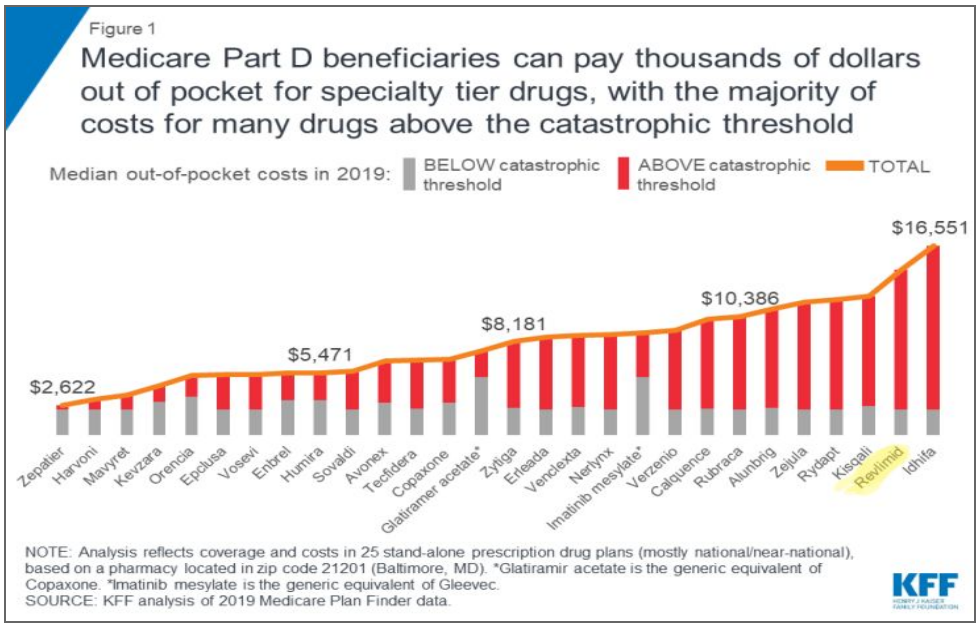
In fact, a recent poll from the Kaiser Family Foundation found that 70% of Americans say lowering prescription drug prices should be Congress' top health care priority. Respondents

[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.

ranked it ahead of addressing surprise billing and ensuring protections for people with pre-existing conditions.[4] People are hurting.

This makes my story far from unique.

When I first got sick, doctors put me on a drug called Revlimid. I was on an employer plan then, and my out-of-pocket costs were $3,250 per year for that one drug. 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.[5,6]



A week ago, I started taking a second generation version of Revlimid. It has gone up in price by 65% over the past six years. Here is how it worked for me under Medicare Part D: My out-of-pocket cost for the first four-week supply was $2,758. My coinsurance every four weeks will be $850. That means my total annual out-of-pocket cost will be more than $13,000 per year — just for one drug.

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

[4] https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-september-2019/
[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/

generic companies trying to bring a competitor to market.[7, 8] It is why we need to pass the CREATES Act.

But Celgene is not the only drug manufacturer gaming our system and abusing patients. Take insulin manufacturers. Three companies control the global insulin market. They have raised prices in lockstep — more than 300% over a recent ten year period.[9] Insulin is like water for people with diabetes.

Nicole Smith-Holt lost her 26-year-old son Alec to diabetic ketoacidosis, three days shy of his payday, because he couldn't afford his $1,300-a-month insulin and supplies.[10] Despite incredible activism from the diabetes community, prices have not fallen. In 2019 alone, reported deaths from insulin rationing have included: Jesimya David Scherer-Radcliff, 21;[11] Kayla Davis, 29;[12] Josh Wilkerson, 27;[13] Meaghan Carter, 47;[14] and Jada Louis, 24.[15] One in four U.S. patients with type 1 diabetes, like Alec, are forced to ration insulin.[16]

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.

Pharma's argument seems to make sense on its face: research and development are expensive.

This claim mangles the facts.

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[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://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf
[10] https://khn.org/news/insulins-high-cost-leads-to-deadly-rationing/
[11] https://www.kare11.com/article/news/family-says-21-year-old-son-died-rationing-insulin/89-d451a01b-9170-4341-9010-155cb87edccc
[12] https://www.t1international.com/blog/2019/08/29/rationing-while-waiting-refill-took-kaylas-life/
[13] https://www.washingtonpost.com/local/he-lost-his-insurance-and-turned-to-cheaper-form-of-insulin-it-was-a-fatal-decision/2019/08/02/106ee79a-b24d-11e9-8f6c-7828e68cb15f_story.html
[14] https://www.theguardian.com/society/2019/sep/23/diabetes-americans-soaring-insulin-prices?CMP=share_btn_tw
[15] https://myglu.org/articles/jada-louis-died-because-she-had-to-choose-between-paying-for-rent-or-insulin
[16] https://www.inquirer.com/health/consumer/insulin-ration-diabetes-drug-costs-20190625.html

There is no direct correlation between R&D costs and the price of a drug. As policy expert Avik Roy wrote: "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."[17]

Dr. Peter Bach of 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."[18]

Right now, drug companies make enormous profits — roughly two to three times the average of the S&P 500 — and spend most of it on expenses outside of R&D.[19] Nine out of 10 big pharmaceutical companies spend more on marketing, sales, and overhead than on research.[20]

From 2013 to 2017, the five largest U.S.-based drug companies spent less than one-fifth of revenue on research and development on average.[21] The same companies — Johnson & Johnson, Pfizer, Merck, AbbVie, and Amgen — spent about 70% more on sales, marketing, and administrative expenses than R&D in this same timeframe.[22]

We must fuel innovation. 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.[23,24]

Under our current system, taxpayers are forced to pay three times for 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.

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[17] https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08
[18] https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/
[19] https://www.gao.gov/products/GAO-18-40
[20] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172
[21] Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).
[22] Analysis of SEC Filings. Top 5 US-based companies by market cap as of November, 2018 (JNJ, PFE, MRK, ABBV, AMGN).
[23] https://www.sciencemag.org/news/2018/09/nih-gets-2-billion-boost-final-2019-spending-bill
[24] https://www.phrma.org/advocacy/research-development

The National Academies of Sciences, Engineering, and Medicine recently hosted a workshop where experts discussed multiple ways to ensure our investment in NIH balances critical innovation with essential access and affordability. Some of the approaches discussed include:

- NIH could reinstate its reasonable pricing provision in Cooperative Research and Development Agreements (CRADA) and Exclusive Licensing Agreements. This provision was removed by the NIH in 1995.[25]
- 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.

A specific legislative proposal to address these issues is the bipartisan WePAID Act introduced in the Senate by Senators Chris Van Hollen (D-MD) and Rick Scott (R-FL). The bill would ensure that drug companies set a reasonable price and limit annual price increases in cases where taxpayers contributed to the development of a new drug.

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.

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

Section IV. Immediate Legislative 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, it should receive a fair return for 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% of the new drug patents issued were for drugs already on the market.[26]

[25] https://www.nytimes.com/1995/04/12/us/us-gives-up-right-to-control-drug-prices.html
[26] https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.[27]

These tactics have led to longer exclusivity than our laws intended. The median length of post-approval market exclusivity for small-molecule drugs is not five years or even the seven years allowed for orphan drugs. It is 12.5 years.[28]

Members of this committee are supportive of numerous bipartisan bills to address patent abuses and anti-competitive industry practices. I thank Committee members for their work. We have lent our support to numerous bipartisan bills making their way through the House and Senate to address gaming of the patent system like: pay-for-delay deals, product hopping, REMS abuses, patent thickets, and sham citizen petitions. We remain hopeful that these bills will be enacted into law this congress.

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

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 should, too.

Given the prices we pay, it is clear that not allowing Medicare to negotiate directly and relying on pharmacy benefit managers to negotiate is not working. We know that not only from the experiences of other nations, but also from the Veterans Administration (VA). The VA negotiates and Medicare Part D could have saved $14.4 billion in 2016 alone by negotiating as the VA did.[31]

Medicare negotiations can take several approaches; the VA's is just one. H.R. 3 — the *Lower Drug Costs Now Act* — takes another comprehensive approach. Here is what makes the bill effective:

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[27] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567
[28] 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.*
[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/
[31] https://www.statnews.com/pharmalot/2019/01/14/medicare-drug-prices-veterans-affairs/

1. **It ends the ban on Medicare negotiating directly with drug companies to lower prescription drug prices** and empowers HHS to negotiate prices for the 250 most costly drugs each year.

   We support the non-compliance penalty of up to 95% of gross sales of a drug if the manufacturer refuses to negotiate. We believe it is a superior penalty to others that have been offered. As patients, we prefer this approach to a formulary. We also prefer the penalty to competitive licensing given documented concerns with access and effectiveness as compared to the penalty.[32]

   Additionally, I believe the bill's focus on the most costly drugs makes sense for the same reason Willie Sutton said he robbed banks: "That's where the money is." In Medicare Part D, the top 250 drugs account for 8.6% of drugs but 78% of spending. Medicare does not need to negotiate for thousands of drugs in Part D that have competition and low prices.

   Finally, it employs an international price index to set a maximum fair price for any negotiated drug. This mechanism is similar to a proposal offered by the Trump Administration and would ensure Americans are finally protected from paying two to three times what other wealthy nations pay for drugs.

2. **It ensures that Americans — regardless of insurance type — have access to lower-priced drugs**. A drug corporation would be required to offer the negotiated price to Medicare and *non-Medicare* insurance plans — including people who buy insurance through their employer, Healthcare.gov, etc. If a drug company overcharges Medicare or fails to offer the fair price to people, it will be subject to a penalty of 10 times the difference between the price charged and the maximum fair price for the drug.

   Prior to retirement, I owned and help manage a small business. We wanted to offer the best benefits we could afford and we did. But rising health costs — and drug costs in particular — were always a challenge.

   Consider specifically the impact when an employee gets a costly disease. *The New York Times* recently brought this issue into sharp focus. A family covered by the Boilermakers' Union health insurance required an expensive drug for a rare bone disease. At one point, for every hour the union's members worked, 35 cents

[32] https://www.healthaffairs.org/do/10.1377/hblog20190724.85223/full/

of his/her pay went to the drug company to pay for the family's prescriptions. High priced prescription drugs are driving up insurance premiums.[33]Extending lower drug prices to private plans will help millions of working people and businesses.[34]

3. **It stops drug companies from increasing prices on Part B and Part D drugs faster than the rate of inflation**, and imposes penalties on drug companies if prices rise above inflation. This provision has the added appeal of being a key feature of bipartisan Senate Finance package.

4. **It caps seniors' out-of-pocket costs for prescription drugs at $2,000 per year**. Currently, out-of-pocket costs for seniors on Medicare can be over $15,000 per year. Just one of my Part D drugs costs me more than $13,000 out-of-pocket annually. Deadly disease and chronic health conditions are not a moral failing, and we should not penalize people, especially older Americans, who are fighting to manage diseases that require high priced drugs.

5. **It directs savings to new drug research and innovation**. Taxpayers already finance much of the early, high risk science that leads to new drugs through the NIH. This plan will ensure that a share of the savings from lower drug prices will go to innovation and new drug development.

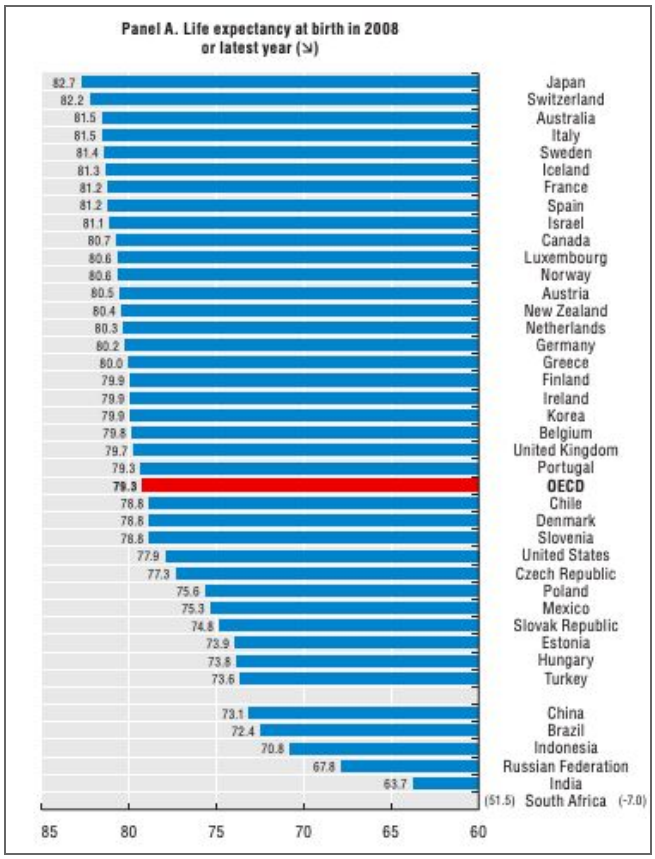
Next, I'd like to spend a moment focusing on the arguments against allowing Medicare to negotiate.

1. **It's socialism.** Competition and negotiation for lower prices are cornerstones of capitalism. Taxpayers negotiate on everything from aircraft carriers to printer paper. The only reason we don't negotiate in Medicare is because drug corporations inserted the prohibition into law in 2003.

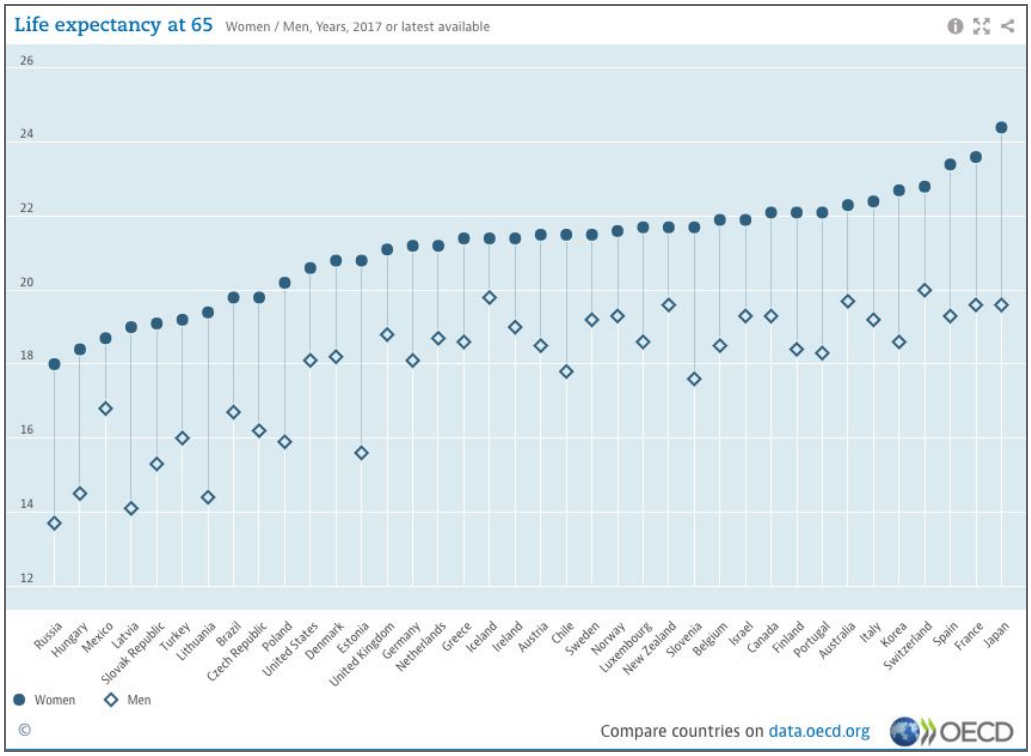
   Negotiating with drug companies who have monopolies on prescription drugs is not anti-competitive, it restores balance to our broken system. When Congress enacted Medicare in 1965, opponents of the program used a similar talking point of "socialism." Today, Medicare is one of the most important and popular advancements in our history.

[33] https://www.fiercehealthcare.com/payer/report-prescription-drug-costs-driving-up-insurance-premiums
[34] https://www.nytimes.com/2019/08/25/health/drug-prices-rare-diseases.html

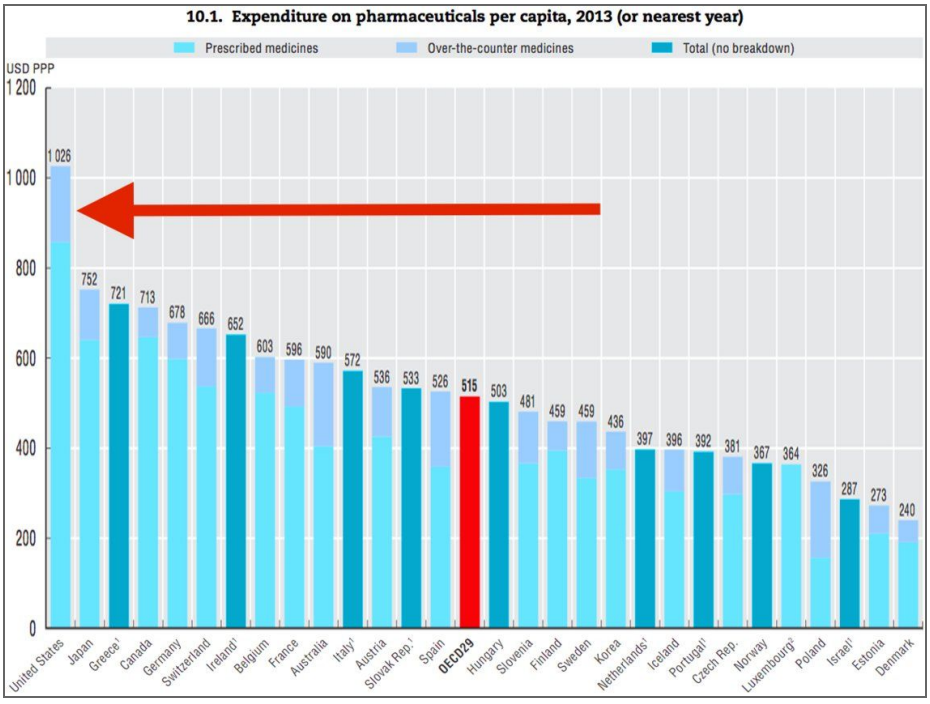
As for the countries that H.R. 3 uses for reference pricing — Australia, Canada, France, Germany, Japan and the UK are all democracies. But more importantly, each has a longer life expectancy at birth and at age 65. They have better health outcomes and each spends far less on prescription drugs per capita than we do.[35,36] Their prices are much lower.[37]



[35] https://www.oecd.org/berlin/47570143.pdf
[36] https://data.oecd.org/healthstat/life-expectancy-at-65.htm
[37] https://www.businessinsider.com/pharmaceutical-spending-by-country-2015-11



[38]



[39]

[38] https://www.data.oecd.org/healthstat/life-expectancy-at-65.html
[39] https://www.businessinsider.com/pharmaceutical-spending-by-country-2015-11

2. **It will kill innovation.** As has previously been covered, there is enough spending in the system to reduce drug prices and not impact R&D. Drug companies collect almost half of all health care profits despite generating less than 20% of industry revenue.[40]

   Some industry reports assert that it costs $2.6 billion to bring a new drug to market. But those reports are based on a study paid for by drug corporations using data the drug companies refuse to disclose. Independent analyses put the cost of a new cancer drug at closer to one quarter of that amount.[41]

   Furthermore, taxpayers already pay for much of the basic science leading to new drugs. Every single drug approved by the FDA from 2010-2016 was based on science funded by taxpayers through the NIH.[42]

3. **It will lead to rationing.** We already have drug rationing in this country. People are skipping doses, cutting pills in half, choosing between food and paying for their drugs every day. People are dying because they can't afford their insulin. H.R. 3 stops rationing and ensures affordable drugs.

4. **It will impose access restrictions.** There is nothing in the bill that restricts access to drugs. Unlike in the private sector, H.R. 3 does not create a formulary, and all drugs will continue to be covered by Medicare at all times, as they are today.

5. **It's a tax on drugs.** H.R. 3 imposes a penalty on a drug corporation that refuses to negotiate with American taxpayers. Drug corporations negotiate with every other country in the world. If they won't negotiate with us, they will pay a penalty. But it's easy for drug corporations to avoid the penalty — by negotiating. And it's important to remember that drug companies acknowledge that they earn a profit in the other countries where they charge much lower prices.

H.R. 3 is long overdue. It undoes an act of corruption that Big Pharma perpetrated in 2003 to block Medicare negotiation, and it levels the playing field for patients and consumers. It has significant bipartisan elements including international reference pricing, an inflation cap on price increases, and limits on out-of-pocket costs for people on Medicare.

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[40] https://www.axios.com/health-care-pharma-hospitals-q2-2019-7c20729d-ab9b-460b-9ea8-b08902491eec.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top

[41] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653012

[42] https://www.pnas.org/content/115/10/2329

And let's be clear, 90% of Democrats, 87% of Independents, and 80% of Republicans support allowing the government to negotiate with drug companies.[43]

Finally, we need more transparency around Pharmacy Benefit Managers (PBMs). They are the middlemen between insurance companies and manufacturers. These groups cut secret rebate 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." [44] 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 and bad medicine. They don't put patients first. They put profits first. We need 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?*

[43] https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/
[44] 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. It's time to enact reforms. It's time to stop these blatant abuses that keep drug prices high. Keep a focus on patients. And keep working together to address this urgent issue.

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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