PATIENTS FOR AFFORDABLE DRUGS™

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

before the

House Committee On Oversight and Reform

for a hearing on

Unsustainable Drug Prices: Testimony from the CEOs

September 30, 2020

Chairwoman Maloney, Ranking Member Comer, Members of the Committee. Thank you for allowing me to offer written testimony.

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.

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

Right now I am on a four-drug combination that carries a list price tag of more than $900,000 per year.

I have already relapsed twice. And there is no telling how long the current regimen will keep working. So the importance of innovation and new drugs 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

Despite claims to the contrary from some quarters, drug prices keep going up. From 2014 to 2020, prescription drug prices increased by 33%, which was nearly five times inflation during that period and was faster growth than any other medical service.[1] In the first six months of 2020, drug manufacturers hiked prices on 857 drugs by an average of 6.8%.[2]

Telling Congress that drugs are too expensive feels a little absurd. This is the one issue just about everyone agrees on. Eight in ten Americans say the cost of prescription drugs is unreasonable.[3] One out of five voters says lowering prescription drug costs should be Congress's top health priority.[4]

This makes my story far from unique.

When I first got sick, doctors put me on Revlimid. I had good private insurance but even so, my out of pocket cost for Revlimid was $3,250 per year. And I was one of the lucky ones. For Medicare beneficiaries on Revlimid, the median out-of-pocket cost can run to almost $15,000 per year — that's half their annual income.[5,6]

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 — which is now owned by Bristol Myers Squibb — gamed the system and refused to sell samples to generic companies trying to bring a competitor to market.[7,8]

Congress closed this loophole last December with the passage of the CREATES Act. Thank you. But Celgene employs other strategies to exploit loopholes in the law and extend monopolies. Just last week, Celgene settled patent litigation with a prospective generic entrant that delays full generic competition until 2026 — another way brand-name companies halt competition.[9] Altogether Celgene/BMS has inked three deals with generic companies in order to limit their US market share until 2026 —meaning Celgene/BMS keeps control of the price.[10]

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[1] https://www.goodrx.com/blog/prescription-drugs-rise-faster-than-medical-goods-or-services/
[2] https://www.cnn.com/2020/08/22/politics/trump-drug-prices-fact-check/index.html
[3] https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/
[4] https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/
[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://seekingalpha.com/news/3614877-bristol-myers-settles-revlimid-patent-dispute-dr-reddys?utm_medium=email&utm_source=seeking_alpha&mail_subject=bmy-bristol-myers-settles-revlimid-patent-dispute-with-dr-reddy-s&utm_campaign=rta-stock-news&utm_content=link-1
[10] https://www.fiercepharma.com/pharma/after-patent-win-at-pto-bms-inks-revlimid-settlement-dr-reddy-s

You will hear a lot about Revlimid in the hearing. I want to make sure you are also aware of the Celgene drug, Pomalyst. Pomalyst is an immunomodulatory drug in the same family as Revlimid. Like Revlimid, it is an analogue of Thalidomide— an old drug invented in the early 1950s.[11] It did not require decades of investment to develop. Celgene made a small tweak to add an amino group to the parent compound.

Pomalyst was approved by the FDA for multiple myeloma in 2013 based on a Phase II clinical trial of only 221 patients.[12,13] So the cost for clinical trials to bring Pomalyst to market was nominal.

Yet today, the list price of Pomalyst is $18,239 for 21 capsules—a 28-day supply.[14] (Pomalyst is often prescribed to be taken in 28 day cycles--21 days on and seven days off--which is how I take it.) Celgene has raised the price of Pomalyst 75 percent over the past seven years — almost 10 percent per year. There is no justification for these increases. The drug isn't any better than on the day it was approved. But the result of these price increases is that my out-of-pocket costs for Pomalyst under Medicare Part D will be more than $15,000 this year.

Although it is more than seven years since Pomalyst was approved as an orphan drug — the intended period for orphan drug exclusivity — there is no generic competing with it. Celgene has filed at least eleven patents on Pomalyst that could block competition until 2027.[15] This thicket stands in the way of timely generic market entry.

This is not what Congress intended with our current system. Generic competition is supposed to drive down prices after a set period of time. But drug companies like Celgene/BMS are gaming the system to defeat our laws and the will of Congress.

Section III. It's Not About Innovation

The good news is, we can fix this — and maintain new drug development. Because, 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.

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[11] https://www.news-medical.net/health/History-of-Thalidomide.aspx
[12] https://www.drugs.com/newdrugs/fda-approves-pomalyst-advanced-multiple-myeloma-3681.html
[13] https://www.cancernetwork.com/view/fda-approves-pomalidomide-pomalyst-multiple-myeloma
[14] AnalySource® as reprinted with permission by First DataBank Inc. All rights reserved. © (2020).
[15] https://www.drugpatentwatch.com/p/tradename/POMALYST

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."[16]

Dr. Peter Bach, an expert from 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."[17]

Right now, drug companies make enormous profits — roughly three times the average of the S&P 500.[18] 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.[19]

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. NIH funding contributed to research associated with every single new drug approved by the FDA from 2010-2019, totaling $230 billion.[20]

Taxpayers should not have to pay exorbitant amounts for drugs that they've already invested millions — or even billions — of dollars in. And it's happening right now on a huge scale with coronavirus vaccines.

This year, the federal government has allocated $12 billion to the development of treatments and vaccines for COVID-19.[21] That money has largely gone to six major drug corporations.

In fact, the government has been forced to fund early-stage research on vaccines. Not until it became clear that the novel coronavirus was highly contagious and spreading rapidly, did pharmaceutical corporations direct attention toward developing a vaccine.

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[16] https://freopp.org/a-market-based-plan-for-affordable-prescription-drugs-931e31024e08
[17] https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full/
[18] https://www.gao.gov/products/GAO-18-40
[19] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.dc7e820c4172
[20] https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade
[21] https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-using-every-available-resource-deliver-safe-effective-vaccine-american-people/

In 2018, only one percent of research and development projects were for emerging infectious diseases.[22] In fact, of the twenty companies that spent $2 billion on research and development in the last year, only four have units dedicated to vaccine development.[23]

Big Pharma is pulling out all the stops now because taxpayers are de-risking the entire venture and multinational drug corporations see enormous profit. The US government is paying for clinical trials, standing up production facilities, and eliminating all liability for drug corporations. Then we will pay again to buy the products — at prices that will yield a handsome profit for the drug companies involved.[24]

In fact, executives from three of the companies in the race to manufacture a vaccine — AstraZeneca, Johnson & Johnson, and Moderna Therapeutics — admitted to a Congressional Committee that they plan to make a profit on the taxpayer-funded drugs.[25]

That's why Congress should act immediately on two bills to stop drug companies from profiteering off a pandemic.

First, the bipartisan *Taxpayer Research and Coronavirus Knowledge (TRACK) Act of 202*0, which has been introduced in both the House and Senate, would create a comprehensive database of taxpayer-funded biomedical investment into COVID-19; this database will be vital for recording taxpayers' investment so that it can be accounted for in final prices Second, the *Make Medications Affordable by Preventing Pandemic Price Gouging Act (MMAPPP) of 2020,* aims to assure that COVID-19 vaccines and treatments are reasonably priced by eliminating exclusive licenses on taxpayer-funded drugs and requiring reasonable pricing in contracts; the bill has been introduced in both chambers and has bipartisan support in the House.[26]

Americans need and deserve transparency and fair prices because it is the right thing, but also because we don't have unlimited resources. The nation faces tremendous needs as a direct result of the pandemic and to address other urgent priorities such as rebuilding our infrastructure or improving our education system. Every dollar of unjustified profits we send to drug companies is a dollar we don't have to pay teachers, repair roads, and get health care to people who lost it during the pandemic.

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[22] https://accesstomedicinefoundation.org/publications/new-products-alone-are-not-enough-pharma-can-do-more-to-halt-covid-19
[23] https://www.bloomberg.com/opinion/articles/2020-01-23/drug-industry-may-lack-pandemic-preparedness
[24] https://www.hhs.gov/about/news/2020/08/11/trump-administration-collaborates-with-moderna-produce-100-million-doses-covid-19-investigational-vaccine.html
[25] https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html
[26] H.R. 7296 and S. 4439

Yes, drug companies should make money when they create innovative drugs. They are entitled to a fair profit. 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. Solutions To Fix A Rigged System

There are three areas of reform our nation must undertake 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.

First, patent law.

When a company brings an innovative drug to market, it should receive a fair return for its risk and investment. But companies like Celgene/BMS 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.[27]

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.[28]

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.[29]

The impact of these abuses is stunning. Just last week a new study showed that branded biologic drugs account for 46 percent of U.S. prescription sales but only 0.4 percent of prescriptions that are written in this country.[30] Their net sales have quadrupled in the last four years.

[27] https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows
[28] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567
[29] 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.*
[30] https://freopp.org/the-growing-power-of-biotech-monopolies-threatens-affordable-care-e75e36fa1529

There are numerous bipartisan bills in Congress to address patent abuses like deals for delay, evergreening, patent thickets, and the use of sham citizen petitions. All these bills should be enacted.

Next, we need Medicare price negotiations. Americans pay 2-3 times what other developed nations pay for the exact same drugs. The key reason why? They negotiate and we don't.

We know negotiation works because the Veterans Administration does it effectively. If Medicare Part D negotiated like the VA, it would have saved $14.4 billion in 2016 alone.[31]

Medicare negotiations can take several approaches; the VA approach is just one. Another approach under consideration would use international reference pricing as a way to frame bargaining. President Trump has proposed pegging U.S. prices to the lowest price in other developed countries. H.R. 3 uses international reference pricing as the starting point for negotiations. So there is bipartisan support for reference pricing as a tool.

When Medicare negotiates, the prices should be extended to the private sector so every American can benefit. Along with negotiations, we support inflation caps as in HR3 and in the Senate Prescription Drug Pricing Reduction Act. Those inflation caps also should extend to the private sector. And seniors need benefit redesign in Part D. No patient should have to pay more than $15,000 out of pocket for just one drug. HR3 would cap out of pocket at $2,000 — a step that is long overdue.

Finally, we need more transparency around Pharmacy Benefit Managers — the middlemen between insurance companies and manufacturers. PBMs 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."[32] 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.

[31] https://www.statnews.com/pharmalot/2019/01/14/medicare-drug-prices-veterans-affairs/
[32]https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm_term=.f9e74687f9af

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?*

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.

All of you hold the power to fix this broken system. I believe this is a problem that we can solve. That we must solve. And with bipartisan support, we will solve.