

# PATIENTS FOR AFFORDABLE DRUGS™

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

*before the*

**Subcommittee on Competition Policy, Antitrust, and Consumer Rights  
of the  
U.S. Senate Committee on the Judiciary**

*for a hearing on*

**“A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription  
Drug Markets”**

**July 13, 2021**

Chairwoman Klobuchar, Ranking Member Lee, Members of the Subcommittee, thank you for having me today for this important hearing examining how we can stop anticompetitive conduct in prescription drug markets that is hurting American patients, consumers and taxpayers.

## ***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 just over four years since we launched, we have collected over 27,000 stories of patients struggling to pay high drug prices. And we have built a community of more than 340,000 patients and allies who support policies to lower drug prices.

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

My doctors currently have me on a four-drug combination of infused and oral cancer drugs. These four drugs carry a combined list price of more than \$900,000 per year. Just one of my oral drugs, called Pomalyst, is priced at almost \$21,000 for 21 capsules, which I must buy every 28

days. And because Medicare beneficiaries like me pay our costs in Part D based on list price, I spent more than \$18,000 out of pocket last year — just for Pomalyst. To help manage the cost of my infused drugs, I spend another \$3,000 per year to purchase a Part B supplement. And of course, I have the base costs of Medicare to pay as well. For people with my cancer — multiple myeloma — drugs account for 60 percent of the cost of treatment.<sup>1</sup> Sixty percent.

I am a very lucky man — these drugs are currently keeping my cancer at bay, and I tolerate them well. But the reason I am on four drugs is because each began to stop working, so the doctors first increased the dose, then increased the frequency, and then added another drug. Eventually I will fail on this combination, too. When that happens, I will be what doctors call “triple refractory” to all of the three major classes of drugs used to treat my disease. The cancer will begin to increase in my blood and I will need a new treatment. Fortunately, there are options out there.

But one of the new drugs approved this year that I might be a candidate for carries a list price of \$419,500. That’s just for the drug — it doesn’t cover the hundreds of thousands of dollars required to administer the drug and manage my health in the wake of the treatment.

The point is: I need these innovative drugs. I care deeply about innovation and new drug development. My life depends on it. Without innovation, I will die sooner than I hope to. That is just an unfortunate fact.

But my 10-year journey as a cancer patient has taught me one irrefutable fact: Drugs don’t work if people can’t afford them.

## ***Section II. The Price of Drugs and Need for Change***

Drugs are too expensive in the United States, and there is no justification for the high prices. When drug makers hike prices each year, they don’t do so because the drug becomes more valuable. Drug companies raise prices because they can. We let them.

The result is that Americans pay nearly four times what people in other wealthy nations pay for the exact same brand-name drugs.<sup>2</sup>

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<sup>1</sup> Tran, D., Kamalakar, R., Manthena, S., & Karve, S. (2019, November 13). Economic Burden of Multiple Myeloma: Results from a Large Employer-Sponsored Real-World Administrative Claims Database, 2012 to 2018. *Blood*, 134, 3414. <https://doi.org/10.1182/blood-2019-131264>

<sup>2</sup> House Committee on Ways and Means. (2019). A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices. [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices\\_0.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf)

Consequently, nearly 40 percent of people report having difficulty affording their medications.<sup>3</sup> When their prescription drug prices are too high, Americans face challenges affording other expenses, such as food and housing. One survey found that over 20 percent of people took on debt or declared bankruptcy because of their medications.<sup>3</sup>

The issue of drug prices disproportionately harms communities of color. One in two Latinos in the United States takes a prescription medication, and 20 percent are uninsured.<sup>4</sup> Black Americans are more likely to live with chronic pain, diabetes, and high blood pressure than white Americans and are nearly two times more likely to be uninsured.<sup>5</sup>

The pandemic only made it worse, as millions of Americans lost jobs, income, and insurance coverage. As expensive as my drugs are, even with Medicare, I never lose sight of the fact that 30 million Americans without insurance are exposed to the full list price.<sup>6</sup>

People struggle to pay the prices with and without insurance.

Americans are desperate for relief. A Politico-Harvard poll from early this year found that nearly 90 percent of voters across both parties thought it was “extremely important” that Congress and the president take action on drug pricing. That includes 91 percent of Democrats and over 80 percent of Republicans.<sup>7</sup> And voters are worried you won’t do enough to help them — over 60 percent fear Congress won’t go far enough to reform our broken drug pricing system.<sup>8</sup>

You can change all this. You can restore balance to ensure we get the innovation we need at prices we can afford. And you can do it now.

### ***Section III. Innovation and Drug Prices: The False Choice***

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<sup>3</sup> Nguyen, A. (2021, March 22). *Survey: Americans Struggle to Afford Medications as COVID-19 Hits Savings and Insurance Coverage*. GoodRx. <https://www.goodrx.com/blog/survey-covid-19-effects-on-medication-affordability/>

<sup>4</sup> UnidosUS Action Fund. (2021). *A Vicious Cycle of Health Inequity: How High Prescription Prices Hurt Latino Health and Prosperity*.

<https://www.lowerdrugpricesnow.org/wp-content/uploads/UNIDOS-RX-REPORT-Vicious-Cycle.pdf>

<sup>5</sup> Patients For Affordable Drugs Now. (2020, December 14). *High Prescription Drug Prices Perpetuate Systemic Racism. We Can Change It*. <https://patientsforaffordabledrugsnow.org/2020/12/14/drug-pricing-systemic-racism/>

<sup>6</sup> Garfield, R. & Tolbert, J. (2020, September 17). *What We Do and Don't Know About Recent Trends in Health Insurance Coverage in the US*. Kaiser Family Foundation. <https://www.kff.org/policy-watch/what-we-do-and-dont-know-about-recent-trends-in-health-insurance-coverage-in-the-us/>

<sup>7</sup> POLITICO & Harvard T.H. Chan School of Public Health. (2021, January). *The American Public's Priorities for the New President and Congress*.

<https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2021/01/Politico-HSPH-Jan-2021-PollReport.pdf>

<sup>8</sup> Hart Research Associates. (2021, April 20). Memo for Protect Our Care.

<https://www.protectourcare.org/wp-content/uploads/2021/04/Garin-Memo-Protect-Our-Care-April-2021.pdf>

Of course, the biopharmaceutical industry opposes any reforms that would curb its unilateral power to dictate prices for brand drugs. So it rolls out its well-worn claim that any limits on its ability to set high prices will destroy innovation and access to new drugs.

No one cares more about innovation than patients. But if you pull back the curtain on this fear-mongering, the argument doesn't hold up.

Experts from both sides of the aisle agree it's possible to curb the pharmaceutical industry's pricing power without threatening valuable innovation.<sup>9-10</sup> There are five reasons why:

- 1) Biopharma corporations enjoy profit margins that are almost three times the average of the S&P 500.<sup>11</sup> Brand-name pharmaceutical companies could lose \$1 trillion in sales over 10 years and remain the most profitable industry in the United States.<sup>12</sup> There is more than enough headroom to lower drug prices and leave drug companies with plenty of profit to attract investment and fund research and development. And if drug pricing legislation curbs profits, the industry can maintain or even increase R&D investment by shifting the billions spent on stock buybacks, marketing, advertising, and lobbying.
- 2) It doesn't cost nearly as much as the industry says it does to develop a new drug. Pharma claims it costs \$2.87 billion to bring a new drug to market. But that's based on industry-funded research and undisclosed source data.<sup>13-14</sup> Independent studies have found the cost to develop a drug is likely less than \$1 billion.<sup>15-16</sup>

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<sup>9</sup> Frank, R. G. (2019, November 13). Drug companies exaggerate — controlling drug prices won't threaten innovation. *The Hill*.

<https://thehill.com/opinion/healthcare/470266-drug-companies-exaggerate-controlling-drug-prices-wont-threaten-innovation>

<sup>10</sup> Waikar, S. (2020, September 2). *Pharma Companies Argue That Lower Drug Prices Would Mean Fewer Breakthrough Drugs. Is That True?*. Kellogg School of Management at Northwestern University.

<https://insight.kellogg.northwestern.edu/article/pharma-companies-argue-lower-drug-prices-fewer-breakthrough-drugs>

<sup>11</sup> Yardeni Research. (2021, January 19). *S&P 500 Sectors & Industries Profit Margins (quarterly)*.

<https://www.yardeni.com/pub/sp500margin.pdf>

<sup>12</sup> West Health. (2019, November 14). *New Analysis Finds Large Drugmakers Could Lose \$1 Trillion in Sales and Still Be the Most Profitable Industry*.

<https://www.westhealth.org/press-release/new-analysis-finds-large-drug-makers-could-lose-1-trillion-in-sales-and-still-be-the-most-profitable-industry/>

<sup>13</sup> DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20-33. <https://doi.org/10.1016/j.jhealeco.2016.01.012>

<sup>14</sup> Tufts Center for the Study of Drug Development. (n.d.). *Financial Disclosure*.

<https://csdd.tufts.edu/financial-disclosure>

<sup>15</sup> Wouters, O. J., McKee, M., & Lutyen, J. (2020). Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*, 323(9), 844-853. <https://doi.org/10.1001/jama.2020.1166>

<sup>16</sup> Prasad, V., & Mailankody, S. (2017). Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. *JAMA Internal Medicine*, 177(11), 1569-1575.

<https://doi.org/10.1001/jamainternmed.2017.3601>

- 3) A tremendous amount of research and development is coming from taxpayers. The National Institutes of Health (NIH) is the single largest biomedical research agency in the world. NIH-funded research is associated with all 356 new drugs that were approved by the FDA from 2010 to 2019.<sup>17</sup> NIH Director Francis Collins has said: “Finding new treatments thus requires NIH to play a lead role — by investing in the early stage of therapeutic development to ‘de-risk’ such projects.”<sup>18</sup> Drug companies argue high drug prices are required to reimburse the industry for the financial and scientific risk it takes on during research and development. In reality, the U.S. government takes on most of those early risks, further undermining the industry’s argument for high prices.

Our experience with COVID-19 vaccines illuminates this point with crystal clarity.

Several years back when the big drug companies were unwilling to invest their own money in technology that led to some of the most effective vaccines today, the U.S. government did.<sup>19-20</sup> The biopharmaceutical industry publication *BioCentury* explains<sup>21</sup>:

“The Defense Research Advanced Projects Agency (DARPA) has taken risks where others wouldn’t. Its pursuit of high-risk, high-reward technologies, combined with its mission-driven approach to managing projects is promising to pay off in the fight against COVID-19. DARPA was behind the creation of DNA and RNA vaccines, funding early R&D by Moderna Inc. and Inovio Pharmaceuticals Inc. at a time when the technologies were considered speculative by many scientists and investors.”

In fact, a study issued recently said: "The unprecedented development of COVID-19 vaccines less than a year after discovery of this virus was enabled by more than \$17

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<sup>17</sup> Ledley, F., Cleary, E., & Jackson, M. (2020, September 2). *US Tax Dollars Funded Every New Pharmaceutical in the Last Decade*. Institute for New Economic Thinking.

<https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade>

<sup>18</sup> Collins, F. S. (2017, May 17). *Testimony on the Transformative Power of Biomedical Research*. National Institutes of Health.

<https://www.nih.gov/about-nih/who-we-are/nih-director/testimony-transformative-power-biomedical-research>

<sup>19</sup> Edwards, D. J. (2020, April 14). *New products alone are not enough. Pharma can do more to halt COVID-19*. Access to Medicine Foundation.

[https://accessmedicinefoundation.org/media/uploads/downloads/5e95d85128fb9\\_ATMF\\_Viewpoint\\_Role\\_for\\_pharma\\_in\\_C-19\\_200414%20\(1\).pdf](https://accessmedicinefoundation.org/media/uploads/downloads/5e95d85128fb9_ATMF_Viewpoint_Role_for_pharma_in_C-19_200414%20(1).pdf)

<sup>20</sup> Johnson, C. Y. (2020, December 6). A gamble pays off in ‘spectacular success’: How the leading coronavirus vaccines made it to the finish line. *The Washington Post*.

<https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/>

<sup>21</sup> Usdin, S. (2020, March 25). DARPA’s gambles might have created the best hopes for stopping COVID-19. *BioCentury*.

<https://www.biocentury.com/article/304691/darpa-jump-started-technologies-behind-some-of-the-leading-covid-19-vaccine-and-antibody-hopes>

billion of research on vaccine technologies funded by NIH *prior to the pandemic.*<sup>22</sup>  
[emphasis added]

According to Kaiser Health News: “Basic research conducted ... at the National Institutes of Health, Defense Department, and federally funded academic laboratories has been the essential ingredient in the rapid development of vaccines in response to COVID-19.”<sup>23</sup>

Of course, the government invested an additional \$20 billion through Operation Warp Speed and other programs.<sup>24</sup> As a result of all that taxpayer investment, The New York Times concluded: “A new method of developing vaccines was already waiting to be tested ... The government was willing to spend whatever it took, eliminating financial risks and ... allowing mass production to begin even before trials were done.”<sup>25</sup>

One noted industry expert, Jack Scannell, summed it up this way: “Before we pat the drug industry on the back too much, one has to recognize it got involved in this partly because the whole thing has been de-risked by government.”<sup>26</sup>

- 4) Pharma’s claims that patients will suffer an alarming loss of new drugs if anything is done to curb its unilateral pricing power isn’t supported by the facts. The Congressional Budget Office found that we could cut pharma revenue by up to \$1 trillion dollars over a 10-year period and lose only eight of 300 expected new drugs.<sup>27</sup> And many of those eight drugs would not be real losses at all because only 10 to 15 percent of new drugs that come to market actually represent true therapeutic advances.<sup>28</sup> The loss of a few drugs each year will have minimal impact on the health of Americans.
- 5) Big Pharma threatens that patients will lose access to newly developed drugs. It points out that more drugs are available — and are available faster — in the United States than in other wealthy countries. It frequently references a white paper from the White House

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<sup>22</sup> Bentley University. (2021, April 22). *COVID-19 vaccine development built on >\$17 billion in NIH funding for vaccine technologies*. [https://www.eurekalert.org/pub\\_releases/2021-04/bu-cvd042121.php](https://www.eurekalert.org/pub_releases/2021-04/bu-cvd042121.php)

<sup>23</sup> Allen, A. (2020, November 18). Government-Funded Scientists Laid the Groundwork for Billion-Dollar Vaccines. *Kaiser Health News*.

<https://khn.org/news/vaccine-pioneers-basic-research-scientists-laid-groundwork-for-billion-dollar-pharma-products/>

<sup>24</sup> Congressional Research Service. (2021, March 1). *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials*. <https://crsreports.congress.gov/product/pdf/IN/IN11560>

<sup>25</sup> LaFraniere, S., Thomas, K., Weiland, N., Gelles, D., Stolberg, S. G., & Grady, D. (2020, November 30). Politics, Science and the Remarkable Race for a Coronavirus Vaccine. *The New York Times*.

<https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html>

<sup>26</sup> Neville, S., & Kuchler, H. (2020, November 27). Covid vaccines offer Big Pharma a chance of rehabilitation. *Financial Times*. <https://www.ft.com/content/75029036-13f3-4ca2-8954-5a7207c0c3db>

<sup>27</sup> Congressional Budget Office. (2019, October 11). *Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare*. <https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf>

<sup>28</sup> Light, D. W., & Lexchin, J. R. (2012). Pharmaceutical research and development: what do we get for all that money?. *BMJ*, 345. <https://doi.org/10.1136/bmj.e4348>

Council of Economic Advisers (CEA) to explain why: “Drug manufacturers usually pursue market access in the United States before other markets due to the higher prices in the United States.”<sup>29</sup> The CEA could also have mentioned the other big reason drug companies file for approval first in the United States: It is the largest market in the world.<sup>30-31</sup>

Given that U.S. prices for brand-name drugs are almost four times what many other wealthy nations pay, we can lower prices by a meaningful amount and still offer the highest prices by far in the largest market in the world, preserving the incentive to file first for approval in the United States.<sup>2, 32</sup>

There are other important policies in the U.S. drug pricing system that lead to more drugs being available here compared to other countries, none of which would be altered by lowering prices:

- Medicare must cover all drugs in six protected classes, which even PhRMA acknowledges ensures access to these drugs.<sup>33-34</sup>
- Medicare must cover at least two drugs in each class of drugs.<sup>35</sup>
- Medicaid must cover every drug offered by a manufacturer in the United States if the manufacturer agrees to give Medicaid a best-price guarantee.<sup>36</sup>

Pharma’s threats to innovation and access don’t hold up. It is clear that we can restore balance to have fair prices and profits and still get the innovation we need.

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<sup>29</sup> The Council of Economic Advisers. (2018). *Reforming Biopharmaceutical Pricing at Home and Abroad*. <https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>

<sup>30</sup> IQVIA. (2020, March 5). *Global Medicine Spending and Usage Trends*. <https://www.iqvia.com/en/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends>

<sup>31</sup> Association of Community Cancer Centers v. Alex M. Azar II. Civil Action No. CCB-20-3531 (2020). <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Complaint-on-MFN-Rule-Filed-2020-12-04.pdf>

<sup>32</sup> Mulcahy, A. W., Whaley, C., Tebeka, M. G., Schwam, D., Edenfield, N., & Becerra-Ornelas, A. U. (2021). *International Prescription Drug Price Comparisons*. RAND Corporation. [https://www.rand.org/pubs/research\\_reports/RR2956.html](https://www.rand.org/pubs/research_reports/RR2956.html)

<sup>33</sup> Centers for Medicare & Medicaid Services. (2019, May 16). *Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)*. <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>

<sup>34</sup> Powaleny, A. (2015, December 10). *Medicare Part D’s six protected classes*. PhRMA. <https://catalyst.phrma.org/medicare-part-d-six-protected-classes>

<sup>35</sup> *What Medicare Part D drug plans cover*. (n.d.). CMS.gov. Retrieved May 3, 2021 from <https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover>

<sup>36</sup> Kaiser Family Foundation. (2019, May 1). *Medicaid’s Prescription Drug Benefit: Key Facts*. <https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/>

Equally important, we must remember that people can't afford existing drugs they need right now. More than 1.1 million Medicare patients could die over the next decade because they cannot afford to pay for their prescriptions.<sup>37</sup>

#### ***Section IV. What We Can Do About It: Patent Reform To Stimulate Innovation and Lower Prices Through Competition***

When a drug company makes a truly innovative discovery, it should be rewarded with a patent and receive a fair return for the risk and investment. Our patent system is designed to facilitate these rewards for innovation so that drug companies are incentivized to pursue true clinical breakthroughs and inventions that bring meaningful benefits to patients.

But the drug industry would have you believe that every patent is deserved and that the sheer volume of patents granted is an appropriate indicator of innovative achievements. That couldn't be further from the truth.

Neither new patents nor new drugs equal new innovation. Worse, in too many cases 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.<sup>38</sup>

Of the roughly 100 best-selling drugs, nearly 80% obtained an additional patent to extend their monopoly period.<sup>39</sup>

In fact, gaming of the patent system to extend monopolies beyond the time intended under law inhibits true innovation patients like me need. If drug companies can block competition and raise prices at will on old drugs to drive profits and executive bonuses, they have far less incentive to take risk and invest in R&D to find innovative new drugs that could command high prices and save lives.

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<sup>37</sup> West Health. (2020, November 19). *New Study Predicts More Than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications*.

<https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/>

<sup>38</sup><https://www.bloomberg.com/news/articles/2017-11-01/most-new-drug-patents-are-for-old-remedies-research-shows>

<sup>39</sup>Feldman, R. (2018). May your drug price be evergreen. *Journal of Law and the Biosciences*.

<https://academic.oup.com/jlb/article/5/3/590/5232981?login=true>

A report issued just last week by the House Oversight Committee highlighted how this works for a drug I took for more than five years — Revlimid<sup>40</sup>:

“Celgene paid its top executives millions of dollars in salaries and bonuses as they repeatedly increased the price of the cancer drug Revlimid. Between 2006 and 2018, Celgene paid its top executives over \$450 million in compensation. Internal company data show that Celgene’s executives would not have met several annual bonus targets if not for their decision to increase the U.S. price for Revlimid.”

There are a variety of strategies used by drug corporations to extend monopolies, including product hopping, patent thickening, pay-for-delay deals, and abuse of the FDA’s citizen petition process.

These tactics lead to longer exclusivity than our laws intend. The median length of post-approval market exclusivity for small-molecule drugs was not five years or even the seven years allowed for orphan drugs. It was 12.5 years.<sup>41</sup>

Let’s start with product hopping. This tactic occurs when a brand-name company switches a patient population from an older product facing competition to a different formulation that has a later expiring patent and therefore, is not facing competition. The “new” drug typically offers little or no new clinical benefit, it can be as simple as changing a product from a tablet to a capsule.

This switching is enabled by two anticompetitive behaviors. In “hard” switches, the brand-name company removes the older product from the market, forcing patients onto the new version. With “soft” switches, the company engages in aggressive marketing to prescribers and patients, urging them to switch to the newer formulation.<sup>42</sup> By switching their market to a new drug, brand-name companies effectively eliminate the market for new generics that rely on automatic substitution state laws to gain traction in the patient populations.

As patients, we support product evolution that improves effectiveness or reduces toxicities of a drug. I take a drug that causes painful peripheral neuropathy — loss of feeling in my feet. If a

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<sup>40</sup> House Committee on Oversight and Reform. (2021, July). Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation. <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf>

<sup>41</sup> FN-Wang B., Liu J., & Kesselheim A.S. (2015). Variations in time of market exclusivity among top-selling prescription drugs in the United States. *JAMA Internal Medicine* 2015;175(4):635-637.

<sup>42</sup> Jones, G. H., Carrier, M. A., Silver, R. T., & Kantarjian, H. (2016). *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States*. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/>

reformulated drug were to reduce this type of side effect, it might meet the standard of an innovative change meriting a patent extension.

Unfortunately, this is often not the case for patients. Two drugs that have been involved in high-profile product hopping cases are Suboxone and Tricor. Here's what patients have told us about both:

Samantha from West Virginia writes:

*“I have been in recovery for over ten years now. The cost of Suboxone is outrageous — especially since, from the time I began taking it until now, the price is still as high or higher. It's ridiculous! It's easier for people to misuse narcotics (the cost is less). The cost for Suboxone is about \$800 [for a 90-day supply].”*

Beatel from Minnesota told us:

*“When I changed to Medicare at 65, my price for 40mg of Tricor went to \$1,800/month. The pharmacist whispered to me, ‘If the doctor changed the order to 160mg tabs and I broke it in half for the 80mg dose, it would cost me \$40.’ The drug company still had the patent on the 40mg tab. The patent for the 160mg tab had expired...same drug.”*

Patent thicketing is a tactic similarly designed to undermine market dynamics at the expense of patients. This strategy occurs when drug companies file dozens of non-innovative patents in order to create an impenetrable patent thicket around a drug product; these patents create a protective “thicket” around a product since a prospective generic or biosimilar competitive must litigate through each of the patents in order to gain market entry.

Imbruvica, a best-selling cancer drug manufactured by AbbVie, provides a perfect case study. The Initiative for Medicines, Access, and Knowledge (I-MAK) found that AbbVie has filed 165 patent applications on the product and *more than half* of these were filed after market approval. Almost sixty percent of the patents cover indications or various formulations of the drug, not active ingredients. The 88 patents granted to date mean that Imbruvica will not face competition until 2036 or later — giving the drug over two decades of monopoly pricing power.<sup>43</sup>

The encouraging news is that there are multiple bills in Congress designed to close loopholes in our patent system that are harming patients. All have bipartisan support.

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<sup>43</sup> Initiative for Medicines, Access, and Knowledge. (2020.) *Overpatented, Overpriced: Imbruvica's Patent Wall*. <https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf>

- *Affordable Prescriptions for Patients Act of 2021* (S.1435)<sup>44</sup>: This bill, led by Senators Cornyn (R-TX) and Blumenthal (D-CT), establishes a definition for product hopping and establishes it as an anticompetitive behavior under the Federal Trade Commission Act. To address patent thickets, the bill narrows permitted patent assertions by biologic companies to 20, effectively limiting the number of patents that have to be challenged by biosimilar competitors.
- The *REMEDY Act*—which has not yet been reintroduced this Congress—is led by Senators Durbin (D-IL) and Cassidy (R-LA). The bill streamlines the generic approval process by allowing brand-name drug makers to assert only one patent during patent infringement proceedings. This patent must be chosen at the time of approval of the brand-name product, thus preventing the company from choosing among frivolous patents which are usually not obtained until after market approval. This legislation curb abusive patent thickets and allow generic manufacturers to bring more affordable drugs to market sooner.

There are two final anticompetitive behaviors that I urge this Congress to address.

First, through “pay-for-delay” or “reverse patent settlement” deals, brand-name companies gives a generic or biosimilar company something of value to delay that company’s introduction of a lower-price competitor. These collusive agreements impede competition and keep prices high for patients.

To address this tactic, we support the bipartisan *Preserve Access to Affordable Generics and Biosimilars Act* (S. 1428), led by Senators Grassley and Klobuchar.<sup>45</sup> This bill presumes that patent infringement settlements where something of value is transferred from a brand-name to a generic company is anticompetitive and permits the Federal Trade Commission (FTC) to enter into proceedings against parties to such an agreement.

Second, the citizen petition process at the FDA was designed so that patients could raise safety concerns about drug approvals. But research has revealed that the process has been co-opted by corporations looking to block competition. Brand-name drug makers were behind 92% of all citizen petitions filed between 2011 and 2015. But they were not raising legitimate safety concerns, which is why the FDA threw out nine of every 10 of the industry’s “sham” petitions.<sup>46</sup>

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<sup>44</sup> Affordable Prescriptions for Patients Act of 2021. S. 1435.  
<https://www.congress.gov/bill/117th-congress/senate-bill/1435?q=%7B%22search%22%3A%5B%22cornyn%22%5D%7D&s=3&r=11>

<sup>45</sup> Preserve Access to Affordable Generics and Biosimilars Act. S 1428.  
<https://www.congress.gov/bill/117th-congress/senate-bill/1428/cosponsors?q=%7B%22search%22%3A%5B%22Preserve+Access+to+Affordable+Generics+and+Biosimilars+Act%22%5D%7D&r=1&s=4>

<sup>46</sup><https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1956&context=aulr>

We support the following citizen petition reform bills in this congress:

- The *Stop STALLING Act* (S. 1425), a bipartisan bill led by the Chair of this Subcommittee, Senator Klobuchar (D-MN), and by Judiciary Ranking Member Grassley (R-IA), deems sham petitions as anticompetitive under the FTC Act, giving the Commission authority to penalize companies engaged in this behavior.<sup>47</sup>
- Under the *Ensuring Timely Access to Generics Act* (S. 562), led by Senators Shaheen (D-NH) and Cassidy (R-LA), FDA can deny a citizen petition that (1) was submitted primarily to delay a generic approval, or (2) does not raise valid scientific or regulatory issues. Currently, the FDA may deny a petition only if it meets both #1 and #2.<sup>48</sup>

To achieve true innovation at prices we can afford over the long haul, we must reform our patent and exclusivity system.

### ***Section V: Stop Anticompetitive Practices Downstream In The Supply Chain***

While the headwaters of our drug pricing problems are the list prices set by drug corporations, there are other reforms needed downstream in the supply chain. Pharmacy benefit managers (PBMs) are black boxes that cut secret mutually beneficial rebate deals with manufacturers, and none of it is transparent.

It is simply wrong that patients like me don't know if the preferred drug on a PBM formulary is there because it is the best drug, because it is the least expensive drug among equally effective options, or because the PBM got a big, legal kickback from the manufacturer. Without transparency, it is impossible to know how much of a rebate is going to the PBM, to the insurer, to lower my premiums, or to reduce my out-of-pocket costs at the pharmacy counter. With more than \$300 billion in drugs moving through PBMs, that is a bad way to run a railroad.<sup>49</sup> It's time for transparency to ensure PBMs are operating in the best interests of those they are supposed to serve — patients and consumers.

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<sup>47</sup> Stop STALLING Act. S 1425.

<https://www.congress.gov/bill/117th-congress/senate-bill/1425/cosponsors?q=%7B%22search%22%3A%5B%22stop+stalling%22%5D%7D&r=1&s=10>

<sup>48</sup> Ensuring Timely Access to Generics Act. S 562.

<https://www.congress.gov/bill/117th-congress/senate-bill/562?q=%7B%22search%22%3A%5B%22s.562%22%5D%7D&r=1&s=3>

<sup>49</sup> Pew Charitable Trusts. (2019, March 8). *The Prescription Drug Landscape, Explored*.

<https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored>

A research letter published just last week in the Journal of the American Medical Association demonstrated this point.<sup>50</sup> The authors revealed that Medicare Part D could have saved \$2.6 billion on 184 generic drugs in 2018 if it had paid what Costco did. The authors report:

"While price competition is strong for these drugs, the program leaves room for intermediaries to capture much of this value. Our findings show that in systems like Costco's, where incentives are set up to deliver value to the consumer, that is what happens."

In other words, PBMs are not maximizing value to patients like me — they are maximizing profit for themselves at the expense of patients and payers. They can do this because they have a stranglehold on their industry — the three major PBMs have 76% of the market share.<sup>51</sup> In addition to this horizontal consolidation, PBMs are increasingly merging vertically with insurance companies themselves. These recent trends give PBMs the ability to have an outsized impact on the choices and prices patients face. We welcome the focus of this Committee and the Biden administration on the potential harm to consumers brought about by potential antitrust violations within the PBM industry.

I also urge Congress to enact transparency requirements and determine how rebates are actually working — how much is going to reduce premiums and out-of-pocket for patients and consumers and how much is going to increase profits for the PBMs or insurer plan manager.

Drug companies and PBMs also enter into rebate arrangements that are designed to thwart lower cost competition. These are commonly called “rebate walls,” defined as:

“Exclusionary contracting practices that a drug manufacturer deploys to limit the ability of rivals from gaining preferred access to the formulary, or any access at all. Branded manufacturers leverage their position as market leaders by offering financial incentives to pharmacy benefit managers and health insurers in the form of ‘all or nothing’ conditional volume-based rebates, in exchange for virtually exclusive positioning on the formulary. ...If the payer does not accept the rebate agreement for a particular indication, it may lose all rebates for its product on all covered indications.”<sup>52</sup>

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<sup>50</sup> Trish E., Gascue L., Ribero R., Van Nuys K., & Joyce G. Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members. *JAMA Internal Medicine*. Published online: [https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810?guestAccessKey=89d9de51-fc11-4451-97aa-90b352b7867b&utm\\_source=For\\_The\\_Media&utm\\_medium=referral&utm\\_campaign=ftm\\_links&utm\\_content=ftl&utm\\_term=070621](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2781810?guestAccessKey=89d9de51-fc11-4451-97aa-90b352b7867b&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=ftl&utm_term=070621)

<sup>51</sup> The Advisory Board. (2019). *Pharmacy benefit managers, explained*. <https://www.advisory.com/en/daily-briefing/2019/11/13/pbms>

<sup>52</sup> Cohen, J. (2021, March 1). Rebate Walls Stifle Prescription Drug Competition. *Forbes*. <https://www.forbes.com/sites/joshuacohen/2021/03/01/rebate-walls-stifle-prescription-drug-competition/?sh=1ccc940366ae>

Let's be clear: These deals are designed to benefit both the manufacturer seeking to block competition and the PBM that gets a bigger rebate. These deals are not designed to help patients like me by lowering prices or increasing patient choice. They are emblematic of our drug pricing system meant to benefit those who profit from it at the expense of those it is supposed to serve.

We are pleased that the FTC made a decision recently to tackle these issues as well, authorizing staff to issue civil investigative demands and subpoenas to drug corporations and PBMs.<sup>53,54</sup> We also hope Congress will ensure the ability of the FTC to seek damages and monetary penalties for consumer protection and competition cases.

Of course, the Biden Administration's new push to promote competition in the U.S. economy is also welcome as it aims to foster and lower prescription drug prices. We hope to offer suggestions and support to HHS as it crafts its comprehensive plan in the next 45 days.

### ***Section VI: Allow Medicare To Negotiate***

Even if Congress and the Administration were to enact all these reforms to curb anticompetitive practices and stimulate competition, we would still have one huge problem with drug prices in the United States: drug corporations would still have the ability to dictate prices unilaterally with no check on how high they can go. In the end, Americans could still be paying almost four times what other wealthy nations pay for the exact same brand name drugs.

That's why comprehensive reform of drug pricing in America must include allowing Medicare to negotiate directly with drug corporations for lower prices.

Two immediate situations drive home the need for Medicare negotiations and lower prices that extend to the private sector:

- **COVID-19 Vaccines.** These vaccines, which are critical to ending the scourge of COVID-19, were developed with government funding and purchased for every American at between \$10 and \$19.50 per dose with taxpayer dollars.

Now they are poised to jump in price — a lot, if you listen to the stated intentions of

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<sup>53</sup> Kelly, C. (2021, June 2). Anticompetitive Drug Rebates May Need FTC Rulemaking for Timely Reform, Commissioners Say. *Pink Sheet*. <https://pink.pharmaintelligence.informa.com/PS144415/Anticompetitive-Drug-Rebates-May-Need-FTC-Rulemaking-For-Timely-Reform-Commissioners-Say>

<sup>54</sup> Sandburg, B. (2021, July 6). U.S. FTC Removing 'Handcuffs' to Pursue Pharma Companies, PBMs for Antitrust Violations. *Pink Sheet*. <https://pink.pharmaintelligence.informa.com/PS144579/US-FTC-Removing-Handcuffs-To-Pursue-Pharma-Companies-PBMs-For-Antitrust-Violations>

vaccine producers. Executives at Pfizer, Moderna and Johnson & Johnson, three of the companies whose coronavirus vaccines have been approved for emergency use in the United States, have said they will maintain their current pricing models during the pandemic but expect to raise prices after it ends. Frank D'Amelio, Pfizer's chief financial officer, recently said that in a post-pandemic environment, "Obviously, we're going to get more on price," noting that vaccine prices are normally \$150 to \$175 per dose.<sup>55,56</sup>

Many experts now predict that Covid-19 booster shots will become a regular part of our lives for years.<sup>57</sup> An increase in the price of coronavirus vaccines would have considerable impact on American health care spending. If Pfizer raised the price of its coronavirus vaccine from \$19.50 per dose to \$175, a yearly shot for every American adult would cost \$44.7 billion and could increase annual U.S. drug spending by 9 percent.<sup>58,59</sup>

- **Biogen's new Alzheimer's drug-Aduhelm.** The price announced by Biogen introduces enormous financial burdens for Medicare, taxpayers, employers, and patients. Roughly three million Americans live with mild Alzheimer's disease, the newly limited label indication for Aduhelm.<sup>60</sup> Biogen has said it expects that 80 percent of patients receiving Aduhelm will be covered by Medicare.<sup>61,62</sup> Aduhelm will cause significant spending burdens to Medicare because it carries a high price *and* could be taken by millions of Medicare beneficiaries. Even if only one million patients take Aduhelm, this would increase Part B drug spending by \$56 billion. To put this number in perspective, Aduhelm by itself could soon double Medicare Part B's annual drug spending, which is currently \$37 billion per year.<sup>63</sup>

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<sup>55</sup> Fang, L. (2021, March 18). Drugmakers Promise Investors They'll Soon Hike COVID-19 Vaccine Prices. *The Intercept*. <https://theintercept.com/2021/03/18/covid-vaccine-price-pfizer-moderna/>

<sup>56</sup> [https://s21.q4cdn.com/317678438/files/doc\\_financials/2020/q4/PFE-USO\\_Transcript\\_2021-02-02.pdf](https://s21.q4cdn.com/317678438/files/doc_financials/2020/q4/PFE-USO_Transcript_2021-02-02.pdf)

<sup>57</sup> Axios. (2021, March 15). *Covid-19 boosters set to become routine: "Immunity doesn't last forever."* [https://www.axios.com/covid-boosters-routine-0a5e0f06-b2e8-4e0c-ac0d-085507e3d404.html?utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=newsletter\\_axiosvitals&stream=top](https://www.axios.com/covid-boosters-routine-0a5e0f06-b2e8-4e0c-ac0d-085507e3d404.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top)

<sup>58</sup> [https://www.census.gov/data/tables/time-series/demo/pepsect/2010s-national-detail.html#par\\_textimage\\_1537638156](https://www.census.gov/data/tables/time-series/demo/pepsect/2010s-national-detail.html#par_textimage_1537638156)

<sup>59</sup> IQVIA. (2020, August 4). *Medicine Spending and Affordability in the U.S.: Understanding Patients' Costs for Medicine*. <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>

<sup>60</sup> National Institute on Aging. (2021, March 18). *Half of Alzheimer's disease cases may be mild*.

<https://www.nia.nih.gov/news/half-alzheimers-disease-cases-may-be-mild>

<sup>61</sup> Alzheimer's Association. (2021). *2021 Alzheimer's Disease Facts and Figures*.

<https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>

<sup>62</sup> Tozzi, J. (2021, June 8). Biogen's Costly, Unproven Drug Feared as Health Budget Buster. *Bloomberg*.

<https://www.bloomberg.com/news/articles/2021-06-08/biogen-s-costly-unproven-drug-feared-as-health-budget-buster>

<sup>63</sup> Owens, C. (2021, June 9). New Alzheimer's drug could blow up health spending. *Axios*.

<https://www.axios.com/alzheimers-drug-health-costs-medicare-aadf854c-e45a-4c6b-b284-e2cb324f08ab.html>

Patients who seek to take Aduhelm will face steep out-of-pocket costs for the drug and related medical services. In Part B, beneficiaries are subject to a 20 percent coinsurance, which will translate to about \$11,500 in coinsurance per year.<sup>64</sup> The median annual income for a Medicare beneficiary is about \$29,650, so paying for this drug could consume nearly 40 percent of a patient’s annual income.<sup>65</sup> If a patient buys a Medigap policy to cover Part B out-of-pocket costs, that can cost \$3,000 per year. These costs are untenable for many of those living with the disease. The nature of the drug — a monthly infusion for the rest of a patient’s life — means that patients *and* taxpayers will foot the bill over a span of many years.

Aduhelm is not proven to work and even the Alzheimer’s Association, a leading advocate for Aduhelm’s FDA approval, has said that the drug’s list price is “simply unacceptable” and will “pose an insurmountable barrier to access.”<sup>66,67</sup>

This is why we need Medicare negotiations. We cannot simply continue to allow drug corporations to set prices as high as they think they can get away with.

The Medicare negotiation bill in the House — H.R. 3 — and reportedly the bill being developed in the Senate Finance Committee won’t only allow Medicare to negotiate, it also includes other common-sense solutions to fix our drug pricing system that have enjoyed bipartisan support. It would penalize companies that hike the prices of Part B and D drugs faster than the rate of inflation. It would limit annual out-of-pocket costs for Medicare beneficiaries so patients like me wouldn’t have to spend upwards of \$18,000 a year for a single prescription. But we cannot lower out-of-pocket costs without lowering prices, or patients, consumers, and taxpayers will wind up absorbing the high list price through higher premiums, higher taxes, or less money in their paychecks.

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<sup>64</sup> Herman, B. (2021, June 8). Aduhelm's price to squeeze Medicare and patients. *Axios*.

<https://www.axios.com/aduhelm-biogen-drug-price-medicare-44628fff-6564-453f-9e01-2b04e80ff8f2.html>

<sup>65</sup> Koma, W., Neuman, T., Jacobson, G., & Smith, K. (2020, April 24). Medicare Beneficiaries’ Financial Security Before the Coronavirus Pandemic. *Kaiser Family Foundation*.

<https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/>

<sup>66</sup> Bulik, B.S. (2021, May 14). Celeb-backed Alzheimer’s Association campaign aims to build grassroots support for Biogen’s aducanumab ahead of FDA decision. *Fierce Pharma*.

<https://www.fiercepharma.com/marketing/alzheimer-s-association-campaign-more-time-supports-biogen-s-aducanumab-awaiting-fda>

<sup>67</sup> Higgins-Dunn, N. (2021, June 14). Biogen’s \$56K price on Aduhelm ‘simply unacceptable,’ Alzheimer’s Association says after vouching for FDA approval. *Fierce Pharma*.

<https://www.fiercepharma.com/pharma/biogen-s-56k-price-tag-for-aduhelm-simply-unacceptable-and-needs-fixed-alzheimer-s>

The legislation in the House is estimated to save the federal government over \$450 billion dollars.<sup>68</sup> We don't know yet the savings that might be generated by a new bill being written in the Senate Finance Committee. Whatever the number, we can put those savings to work in a variety of important ways.

Big Pharma claims using these savings to address other critical needs is tantamount to using the industry as a “piggy bank”.<sup>69</sup> But in reality, it is pharma that has treated patients and taxpayers as piggy banks for years — raising prices at will to hit profit targets and trigger executive bonuses.<sup>70</sup>

Pharma is absolutely right about one thing: America does have other priorities. We don't have unlimited resources and we can only spend a dollar once, and every dollar we send to pharma in unjustified profits — or “rents,” as economists like to call them — is a precious dollar we don't have to tackle other urgent needs. It's a dollar we don't have to reduce health care disparities, provide coverage to the uninsured, or increase funding for research on new drugs based on public health needs instead of private profit seeking.

That's why it is so important that H.R. 3 directs a portion of the savings to the NIH to fund the very innovation pharma claims will come to a halt if we rein in prices. We hope that legislation under consideration in the Senate will do the same.

It's no surprise that Medicare negotiation is so popular, with 90 percent of Americans saying they support the policy.<sup>10</sup> That includes overwhelming majorities from both political parties.

Increasingly, employers support government intervention to limit the prices of drugs. In a recent survey of employers with more than 5,000 employees, almost 4 in 10 said they somewhat or strongly agreed that the government should negotiate lower drug prices; only three percent disagreed.<sup>71</sup>

Medicare negotiation is a solution with massive bipartisan support among the American people. It is time for Congress to finally pass it into law.

## ***Section VII: Conclusion***

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<sup>68</sup> Congressional Budget Office. (2019, December 10). Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. [https://www.cbo.gov/system/files/2019-12/hr3\\_complete.pdf](https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf)

<sup>69</sup> Florko, N. (2021, April 13). PhRMA chief talks strategy — and he's surprisingly optimistic about drug pricing reform. *STAT*. <https://www.statnews.com/2021/04/13/phrma-chief-talks-strategy/>

<sup>70</sup> McAuliff, M. (2020, September 30). Sky-High Drug Prices Driven by Pharma Profits, House Dems Charge. *Kaiser Health News*. <https://khn.org/news/sky-high-drug-prices-driven-by-pharma-profits-house-dems-charge/>

<sup>71</sup> Claxton, G., Levitt, L., Gremminger, S., Kramer, B., & Rae, M. (2021, April 29). How Corporate Executives View Rising Health Care Cost and the Role of Government. Kaiser Family Foundation. <https://www.kff.org/report-section/how-corporate-executives-view-rising-health-care-cost-and-the-role-of-government-findings/>

Let's be clear: Big Pharma is not fighting for the interest of patients — it's fighting to maintain its unilateral power to dictate prices of brand-name drugs. Recently, the head of the trade association PhRMA affirmed that fact in a moment of candor. He said his industry is “particularly adept at ... rolling the tanks, if you will, to push back against policy proposals *adverse to the industry's interests.*”<sup>43</sup>

Of course, Big Pharma wants to disguise that truth. Instead, it blames others and distracts attention from its central role in making drugs unaffordable.

And it tries to scare us by saying that if we don't bend to its will, we won't get the drugs we need for the future. It poses questions like: How much would you pay to save a life?

And that's easy. When it's you or someone you love, the answer is anything. You'll empty your bank account, mortgage your home, cash out your 401k.

But that's the wrong question. We should be asking: *How do we restore balance to ensure we get the innovation we need at prices we can afford?*

One of our patients is Marcus LaCour from Ohio.<sup>72</sup> He's a husband, a father, and a minister. He is also a person with type 1 diabetes. Since he was diagnosed in high school, struggling to afford insulin has been a pattern in his life. He's been forced to rely on samples from his doctor, ration his insulin, or simply go without. In some of his hardest times, he rationed his insulin while his wife skipped meals to help pay for it. This should not happen in America.

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

All of you hold the power to fix this broken system. It's time to enact comprehensive reforms to make our system work for the people it is supposed to serve and lower prescription drug prices.

Thank you.

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<sup>72</sup> Patients For Affordable Drugs. (2021, April 5). *I've been forced to ration my insulin or simply go without.* <https://patientsforaffordabledrugs.org/2021/04/05/marcus-lacour-innovation/>