



The Honorable Elijah Cummings
Chairman,
House Oversight and Reform Committee

The Honorable Jim Jordan
Ranking Member,
House Oversight and Reform Committee

Statement for Hearing on The Patient Perspective: The Devastating Impacts of Skyrocketing Drug Prices on American Families

July 26, 2019

Dear Chairman Cummings and Ranking Member Jordan,

The Initiative for Medicines, Access & Knowledge (I-MAK) is grateful for the opportunity to weigh in on the devastating impact of skyrocketing drug prices on American families. We applaud the Committee's decision to ensure that the voices of those most directly impacted are front and center on this critical issue.

I-MAK has worked with patients for 13 years to ensure access to affordable medicines in America and in 49 countries across the world. Our organization is comprised of former private sector attorneys, former pharmaceutical industry scientists, and health and market dynamics experts. We are also mothers, fathers, aunts, uncles, daughters and sons who, like so many Americans, have been personally touched by the high cost of medicines. Our primary area of focus is addressing drugmaker monopolies that exacerbate skyrocketing drug costs. On the 12 best-selling drugs in the country, drugmakers have filed an average of 125 patent applications and have been granted an average of 71 patents each.¹ This kind of "overpatenting" blocks competition and enables pharmaceutical companies to set prices at will.

This problem is compounded by the current lack of transparency and public participation in the patent process. That's why we work closely with impacted communities, who we believe must be at the forefront of any efforts to address the prescription drug crisis. Every year in the U.S., patent decisions are made based entirely on the inputs of drug companies, with no opportunity for patients – whose lives depend on accessing treatment – to be heard. The result is a system that is disproportionately tilted in favor of industry, at the expense of families.

That must change, given how critically important this issue is to Americans irrespective of ideology. Prescription drug spending has tripled in the last decade² and is poised to double again in the next decade³, with dire consequences for patients. One in four American families report being unable to

¹ I-MAK. Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices. Aug 2018. <https://www.i-mak.org/overpatented>

² R Kamal and C Cox. What is the recent and forecasted trends in prescription drug spending? Peterson-KaiserHealth System Tracker. 22 May 2017. <https://www.healthsystemtracker.org/chartcollection/recent-forecasted-trends-prescriptiondrug-spending>.

³ 2016-2025 Projections of National Health Expenditures. Centers for Medicare and Medicaid Services, Office of the Actuary. 15 Feb 2017.

fill a prescription due to the high cost of drugs.⁴ Not surprisingly, tackling high prescription drug prices is now the number one priority for American voters.⁵

When medicines are priced out of reach, all Americans are affected – either personally when their own health or the health of a loved one is at risk, or as taxpayers. At the same time, the most vulnerable⁶ communities often bear the burden of high drug prices disproportionately. These include senior citizens, women, and individuals in the criminal justice system.

High drug prices are destroying retirement for millions of senior citizens

Among those hardest hit by high drug prices are seniors like Sue Lee from Kentucky, who we met last year. Lee was 76 at the time and was living with plaque psoriasis, an incurable, chronic skin condition that causes itchy, painful sores. To give her some relief, Lee's doctor had prescribed Humira, a drug that is protected by 132 patents. In 2012, the drug cost about \$19,000 a year. Today, it costs approximately \$40,000 a year. Even with Medicare, Lee was facing the prospect of draining the little savings she had in order to afford the drug. Retirement should be the peaceful denouement of a lifetime of work. Instead, millions of seniors are being forced to draw down on their retirement savings or forgo necessities like food and rent to pay for arbitrarily and mercilessly high-priced prescription drugs.

As the proportion of seniors to the total population grows, the drug crisis is only going to get worse. People aged 65 and older use far more prescription drugs than younger Americans;⁷ at any given time, older Americans are taking an average of 4.5 different prescriptions.⁸ Seniors are also three times more likely than those in their twenties to need costly specialty drugs,⁹ like Humira, that treat relatively uncommon conditions and have few, if any, generic alternatives. Making matters worse, over the last decade drugs widely used by older Americans have tripled in price on average¹⁰, far exceeding the rate of inflation. With one in five Americans expected to be 65 or older by 2030,¹¹ the country is staring down the barrel of a fiscal crisis.¹²

Low wages and pay disparities make women more susceptible to high drug prices

Women are disproportionately affected by high drug prices. Women, especially Black and Latina women, are more likely to be employed in low-wage or part-time jobs with no benefits and far less likely than men to have health insurance through their work¹³ — and since they are more likely to

⁴ A Kirzinger, L Lopes, B Wu, and M Brodie. KFF Health Tracking Poll – February 2019: Prescription Drugs. Henry J Kaiser Family Foundation. 1 Mar 2019. <https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs>.

⁵ A Kirzinger, L Hamel, B DiJulio, et al. KFF Election Tracking Poll: Health Care in the 2018 Midterms. Henry J Kaiser Family Foundation. 18 Oct 2018. <https://www.kff.org/health-reform/poll-finding/kff-election-tracking-poll-health-care-in-the-2018-midterms/>.

⁶ <http://nccd.ca/glossary/entry/vulnerable-populations>

⁷ National Center for Health Statistics. Health, United States, 2016: With Chartbook on Long-term Trends in Health. Hyattsville, MD. 2017. <https://www.cdc.gov/nchs/data/abus/abus16.pdf#079>.

⁸ SW Schondelmeyer, L Purvis. Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015. AARP Public Policy Institute. Dec 2017. <https://www.aarp.org/content/dam/aarp/ppi/2017/11/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans-december.pdf>.

⁹ A Lotvin. What's Special About Specialty? CVS Health. <https://cvshealth.com/thought-leadership/whats-special-about-specialty>.

¹⁰ SW Schondelmeyer, L Purvis. Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015. AARP Public Policy Institute. Dec 2017. <https://www.aarp.org/content/dam/aarp/ppi/2017/11/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans-december.pdf>.

¹¹ SL Colby and JM Ortman. Projections of the Size and Composition of the U.S. Population: 2014 to 2060. Population Estimates and Projections. U.S. Census Bureau. Current Population Reports. Mar 2015. <https://www.census.gov/content/dam/Census/library/publications/2015/demo/p25-1143.pdf>.

¹² P Krishtel. A Humira Prescription Costs \$38,000 A Year Because Our Patent System Is Being Abused. Huffington Post. 28 Oct 2018. https://www.huffpost.com/entry/opinion-humira-costs-patents_n_5bd0c893e4b0a8f17ef3961f.

¹³ J Arons and L Rosenthal. The Health Insurance Compensation Gap. Center for American Progress. 16 Apr 2012. https://cdn.americanprogress.org/wp-content/uploads/issues/2012/04/pdf/health_insurance_gap.pdf.

be covered as dependents, women are more susceptible to losing health coverage if family benefits are reduced or in the event of divorce.

These disparities are compounded by the fact that 80 percent of single parents are women.¹⁴

Sabrina Burbeck from Maine is one of those mothers. Her youngest of two sons has Type 1 diabetes and needs insulin to survive. When we met Sabrina, she had state-subsidized insurance that paid for the bulk of her son's treatment, which cost \$325 for a one-month supply. Sabrina had recently gone back to work, but she couldn't afford the coverage offered by her employer. Despite wanting to take on more shifts, she was forced to limit her hours to remain eligible for state-sponsored insurance.

Millions of other low- and middle-income women face similarly unfathomable choices, like rationing doses or forgoing treatment altogether. In a survey by Kaiser Health, 22 percent of women reported leaving a prescription unfilled or rationing doses because of cost; only 12 percent of men reported doing the same.¹⁵ Any solutions to the current drug crisis must include addressing the systemic disparities that make it harder for women, particularly women of color, to access treatment.¹⁶

Constitutionally guaranteed treatment for incarcerated individuals is routinely denied or delayed due to cost, and treatment costs are breaking budgets

Our nation's prisons and jails are another place where patients disproportionately suffer from lack of access to treatment or the effects of high drug costs. Incarcerated individuals – the vast majority of whom have been convicted of nonviolent drug crimes or are awaiting trial – have a constitutional right to medical treatment. This right is regularly violated. Treatment for people behind bars living with diabetes, asthma, hepatitis C, and other chronic diseases is frequently delayed or denied altogether. Some formerly incarcerated people refer to the practice of "diesel therapy," the repeated transferring of people who are sick and incarcerated from one prison to another in order to avoid the cost of treating them.

Hepatitis C is an illustrative example. People who are incarcerated represent less than one percent of the population, but they account for about a quarter of all diagnosed hepatitis C cases in the U.S. There is a cure for hepatitis C, a drug manufactured by Gilead Sciences called Sovaldi. Prisons have paid anywhere from \$22,000 to list prices of \$90,000 for a two- or three-month course. Using the low end of that range, it would cost \$1.1 billion to treat 50,000 people – just 12 percent of the number of incarcerated people with hepatitis C. As of mid-2018, 97 percent of people in state prisons with Hep C were not being treated.¹⁷ State administrators point to the prohibitive price of hepatitis C treatment, but the courts have consistently affirmed that cost cannot be used as justification for failing to screen for or treat hepatitis C, or treating with older, less effective drugs.

Left untreated, many of these individuals will return to their communities with debilitating chronic disease. State and federal corrections budgets are already under pressure. Unless high drug prices are addressed, prisons and, to a lesser extent, jails will face a difficult trade-off between providing constitutionally required healthcare and enacting the rehabilitative reforms needed to keep people out of the system for good.¹⁸

¹⁴ U.S. Census Bureau. Historical Living Arrangements of Children. Nov 2018. <https://www.census.gov/data/tables/time-series/demo/families/children.html>.

¹⁵ Gender Differences in Health Care, Status, and Use: Spotlight on Men's Health. 31 Mar 2015. Henry J Kaiser Family Foundation. <https://www.kff.org/womens-health-policy/fact-sheet/gender-differences-in-health-care-status-and-use-spotlight-on-mens-health/>.

¹⁶ P Krishtel. Women Are Being Hurt the Most by the Drug Pricing Crisis. Ms Magazine. 30 Oct 2018. <https://msmagazine.com/2018/10/30/women-hurt-drug-pricing-crisis/>.

¹⁷ S Thanthong-Knight. State Prisons Fail To Offer Cure To 144,000 Inmates With Deadly Hepatitis C. Kaiser Health News. 9 Jul 2018. <https://khn.org/news/state-prisons-fail-to-offer-cure-to-144000-inmates-with-deadly-hepatitis-c/>.

¹⁸ P Krishtel. How High-Priced Drugs Cripple Prison Health Care—and Reform. The Crime Report. 18 Dec 2018. <https://thecrimereport.org/2018/12/18/how-high-priced-drugs-cripple-prison-health-care-and-reform/>.

Recommendations

As we work to reimagine medicines access, we can and must do more to ensure that patients, especially those most affected by high drug prices, have a voice in policy decisions that impact their well-being in the most fundamental and personal way imaginable.

Hearings like this one focused on patients and families are an encouraging step toward greater public participation in the national drug pricing conversation. We need more like it, including with the involvement of Congress, the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and the Patent and Trademark Office (PTO). Unlike the FDA and FTC, the PTO has yet to acknowledge the direct relationship between patent decisions and drug prices. In the current drug pricing climate, it is increasingly important that the PTO meaningfully engage the broader public on policy decisions that have enormous implications for their health and well-being.

When the public is allowed to weigh in, even on ostensibly technical matters, it makes a difference. An analysis of FDA decisions showed that when public sentiment was skewed in favor, the relevant committee voted for approval 81 percent of the time.¹⁹ When public sentiment was opposed, it opposed approval 73 percent of the time. The odds of approval were 11 times higher when that decision was in keeping with the public will. Americans deserve a similarly democratized patent system, one that is open, encourages public input and does not reward anti-competitive overpatenting that harms patients and families.

The consequences of the current approach are painfully clear. Americans spend more on health care and have worse health outcomes compared with other developed countries.²⁰ Medicare and Medicaid are cracking under the weight of high drug prices, and taxpayers are footing the bill. Americans are rationing medicines while our system generously hands out patents that send drug prices soaring, and keeps them high for decades.²¹ Raising the bar on which patents are granted and ensuring that communities are at the forefront of the national response to runaway drug prices will lead to more informed policymaking and, ultimately, better health outcomes.

We appreciate the House Oversight Committee's leadership in calling this hearing. You are sending a message today that the experiences of everyday Americans affected by high drug prices matter. For this, we thank you.

Respectfully yours,



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¹⁹ N Vargas. Do public hearing participants influence outcomes of FDA advisory committee meetings? 3D Communications. Sep 2015. <https://www.3dcommunications.us/insight/fda-open-public-hearing-outcomes/>.

²⁰ EC Schneider, DO Sarnak, D Squires, et al. Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care. The Commonwealth Fund. <https://interactives.commonwealthfund.org/2017/july/mirror-mirror/>.

²¹ P Krishtel. Public Participation in the Patent System Will Lower Drug Costs. Morning Consult. 4 January 2019. <https://morningconsult.com/opinions/public-participation-patent-system-will-lower-drug-costs/>.