



**Written Testimony of Frederick Isasi, J.D., MPH
Executive Director, Families USA**

Promoting Competition to Lower Medicare Drug Prices

U.S. House of Representatives
Committee on Ways and Means, Health Subcommittee
Submitted to Chairman Lloyd Doggett and Ranking Member Devin Nunes
March 4, 2019

Families USA
1225 New York Avenue, NW, Suite 800
Washington, D.C. 20005
202-628-3030
press@familiesusa.org

Chairman Doggett, Ranking Member Nunes, and Members of the House Ways and Means Subcommittee on Health – thank you for the opportunity to speak with you today. I am Frederick Isasi, the Executive Director of Families USA. For nearly 40 years, we have served as one of the leading national voices for health care consumers both in Washington, D.C. and on the state-level. Our mission is to allow every individual to live to their greatest potential by ensuring that the best health care is equally accessible and affordable to all.

The Experience of Consumers

Unfortunately, while our country has made substantial progress in health care coverage over the last several decades, the incredibly high prices of prescription drugs have made it increasingly difficult for consumers to access life-saving care. It is unconscionable that in a country as great as ours, that almost three in ten (29 percent) of patients don't take their medicine as prescribed due to cost. It is unconscionable that approximately one in five forgo essential medications altogether because they can't afford to fill their prescription (19 percent), and more than one in ten, or 12 percent, of patients cut their pills in half or skip dosages to stretch the limited supply of drugs they can afford to buy.¹

These are the experiences of the “broad middle” of health care consumers — those who are neither wealthy nor poor. For them, the high cost of prescription drugs can have life-threatening effects.

For example, we recently heard from Tammy from Nacogdoches, Texas. She and her young-adult son both have hemophilia. Both of them require a different clotting factor to help treat their condition. Tammy's clotting factor costs a truly staggering \$500,000 per year and her son's costs even more — approximately \$750,000 per year. While Tammy and her son are insured, they have faced an uphill battle with insurers because of the extraordinary costs of their drugs. For example, their insurer often demands lengthy medical records to prove the medical necessity of those drugs and often delays payment for claims, particularly for Tammy's son. While going through this intense bureaucratic process, Tammy's son has sometimes had to go without his medication for months-long periods. And each time, he risks serious injury because without his medication, even a small injury could lead to serious internal bleeding — which can be fatal.

The Underlying Problem – Abuse of Patent and Market Exclusivity Laws

We all know that the health care financing system is complicated, and prescription drug pricing doubly so. Yet, at its core, the fundamental problem driving up prescription drug prices is astonishingly simple: flagrant abuses of the federal patent and market exclusivity laws by pharmaceutical manufacturers. Congress has sole authority over both these sections of federal law. Frankly, Congress created the rules that drug manufacturers have so blatantly abused, and it alone has the power to change those rules.

Drug makers and other actors have worked hard to complicate the picture. As we saw at the Feb. 26, 2019 Senate Finance Committee hearing, manufacturers blame virtually all other stakeholders for exorbitant prescription drug prices. They blame hospitals for marking up the prices of drugs that are sold to patients.

They blame pharmacy benefit managers (PBMs) for taking advantage of drug rebates, and pocketing most of the savings. They blame insurers for subjecting consumers to the costs of drugs through high deductibles. Each of those arguments has a nugget of truth, but manufacturers really are just deflecting attention from the root cause—their unchecked abuses of patent and market exclusivity laws.

For decades, drug makers have systematically abused patent and market exclusivity rules to quell product competition.ⁱⁱ For example, at last week's Senate Finance Committee Hearing, AbbVie received appropriate criticism for the wall of more than 100 abusive patents it has erected around its drug Humira, helping it to generate \$100 billion from this drug alone.ⁱⁱⁱ And AbbVie is not alone in these abusive practices. The makers of the top 12 best-selling drugs in the United States have filed, on average, 125 patents per drug, resulting in an average 38 years of blocked competition.^{iv} Instead of investing in real innovation, drug makers would rather make outsized profits on minor tweaks to existing drugs, which is why more than three quarters of new patents are for existing drugs.^v

Drug makers try to appeal to Congress' interest in free and open markets to protect the status quo. But what could be less free and less open than government-sanctioned monopolies that are allowed to abuse their market power to drive up costs on consumers and fleece American taxpayers at abandon? The fleecing of American taxpayers is particularly galling because taxpayers themselves have helped to fund the development of new drugs. Specifically, National Institutes of Health (NIH) funding contributed to research associated with every single one of the new drugs approved between 2010-2016.^{vi} Since the public pays for the foundational research to create new drugs, shouldn't we ensure they have access to these drugs?

When asked to defend prices on the merits, drug makers typically point to the need to invest in innovative, new drugs for the future, a canard. Clearly, most of us support the notion that drug companies should be incentivized to use their profits to drive innovations for new, lifesaving-drugs. If only that was the reality. Nine of the 10 largest pharmaceutical corporations spend more on marketing and sales, sometimes twice as much or more, than on research and development (R&D).^{vii} The argument that R&D costs can explain higher prices in the United States has been effectively debunked.^{viii} And this all occurs while consistently being among the most profitable industries,^{ix} with total revenues exceeding \$1 trillion world-wide.^x

And, even when drug manufacturers do allocate a small percentage of their revenue toward bona fide innovations, all too often they focus their resources on drugs that don't address the most urgent needs of families and instead focus on niche drugs that yield the greatest profit.^{xi} For example, experts agree that across the world there is an urgent need for new antibiotics to combat increasing drug-resistance, but major pharmaceutical corporations continue to step back from that life-saving research.^{xii}

Finally, think of the gifted women and men who are dedicating their lives to biomedical research both through our universities and in the pharmaceutical industries. These individuals represent some of the most talented scientific minds in our nation. Instead of ensuring federal law primarily rewards the innovations of these scientists, our federal laws are being leveraged to reward the manipulation of patent laws by pharmaceutical companies, as described above.

Medicare Drug Pricing Negotiation

One option policy makers have considered to reduce drug costs is to allow Medicare to negotiate the price it pays for pharmaceuticals. Families USA believes such a policy is a very important step towards addressing the rapidly-growing crisis around prescription drug costs. Let me be clear: Medicare drug-pricing negotiation does not address the heart of the drug pricing problem, i.e., the abuses of existing patent laws and market exclusivity; but is critically important nonetheless. It is perhaps the boldest approach being considered on Capitol Hill today, and represents a real opportunity to save money for taxpayers and patients alike.

Families USA strongly supports Chairman Doggett's legislation, the Medicare Negotiation and Competitive Licensing Act. The bill would allow Medicare to join other payers in negotiating the price it pays for prescription drugs. If a manufacturer refuses to negotiate in good faith, the Centers for Medicare and Medicaid Services (CMS) could issue a competitive license on the drug, effectively bringing competition into the market by allowing a generic manufacturer to produce the drug. The name-brand manufacturer would receive royalties on the sales, thus recouping its investment costs.

We particularly like the competitive licensing approach because it provides a strong incentive for name-brand manufacturers to negotiate while protecting patients' access to drugs. We are open to alternative methods to bring pharma to the negotiating table, if those methods are mandatory and have real effect.

Medicare negotiation would greatly help all Medicare beneficiaries. Beneficiaries like Catherine, a 63-year-old adult with disabilities from Wheeling, Illinois. Within three months of going to the doctor with a cough that wouldn't go away, she was told that, without a lung transplant, she would not live to see the end of the year. Her condition worsened. Her doctors prepared her to die — she prepared herself to die. Catherine was eventually able to receive a new lung in November 2014.

Because lung transplants have a high risk of complications, Catherine must be constantly monitored by doctors. Catherine takes 36 pills every day, including anti-rejection and pain medications. Each year, her medication costs put her in the Medicare Part D coverage gap — the doughnut hole. In fact, before each year ends, Catherine starts to ration her medications to make them last until her benefits are renewed at the beginning of the year. She spends \$1,000 each month on her medications, which is exactly half of her monthly income. Catherine sold her home and moved in with her parents to reduce her living expenses. She lives an extremely frugal life, but as her drug costs escalate year over year, she moves closer and closer to financial ruin and deep poverty. At the end of each year, she finds herself several thousands of dollars in the negative, wondering how she will make up the shortfall.

The American People Demand Real Change

Our nation's families continue to struggle with ever increasing health care costs. Approximately 44 percent of the public report foregoing seeing a doctor when they need to because of cost, and about one-third of Americans report that the cost of medical care interferes with their basic needs such as food, housing, or heat.^{xiii}

This problem is only growing more acute. In last fall's midterm Congressional elections, the American people sent a strong signal to Capitol Hill. Sixty-three percent of voters cited health care as an important issue facing the country.^{xiv} And even more to the point, an astounding 82 percent of Republicans and 90 percent of Democrats said, "Taking action to lower prescription drug prices" should be a top priority for the new Congress.^{xv}

Overcoming the Political Clout of Pharmaceutical Industry

Representatives of the pharmaceutical industry have done an incredible job of defending the status quo despite ample evidence that drug prices are out of control. This comes as no surprise as the pharmaceutical industry is one of, if not the most, powerful lobby in Washington and in many state capitals. As I'm sure many of you know, more lobbying money is spent on health care than any other economic sector.^{xvi} And within the health care sector, no industry spends more on trying to influence all of you than pharmaceutical companies — an astounding \$280 million dollars on lobbying in 2018.^{xvii} In fact, the pharmaceutical industry spent more than health insurers, doctors, nurses, other health professionals, hospitals and nursing homes, and literally every other health care industry stakeholder *combined* in 2018.^{xviii}

It is no wonder Congress has not taken major action thus far to stem the rapid growth in drug prices. There's literally a quarter billion dollars per year being spent to keep you and others from acting. I commend the subcommittee and the entire Congress for your efforts to stand up to the combined power of the drug industry and for putting consumers first. This and other hearings are all positive steps toward reaching real, lasting change. But make no mistake, this problem only will be addressed when you pass and the President signs, legislation that allows for real, meaningful change in federal laws. Until then, millions of America's families, like Tammy's and Catherine's, are looking to you — and waiting — for leadership.

ⁱ Kirzinger, Ashley, Lunna Lopes, Bryan Wu, and Mollyann Brodie. "KFF Health Tracking Poll—February 2019: Prescription Drugs." The Henry J. Kaiser Family Foundation. March 01, 2019. <https://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

ⁱⁱ I-MAK. "Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving up Drug Prices." December 3, 2018. <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>

ⁱⁱⁱ Ibid.

^{iv} Ibid

^v Feldman, Robin. "May Your Drug Price Be Evergreen." Journal of Law and the Biosciences, December 7, 2018. <https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lxy022/5232981>.

^{vi} Galkina Cleary, Ekaterina, Jennifer M. Beierlein, Navleen Surjit Khanuja, Laura M. McNamee, and Fred D. Ledley. "Contribution of NIH Funding to New Drug Approvals 2010–2016." Proceedings of the National Academy of Sciences of the United States of America 115, no. 10 (February 12, 2018): 2329-334. <https://www.pnas.org/content/115/10/2329>.

^{vii} Anderson, Richard. "Pharmaceutical Industry Gets High on Fat Profits" (original analysis by GlobalData not publicly available). BBC News. November 06, 2014. <https://www.bbc.com/news/business-28212223>

^{viii} Yu, Nancy L., Zachary Helms, and Peter B. Bach. "R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices." Health Affairs Blog. March 7, 2017. <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full/>.

^{ix} Government Accountability Office. "Drug Industry Profits, Research and Development Spending, and Merger and Acquisition Deals." Report to Congressional Requesters. November 2017. <https://www.gao.gov/assets/690/688472.pdf>

^x US Department of Commerce International Trade Administration. "2016 Top Markets Report Pharmaceuticals." May 2016. https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf.

-
- ^{xi} Bach, Peter B. "Could High Drug Prices Be Bad for Innovation?" Forbes.com. October 23, 2014. <https://www.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-for-innovation/#6083d6285a80>.
- ^{xii} Paton, James, and Naomi Kresge. "Superbugs Win Another Round as Big Pharma Leaves Antibiotics." Bloomberg.com. July 13, 2018. <https://www.bloomberg.com/news/articles/2018-07-13/superbugs-win-another-round-as-big-pharma-leaves-antibiotics>.
- ^{xiii} NORC at the University of Chicago. "Americans' Views on Healthcare Costs, Coverage and Policy." March 2018. <http://www.norc.org/PDFs/WHI%20Healthcare%20Costs%20Coverage%20and%20Policy/WHI%20Healthcare%20Costs%20Coverage%20and%20Policy%20Topline.pdf>.
- ^{xiv} Jensen, Tom. "NEW EXIT POLL: Health Care Defined Midterm, Fueled Democrats' Win." Protect Our Care. November 07, 2018. <https://www.protectourcare.org/ppp-exit-polling-shows-health-care-defined-midterm-fueled-democrats-win/>.
- ^{xv} "Americans' Priorities for the New Congress in 2019." Politico. December 2018. <https://www.politico.com/f/?id=00000168-1450-da94-ad6d-1ffa86630001>.
- ^{xvi} "Lobbying Spending Database Health, 2018." OpenSecrets.org. January 24, 2019. <https://www.opensecrets.org/lobby/indus.php?id=H>.
- ^{xvii} "Lobbying Spending Database Pharmaceuticals/Health Products, 2018." OpenSecrets.org. January 24, 2019. <https://www.opensecrets.org/lobby/indusclient.php?id=H04>.
- ^{xviii} Ibid.