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Subcommittee on Health, Education, Labor, and Pensions

Lower Drug Costs Now: Expanding Access to Affordable Health Care

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Chairman DeSaulnier, Ranking Member Allen, and members of the House Education and Labor Committee, Subcommittee on Health, Education, Labor, and Pensions: Thank you for the opportunity to speak with you today. I am Frederick Isasi, the Executive Director of Families USA. For more than 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 the best health and health care are equally accessible and affordable to all.

I am delighted to be speaking to this subcommittee at this pivotal time. Some of you may remember that I testified before this subcommittee two years ago. While so much in our world over the last two years has changed dramatically – including the biggest health and economic crisis our country has weathered in a generation – when it comes to drug prices, the story is frustratingly much the same.

After decades of egregious price increases and staggeringly high-launch prices, it is time to solve the problem and reduce the burden of prescription drug costs on America's families. Poll after poll shows that this is a pressing concern for the vast majority of people in this country, no matter their political persuasion. Nearly 9 out of 10 voters want Congress to act to address high drug prices and *to do it this year*.¹ Congress created this problem by giving pharmaceutical companies the monopolies that they abuse; and ultimate only Congress can solve this problem. And every year that we allow this to continue not only do people face illness, death and financial ruin; but we incentivize the tricks of drug companies and their lawyers, instead of rewarding the innovative, life-saving drugs we all want and need.

Ninety-five percent of voters, across the aisle, overwhelmingly support giving Medicare the power to negotiate for lower prices.² Now is the time to build on the unprecedented progress made in the 116th Congress to finally realize the will of voters. On behalf of the millions of families struggling every day to afford prescription drugs, thank you and the entire Committee, including Chairman Scott and Ranking Member Foxx, for your leadership in this effort.

The Impact of High Drug Prices on Families

While high drug prices are a source of seemingly constant policy debate in Washington, D.C., for millions of America's families, they are a painful and burdensome reality that often impacts their basic necessities of life. For example, consumers facing increased drug costs report cutting-back on key areas of their budget, such as buying food.³ And for some, the choice is even more dire. Incredibly, nearly three in ten adults – approximately 80 million people – in our country have not taken required medicine due to its costs.⁴ And, approximately one in five forgo essential medications altogether because they can't afford to fill their prescription.

While people who need high-priced drugs often face the most significant financial pain from high and rising prices, the impact of the skyrocketing cost of drugs is spread across all consumers. In fact, almost 22 percent of a privately-insured health care consumer's

monthly premium goes to prescription drugs.⁵ And overall, people in America pay exponentially more. A recent RAND report found that drug prices in the United States are over 250% higher than prices in 32 other countries. For brand-name drugs, the figure rises to 344%.⁶

Please allow me to share the story of just one of the millions of consumers struggling under the burden of high drug costs – a woman named Maureen, who is 80 years old and living in a small house in the North Georgia Mountains:

Maureen depends on Medicare for her health insurance and social security for income – living check to check - and describes herself as extremely healthy with the exception of blood clots in her left leg and lungs.

She was prescribed an anticoagulant treatment, and told she would need to take the medication for the rest of her life. She pays \$400 every three months, as prescribed. But at that price, Maureen simply cannot make ends meet and live out her retirement dream of focusing on animal rescue. So, she has decided to "give up food." She eats one meal a day and drinks tons of water because it fills her up, and she has also given up the dentist and non-essential driving to save on gas and repair costs.

There are currently no generic competitors for this class of drugs and despite brand competition, prices have been going up over the past 5 years for these life-saving drugs.[1] Maureen is resigned “you either pay it or you take your marbles and go home.” “Funding Big Pharma was not in my Social Security budget plan, yet here I am. Drug prices are life-changing, and not in a good way.”

These are the impossible trade-offs people are making as a result of our broken system. An 80-year old woman *gave up food* to pay for her prescription. It is unconscionable that she should feel compelled to choose trading food for medicine.

Exploitative pricing is more than academic for those who rely on lifesaving drugs. Ten years ago, Naloxone, a life-saving drug used to treat opioid overdoses, cost just one dollar. In the midst of the opioid crisis, the price rose to \$150 (for a two doses), and the auto-injectable version to a stunning \$4,500.⁷ Just this year, the Senate Finance Committee report on Insulin revealed a surge in prices for this century-old drug, unrelated to any new clinical benefit. They found that, rather than competing, manufacturers aggressively increased prices “in lock step”, invested only a small fraction in research and development, and pocketed the additional revenues.⁸ Even dexamethasone – a key therapeutic now considered a standard of care for COVID-19 and hailed for being inexpensive and accessible – increased in price by 137% in recent months, from \$0.59 to \$1.39 per unit, all while it sits on the Food and Drug Administration (FDA) shortage list.⁹

Debunking the Innovation Canard

At the foundation, Congress created drug exclusivity and patent laws to incentivize the real, life-saving innovations that we all want and need. There is no question that Congress got it wrong; and in the end, only Congress can truly fix the problem.

Despite pharmaceutical industry claims that high prices are fueled by the risk and cost of drug research and development (R&D), recent evidence suggests these costs make up a small share of their spending. In fact, large, brand-name drug manufacturers would still be the most profitable industry sector— while sustaining current levels of research investments — *even if they were to lower their sales by \$1 trillion.*¹⁰ Meanwhile, taxpayer-funded research contributed to every single new drug developed and approved from 2010 to 2019, totaling more than \$230 billion.¹¹

For decades, drug makers have systematically abused patent and market exclusivity rules to quell product competition.¹² For example, AbbVie has nearly 250 patent applications around a single product – Humira – with the aim of extending the company’s monopoly and delaying competition for 39 years at an estimated cost of \$14.4 billion to American taxpayers¹³ 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, far in excess of the exclusivity envisioned under Federal law.¹⁴ 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.*¹⁵

When patents on blockbuster drugs do finally expire, brand name manufacturers have turned toward increased prices on their remaining products to maintain and expand high revenues.¹⁶ According to a 2017 study, revenues generated by new drugs failed to make up for loss in revenues due to expiration of patents. Increases in invoice prices for current drugs under exclusivity, however, generated \$187 billion in revenues.¹⁷ Were it not for these price increases, revenues for name brand pharmaceutical companies would have been flat over the last decade, and overall spending on drugs would have fallen due to increased utilization of generic drugs.¹⁸

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.¹⁹ 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.²⁰

It is clear that the current drug exclusivity and patent regime is achieving the opposite of its goals. Instead of incentivizing true, life-saving innovation, it is incentivizing high-powered lawyers to leverage loopholes in the law to make some of the largest profits in the world. And as a result, every year that Congress continues to fail to act, is another year that drug companies play their tricks and all of us *do not* get the benefit of the real, life-saving innovations that could be achieved with improved financial incentives.

COVID-19: A Novel Coronavirus with the Same Old Story

Certainly COVID-19 vaccines are extraordinary public health advances. The speed at which they have become available could not have been anticipated, and as a result, millions upon millions of lives will be saved. But let's be clear, we hear a lot about the industry taking on financial risk to produce these innovations and rarely hear about the significant financial investment made by the average person. Across all COVID-19 vaccine development, taxpayer funded government and charitable investments account for almost 43% of dollars invested, including 100% of the Moderna vaccine. Return on investment is coming swiftly to shareholders. Wall Street forecasts \$38.5 billion in sales for the top five COVID therapeutics in 2021. Pfizer is projecting \$15 billion in sales this year and their CEO alone collected \$21 million in 2020.²¹ But, families in America, almost half of whom don't own stock, are tightening their belts and waiting for their return on investment. At the same time, drug makers increased prices on a record-setting 900+ drugs before the end of January 2021.²²

Anticipating that they may have to pay twice (for the fundamental research and development and then again at the pharmacy), Americans have expressed overwhelming support across party lines for legislation that would cap the price on any COVID-19 vaccine or treatment developed with federal funding. In fact, the pandemic has elevated the urgency of addressing high prescription drug costs, especially among Black, Latinx, and younger voters.²³

Current Medicare Drug Payment Policy Represents Total Market Failure

In his first address to a joint session of Congress last week, President Biden reiterated his call to action on drug pricing and specifically pointed to Medicare-based solutions:

“...let's lower prescription drug costs. We all know how outrageously expensive they are. In fact, we pay the highest prescription drug prices in the world right here in America – nearly three times as much as other countries. We can change that. Let's do what we've always talked about. Let's give Medicare the power to save hundreds of billions of dollars by negotiating lower prices for prescription drugs. That won't just help people on Medicare – it will lower prescription drug costs for everyone.”²⁴

Critics of a move to allow Medicare to negotiate on prices claim that these bills will “would end the current market-based system.”²⁵ To suggest that the current way in which brand name drugs are purchased by Medicare as “market-based” is utterly absurd. In truth, Medicare payment for brand name drugs is as far from a competitive marketplace as can be imagined. First, Congress has granted government-sanctioned monopolies on brand name drugs through patent and market exclusivity laws. Second, Congress tied Medicare's hands by barring it from negotiating on prices for these drugs. Finally, Congress legally bars the government from saying no to drugs at exorbitant prices. *Let us be very clear: this is not a competitive market. It is a hostage situation.*

State Remedies are Limited without Action by Congress

Many states are doing everything in their power to address the drug affordability crisis for their consumers but they need the federal government to take action if they are to have the ability to fully address high and rising drug prices. During the 2021 legislative session, state legislators in 44 states have filed 275 bills to control drug costs.²⁶ Fourteen states have introduced legislation to create Prescription Drug Price Review Boards, which increase access to certain high-cost drugs by determining an affordable rate.²⁷ Other states have introduced legislation to use international reference pricing approaches or to address egregious price increases on drugs that show no evidence of additional clinical benefit.²⁸ These state efforts are challenged by lawyers from the pharmaceutical industry based on the theory that their ability to set outrageous prices comes from the U.S. Congress and federal law. And, without action from the federal government, state legislation can only do so much. Congress created the rules that drug manufacturers have so blatantly abused, and it alone has the power to truly solve the problem.

Legislation under Consideration

One option Congress is currently considering to reduce drug costs is H.R. 3, *the Elijah E. Cummings Lower Drug Costs Now Act*, which represents a critical and clearly necessary step in addressing the rapidly-growing crisis around prescription drug costs.

The *Elijah E. Cummings Lower Drug Costs Now Act* is the kind of legislation consumers are demanding—it requires government to take action so that they can afford their medicines without bankrupting themselves in the process. And it does this without risking access to lifesaving medicines through a restrictive formulary. Specifically, the *Elijah E. Cummings Lower Drug Costs Now Act*:

- Authorizes and mandates that the Secretary negotiate directly with drug manufacturers on insulin and at least 50 other drugs that lack competition with the greatest costs to Medicare and the U.S. health system.
- Establishes a maximum negotiated price of no more than 1.2 times the average price offered in six other countries (Australia, Canada, France, Germany, Japan, and the United Kingdom).
- Requires manufacturers to make the negotiated price available to other purchasers.
- Provides a strong incentive for manufacturers to negotiate in good faith and to provide the negotiated price to Medicare and other purchasers through the use of an escalating excise tax and civil monetary penalties.
- Limits manufacturers' ability to hike the price of drugs year after year by imposing inflation rebates in Medicare Parts B and D.
- Caps out-of-pocket spending for seniors in Part D at \$2000.

When enacted, the *Elijah E. Cummings Lower Drug Costs Now Act*, will significantly improve the affordability of prescription drugs for consumers and produce substantial savings in the Medicare Program. A Congressional Budget Office and Joint Committee

on Taxation analysis (of HR3 introduced in the 116 Congress) found that the price negotiation provision would lower spending by \$456 billion.

These savings can then be reinvested in ways that promise to improve health and health care for all consumers. Families USA supports using these savings to improve Medicare benefits, such as providing much-needed Medicare dental coverage and improved support for low-income Medicare beneficiaries, as well as critical investments in affordable health coverage for people who get their insurance through Medicaid and the marketplaces.

While Families USA strongly supports the passage of the *Elijah E. Cummings Lower Drug Costs Now Act*, we recommend several critical improvements to strengthen the bill to ensure that it fully delivers on its promise to make prescription drugs affordable. These improvements include:

- **Expanding the selection of drugs subject to negotiation:** The government should be authorized to expand, over time and with experience, the minimum number of drugs for which the Secretary must negotiate a fair price annually. There also should be stronger criteria in place to ensure that it is the price for costliest drugs that are negotiated. I do want to acknowledge that this latest version of HR 3 has been improved in this area, as the previous version of the bill included 25 drugs eligible for negotiation instead of 50. Additionally, the definition of a negotiation-eligible drug should be expanded to include drugs that face competition from less than three generics, as it is at this level of competition that prices are significantly reduced.²⁹ The Secretary should also have the discretion to select additional drugs for negotiation if the manufacturer is engaging in particularly abusive pricing practices.
- **Ensuring all consumers and purchasers are protected by price spikes:** The vast majority of American families below retirement age receive their health coverage through employer-sponsored insurance (ESI), others through the health insurance marketplaces, and others through Medicaid. Some of this coverage falls squarely in the jurisdiction of this Committee and this Committee must act to improve that coverage. There should be strong incentives and/or penalties in place to ensure that manufacturers cannot raise prices above the rate of inflation for non-Medicare purchasers as well. This is particularly critical for drugs which have a relatively low exposure to Medicare – such as pediatric drugs.
- **Protecting uninsured consumers:** Though under this bill manufacturers would be required to make the negotiated price available to other health plans, this leaves uninsured consumers subject to high prices. As the consumers most vulnerable to high and rising prices, Congress should ensure that uninsured consumers can purchase drugs at no more than the prices negotiated for Medicare.

The American People – Across the Political Spectrum – Want Action NOW

In the 2020 Presidential and Congressional elections, the American people sent a strong signal to Capitol Hill that they want real solutions to make health care more affordable. Again in early 2021, voters expressed concern that Congress won't go far enough, especially in addressing high cost of prescription drugs (67%).³⁰ Fully 82% believe that the healthcare system today works more for the benefit of the drug industries and insurance companies rather than for the benefit of the average person, a sentiment that holds true across demographic groups and partisan lines. Likewise nine out of ten employers report that drug prices are among the greatest threats to affordability of health coverage for their employees.³¹ Poll after poll, year after year.

Now is the time for Members of Congress to act boldly on behalf of their constituents. I ask you today, will you support this commonsense legislation to protect taxpayers and your constituents from profiteering by pharmaceutical industry and fix the broken system, or will you side with drug makers, who hope to continue to exercise unfettered and unregulated monopolies over their products?

Thank you for your time today. Let's finally solve this life and death health and economic issue. I look forward to continuing to work with this committee and your colleagues across Capitol Hill to bring real relief from high drug prices to America's families.

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