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Subcommittee on Health

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Chairwoman Eshoo, Dr. Burgess, and members of the House Energy and Commerce Committee, 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 and health care are equally accessible and affordable to all.

The Impact of High Drug Costs on Families

While high drug prices are a source of seemingly constant debate in Washington, D.C., for millions of America's families, they are a painful and burdensome reality and can impact the basic necessities of life. For example, nearly one in three consumers facing increased drug costs cut-back on buying food to account for the increase.[1] 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.[2] For example, one in ten cut their pills in half or skip dosages to stretch the limited supply of drugs they can afford to buy.[3] And, approximately one in five forgo essential medications altogether because they can't afford to fill their prescription.

While people who need high-cost drugs 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 25 percent of a privately-insured health care consumer's monthly premium goes to prescription drugs.[4]

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 Catherine, a 63-year-old with disabilities from Wheeling, Illinois:

> *Within three months of going to the doctor with a cough that wouldn't go away, Catherine 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.*
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> *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.

Catherine lives every day with a serious chronic illness. It is unconscionable that she should simultaneously deal with the stress and hardship that comes with such a significant financial burden.

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 for a nasal spray. Now, it costs $150, and the auto-injectable version costs $4,500.[5] EpiPen — a drug intended for emergency allergic reactions, and essential in childcare settings and schools. About a decade ago, after Mylan acquired the EpiPen, they sued generic companies trying to produce it and increased costs from $100 to over $600.[6] After a great deal of public outcry the company introduced a generic version of the EpiPen priced at $300 in the U.S. , while its price is $100 in Canada, and $38 in the UK.[7]

Debunking the Innovation Canard

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 2017, drug makers spent a measly 22% of their revenues on R&D.[8] Meanwhile, taxpayer-funded research contributed to every one of the 210 drugs approved between 2010 and 2016.[9]

For decades, drug makers have systematically abused patent and market exclusivity rules to quell product competition.[10] For example, AbbVie has nearly 250 patent applications around a single product – Humira – helping it to generate $100 billion from this drug alone.[11] 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.[12] 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.[13]

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.[14] 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.[15] 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.[16]

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.[17] 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.[18]

Even Competitive Markets Need Strong Oversight

While generic substitution has helped to somewhat ameliorate continued higher spending on pharmaceuticals, it is not a panacea. Between 2008 and 2016, the average costs of oral generics increased by4.4 percent annually.[19] The cost of injectable generic drugs increased by more than 7 percent annually.[20] While these price increases are lower than those for drugs without competition, the consumer price index for urban areas (CPI-U) during that period was just 1.69 percent.[21] To be clear: the costs of generics is rising much more quickly than inflation and affordability of generics may soon be out of reach for many American families.

The reason for the failure of generic markets to fully moderate drug price increases is not fully known. Some point to the consolidation of generic manufactures as a serious concern.[22] Even more problematic, states across the nation are positing that generic drug makers have actively colluded to keep prices high. Just last week, the attorneys general of 43 states and Puerto Rico filed suit against 20 generic drug makers, alleging the companies colluded to fix and inflate the price of more than 100 generic drugs.[23] According to the suit, some drugs saw price increases of more than 1000 percent.[24]

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 2019 legislative session, 44 states have filed 244 bills to control drug costs, many of which are focused on enhanced price transparency[25] Precedent-setting legislation in Maryland will create a Prescription Drug Price Review Board to determine the appropriate price for government payers in the state to pay for high-cost drugs.[26] Additionally, Oregon, California, Connecticut, Nevada, and Vermont, recently enacted drug price transparency laws to require drug makers to justify dramatic price increases.[27]

While most state drug price transparency laws are too new to have produced meaningful data, in conformance with a law enacted in 2017, the State of California now publicly reports on the Wholesale Acquisition Price of new prescription drugs with a monthly course of treatment exceeding $670.[28] Under the California law, manufacturers must justify price increases on certain drugs. The findings from these disclosures will begin to be made public later this year.[29]

Legislation Under the Committee's Consideration

The subcommittee is considering four different bills today. Three of the bills, namely: H.R. 2113 - *Prescription Drug STAR Act*, H.R. 2296 - *FAIR Drug Pricing Act*, and H.R. 2376 - *Prescription Pricing for the People Act,* focus on enhancing transparency in how drug makers set prices. The fourth bill, H.R. 2757 – *Creating Lower Cost Alternative for Your (CLAY) Prescription Drug Act,* seeks to limit out-of-pocket drug costs for low-income Medicare beneficiaries. Taking them in order:

The *Prescription Drug STAR Act* was affirmatively reported out of the Ways and Means Committee last month on a bipartisan vote. Per the Ways and Means Committee's summary, the STAR Act:

- "Requires drug manufacturers to publicly justify large price increases for existing drugs and high launch prices for new drugs.
- Requires applicable manufacturers to report to the Secretary the total aggregate monetary value and quantity of samples provided to covered entities.
- Requires the Secretary to conduct a study on inpatient (Medicare Part A) drug costs, including trends in the use of inpatient drugs by hospital type.
- Requires the Secretary of Health and Human Services to publicly disclose the aggregate rebates, discounts, and other price concessions achieved by pharmaceutical benefits managers (PBMs) on a public website, so consumers, employers, and other payers can understand and compare the discounts PBMs receive.
- Requires all drug manufacturers to submit information to the Secretary on the average sales price (ASP) for physician-administered drugs covered under Medicare Part B."[30]

Families USA supports the STAR Act, though we recommend one change: Currently, the STAR Act requires drug makers to justify the launch price of a drug if its annual cost exceeds $26,000. Such a high threshold would allow nearly all high priced drugs to escape scrutiny. We urge the committee to consider lowering this threshold to a more reasonable level. One option would be to require manufacturers to justify any launch price that exceeds the threshold in Medicare to qualify as a specialty drug, currently $670 per month ($8,040 annually).

The *FAIR Drug Pricing Act* is a corollary to the STAR Act's provisions requiring justification for large price increases. The two bills both require manufacturers to justify price increases of more than 10 percent in a single year or 25 percent over three consecutive years. The STAR Act further requires manufacturers to justify price increases of more than $10,000 in a single year or $25,000 over three years. This would capture smaller percentage increases on very expensive drugs. While the FAIR Act does not include this provision, we support its inclusion in legislation marked up by the committee. Further, while both bills stipulate financial penalties for failure to disclose required information, the STAR Act also requires manufacturer executives to certify the

accuracy of their disclosure and mandates financial penalties for knowingly providing false information. We support this provision.

H.R. 2376 - *Prescription Pricing for the People Act* – was approved by the Judiciary Committee on April 30. The bill requires the Federal Trade Commission to issue a report on the prescription drug supply chain. We support this legislation.

H.R. 2767- *CLAY Act* - would eliminate cost-sharing for generic drugs for low-income Medicare beneficiaries. We support efforts to promote the use of generics, where available and appropriate, and are happy to support legislation that provides relief for low-income seniors.

The American People – Across the Political Spectrum – Want Action

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.[31] 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.[32]

Perhaps surprisingly to those in the political trenches, various solutions to solving the problem of high drug prices have public support across the political spectrum. A recent public polling finds that:

- 86 percent of Americans support requiring drug companies to release information to the public on how they set their drug prices – particularly salient for today's conversation.[33]
- 86 percent of Americans favor allowing Medicare to negotiate with drug companies to get a lower price on medications.[34]
- 75 percent of Americans favor shortening the length of monopoly granted on prescription drugs so that cheaper generic drugs are made available sooner.[35]

Transparency Alone is Insufficient – Consumers Demand Real Action

I want to be very clear: while Families USA supports the legislation under consideration by the subcommittee and believes that price transparency can help families, policymakers, researchers, and other stakeholders better understand how drug prices are set, these bills alone will not significantly affect the price of drugs. We are pleased that the House recently passed meaningful legislation, approved by this committee, to hasten generic competition. Yet even the CREATES Act and banning pay-for-delay schemes, while significant, are nowhere near the level of reform needed to really help families access affordable drugs.

The American people are fed up with the games drug makers play and are suffering mightily under the weight of high drug costs. Now is the time for Congress to act boldly

on behalf of their constituents. As a next step, we strongly encourage Congress to allow Medicare to negotiate with drug makers on the price of drugs. We support legislation sponsored by Rep. Lloyd Doggett (D-TX), which now has more than 120 cosponsors.[36] I am pleased that to date the legislation passed by this committee and under its consideration today has been bipartisan in nature.

The pain of high drug costs is felt in communities across the country. There is no reason why a real solution to this seemingly intractable problem cannot be bipartisan. We 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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