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THE VOICE FOR HEALTH CARE CONSUMERS

Statement for the Record

Senate Judiciary Committee

Hearing on
"Prescribing Sunshine: How Competition & Transparency Lowers Prescription Drug Costs"

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Chair Grassley and Ranking Member Durbin, we want to thank you for holding this important and timely hearing on high drug costs, the need for greater transparency, and the lack of healthy prescription drug market competition in the United States. Families USA, a leading national, nonpartisan voice for health care consumers, is dedicated to achieving high-quality, affordable health care and improved health for all. Central to that work is ensuring people have access to lifesaving and life-sustaining medication at a price they can afford.[1] This Committee has demonstrated strong bipartisan leadership on pharmaceutical patent reform, and we urge you to work with your Senate and House colleagues to pass urgently needed changes before the end of the year.

Just weeks ago, millions of voters across America made clear that they want their representatives in Congress to act boldly to address the cost of basic goods and services — including skyrocketing health insurance premiums and health care prices. Rising prescription drug costs remain a major driver of unaffordable health care. Between 2000 and 2022, U.S. per capita prescription drug spending increased from $432 to $1,217, a nearly three-fold increase.[2] Over the past 15 years, launch prices (the initial prices of drugs set by manufacturers) grew by more than 20% each year.[3]And even after launching, prices continue to increase at staggering rates, leaving families and individuals paying more and more, year after year, for their needed medications. Notably, consumers pay the price of high and rising drug costs whether or not they ever fill a prescription at the pharmacy counter: For decades, annual insurance rate filings have highlighted the impact of high costs for specialty drugs and biologics as leading drivers of rising health insurance premiums.[4]

Without question, soaring prescription drug prices are the result of widescale manipulation of federal patent and market exclusivity laws by drug companies. The business model of big drug companies is rooted in creating a monopolistic drug market and abusing it for exorbitant profit through price-gouging, anticompetitive behavior to extend drug exclusivity, and increasing profits on decades-old drugs rather than investing in new and innovative treatments to help our nation's families.

Shining a light to better understand ownership structures, how costs are being increased, and what prices are actually being charged is critical. However, we also strongly believe there are well-vetted, bipartisan, proven solutions to directly address the underlying drivers of high drug prices that could be enacted today. Families USA supports several bills already advanced by this Committee, and additional opportunities remain to advance key bills such as S.2276, the *ETHIC Act*. Ensuring final passage of these bills is an essential step to increasing competition and stopping big drug companies from gaming the patent system and continuing abusive price increases.

Big Drug Companies Abuse the U.S. Patent System to Protect Profit and Limit Competition

One of the biggest challenges in drug patent policy is striking a balance between the need to drive innovation that yields new products with the need to increase access to generic drugs that allows for greater affordability for families. This was the goal of the Drug Price Competition and Patent Term Restoration Act of 1984 – also known as the Hatch-Waxman Act[5] – which established the modern system of generic drug regulation in the U.S. by attempting to facilitate the entry of new generic drugs into the market in order to increase competition and lower drug prices. However, drug companies have unabashedly gamed the system and undermined the intent of this law to make outsized profits through their efforts to limit competition and keep generics off the market.

Common examples of tactics drug companies use to extend exclusivity include blanketing one drug with multiple and overlapping patents to create a "patent thicket," and "product hopping" from one patent to the next by making minor tweaks to existing drugs that create extended patent protections but do not provide additional clinical benefit. These abuses are widespread: Since the Hatch-Waxman Act was passed, the average number of patents for each new drug that has come on the market has tripled.[6] As it stands, there are now on average over 140 patents filed for *each* of the top twelve selling drugs on the market – with an average of roughly 70 patents ultimately granted per drug. More than half of these patents (56%) were filed *after* the drug was initially approved by the Food and Drug Administration (FDA),[7] underscoring that these excessive patent applications had far more to do with maximizing profits than protecting and promoting innovation.

Big drug companies also reduce competition by offering patent settlements that pay generic companies *not* to bring lower-cost alternatives to market through "pay-for-delay" schemes. According to annual reports by the Federal Trade Commission (FTC), as many as 142 generic versions of brand-name drugs were delayed by pay-for-delay arrangements between drug manufacturers between 2005 and 2012.[8] By compensating generic manufacturers to delay market entry, pay-for-delay settlements effectively shut out competition, entrench brand-name exclusivity, and drive-up drug costs that families pay at the pharmacy counter. One study estimates that pay-for-delay settlements result in $12 billion in increased drug costs a year, including $3 billion in direct costs to consumers.[9]

Once big drug companies have successfully blocked competition, they are free to raise prices year after year at shocking rates, long after a drug's initial release. This pricing pattern is pervasive across the drug market. From 2022 to 2023, approximately 4,200 existing prescription drugs experienced price increases - roughly half of which had increases above the rate of inflation.[10] During this period, drug prices increased by 15.2% (or $520 per drug) rising more than four times faster than the 3.4% inflation rate.[11, 12] These price increases are not justified by additional benefits or effectiveness of the drug. In fact, one study of high-spend drugs showed that seven of the 10 drugs reviewed provided no additional clinical benefit relative to other available drugs.[13] Rather, these abuses occur because drug companies exploit loopholes in our patent system for profit.

Making matters worse, rather than taking the profits from market exclusivity and investing in new cures, drug companies are simply growing their own wealth while our nation's families struggle to afford their medicines. From 2012-2021, the top 14 drug companies spent $747 billion in distributions to stakeholders (including stock buybacks and dividends) compared to only $660 billion on research and development (R&D) — *a shocking 13% less*.[14]

Patent systems should spur innovation and reward the investment in and discovery of new cures. Instead, drug companies demonstrate time and time again that it is easier and more profitable for them to abuse patent law, limit competition, and raise prices than to invest in new, innovative treatments that will help people live longer, healthier lives.[15]

Existing Legislation Provides Solutions

This committee has taken important action to address these abuses but has yet to advance S.2276, *the ETHIC Act*, which would rein in drug companies' ability to utilize patent thickets. We

urge the Committee to advance this bipartisan legislation without delay and to work toward its swift passage in the full Senate before the end of the 119th Congress.

We also support a number of bills already advanced by this Committee on a bipartisan basis and hope this Committee will continue to urge Senate passage, including:

- *Drug Competition Enhancement Act (*S.1040), which prohibits product hopping.
- *Affordable Prescriptions for Patients Act of 2023* (S.1041), which cracks down on patent thickets.
- *Preserve Access to Affordable Generics and Biosimilars Act* (S.1096), which curbs pay-for-delay practices.
- *Stop STALLING Act* (S. 1095), which stops drug company abuse of citizen petitions before the Food and Drug Administration (FDA) to delay generic and biosimilar market entry.
- *Interagency Patent Coordination and Improvement Act of 2023* (S. 1097), which establishes a task force between the U.S. Patent and Trademark Office and the FDA in order to strengthen and improve each agency's patent-related activities.

Families USA commends the work of the Senate Judiciary Committee to move forward these bipartisan reforms. It is critical that they all be brought to a vote before the full Senate.

Conclusion

The high and rising prices of prescription drugs threaten the health and financial security of families and individuals. Under the current system, big drug companies abuse patents, delay the entry of generic drugs into the market, and price gouge to support their greed, all while families and individuals go into medical debt, ration or skip medications, and have to choose between their medications and paying for daily necessities. Even those not taking prescription drugs are left with difficult financial decisions due to rising insurance premiums, higher deductibles, and stagnant wages — all of which can be tied back to rising drug prices.

Only Congress can end these egregious practices and bring much needed relief to millions of families across the country. We appreciate the work of this Committee — now is the moment to finish the job. American's have made clear that the costs of health care, including prescription drugs, are untenable and looking to Congress to take action. We urge the Committee to work with Senate and House colleagues to pass critical patent reforms before the end of the year.

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