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THE VOICE FOR HEALTH CARE CONSUMERS

Statement for the Record

House Judiciary Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet

Hearing on "Medicines and IP: Balancing Innovation and Access"

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Chairs Jordan and Issa, and Ranking Members Raskin and Johnson, on behalf of Families USA, thank you for holding this important and timely hearing highlighting the reality of high drug costs and 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. We appreciate the important work being done by the Courts, Intellectual Property, Artificial Intelligence, and the Internet Subcommittee with the House Judiciary Committee, and your colleagues in Congress, to explore ways to strengthen our patent system so that it more appropriately incentivizes and protects true innovation while ensuring that affordable pharmaceuticals are available to people who need them.

With millions of Americans increasingly concerned about the cost of basic goods and services — including skyrocketing health insurance premiums — the need to rein in the cost of health care is more urgent than ever.[1] Rising prescription drug costs remain a major driver of unaffordable health care.[2] Between 2000 and 2022, U.S. per capita prescription drug spending increased from $432 to $1,217, a nearly three-fold increase.[3] Over the past 15 years, launch prices (the initial prices of drugs set by manufacturers) grew by more than 20% each year.[4] 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. For example, the price of Victoza (a popular diabetes and weight loss medication launched in 2010) increased a staggering 42% in just five years, rising from $7,936 per year in 2015 to $11,300 per year in 2020.[5] 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.[6]

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.[7]

Congress has the power to rein in these abuses and take significant steps toward making medications accessible and affordable for our nation's families and individuals. Families USA supports an array of bipartisan and well-vetted solutions that would make meaningful and lasting improvements to the U.S. patent system, including two bills currently under consideration by this Committee: H.R. 3269, *Eliminating Thickets to Increase Competition Act* and H.R. 4570, *Interagency Patent Coordination and Improvement Act of 20235* (H.R.4570). We urge you to advance this legislation to the House floor.

Big Drug Companies Abuse 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[8] – 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 mean number of patents for each new drug that has come on the market has tripled.[9] 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),[10] 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 have been delayed by pay-for-delay arrangements between drug manufacturers since 2005. 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.[11]

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 pattern is pervasive across the drug market. From 2022 to 2023, 4,200 existing prescription drugs experienced price increases - roughly half of which had increases above the rate of inflation.[12] 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.[13] [14] 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.[15] 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* spent on finding new treatments for families and individuals than paying their stakeholders.[16]

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 rather than investing in new, innovative treatments that will help people live longer, healthier lives.[17]

Existing Legislation Provides Solutions to Patent Abuses

Congress must do all it can to end these corporate abuses in health care and intervene on behalf of the American people who are counting on them for relief.

There are two bills before this Committee that would help close loopholes that companies are currently taking advantage of, including:

- *Eliminating Thickets to Increase Competition Act* (H.R. 3269), which would rein in drug company ability to utilize patent thickets.
- *Interagency Patent Coordination and Improvement Act of 2025* (H.R. 4570), which establishes a task force between the U.S. Patent and Trademark Office and the FDA to strengthen and improve each agency's patent-related activities.

Additionally, Families USA strongly supports bills introduced in the Senate that do not currently have a corresponding version in the House, including:

- *Preserve Access to Affordable Generics and Biosimilars Act* (S. 1096), which curbs pay-for-delay practices.
- *Affordable Prescriptions for Patients Act of 2025* (S. 1041), which cracks down on patent thickets and product hopping.
- *Stop STALLING Act* (S. 1095), which stops drug company abuse of citizen petitions before the FDA to delay generic and biosimilar market entry.

Families USA urges members of this Committee to consider introducing House companion legislation to move forward these critical reforms.

Conclusion

High and rising prescription drug prices threaten the financial security of families and individuals and, by extension, their health. 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. Meanwhile, 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 and higher deductibles — 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 important work of this Committee to address these concerns and look forward to continuing to work with you to ensure all families can achieve affordable health care and improved health.

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