



**Statement for the Record**

**Senate Judiciary Committee**

**Hearing on “Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market”**

**Prepared by Families USA**

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Chair Durbin and Ranking Member Graham, 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 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 Senate Judiciary Committee to explore ways to strengthen our patent system, so it more appropriately incentivizes and protects true innovation while ensuring that affordable versions of pharmaceuticals are available to people who need them.

Currently, 60% of adults in America take at least one prescription medication and 25% take four or more.<sup>1</sup> But many people who rely on prescription drugs for their health are forced to make the choice between filling their prescription or filling their refrigerator because of the cost. Over the past 15 years, launch prices – the initial prices of drugs set by manufacturers – grew more than 20% each year.<sup>2</sup> 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.<sup>3</sup>

Without question, one of the fundamental drivers of soaring prescription drug prices is widescale abuses of federal patent and market exclusivity laws by drug companies. Drug companies intentionally manipulate the patent system to minimize competition, delay the entrance of generic drugs to the market, increase prices, and drive excessive profit margins on decades-old drugs.<sup>4</sup> But there is a wide array of bipartisan and well-vetted solutions to rein in these abuses, and Congress has the power to take significant steps in making medications accessible and affordable for our nation's families and individuals.

Families USA supports several bills introduced to the Committee, including many that have advanced to the full Senate. Ensuring passage of these bills is an essential step to stop big drug companies from gaming the patent system and adopting abusive price increases.

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

The entire 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 old drugs rather than investing in new and innovative treatments to help our nation's families.<sup>5</sup>

One of the biggest challenges in drug patent policy has been the need to balance innovation of new products with increasing access to generic drugs to allow for greater affordability for families. High prices for brand name medicines are an unintended result of the Drug Price Competition and Patent Term Restoration Act of 1984 – also known as the Hatch-Waxman Act.<sup>6</sup> This law 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 to enable more affordable 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,” or “product hopping” from one patent to the next by making minor tweaks to existing drugs that typically confer no additional clinical benefit but allow for extended patent protections. In fact, the 10 top-selling drugs on the market today have been granted an average of 74 patents per drug, with an average of 140 patents filed for each of them.<sup>7</sup> And three quarters of new patents are for existing drugs. From 2005 until 2015, 5,369 patents were granted to manufacturers for drugs that already had patents, representing 74% of new drug patents.<sup>8</sup> 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; in an analysis of 20 of these drugs, the companies made an estimated \$98 billion in total sales while the generic versions were delayed.<sup>9</sup>

Just looking at drug companies’ dwindling investment in innovation can highlight how much they are not incentivized to participate in promising drug research. From 2012-2021, the top 14 drug companies spent \$747 billion in distributions to stakeholders (including stock buybacks and dividends) and only \$660 billion on research and development (R&D), a shocking 13% less on doing their truly important job of finding new treatments for families and individuals than paying their stakeholders.<sup>10</sup>

Once big drug companies have blocked competition, they are free to raise prices year after year at shocking rates, long after the drug’s release. This pattern is pervasive across the drug market. Between July 2021 and July 2022, 1,216 drug products had price increases that were higher than the inflation rate (8.5%). Some increased by more than 500%.<sup>11</sup> 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.<sup>12</sup> Rather, these abuses occur because drug companies exploit loopholes in our patent system.

Patent systems should spur innovation and rewarding investment in and the 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.<sup>13</sup>

### **Existing Legislation Provides Solutions to Patent Abuses**

There are several pieces of proposed legislation to address these abuses, a number of which of which have been considered and advanced by this Committee on a bipartisan basis. Families USA strongly supports these efforts, including:

- *Preserve Access to Affordable Generics and Biosimilars Act* (S.142), which curbs pay-for-delay practices.

- *Affordable Prescriptions for Patients Act of 2023* (S.150), which cracks down on patent thickets and product hopping.
- *Stop STALLING Act* (S. 148), 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. 79), 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.
- *A Bill to Address Patent Thickets* (S.3583), which would rein in drug company ability to utilize patent thickets.

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

### **Conclusion**

The high and rising prices of prescription drugs 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, 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 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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- <sup>4</sup> Berkeley Lovelace Jr., “’Gaming’ of U.S. patent system is keeping drug prices sky high, report says.” NBC News, September 15, 2022. <https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507>
- <sup>5</sup> Bailey Reavis and Hazel Law, “The Reality of Prescription Drug Innovation: Drug Manufacturers Limit Innovation to Protect Patents and Profits,” Families USA, August 2023, <https://familiesusa.org/wp-content/uploads/2023/08/Drug-Companies-Limit-Innovation-for-Profit-2.pdf>.
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- <sup>7</sup> Tahir Amin and David Mitchell, “Big Pharma’s Patent Abuses Are Fueling the Drug Pricing Crisis,” Time, February 24, 2023, <https://time.com/6257866/big-pharma-patent-abuse-drug-pricing-crisis/#:~:text=A%20recent%20national%20report%20reveals,for%20very%20minor%20product%20modifications>.
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- <sup>9</sup> “Top Twenty Pay-For-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers,” Community Catalyst, US PIRG, July 2013, [https://publicinterestnetwork.org/wp-content/uploads/2013/07/Top\\_Twenty\\_Pay\\_For\\_Delay\\_Drugs\\_USPIRG.pdf](https://publicinterestnetwork.org/wp-content/uploads/2013/07/Top_Twenty_Pay_For_Delay_Drugs_USPIRG.pdf)
- <sup>10</sup> William Lazonick and Oner Tulum, “Sick with ‘Shareholder Value’: US Pharma’s Financialized Business Model During the Pandemic,” Institute for Economic Thinking, December 2022, <https://www.ineteconomics.org/perspectives/blog/sick-with-shareholder-value-us-pharmas-financialized-business-model-during-the-pandemic>
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- <sup>12</sup> Eliot Fishman, “Our Broken Drug Pricing and Patent System Diverts Resources Away From Innovation and Into Mergers, Patent Gaming and Price Gouging,” Families USA, August 2021, [https://familiesusa.org/wp-content/uploads/2021/08/RX-2021-209\\_Innovation-Drug-Pricing-Issue-Brief.pdf](https://familiesusa.org/wp-content/uploads/2021/08/RX-2021-209_Innovation-Drug-Pricing-Issue-Brief.pdf).
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