



STATEMENT FOR THE RECORD

**Submitted to the
House Judiciary Committee
Subcommittee on Regulatory Reform, Commercial, and Antitrust Law**

Antitrust Concerns and the FDA Approval Process

July 27, 2017

America's Health Insurance Plans
601 Pennsylvania Avenue, NW
Suite 500, South Building
Washington, D.C. 20004

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access and well-being for consumers.

We appreciate this opportunity to comment on anticompetitive strategies deployed by some drug manufacturers that increase prescription drug prices and costs by limiting competition for Food and Drug Administration (FDA) regulated products. We applaud the subcommittee for focusing on this critical issue. Out-of-control prescription drug costs impose a heavy burden on all Americans. Artificial monopolies and anticompetitive market distortions are exploiting a broken market to price gouge hardworking Americans – from FDA REMS abuses and patent evergreening to co-pay coupons and third-party payment schemes.

Health plans have developed effective solutions to address sustained cost increases. These solutions ensure access to life-saving medications for the patients who need them while also holding down costs for all consumers. Consumers are taking a more active role in their health decisions, including how to manage the rising prices of prescription drugs – and health plans are providing better cost and quality comparison tools for individuals and families to make informed choices about their care. Important patient protections include annual limits on maximum out-of-pocket costs for nearly all consumers with minimum essential coverage. Notably, consumer out-of-pocket spending – deductibles, coinsurance, and co-payments – have significantly declined since the 1990s – from 57 percent of U.S. retail drug spending in 1990 to 14 percent in 2015.¹

Delaying generic entry, blocking competition, and problematic legal and regulatory strategies by pharmaceutical companies to extend patent lives and market exclusivity periods drive up costs and jeopardize patient access to treatments. By protecting product monopolies, pharmaceutical companies put their bottom line ahead of patient access and affordability. Americans deserve better. We should all work toward a strong, sustainable market that works for consumers, small and large businesses, and hardworking taxpayers. With the right solutions that increase competition, choice, and patient control, we can deliver affordable prescription drugs – while

¹ Centers for Medicare & Medicaid Services (CMS), “National Health Expenditures Projections 2016-2025,” and National Health Expenditures (NHE), “Historical and Projections 1960-2025.”

protecting and supporting the essential innovations to deliver new treatments and cures for patients.

Our statement focuses on the following topics:

- Tactics used by the pharmaceutical industry to block competition and keep prices high;
- The consequences these tactics have on consumers; and,
- Recommendations for fixing the prescription drug market and reducing prescription drug prices.

Tactics Used by the Pharmaceutical Industry to Block Competition and Keep Prices High

The out-of-control growth of prescription drug spending is driven by artificial monopolies and anticompetitive behavior. Delaying generic entry, blocking competition, and extending patent life serves to protect monopoly pricing by branded pharmaceuticals – at the expense of the entire health system.

We recognize that some of these may be out of the scope of the hearing topic or require work with other congressional committees. However, we urge the subcommittee to take a comprehensive look at this critical issue to ensure the most effective solutions are pursued.

- **Abuses of FDA REMS Programs and Private Restricted Distribution Systems:** Since the introduction of FDA Risk Evaluation and Mitigation Strategies (REMS), branded manufacturers have increasingly exploited the rules surrounding the distribution restrictions to thwart access to samples of their original product from generic developers, even if the FDA has certified that the sale of samples would not be in violation of a REMS program. If generic or biosimilar developers are denied the ability to conduct bioequivalence testing of original products due to anticompetitive activities, the developers are essentially prevented from developing a generic or biosimilar version and bringing it to market.

According to CDER Director Dr. Janet Woodcock, as of March 2017, the FDA had received over 150 inquiries from generic developers unable to access samples of original products.² This method of restricting access to samples has evolved to the point where branded manufacturers are now moving to limit the distribution of their product *outside* of FDA REMS programs through private restricted distribution systems. There is nothing stopping a manufacturer from doing this and, in fact, it was one of the tactics used by Turing Pharmaceuticals to limit the availability of their life-saving product, Daraprim.³

A recent study estimated the total sales for products subject to FDA REMS restricted distribution systems and private restricted distribution systems to be over \$20 billion in 2016.⁴ A 2014 analysis estimated that, of 40 drugs on the market in 2014 for which generic developers reported their inability to get access to samples, \$5.4 billion could have been saved in *annual* drug spending if those generic versions were on the market.⁵

- **“Evergreening” of Patent Protections:** There is growing evidence that prescription drug manufacturers are gaming patent protections to artificially prolong the exclusivity period for some drugs and prevent less costly generic versions from reaching the market.⁶ By making minor changes to a drug’s chemical composition or delivery mechanism (e.g., an extended release version of a previously patented drug that had to be taken twice daily), manufacturers can extend patents that would have otherwise expired. These “evergreening” schemes do not typically provide any enhanced clinical benefit to consumers – rather they are aimed at maintaining monopolistic pricing for products that are just as effective as their less expensive, generic counterparts.

Other anti-competitive strategies such as “product hopping” – when pharmaceutical manufacturers withdraw a certain drug from the market and introduce a newer version with

² U.S. Congress, House Committee on Oversight and Government Reform, Subcommittee on Health Care, Benefits and Administrative Rules, *Examining the Impact of Voluntary Restricted Distribution Systems in the Pharmaceutical Supply Chain*, 115th Cong., March 22, 2017.

³ Pollack, Andrew. “New York Attorney General Examining Whether Turing Restricted Drug Access,” *New York Times*, October 12, 2015.

⁴ Brill, Alex. “REMS and Restricted Distribution Programs: An Estimate of the Market,” Matrix Global Advisors, June 2017.

⁵ Brill, Alex. “Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry,” Matrix Global Advisors, July 2014.

⁶ Collier, Roger. “Drug patents: the evergreening problem,” *CMAJ/ JAMC*, June 2013. Vernaz, Nathalie, et. al. “Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis.” *PLOS Medicine*, June 2013. Kesselheim, Aaron. “Rising Health Care Costs and Life-Cycle Management in the Pharmaceutical Market.” *PLOS Medicine*, June 2013.

minor changes in an effort to delay the entry of a generic substitute – frustrate efforts to realize savings from generic drugs. Strategies like these have resulted in a market for insulin – a drug widely available for the last 90 years – with only brand-name versions costing hundreds of dollars per vial.⁷

- **Prescription Co-Pay Programs:** Drug manufacturers often point to coupons or co-pay cards as a method for helping patients afford their prescriptions. While drug copay coupons can reduce out-of-pocket costs for specific (likely branded) drugs for individual consumers, they actually artificially inflate costs for everyone by hiding the true impact of rising costs. They do this by directing patients away from lower-cost generic alternatives and guiding them to higher-cost branded drugs, adding to the cost of coverage for everyone and distorting an already dysfunctional market.⁸ According to a recent perspective in the *New England Journal of Medicine*, co-pay programs are a “triple boon” for manufacturers because “they increase demand, allow companies to charge higher prices, and provide public relations benefits.”⁹
- **“Pay-for-Delay” Agreements:** Anticompetitive settlements with generic manufacturers that prevent generics from entering the market in a timely manner cost consumers and the health system. A staff study compiled by the Federal Trade Commission (FTC) concluded that “‘Pay for delay’ agreements are a ‘win-win’ for the companies: brand name pharmaceuticals stay high, and the brand and generic share the benefits of the brand’s monopoly profits.”¹⁰ The FTC estimated that these agreements are costing consumers \$3.5 billion per year. The Congressional Budget Office estimated that prohibiting these settlements would save the federal government \$3 billion over ten years and would accelerate the availability of lower-priced generic drugs.¹¹
- **Shadow Pricing for Older Drugs:** An April 2015 study, published in *Neurology*, found that the cost of disease-modifying therapies (DMTs) for the treatment of multiple sclerosis

⁷ Greene, Jeremy. “When Old Drugs Are Made New Again.” *Forbes*, April 23, 2015.

⁸ Dafney, et al. “When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization.” National Bureau of Economic Research. NBER Working Paper No. 22745, Issued in October 2016.

⁹ Howard, David H. “Drug Companies’ Patient-Assistance Programs—Helping Patients or Profits?” *N Engl J Med* 2014; 371:97-99, July 10, 2014.

¹⁰ Federal Trade Commission Staff Study. “Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions,” January 2010.

¹¹ Congressional Budget Office Cost Estimate: S. 2019, Preserve Access to Affordable Generics Act. October 20, 2015.

increased sharply despite the availability of an increased number of these treatments. Known as “shadow pricing,” the study noted that older first generation DMTs previously ranged in price from \$8,000-\$11,000 a year but after “shadow pricing” the newer agents, all DMTs cost upward of \$60,000 annually even if they had been on the market for decades.¹²

- **Orphan Drug Abuse:** A recent AHIP data brief found that many drugs classified as orphan drugs are being used to treat common medical conditions, making such medications more expensive for patients and the health care system.¹³ Our analysis looked at a sample of 45 orphan drugs available from 2012 to 2014 and found that almost half of the utilization of these drugs (44 percent) was for non-orphan diseases. We also found that drugs having little-to-no orphan utilization increased their prices during this time period by 180 percent more than those orphan drugs used almost exclusively to treat orphan diseases (42 percent versus 5 percent, respectively). These findings demonstrate how many drug companies are manipulating the Orphan Drug Act and its market exclusivity protections to excessively increase prices as part of a scheme to generate blockbuster profits. Our concerns regarding abuse of the Orphan Drug Act have been reinforced by the research of numerous academics, including a study published in the *American Journal of Clinical Oncology*.¹⁴

The Consequences of These Tactics on Consumers and Taxpayers

Everyone agrees: prescription drug prices are out of control. From patients who cannot afford life-saving medications, to consumers who pay higher premiums because of higher drug prices, to hardworking taxpayers who fund public programs like Medicaid and Medicare, the consequences are profound. All too often, the causes are deliberate anticompetitive distortions that game the system and threaten the balance of innovative drug development and competition envisioned by the Hatch-Waxman Act and the Biologic Price Competition and Innovation Act (BPCIA). The savings that could have been achieved without these distortions would have had a real impact on lowering the cost of care and reducing premiums, without sacrificing consumers’ access to essential medications.

¹² Hartung, et al. “The Cost of Multiple Sclerosis Drugs in the U.S. and the Pharmaceutical Industry,” *Neurology*, April 4, 2015.

¹³ “Orphan Drug Utilization and Pricing Patterns (2012-2014),” AHIP, October 2016. Orphan drugs are defined as those intended to treat rare diseases that affected fewer than 200,000 people in the United States.

¹⁴ Daniel, et al. “The Orphan Drug Act: Restoring The Mission To Rare Diseases,” *American Journal of Clinical Oncology*, November 2015.

When drug companies use regulatory loopholes to extend their market monopoly, everyone pays more. This must change. With the right solutions that increase competition, choice, and patient control, we can deliver affordable prescription drugs – while protecting and supporting the essential innovations to deliver new treatments and cures for patients.

Recommendations for Fixing the Prescription Drug Market and Reducing Prescription Drug Prices

The problem with prescription drug pricing does not lie with health plans, pharmacy benefit managers, wholesalers, pharmacies, or patients. The cost crisis is a direct result of actions by the pharmaceutical industry to take advantage of a broken market. But what is broken can be fixed. As the subcommittee explores strategies for reducing prescription drug prices, we urge you to consider our recommendations for effective, market-based solutions:

Delivering Real Competition

- **Reduce Rules, Regulation and Red Tape to Generic Entry.** Legislation should be enacted to ensure brand manufacturers cannot effectively block information and scientific samples from generic drug developers – like the CREATES Act and the FAST Generics Act. Anti-competitive tactics such as “pay for delay” settlements and “product hopping” should be prohibited, and the Inter Partes Review (IPR) process through the U.S. Patent and Trademark Office should be preserved.
- **Revisit and Revise Orphan Drug Incentives.** The Orphan Drug Act is being exploited. We urge Congress to ensure that the Orphan Drug Act’s incentives are used by those developing medicines to treat rare diseases – not as a gateway to premium pricing and blockbuster sales beyond orphan indications. In cases of rare diseases for which no effective therapy yet exists, we need to ensure that newly approved drugs are priced in accordance with their efficacy.

Ensuring Open and Honest Price Setting

- **Limit Third-Party Schemes that Raise Costs.** Policymakers should examine and address the impact of drug coupons and co-pay card programs – and related charitable foundations – on overall pharmaceutical cost trends. These programs hide the true impact of rising

prescription drug costs. It is important to ensure that existing protections aimed at prohibiting their use in certain federal programs are sufficient. In the commercial market, we need more transparency into when co-pay cards and coupons are being used.

Thank you for considering our perspectives on these important issues. We are committed – as you are – to solving the cost crisis. With the right solutions that deliver real competition and create more consumer choices, we can bring down the cost of prescription drugs. We look forward to working with the committee to advance market-based solutions to ensure that consumers have access to affordable medications.