AHIP Statement

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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. 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 issues surrounding the high cost of prescription drugs and the need for market-based solutions, and we applaud the Food and Drug Administration (FDA) for focusing on this critical issue.

Prescription drug prices are out of control. When drug companies are granted extraordinary protections through the patent system or market exclusivity protections, they have a monopoly and can set any price they choose – and raise prices at any time for any reason as we have seen in the well-publicized example of epinephrine autoinjectors (EpiPens).[1] We recognize that manufacturers who take large risks in developing new therapies should be fairly-rewarded. However, when monopoly power is abused, everyone overpays, from patients, businesses and taxpayers to hospitals, doctors, and pharmacists.

A study recently published in the *Annals of Internal Medicine* [2] highlights specific examples of generic drugs that were subject to dramatic price increases, including hydrocortisone acetate–lidocaine hydrochloride cream, which increased from $0.92 per application in 2008 to $42.27 per application in 2013. The study found that generic drugs with monopoly levels of competition were associated with price increases of 25.4% to 73.2%. By contrast, generic drugs with relatively high levels of competition were associated with price reductions of -34.4% to -28.9%.

Rising prescription drug costs impose a heavy burden on all Americans. A recent AHIP analysis concluded that 22 cents of every dollar spent on health insurance premiums goes to pay for prescription drugs – outpacing the amount spent on physician services, inpatient hospital services, and outpatient hospital services.[3]

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[1] Calculated by using EpiPen list prices from 2008 and 2016, assuming a 30% co-insurance rate off of PBM payment rate, and using CBO's reported "typical" PBM payment rate of 85% of list price plus a $2.00 dispensing fee (https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf)

[2] "High Generic Drug Prices and Market Competition," *Annals of Internal Medicine*, July 4, 2017. In this study, price changes were adjusted for drug shortages, market size, and dosage forms.

[3] "Prescription Drugs Are Largest Single Expense of Consumer Premium Dollars," AHIP, March 2, 2017. https://www.ahip.org/health-care-dollar/. This AHIP estimate understates the actual impact of prescription drugs on insurance premiums, as drugs administered in hospital inpatient settings were excluded.

AHIP's Recommendations for Reducing Prescription Drug Prices

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. Our recommendations for effective, market-based solutions focus on: (1) delivering real competition; (2) ensuring open and honest drug pricing; and (3) delivering value to patients.

We recognize that some of the solutions may not be directly under the FDA's purview or require working with other federal agencies. However, we urge the FDA to look holistically at this critical issue to ensure that the most effective solutions are pursued.

Delivering Real Competition for the Generic Drug Market:

- **Reducing Rules, Regulation and Red Tape to Generic Entry.** The FDA should be provided the necessary resources to clear the backlog of generic drug applications, particularly for classes of drugs with no or limited generic competition. We strongly support the FDA's efforts in this area.

- **Stopping REMS Abuse and Other Tactics.** We applaud the FDA's new focus on the abuse of Risk Evaluation and Mitigation Strategies (REMS) and other restricted distribution systems which have effectively allowed brand manufacturers to form artificial monopolies to halt the development of generic alternatives by denying access to samples of their products. Anti-competitive tactics such as "pay for delay" settlements and "product hopping" should also be prohibited.

If we are serious about promoting competition, there are other important steps that FDA should consider. For example:

- **Creating a Robust Biosimilars Market.** Some of the costliest and most widely-used biologics have been on the market for decades without biosimilar competition. In order for biosimilars to generate promised cost savings for consumers, FDA regulations must promote a robust market, ensure that providers and patients have unbiased information about the risks and benefits of biosimilars, and do not allow pharmaceutical manufacturers to delay the availability of or limit access to biosimilars by taking advantage of regulatory loopholes or exploiting the patent system.

- **Targeting Orphan Drug Incentives.** The Orphan Drug Act is being exploited. We urge the FDA to utilize its authority to ensure that Orphan Drug designation rewards research by companies that are developing medicines to treat rare diseases and not used as a gateway to premium pricing and blockbuster sales beyond orphan indications.

We also urge the FDA to consider approaches to ***Ensuring Open and Honest Price Setting:***

- **Publishing True R&D Costs and Explaining Price Setting and Price Increases.** As part of the FDA approval process, we believe manufacturers should be required to disclose information regarding the intended launch price, the use of the drug, and direct and indirect research and development costs.

- **Evaluating DTC Advertising Impact.** We strongly support the FDA's focus on the impact of direct-to-consumer advertising (DTC), especially given that many companies spend nearly twice as much on sales, marketing, and advertising than R&D.[4] We urge the FDA to assess the impacts of the growth in DTC advertising, particularly broadcast advertising, and evaluate the best approaches for conveying information to consumers.

Finally, we urge the FDA to consider how it can support efforts to ensure that we are ***Delivering Value to Patients:***

- **Informing Patients and Physicians on Effectiveness and Value.** Increased funding is needed for private and public efforts to provide information to physicians and patients on the comparative and cost-effectiveness of different treatments. This includes looking at financial sustainability and budgetary impacts, such as the framework proposed by the Institute for Clinical and Economic Review (ICER).[5]

- **Expanding Outcomes-Based Formulary Programs.** It is important to promote outcomes-based payments in public programs like Medicare for drugs and medical technologies, based on agreed-upon standards for quality and outcomes. However, this must not become a back

[4] "Big pharmaceutical companies are spending far more on marketing than research," *Washington Post*, February 11, 2015.
[5] Final Value Assessment Framework for 2017-2019, Institute for Clinical and Economic Review (ICER). https://icer-review.org/final-vaf-2017-2019/

door to discriminatory monopoly pricing as recently described in a *New England Journal of Medicine* analysis.[6] We encourage the FDA to consider ways to work with CMS in this area.

Thank you for considering our perspectives on these important issues. With the right solutions, we can bring down the cost of prescription drugs, including generic and branded drugs. We look forward to working with the FDA to advance market-based solutions to ensure that consumers have access to affordable medications.

[6] "The Economics of Indication-Based Drug Pricing," Amitabh Chandra, Ph.D., and Craig Garthwaite, Ph.D., *New England Journal of Medicine*, July 2017.