Statement

of the

American Medical Association

for the record

U.S. House of Representatives Committee on Oversight and Reform

Re: Examining the Actions of Drug Companies in Raising Prescription Drug Prices

January 29, 2019

Division of Legislative Counsel
(202) 789-7426

STATEMENT

of the

American Medical Association

to the

U.S. House of Representatives Committee on Oversight and Reform

Re: Examining the Actions of Drug Companies in Raising Prescription Drug Prices

January 29, 2019

The American Medical Association (AMA) appreciates the opportunity to present our views to the U.S. House of Representatives Committee on Oversight and Reform. The AMA supports examination of the actions of drug companies in raising prescription drug prices. As the largest professional association for physicians and the umbrella organization for state medical associations and national medical specialty societies, the AMA hears regularly and with increasing frequency from physicians that the escalating prices of prescription medication negatively impacts patient access, medication adherence, and health outcomes while increasing costs of health care overall. It is our goal to ensure that patients have access to and receive the right medical treatment at the right time, and we welcome the opportunity to share with the Committee AMA policy recommendations on how to increase patient access to and affordability of medically necessary prescription drugs through increased transparency and competition. The AMA has a large body of policies that address the rising cost of prescription drugs and we look forward to continuing dialogue to seek solutions to improve access, lower costs, and reduce the administrative burdens without stifling innovation.

The Impact of the Escalating Cost of Prescription Medication

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on our patients, on physician practices, and the broader health care system. Patients delay, forgo, or ration their medication when treatments are cost prohibitive, putting their health at risk.

Patients take greater clinical risks when treatments are cost prohibitive. For example, in a 2018 national survey 32 percent of the respondents reported that they have not filled a prescription or have taken less than the prescribed dose of medicine.[i] When patients delay, forgo, or ration their medication, their health status may deteriorate. Patients who cannot afford their medication and therefore do not adhere to the medication regimen as prescribed by their physician may eventually require medical interventions in more-costly care settings, such as emergency departments, when their condition is at a more advanced stage of disease. Price increases continue to occur among all segments of the pharmaceutical market from innovator biologics to previously low-cost established generics. Physicians see every day that costs have become a major barrier to our patients getting the right medication at the right time.

The high cost of pharmaceuticals not only negatively impacts the patient who requires them and cannot afford them, but the cost is also passed on to other patients through broad increases to premiums. It also reduces time available to other patients as the health care team spends additional time to identify affordable alternatives or complies with time intensive utilization management documentation requirements put in place by insurers in the face of escalating medication prices.

As part of the AMA's TruthInRx.org grassroots campaign and website, patients and members of the health care team have shared their stories on how high drug costs have impacted patient access and health outcomes. The goal of the TruthinRx.org campaign is to highlight the opaque process that pharmaceutical companies, pharmacy benefit managers (PBMs), and health insurers engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to require transparency. To date, the campaign has generated more than 827,000 messages to Congress seeking prescription drug price transparency, and more than 275,000 petition signatures calling for increased prescription drug price and cost transparency. The following are representative statements shared by patients and health care providers:

- Since 1998, I was put on Corgard's generic Nadalol. Over the years the medication went from $5 dollars a month to $10 dollars then suddenly in 2015 it went to over $250.00 per month. That did not include what insurance covered. I have never been able to get a straight answer from the manufacturer. –Diane G.
- I had a patient on a rotation in [. . .] with newly-diagnosed adult-onset Still's disease. The patient's discharge from the hospital was delayed because of several disagreements between the medical team and the rheumatologist. One of the points of contention was how the patient would be able to afford the anakinra that the rheumatologist had prescribed for the patient. The patient's insurance would not cover the cost of the drug, upwards of $25,000. I watched as the case manager and social worker tirelessly contacted patient assistance programs. Unfortunately, I finished the rotation before the patient was discharged. –Nikhil J.
- As an asthma patient I have experienced a step plan requirement, as well as cost so high I can only take half my treatment requirements. In changing my drug insurance company, I was told I couldn't take my regular [ADVAIR] [and] I would have to first use their approved meds and then step up to my regular [ADVAIR]. I spent a year in and out of the emergency room being treated for bronchitis and other asthma related problems before I could go back to my [ADVAIR]. All this extra illness and expenses could have been avoided. Plus, the cost of the [ADVAIR], even with special help, means I usually only use it once a day. I'm retired and live on my Social Security. –Sandra F.
- We discovered that my patient would have to pay more if they used their insurance for their prescription compared to just paying cash. - Dr. J. Augusto B.
- I had my first heart attack, and I am having to spend over $500 a month to take the cardiac medications I require. Some of these drugs are not new ones; they have been around for over 25 years. They used to cost very little. - Kenneth W.
- Some of my patients with life-threatening melanoma or severe psoriasis need new, targeted biologics. We need these innovative treatments, but I've watched as they triple in cost years after being released. Why? –Jack R.

Competition and Transparency

At a time of significantly increasing drug prices, increased competition and fair and transparent markets are more important than ever. Sustainable solutions to addressing high and unaffordable prescription drug prices can be found by addressing the flaws and inefficiencies in the U.S. pharmaceutical marketplace. The AMA urges the Committee to consider advancing the policies outlined below.

Increase Pharmaceutical Market Competition and Combat Anticompetitive Practices

The AMA continues to vigorously support expanded authority and funding for the Federal Trade Commission (FTC) in a number of areas to address anti-competitive practices as well as to advance consumer protections. The AMA strongly supports increased resources and direction to:

- combat pay-for-delay settlements, whereby a brand-name pharmaceutical manufacturer pays a potential generic competitor to abandon its patent challenge and delay offering a generic drug product for a number of years for anti-competitive purposes.
- limit efforts by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections.
- more rigorously and expansively evaluate the impact of mergers and consolidations among pharmaceutical companies on competition as well as consumer access by, among other things, expanding clinical expertise within the FTC and consulting with the relevant national medical specialty societies.
- investigate collusion and price fixing among pharmaceutical companies and recommend enforcement action against manufacturers that engage in anticompetitive actions to the U.S. Department of Justice.

The AMA also continues to support measures to address the misuse of Food, Drug, and Cosmetic Act (FDCA) provisions for anti-competitive purposes while at the same time advocating for modifications to FDCA to increase access to some of the most-costly prescription medications: biologicals. The AMA strongly urges action to:

- end the ability of generic manufacturers to indefinitely "park" the 180-day exclusivity period authorized by the FDCA by delaying final approval of their application by the U.S. Food and Drug Administration (FDA) as part of a settlement agreement with a brand manufacturer;
- further expand the ability of the FDA to address anticompetitive abuse of Risk Evaluation and Mitigation Strategies (REMS) by brand manufacturers—particularly voluntary elements to assure safe use that involve proprietary measures that pose barriers to use by generic competitors; and
- make necessary refinements to law to prevent the inappropriate extension of the exclusivity and patent life of pharmaceuticals.

Finally, the AMA strongly urges Congress to shorten the exclusivity period for biological products. The AMA was an early and strong supporter of establishing a pathway for follow-on

biologicals. The reduction in the exclusivity period is warranted to spur competition while not decreasing the impetus to innovate.

Require Pharmaceutical Supply Chain Transparency

The second component of AMA advocacy has been to encourage transparency throughout the pharmaceutical supply chain. The ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. The practices and policies of pharmaceutical manufacturers, PBMs, and health insurers warrant steps by Congress to interject much needed transparency. To that end the AMA strongly supports:

- Requiring pharmaceutical manufacturers to provide public notice before increasing the price of any drug by 10 percent or more each year or per course of treatment and provide justification for the price increase.
- Requiring pharmaceutical manufacturers to publicly disclose a variety of information, which could include research and development costs; expenditures on clinical trials; total costs incurred in production; and marketing and advertising costs.
- Requiring PBMs to apply manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well as eliminate some incentives for higher drug list prices.
- Requiring increased transparency in formularies, prescription drug cost-sharing, and utilization management requirements for patients and physicians at the point-of-prescribing as well as when beneficiaries make annual enrollment elections.
- Prohibiting removal of drugs from a formulary or moving to a higher cost tier during the duration of the patient's plan year unless a change is made for safety reasons.

We appreciate the opportunity to provide our comments and recommendations, and we look forward to continuing to work with the Committee to advance legislation that will positively impact patients.

[i] Issue Brief: Americans' views of healthcare costs, coverage, and policy, NORC at the University of Chicago and West health Institute (2018)