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Before the

UNITED STATES HOUSE OF REPRESENTATIVES

JUDICIARY SUBCOMMITTEE ON REGULATORY REFORM, COMMERICAL AND ANTITRUST LAW

Treating the Opioid Epidemic:

The State of Competition in the Markets for Addiction Medicine

September 22, 2016

Introduction

Good afternoon. Chairman Marino and Ranking Member Johnson, members of the Subcommittee, ladies and gentlemen, my name is Mark Merritt, President and CEO of the Pharmaceutical Care Management Association (PCMA). I appreciate this opportunity to appear before the Committee for this hearing examining sudden price spikes in opioid antagonists. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the ACA Exchanges.

PBMs offer a wide variety of services aimed at making prescription drug benefit programs operate safely, efficiently, and affordably for their clients, including health plans, employers, unions, and governments. PBMs are projected to save employers, unions, government programs, and consumers $654 billion — up to 30 percent — on drug benefit costs over the next decade.

America's Opioid Crisis

Too often we have seen the heartbreaking stories coming out of nearly every corner of America about the destruction of lives due to opioid addiction. According to the Centers for Disease Control and Prevention, overdose deaths involving prescription opioids have quadrupled since 1999, commensurate with sales of these prescription drugs.[i] From 1999 to 2014, more than 165,000 people have died in the U.S. from overdoses related to prescription opioids.[ii] The same period has seen a quadrupling of deaths due to overdoses of illicit heroin, including over 10,500 deaths in 2014 alone.[iii]

CARA: A Good First Step to Addressing the Problem

As a first step to address these problems, we commend the Congress for passing the Comprehensive Addiction and Recovery Act (CARA). My organization and our member companies strongly supported this legislation, which, among many provisions, created a Part D "lock-in" program to curb substance abuse in the Medicare Part D Program and expanded the availability of naloxone to law enforcement agencies and other first responders to reverse overdoses and save lives.

Opioid Antagonists and Addiction Treatment Price Increases

Along with efforts to make opioid antagonists more widely available, we are seeing unprecedented increases in the price of products to deliver the drugs. On the market since 1971, naloxone works by blocking opioid drugs from interacting with the brain's receptors, counteracting both the high and the drugs' dangerous side effects, like slow respiration, coma,

and death, during an overdose. The drugs almost instantly pull an overdose victim back to sobriety.

For decades, naloxone was typically administered in a hospital or similar setting via hypodermic needle. However, naloxone in self-contained, nasal-spray delivery packaging (branded as Narcan from Adapt Pharma) was approved by FDA last year. The new mechanism makes it easier for users without medical training to administer the drug, since the drug is increasingly being provided to laypeople.

In addition to the Narcan nasal spray product and the traditional injectable version, there is also an auto-injector version approved in 2014 (Evzio, from kaléo) as well as kits that combine the syringe (from several manufacturers) with a twist-on atomizer to create a nasal spray (assembled into kits by pharmacists) that have been used by first responders for years and now by family members and friends but are not specifically FDA approved.[iv]

Given the high demand and limited sourcing of auto-injectable and nasal-spray delivery versions of naloxone, it appears their manufacturers saw the opportunity to raise prices in a market with limited competition. As many have observed, naloxone has seen drastic price increases in recent years[v]. A popular injectable version of the drug has gone from $0.92 a dose to more than $15 a dose over the last decade. An auto-injector version is up to more than $2,000 a dose.[vi] Observers have noted that prices have risen in part because a field with fewer competitors has reduced pressure on companies to keep prices down. The drug has been made at one time or another by as many as a dozen companies since Endo International Plc received FDA approval for the brand-name version, Narcan, in 1971.[vii]

Unfortunately, this is a story we have seen before—certain manufacturers raising prices on previously affordable drugs once competition recedes or disappears. Just a few months ago, I testified before the House Government Reform Committee on the widely-reported practices of Turing Pharmaceuticals, which raised the price of Daraprim 5,000 percent after acquiring the rights to produce that medication. In this case, Turing acquired the rights to the drug from its sole manufacturer. In the face of no competition, it was able to set any price it wanted.

It is also important to look at the landscape of opioid treatments beyond naloxone. While that drug can save lives as it arrests an overdose, it does little to treat a patient's addiction to opioids. Indeed, patients may immediately feel symptoms of withdrawal as the opioid intoxication recedes. Many people seek treatment for opioid addiction through medication-assisted therapy (MAT) programs. Combining counseling and other services with drugs such as methadone, naltrexone, and buprenorphine, MAT has proven to be clinically effective and to significantly reduce the need for inpatient detoxification services.[viii] The Administration recently nearly tripled the cap on the number of patients a practitioner may treat with buprenorphine to 275. We encourage policymakers to monitor the effects of this change to see if it might be increased

further—the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) states that MAT services are "greatly underused."[ix]

Of course, treatment of opioid addiction is also subject to changes in the drug market just like drugs for any other condition. While once-daily buprenorphine pills, for example, can reportedly cost $130 to $190 a month, a newly approved six-month implanted version of the drug is priced at the equivalent of $800 a month. One study showed the subcutaneous implant version was somewhat more successful in preventing relapse, but the marginal improvement in adherence comes at a significantly higher cost.[x]

PBMs' Role

The key to making prescription drugs affordable is competition. It is PBMs who help bring down the prices of prescription drugs across the market by harnessing competition among manufacturers. PBMs aggregate the buying clout of millions of enrollees through their client health plans, employers and government payers, enabling plan sponsors and individuals to obtain lower prices for their prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and the efficiencies of mail-service pharmacies.

Lack of competition and the presence of coverage mandates reduce PBMs' ability to negotiate lower drug costs. For example, the State of New York recently enacted legislation that requires insurance coverage of naloxone when prescribed to a person who is addicted to opioids and to her family members on the same insurance plan.[xi] While well-intentioned, such actions tie the hands of PBMs to negotiate discounts and rebates, since the drug manufacturers know the drug must be covered no matter the price set.

Given the immediate need to stop an overdose, today 43 states allow purchase of naloxone without a prescription, or will soon operationalize plans to do so. A person who is at risk of overdose, his or her caregiver, or a family member can now walk in to a retail pharmacy and obtain naloxone. Many first responders such as police, fire fighters, paramedics, and others keep naloxone on hand or nearby at all times. The ready availability of the drug has saved many lives. However, as dozens of states have passed laws to make naloxone injectors and/or inhalers available without a prescription, prices have gone up. Given consumers' ability to obtain naloxone, without a physician's prescription, directly at the pharmacy counter, naloxone is increasingly being dispensed to people other than the intended end-user. This raises questions about individuals' medical records as well as presents challenges to insurers.

Policy Changes Could Improve the Opioid Crisis

While the focus of this hearing has been on naloxone, I think it is important to note that opioid reversal drug is but one tool we have to fight the opioid epidemic. Indeed, even if a patient's overdose is stopped, he or she may still remain addicted to the opioid. A comprehensive, multi-

faceted solution is the only way to stop and reverse the alarming trends seen in the past few years.

We believe a number of practical steps can be taken to ameliorate the rising tide of abuse. At least in the case of abuse of prescription opioids, we recommend:

- **Mandatory eRx for Controlled substances**: Although adoption of e-prescribing has been shown to dramatically reduce medication errors and fraud, challenges to efficient processes and errors still persist, hindering the wider adoption of e-prescribing for controlled substances (EPCS).

- **Improving/Integrating PDMPs:** State governments should make their PDMP databases more easily accessible, more user-friendly, and better integrated across the country, and to make the data accurate in real-time. The goal would be to create prescriber, pharmacist, and insurer access to real-time information, or come as close as possible to real-time information.

- **Provider Check of PDMP for Controlled Substance Prescriptions:** Prescribers should be required to check state Prescription Drug Management Program (PDMP) databases when prescribing a schedule II opioid, such as oxycodone or morphine.

- **Allow Stronger Measures to Remove or Discipline Rogue Pharmacies from Plan Networks.** Today, any-willing-provider and other pharmacy network laws make it difficult for plans and PBMs to remove pharmacies that engage in fraudulent practices from plan- and provider-contracted networks. There should be common-sense measures to allow rogue pharmacies to be excluded from such networks and to allow plans to suspend payments for suspect claims.

- **Engage the Public on the Dangers of Controlled Substances:** Given clear evidence of past malfeasance by certain drug manufacturers on downplaying the risks of opioids to prescribers, the drug industry should fund a campaign to warn prescribers and consumers about the inappropriate use of opioids and other controlled substances.

- **Expand Drug Take-back Programs**: The Drug Enforcement Administration (DEA) coordinates a nationwide program with neighborhood pharmacies, local law enforcement, and other community activists to offer a means of prescription drug disposal. However, regulatory hurdles may be preventing more pharmacies from taking advantage of this opportunity. Senators Joni Ernst and Chuck Grassley have requested that the Government Accountability Office report on the DEA's regulations that pose barriers to voluntary participation.

Policy Changes Could Enhance Competition to Manage Drug Spending

We have specifically discussed the price of naloxone in this hearing, but news reports have shown again and again that manufacturers of any drugs not subject to competition can exploit their position in the market. Recent examples, including the high initial launch prices of hepatitis C drugs and PCSK9 cholesterol drugs, show that where competition exists, PBMs can leverage it to bring prices down. A number of policy changes to enhance competition could lower the cost of drugs generally or lessen the ability to exploit loopholes in the law that have allowed some manufacturers to implement price gouging and anticompetitive distribution regimes.

- **Removing the Generic Drug Backlog:** PBMs could bring additional competition to the market for other drugs, but FDA prioritizes breakthrough therapies, leaving generic and "me-too" brand drugs languishing on the approval sidelines. While the FDA has argued it has cleared the generic backlog, in actuality it has merely given the applications an initial look. The generic approval backlog, at 36 months, is down slightly from recent years, but still lengthy.[xii]

- **Bringing Speedier Approval of Drugs Based on Economic Need:** A number of recently approved drug and biologic therapies have entered the market with historically high manufacturer prices. Rather than directly intervening in manufacturer pricing, policymakers could better encourage price competition in the marketplace by accelerating FDA approval of drugs in development for conditions where the cost of existing medications is a barrier to treatment and where manufacturers of current therapies have little incentive to compete on price, e.g., where there are only one or two drugs in the class and no generics.

- **Eliminating Any or All of Medicare Part D's Protected Classes:** Part D requires that "all or substantially all" drugs in six different classes be covered by Part D plans. This requirement significantly weakens the power of PBMs to negotiate rebates and lower prices. The Medicare Payment Advisory Commission (MedPAC) has recommended lifting the requirement for antidepressants and immunosuppressants.

- **Unlocking More Innovative Pricing Arrangements:** The rapid increase in the cost of specialty drugs is driving the market to begin to consider alternative ways of paying for these expensive therapies. For PBMs and drug manufacturers, these trends will demand innovative approaches to pricing. To enable more creative value-based arrangements, however, our laws and regulations will need to be updated. For example, Medicaid best-price rules make drug manufacturers reluctant to offer pricing schedules that could, in theory, result in very low unit prices for some groups of patients, because manufacturers must then give that price to all Medicaid enrollees.[xiii]

PBMs exist because they increase the quality and affordability of prescription drug benefits. PCMA's member companies harness market forces and competition to corral drugs costs and deliver high-quality benefits and services to their health plan clients and enrollees. PCMA appreciates the opportunity to testify on the market for addiction medications, and looks forward to working with the Congress on ways to address the opioid crisis.

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