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BEFORE THE U.S. SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR &
PENSIONS (HELP)

THE COST OF PRESCRIPTION DRUGS: HOW THE DRUG DELIVERY SYSTEM
AFFECTS WHAT PATIENTS PAY, PART II

TUESDAY, OCTOBER 17, 2017

Good morning.

Thank you Chairman Alexander and Ranking Member Murray for inviting me to testify today on a very important topic for our nation's patients, families, and their pharmacists: prescription drug prices.¹ It is an honor to be here.

My name is Tom Menighan and I am the Executive Vice President and CEO of the American Pharmacists Association, or APhA.

APhA is America's oldest, largest and most diverse pharmacist organization. APhA was founded in 1852, and represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and other parties invested in improving medication use and advancing patient care. APhA members practice and contribute to providing care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services. APhA promotes patient access and coverage for pharmacists' quality patient care services.

I was a practicing community pharmacist and specialty pharmacy owner for many years. Like many other pharmacists, I needed to make careful purchasing decisions to provide patient access to needed medications and negotiate with other members of the supply chain and payers to stay viable. I've also shared the challenges with patients who face financial choices between food and medicine for themselves or loved ones. Today's topic is of major concern to America's 300,000 pharmacists—the health care professional most often at the front lines of informing patients about their medication cost or copay amount and explaining complicated insurance coverage policies.

Pharmacies are where millions of Americans are first exposed to the impact of complex pharmaceutical pricing policies or confronted with changes in coverage, formularies, prior authorization, deductibles and co-payments or co-insurance, many of which they didn't know existed or understand. My comments today will focus on the following areas – cost versus value, patients' access to medications, and medications' safety and affordability.

Cost Versus Value

As drugs become more and more expensive, complex, and personalized, the need to optimize their impact also increases. In order to get the greatest benefit from medications, patients must understand how to use their medications safely and effectively. Pharmacists have more

¹ The cost of prescription drugs increased by 8.77% in 2016, according to data from the TruVeris National Drug Index. Over the past 3 years, annual price increases have increased by an average of 9.98%. See, TruVeris. Prescription Drug Prices Continue to Climb, Soaring 8.77% in Latest TruVeris NDI Report. Press Release. May 10, 2017. Available at:

<https://www.truveris.com/resources/press-releases/prescription-drug-prices-continue-to-climb-soaring-8.77-in-latest-truveris-ndi-report>

medication-related education and training than any other health care professional. Pharmacists can and do assist patients in optimizing the impact of medications and decreasing patients' costs by providing services focused on safe and appropriate medication use. For example, pharmacists provide medication management services, which are especially important for patients who have complex care plans, take multiple drugs or have chronic conditions. Additionally, to address hospital readmissions, pharmacists help patients transition between care settings.

Unfortunately, despite the fact that many states and Medicaid programs are turning to pharmacists to increase access to health care and address medication-related costs, Medicare Part B does not cover the services pharmacists can provide. Pharmacists are trained to do more than place medication in a container and while 91% of Americans live within 5 miles of a community pharmacy² many of our Nation's seniors are medically underserved. Pharmacists are an underutilized health care resource which can positively affect beneficiaries' care³ and the entire Medicare program.

APhA strongly believes S.109, the *Pharmacy and Medically Underserved Areas Enhancement Act*, is a bipartisan proposal that will improve patient care, health outcomes, impact of medications,⁴ and consequently, the viability of the Medicare program. Introduced by former Health Subcommittee Chair Chuck Grassley (R-IA) and Senators Bob Casey (D-PA), Susan Collins (R-ME), and Sherrod Brown (D-OH), S. 109 has 45 bipartisan cosponsors. Similar legislation obtained 51 cosponsors in the 114th Congress.

The legislation will enable Medicare patients in medically underserved communities to better access health care through state-licensed pharmacists practicing according to their own state's scope of practice. In medically underserved communities, pharmacists are often the closest health care professional and accessible outside normal business hours. Helping patients receive the care they need, when they need it, is a common sense and bipartisan solution that will improve outcomes and reduce overall costs.

The importance of medication-related services cannot be overstated, especially in the Medicare program. Medications are the primary method of treating chronic disease and are involved in 80 percent of all treatment regimens. Moreover, the United States spends nearly \$300 billion annually on medication-related problems, including nonadherence.⁵ Accordingly, not only will

² NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

³ CMS. Evidence Supporting Enhanced Medication Therapy Management. Center for Medicare and Medicaid Innovation. 2016. Available at: <https://innovation.cms.gov/Files/x/mtm-evidencebase.pdf>

⁴ See Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014. Available at: <http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment> Also, See Avalere Health. Developing Trends in Delivery and Reimbursement of Pharmacist Services. October 2015. Available at: <http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o>

⁵ New England Healthcare Institute. Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Adherence for Chronic Disease. August 2009. Available at:

S.109 increase beneficiaries' access to health care, it will help improve their outcomes—particularly those impacted by medications. APhA appreciates the support by many Committee members for the *Pharmacy and Medically Underserved Areas Enhancement Act* and urges its swift passage to allow pharmacists to deliver these vital services as providers in medically underserved areas.

We also encourage the Committee, when considering policy changes, to look beyond isolated components of health care to determine cost and value. Because health coverage is frequently analyzed by the benefit type such as inpatient, outpatient, and drug coverage, a patient's overall services, costs and outcomes may never be reviewed comprehensively. Policies cannot continue to consider drug and medical coverage, and their related costs and outcomes, separately if we are to achieve true value in health care. Current coverage and payment policies related to prescription drugs place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the impact to their medical costs. Breaking down the many silos within our health care system will help address that \$300 billion dollars spent on medication-related problems—many of which are preventable.⁶

Patients' Access to Medications

As the organization representing pharmacists in all practice settings, APhA has been, and is, a strong supporter of policies which increase patients' access to affordable and cost effective medicines. Decisions along the entire drug supply chain impact patients' medication costs, including arrangements between manufacturers, wholesalers, insurers, and pharmacy benefit managers, or PBMs. Because of these upstream stakeholder policies, for most patients, pharmacists have limited options to impact patients' final drug costs. Moreover, complex coverage and payment policies hinder the full potential of community pharmacists' clinical education and training from being realized as much of their day is spent on the phone trying to find an appropriate treatment that is not only covered, but the patient can afford. Consequently, APhA supports a transparent pricing framework which would eliminate such mechanisms as hidden discounts, free goods and post point-of-sale price fees imposed on pharmacies.

To address post point-of-sale fees, known as Direct and Indirect Remuneration (DIR) fees, APhA supports S. 413, the *Improving Transparency and Accuracy in Medicare Part D Spending Act*, that would prohibit Medicare Part D plan sponsors and their PBMs from retroactively reducing payment on clean claims submitted by pharmacies under Medicare Part D. The Centers for Medicare and Medicaid Services (CMS) has acknowledged a notable growth in DIR fees, which have more than tripled in recent years.⁷ These policies generally result in higher prices at point of sale which result in the beneficiary paying more because cost-sharing is based on sales prices. S. 413 will boost transparency in drug pricing and facilitate better CMS oversight.

<http://www.nehi.net/publications/17-thinking-outside-the-pillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view>

⁶ Ibid.

⁷ See, Wakely Consulting Group analysis of S. 413/H.R. 1038. 2017. Available at: <http://www.ncpa.co/pdf/wakely-report.pdf>

An additional problem facing some pharmacies is the inability to enter into contracts with health plans due to the growth in narrow networks. APhA reiterates the need for Part D plans to be required to contract with any pharmacy willing to accept their contractual terms and conditions. Increasing patient choice will not only improve patients' access to benefits and services, but will likely positively impact patient satisfaction and outcomes, such as adherence. A related issue is limited distribution of some medications. As more costly and complex medications are being developed, some manufacturers, clinics, practitioners' offices and pharmacies have entered into contracts that effectively limit the distribution of certain medications. To address these issues, APhA encourages the Committee to examine narrow networks and the limited distribution of certain medications and the impact these mechanisms have on patients and competition.

Drug shortages are another factor that can negatively affect patients in terms of cost and the availability of their treatments. APhA urges the Committee to consider mechanisms to both better control the price of medications in shortage and also to improve tracking and prediction systems used to identify drugs in shortage. APhA also strongly supports the appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

Medications' Safety and Affordability

APhA supports congressional efforts to increase patients' access to appropriate, safe, effective, and affordable prescription medications. We are a strong supporter of the user fee acts, like the *FDA Reauthorization Act of 2017 (FDARA)*, which have helped innovative and cost affordable treatments reach patients more quickly. Equally, we have encouraged the development and implementation of a framework by the U.S. Food and Drug Administration (FDA) for determining biologic product interchangeability. APhA opposes practices which circumvent the intent of drug product review laws and negatively impact the pharmacist's ability to substitute medications to safe, effective, lower-cost alternatives. Conversely, APhA supports pharmacists collaborating with prescribers and patients to design cost-effective treatment regimens, identify formulary or generic products as a means to reduce costs, and intervene on behalf of the patient to identify alternate therapies.⁸

⁸ See Brief for the FTC as Amicus Curiae, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott plc, et al.* U.S. 3d Cir. (2016), describing a typical product-hopping scheme, "A brand-name pharmaceutical company expects generic rivals to win FDA approval to compete with the company's profitable brand-name drug using automatically substitutable AB-rated equivalents. To thwart such substitution, the brand-name company introduces minor changes to the drug's formulation, such as therapeutically insignificant tweaks to dosage levels or to the form of administration (e.g., capsules vs. tablets). Before generic equivalents have a change to enter, the brand-name manufacturer then takes various steps to extinguish demand for the original version... The shift in prescriptions is generally a one-way street: once doctors prescribe a medicine and find that it works, they are generally reluctant to switch users back to the original formulation even if a cheaper generic version of it later becomes available." Available at: https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.warner-chilcott-plc-et-al./151001mylanamicusbrief.pdf

Although APhA supports congressional efforts to address patients' medication costs, APhA has significant concerns with turning to drug importation to achieve lower prices. We believe proposals to legalize importation of non-FDA approved drugs is not a comprehensive solution to the complex issue of drug pricing, threatens patient safety, disrupts care, and directly conflicts with efforts by Congress and federal agencies to increase the integrity and security of the U.S. drug supply pursuant to the *Drug Supply Chain Security Act (DSCSA)*. Furthermore, APhA is concerned savings, if any, will be short-term and importation will instead result in long-term costs to patients and the health care system.

Because drug importation policies effectively encourage patients to buy medications online from foreign sources, APhA fears patients will be at an even greater risk of taking ineffective or harmful medications, including controlled medications in which they weren't prescribed. The lack of a strong regulatory framework for internet pharmacies in certain foreign countries has led to the large number of illegitimate foreign internet pharmacies. APhA's concerns regarding foreign internet pharmacies are compounded by the large number of illegitimate internet "pharmacies" which have increased and become more sophisticated in recent years, making them difficult to track and permanently stop.

Importantly, broader importation laws will further fragment care and hinder the progress made by Congress to move U.S. health care delivery and payment towards value. Because Canadian pharmacists may only fill prescriptions written by Canadian prescribers, expanded importation policies will encourage Americans to seek care from foreign prescribers and pharmacists, whose systems and standards are not integrated into, or consistent with, U.S. systems or care. Value-based care models and other efforts to produce savings and promote quality, such as outcomes-based reimbursement, will be more difficult to measure and optimize if patients are allowed to receive care outside the model's mechanisms to drive results.

As previously noted, obtaining safe and effective medications is only one part of appropriate medication use. It also requires a health practitioner's knowledge of the patient's complete medication profile and an understanding by the patient of how to take the medication, side effects and/or potential interactions — all of which could be negatively affected by importation proposals. APhA believes importation of non-FDA approved drugs could hurt the very patients intended to benefit from importation proposals. Consequently, the risks to patient safety from harmful or ineffective products or avoidable medication errors due to fractured care outweighs any increase in access or cost-savings.

In summary, thank you today for including pharmacists—the medication expert on the patient's health care team—in this discussion. Ultimately, the most expensive medicine is the one not purchased, not taken, or not used correctly by patients. Pharmacists stand ready to help.

I look forward to answering any questions on the positive role pharmacists can and do play in reducing patients' prescription drug costs.

Addendum: APhA House of Delegates Policies Related to Drug Pricing

2004, 1968 **Manufacturers' Pricing Policies**

APhA supports pharmaceutical industry adoption of a "transparent pricing" system which would eliminate hidden discounts, free goods, and other subtle economic devices.

(JAPhA NS8:362 July 1968) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

1985 **Pharmaceutical Pricing**

APhA supports a system of equal opportunity with the same terms, conditions, and prices available for all pharmacies.

(Am Pharm NS25(5):52 May 1985) (Reviewed 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

2004, 1977 **Prescription Drug Advertising**

APhA does not oppose the dissemination of price information to patients, by advertising or by any other means.

(JAPhA NS17:448 July 1977)(JAPhA NS44(5):551 September/October 2004)(Reviewed 2006)(Reviewed 2011)(Reviewed 2016)

2016, 1994 **Pharmacy Services Benefits in Health Care Reform**

A single set of pricing rules, eliminating class-of-trade distinctions, for medications, medication delivery systems, and other equipment so that no payer, patient, or provider is disadvantaged by cost shifting.

The right for every American to choose his/her own provider of medications and pharmacists' services and for all pharmacists to participate in the health plans of their choice under equally applied terms and conditions.

(Am Pharm NS34(6):58 June 1994) (Reviewed 2004) (Reviewed 2010) (Reviewed 2011)(JAPhA 56(4); 379 July/August 2016)

2016 **Biologic, Biosimilar, and Interchangeable Biologic Drug Products**

APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.

(JAPhA 56(4); 369 July/August 2016)

2005, 1977 **Government-Financed Reimbursement**

APhA supports only those government-operated or -financed, third-party prescription programs which ensures that participating pharmacists receive individualized, equitable compensation for professional services and reimbursement for products provided under the program.

(JAPhA NS17:452 July 1977) (JAPhA NS45(5):558 September/October 2005) (Reviewed 2009)(Reviewed 2011)(Reviewed 2012)(Reviewed 2017)

2012 **Drug Supply Shortages and Patient Care**

APhA encourages the active investigation and appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

(JAPhA NS52(4) 457 July/August 2012)(Reviewed 2017)

2005, 1981 **Third-party Reimbursement Legislation**

APhA supports enactment of legislation requiring that third-party program reimbursement to pharmacists be at least equal to the pharmacists prevailing charges to the self-paying public for comparable services and products, plus additional documented direct and indirect costs, which are generated by participating in the program.

(Am Pharm NS21(5):40 May 1981) (Reviewed 2005) (Reviewed 2009)(Reviewed 2014)

1967 **Drugs Provided Under Social Security Act: Guidelines for Pharmaceutical Service**

Since it is probable or likely that APhA may have to consider and act upon some proposals in the area of drug costs before the next annual meeting, we recommend that APhA Board of Trustees be guided by whether the proposals:

(a) Permit pharmacists to select and dispense a quality drug product; (b) Establish some mechanism to assist pharmacists in selecting quality, drug products under the cost and other criteria established; (c) Permit the use of any available drug product when unique medical circumstances so require; (d) Establish a reasonable remuneration base for pharmacists rendering services under the program; (e) Guarantee recipients free choice of pharmacy; and (f) Limit the reimbursement for pharmacists' services to those provided by duly licensed pharmacists.

(JAPhA NS7:315 June 1967) (Reviewed 2005) (Reviewed 2009)(Reviewed 2014)

2017 **Pharmacy Performance Networks**

APhA supports performance networks that improve patient care and health outcomes, reduce costs, use pharmacists as an integral part of the health care team, and include evidence-based quality measures.

(JAPhA 57(4): 441 July/August 2017)