U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

TO: Members, Committee on Energy and Commerce, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing on "Examining the Drug Supply Chain"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, December 13, 2017, at 10:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled "Examining the Drug Supply Chain."

II. WITNESSES

- Chip Davis, President and CEO, Association for Accessible Medicines;
- Tom DiLenge, President, Advocacy, Law, and Public Policy, Biotechnology Innovation Organization;
- Matt Eyles, Senior Executive Vice President and Chief Operating Officer for Policy and Regulatory Affairs, America's Health Insurance Plans;
- Elizabeth Gallenagh, Senior Vice President, Government Affairs and General Counsel, Healthcare Distribution Alliance;
- Gerald Harmon, MD, Chair, Board of Trustees, American Medical Association;
- B. Douglas Hoey, CEO, National Community Pharmacists Association;
- Mark Merritt, President and CEO, Pharmaceutical Care Management Association;
- David Mitchell, Founder and President, Patients for Affordable Drugs;
- Tom Nickels, Executive Vice President for Government Relations and Public Policy, American Hospital Association; and
- Lori Reilly, Executive Vice President for Policy, Research and Membership, Pharmaceutical Research and Manufacturers of America.

III. BACKGROUND

Prescription drugs play an important role in the U.S. health care system. Innovative, breakthrough drugs are providing cures for diseases and helping individuals with chronic conditions lead fuller lives. These vital medicines can both dramatically improve patients' lives and produce health care savings by reducing the number and frequency of hospitalizations and other costly medical procedures.

An important factor in a patient's access to a prescription drug—and the price paid for it—is the complex pharmaceutical supply chain linking an original drug manufacturer to the patient. Although pharmaceutical supply chains exist in numerous and frequently evolving variations, prescription drugs typically originate in domestic or foreign manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price

negotiations and processed through quality and utilization management screens by pharmacy benefit management companies; dispensed by pharmacies; and ultimately delivered to and taken by patients.[1]

Pharmaceutical Manufacturers:

Pharmaceutical firms research, develop, and produce a variety of products including traditional small-molecule or chemical drugs, generic drugs, biologics, and biosimilars. U.S. prescription drug sales accounted for nearly 42 percent of the global pharmaceuticals market in 2016.[2] Generic drugs accounted for nearly 90 percent of U.S. prescriptions in 2016, but 26 percent of U.S. drug spending.[3] The industry is increasingly focusing on research and development efforts on biologic products, which account for over a third of new drugs in clinical trials or awaiting FDA approval.[4] There is also an increased emphasis on orphan drugs, which are designed to treat patient populations of less than 200,000.[5]

Wholesalers:

Pharmaceutical wholesalers purchase drugs from U.S. and international manufacturers, which they store in regional distribution centers for deliver to pharmacies, retailers such as supermarkets and big box stores, hospitals, physician practices, and health care providers.

Wholesalers also offer a host of associated services to retailers and health care providers including repackaging drugs. For example, a wholesaler could buy a 100-pill bottle of a drug from a manufacturer and then distribute the pills in smaller 10-pill bottles or in drug blister-packs. Other services include business consulting, inventory management, administration of manufacturer prescription drug sample and consumer discount coupon programs,[6] data analytics, and group purchasing organizations. Additionally, some wholesalers distribute and produce medical and surgical supplies.

Pharmacy Benefit Managers:

Pharmacy Benefit Managers (PBMs) are third party firms that manage prescription drug benefits on behalf of employer and union sponsored health insurance plans, health maintenance organizations, and state and federal health programs including Medicare Part D and Medicaid managed care plans. According to industry data, PBMs manage health plan prescription drug

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[1] See Kaiser Family Foundation, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, March 2005. Available at: https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf
[2] Standard & Poor's, "Pharmaceuticals," June 2017.
[3] Association for Accessible Medicines, "Generic Drug Access & Savings in the U.S.," 2017, p. 16," https://www.accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf.
[4] U.S. Department of Commerce, International Trade Administration, "BioPharmaceutical Spotlight," http://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states
[5] Evaluate Pharma, "Evaluate Pharma World Preview 2017, Outlook to 2022," http://info.evaluategroup.com/rs/607-YGS-364/images/WP17.pdf.
[6] McKesson, "Loyalty Script," http://www.mckesson.com/manufacturers/pharmaceuticals/patient-adherence-and-acquisition-(continued...)

benefits for 266 million insured consumers, including 187 million enrolled in private health plans, 41 million enrolled in Medicare Part D plans, and 38 million enrolled in Medicaid managed care plans.[7]

PBMs determine payment and pricing for drugs, but generally do not take delivery of drugs except for their in-house pharmacies. PBMs help manage prescription drug costs for health payers by processing pharmacy drug claims, negotiating rebates and discounts from pharmaceutical manufactures; designing plan formularies; creating networks of retail pharmacies that dispense drugs for health payers at contracted reimbursement levels; providing consulting and marketing services; and operating mail-order and specialty pharmacies.

Pharmacies:

About 70 percent of prescription drug spending is for drugs dispensed through retail operations.[8] The U.S. retail drug system includes large pharmacy chains, pharmacies in supermarkets and big box retailers, as well as independent or community pharmacies. According to industry estimates, chains operate 40,000 pharmacies.[9] There are tens of thousands of independent pharmacies in the United States.[10] The top three drugstore chains account for more than 60 percent of industry revenue according to one analysis.[11]

Pharmacies buy their inventory from drug wholesalers or may purchase some drugs directly from manufactures depending on their size and operations. Drug stores contract with health care payers and PBMs to join health plan pharmacy networks; this means they agree to accept set reimbursement and follow specific rules for dispensing drugs to health plan enrollees. Pharmacies may join a number of health plan networks. Community pharmacies work through Pharmacy Services Administrative Organizations (PSAO) to increase their pricing and bargaining power.[12] About 80 percent of independent pharmacies are represented by PSAOs, which can negotiate reimbursement rates, payment terms, audits of pharmacies by third-party payers or their PBMs, price updates and appeals, and administrative requirements. Some pharmacy chains have also entered into joint ventures with PBMs and insurers.

Private Health Insurance:

As noted, the Affordable Care Act requires most plan in the non-group and small-group market to offer a package of ten essential health benefits (EHB) including prescription drugs. The

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[7] Visante for the Pharmaceutical Care Management Association (PCMA), "The Return on Investment (ROI) On PBM Services," November 2016, Slide 3, https://www.pcmanet.org/wp-content/uploads.2016/11/ROI-on-PBM-Services-FINAL.pdf.
[8] Department of Health and Human Services (HHS), Office of the Assistant Secretary for Planning and Evaluation, "Observations on Trends in Prescription Drug Spending," March 8, 2016, at https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf .
[9] National Association of Chain Drug Stores, https://www.nacds.org/.
[10] The National Community Pharmacists Association, see: www.ncpanet.org
[11] IBIS World, "Pharmacies & Drug Stores in the US," Report 44611, January 2017.
[12] Government Accountability Office, *Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, January 2013, http://www.gao.gov/assets/660/651631.pdf.

EHB package for each state is based on a single health plan, which each state identified as a reference plan that most non-group and small-group market plans must base their benefits packages.

As part of the EHB prescription drug requirements, non-group and small-group market plans must cover at least the greater of (1) one drug in every United States Pharmacopeia (USP) category or class of (2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. For the 2017 coverage year, the Department of Health and Human Services (HHS) also requires plans to use a pharmacy and therapeutics (P&T) committee system. The P&T committees develop formulary drug lists that cover prescription drugs across a broad range of therapeutic categories and classes and that do not discourage enrollment by any group of consumers. The P&T committees also review and approve plan policies that affect consumer access to drugs.

Most health plans must comply with annual limits on out-of-pocket spending on in-network coverage of the EHB. In 2017, the limits cannot exceed $7,150 for self-only coverage and $14,300 for coverage other than self only.

Separately, the Kaiser Family Foundation carries out an annual survey of employer-provided health benefits, including prescription drug coverage. According to the most recent Kaiser survey, nearly all workers covered by employer-provided health insurance (which includes both large- and small-group plans) are at a firm that provides prescription drug coverage in its largest health plan.[13] Employer-provided drug benefits are becoming more complex as companies institute utilization controls to manage drug costs. The most recent Kaiser data show more than 80 percent of covered workers are in plans that use a drug formulary with three, four, or more cost-sharing tiers. In general, in tiered formularies, less expensive generic drugs are placed on lower tiers with minimal cost sharing, while more expensive drugs are placed on tiers with higher cost-sharing or other requirements, such as plan prior authorization. Many specialty tiers with higher cost-sharing or other requirements, such as plan prior authorization. Many specialty tiers require coinsurance (for example, 30 percent of the price of a drug) rather than a flat co-payment ($30).

Health plans assume risk for the cost of drugs as part of their provided benefit offering. According to Kaiser, prescription drug spending makes up about 21 percent of employer-sponsored insurance benefits.[14]

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Adam Buckalew, James Paluskiewicz, Danielle Steele, and Paul Edattel of the Committee staff at (202) 225-2927.

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[13] Kaiser Family Foundation, "Employer Health Benefits: 2017 Annual Survey," Section 9, files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.

[14] Peterson-Kaiser Health System Tracker, "Examining High Prescription Drug Spending for People with Employer Sponsored Health Insurance," October 27, 2016, at http://www.healthsystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-esponsored-health-insurance/.