COMMITTEE ON
ENERGY & COMMERCE
CHAIRMAN FRANK PALLONE, JR.

MEMORANDUM

May 7, 2019

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

On **Thursday, May 9, 2019, at 10:00 a.m., in room 2322 of the Rayburn House Office Building**, the Health Subcommittee will hold a hearing entitled, "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain."

I. THE DRUG SUPPLY CHAIN

A. Pharmaceutical Manufacturers

Pharmaceutical manufacturers research, develop, and produce drugs. Once the Food and Drug Administration (FDA) approves a drug for purposes of marketing, the pharmaceutical manufacturer establishes a list price (also known as the wholesale acquisition cost). The list price could be determined by a number of factors such as research and development costs, demand, market competition, and manufacturing and marketing costs. Notwithstanding these factors, manufacturers may set any price they choose.

Manufacturers earn revenue when pharmacies, hospitals, and other health care entities purchase their drugs. For 2017, drug manufacturers earned about $324 billion in net revenues.[1]

The type of drug affects the manufacturer's costs, as well as the revenue a company earns. Generally, small molecule drugs and their bioequivalent competitors, generic drugs, are cheaper to develop and have a lower list price than biologics. Biologics are made from living organisms and are used to treat serious diseases such as cancer, rheumatoid arthritis, and multiple sclerosis. Biologics often launch at very high prices, with annual list prices reaching tens of

[1] Murray Aitken, et al., *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, IQVIA Institute (Apr. 19, 2018) (https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf).

thousands of dollars.[2] In addition, unlike the small molecule drug market, many biologics still do not face competition from biosimilar or interchangeable biological products.[3] In 2017, biologics represented two percent of all U.S. prescriptions, but 37 percent of net drug spending.[4] Generic drugs represent nearly 90 percent of all U.S. prescriptions, but only 23 percent of net drug spending.[5]

In 2017, total retail drug spending was $333.4 billion,[6] which was a 0.4 percent year-over-year increase from 2016.[7] The key drivers of the slower growth in spending were a continued shift to lower-cost generic drugs and slower sales volume growth in some high-cost drugs.

B. Pharmacy Benefits Managers (PBMs)

Pharmacy Benefit Managers (PBMs) are third-party firms hired by insurers, federal health programs, and plan sponsors to manage and administer the prescription drug benefits of health insurance coverage. This includes negotiating the prices of drugs to create formularies, as well as deciding which pharmacies are included in a plan's network. Formularies developed by PBMs play a role in determining the cost of a prescription drug. The formulary is used to negotiate rebates and discounts with manufacturers, but it is also used to manage prescription drug use and spending by plan members.[8] For example, cost-sharing, drug coverage, prior authorization, and member cost are all determined through a formulary.[9] PBMs also negotiate fees and services with pharmacies, fees that may be based on each filled prescription.

PBMs mostly earn revenue by charging fees to the plans, pharmacies, and drug manufacturers, as well as by keeping a portion of the rebate they negotiate with the drug manufacturers.[10] Increasingly, the large PBMs also earn revenue through the ownership of other parts of the supply chain including insurers and specialty pharmacies. Three companies cover about 70 percent of all prescription claims in the United States: CVS Health, Express Scripts,

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[2] Testimony of James Mathews before the House Committee on Energy and Commerce, April 30, 2019.

[3] Food and Drug Administration (FDA), "*Biosimilar Product Information.*" (https://www.fda.gov/drugs/biosimilars/biosimilar-product-information).

[4] *See* note 1.

[5] Association for Accessible Medicines, *Generic Drug Access & Savings in the US* (2018) (https://accessiblemeds.org/resources/blog/2018-generic-drug-access-and-savings-report).

[6] Health Affairs, *National Health Spending in 2017* (Dec. 6, 2018) (https://www.healthaffairs.org/do/10.1377/hblog20181206.671046/full/).

[7] *Id.*

[8] MedPAC, *Overview: The Drug Development and Supply Chain* (June 16, 2016) (http://www.medpac.gov/docs/default-source/fact-sheets/overview-of-the-drug-development-and-supply-chain.pdf?sfvrsn=0).

[9] *Id.*

[10] *Id.*

and UnitedHealth Group.[11] According to one study, the PBM industry had an estimated gross profit of $23 billion in 2016.[12]

C. Insurers

Health plans assume the financial risk for the cost of drugs their customers receive as part of offering a prescription drug benefit. Insurers such as Medicare, Medicaid, private insurance companies, and self-insured large employers reimburse pharmacies, hospitals, and other healthcare entities for the amount paid to purchase the drug and related fees. The actual amount paid by the health care entities is confidential, therefore insurers generally can only estimate the reimbursement amount.

Plans manage the prescription drug benefit by contracting with an external PBM, operating their own PBMs, or by purchasing drugs directly from manufacturers and dispensing the medication to consumers at their own pharmacies.

Plans earn revenue when the premiums they charge exceed the health care claims they pay. Plans use a range of strategies to hold down their drug costs, including through:

- Formulary tiers (varying cost-sharing to encourage preferred or low-cost generic drugs);
- Prior authorization (a physician must obtain approval from the insurer prior to prescribing a particular medication);
- Step-therapy (a physician must begin treatment using the most cost-effective drug therapy before moving to more costly therapies if necessary); and
- Cost-sharing and copayments (when a patient must pay a portion of health care costs not covered by the health insurance plan).

D. Hospitals and Physicians

Hospitals and physicians will often purchase large volumes of drugs from manufacturers or wholesalers through Group Purchasing Organizations (GPOs). GPOs help hospitals and physicians aggregate purchasing volume to negotiate discounts with manufacturers and distributors. If the physician or a hospital administers a drug to a patient, then the physician or hospital will use a buy-and-bill model, meaning that they will purchase the drug from a manufacturer first (sometimes with the help of a GPO), and then bill for it after it is administered.

Physicians and hospitals earn revenue if they are reimbursed at a higher rate than what it costs them to purchase and administer the drug.

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[11] Endocrine Society, *"Increasing Insulin Affordability: An Endocrine Society Position Statement"* (Nov. 2018) (www.endocrine.org/advocacy/priorities-and-positions/increasinginsulin-affordability).

[12] Health Affairs, *"Spending on Prescription Drugs in the US: Where Does All the Money Go?" (*July 31, 2018) (https://www.healthaffairs.org/do/10.1377/hblog20180726.670593/full/).

E. Pharmacies

Pharmacies dispense prescription drugs to individual patients. There are retail, mail, long-term care, and specialty pharmacies.

Pharmacies negotiate with manufacturers or wholesale distributors and purchase drugs at a confidential price. They will also negotiate with PBMs to be included in a PBM's network and for reimbursement from the PBM, as well as other types of government and private payers. In addition to reimbursement for the cost of the drug, pharmacies will also receive a dispensing fee, which varies based on the payer. Total prescription dispensing revenues reached $423.7 billion in 2018.[13]

F. Patients

Patients depend on prescription drugs to manage chronic conditions, prevent, treat, or cure diseases, and reduce side effects from diseases or conditions. When patients purchase a drug, the price they pay may depend in part on how much of the cost their health plan covers. Patients are increasingly exposed to the list price of their prescriptions, either through their deductible or through a coinsurance percentage.[14]

If the patient is not enrolled in a health plan, then they typically pay the full list price of a drug. Patients may access patient assistance programs and discount cards from manufacturers to lower the price they pay for a particular drug depending on criteria that is set by either the program or the manufacturer.

A recent poll found that a quarter of people who take prescription drugs say it is difficult for them to afford their medications.[15] People are more likely to have difficulty affording their medications if they have monthly drug costs of $100 or more, are in fair or poor health, have annual incomes of less than $40,000, or take at least four drugs monthly.[16] Three in 10 50-64 year olds report problems affording their drugs.[17]

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[13] Drug Channels Institute, *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers* (Mar. 2019) (https://drugchannelsinstitute.com/files/2019-PharmacyPBM-DCI-Overview.pdf).

[14] Centers for Disease Control and Prevention (CDC), *"High-deductible Health Plan Enrollment Among Adults Aged 18-64 with Employment-based Insurance Coverage"* (August 2018) (https://www.cdc.gov/nchs/products/databriefs/db317.htm).

[15] Kaiser Family Foundation, *Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age* (Mar. 1, 2019) (https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/).

[16] *Id.*

[17] *Id.*

II. WITNESSES

The following witnesses have been invited to testify:

Panel I

Justin McCarthy
Senior Vice President, Patient & Health Impact Group
Pfizer

Kave Niksefat
Vice President, Value and Access
Amgen

Jeffrey Hessekiel
Executive Vice President & General Counsel
Exelixis

Amy Bricker
Senior Vice President, Supply Chain
Express Scripts

Brent Eberle
Chief Pharmacy Officer
Navitus Health Solutions

Panel II

Estay Greene
Vice President of Pharmacy Services
Blue Cross Blue Shield of North Carolina

Lynn Eschenbacher
Chief Pharmacy Officer
Ascension

Jack Resneck, M.D.
Chair, Board of Trustees
American Medical Association

Richard Ashworth
President of Pharmacy
Walgreens

Leigh Purvis
Director of Health Services Research
AARP