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ONE HUNDRED FIFTEENTH CONGRESS

# Congress of the United States
## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

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**MEMORANDUM**

**December 11, 2017**

**To: Subcommittee on Health Democratic Members and Staff**

**Fr: Committee on Energy and Commerce Democratic Staff**

**Re: Hearing on "Examining the Drug Supply Chain"**

On **Wednesday, December 13, 2017, at 10:00 a.m., in room 2123 of the Rayburn House Office Building**, the Subcommittee will hold a hearing titled "Examining the Drug Supply Chain."

## I. THE DRUG SUPPLY CHAIN

### A. Pharmaceutical Manufacturers

The drug supply chain begins with the research, development, and approval process. Companies spend significant time and capital developing a drug product. Some estimate that bringing a single therapy to market can take between ten and 15 years and cost approximately $1 to $2.6 billion.[1] In addition, for every drug that receives approval from the Food and Drug Administration (FDA) there could be 5,000 to 10,000 compounds that fail.[2]

[1] The Pew Charitable Trusts, *From Lab Bench to Bedside: A Backgrounder on Drug Development* (Mar. 12, 2014) (http://www.pewtrusts.org/en/research-and-analysis/analysis/2014/03/12/from-lab-bench-to-bedside-a-backgrounder-on-drug-development); Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion* (Nov. 18, 2014) (http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study).

[2] The Pew Charitable Trusts, *From Lab Bench to Bedside: A Backgrounder on Drug Development* (Mar. 12, 2014) (http://www.pewtrusts.org/en/research-and-analysis/analysis/2014/03/12/from-lab-bench-to-bedside-a-backgrounder-on-drug-development).

The length of time to receive approval by the FDA has decreased dramatically, from an average of 29 months to 10 months, making it now the shortest part of the development timeframe.[3] Innovative pharmaceutical products are also increasingly available in the U.S. before anywhere else in the world. An estimated two-thirds of new, active pharmaceutical substances approved globally are launched first in the United States.[4] In fact, a recent study found between 2003 and 2016, 97 percent (or 71) of new oncology drugs were available in the U.S. before Europe, and that FDA approved the new oncology drugs an average of six months faster than the EMA.[5]

Once a product receives approval the 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, and manufacturing and marketing costs. Notwithstanding these factors, brand name manufacturers may set any price they choose. Generic drugs generally cost 80-85 percent less than their branded drug competitors.[6]

### B. Wholesale Distributors

Wholesale distributors link manufacturers to pharmacies, hospitals, long-term care facilities, and other healthcare entities. Wholesalers supply their clients with a range of products, including pharmaceuticals, medical supplies, and durable medical equipment. The wholesaler typically purchases the drug from the manufacturer at a discounted rate (lower than the wholesale acquisition cost). For example, a wholesale distributor may receive a discount from the manufacturer for high sales volume or prompt pay. The manufacturer ships large quantities of their products to wholesalers who then store, sell, and deliver smaller quantities of the products to downstream healthcare entities. Wholesalers sell products to dispensing outlets like pharmacies at the wholesale acquisition cost plus a negotiated rate.

Wholesalers generally earn revenue from the sale of drugs to dispensing outlets but can also earn revenue through fees on the services they provide. These services include inventory

[3] Testimony of Anne Pritchett before the House Committee on Energy and Commerce, March 22, 2017.

[4] Testimony of Janet Woodcock before the House Committee on Energy and Commerce, March 22, 2017.

[5] Roberts S, Allen J, and Sigal E, *Despite Criticism Of The FDA Review Process, New Cancer Drugs Reach Patients Sooner In The United States Than In Europe*, Health Affairs (July 2011) (http://content.healthaffairs.org/content/30/7/1375.full.html).

[6] FDA, *Facts About Generic Drugs* (https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM305908.pdf).

handling and management, data collection, and customer verification. In 2013, the top three wholesale distributors accounted for 85 to 90 percent of all revenues from drug distribution.[7]

### C. Pharmacy Benefit Managers (PBMs)

PBMs are hired by payers across the market to develop and administer the prescription drug benefit portion of health insurance coverage. PBMs privately negotiate the product's cost with manufacturers and pharmacies on behalf of the payer. Entities such as private insurance companies and federal health programs utilize PBMs to build and manage the pharmacy benefit and negotiate discounts and rebates with manufacturers. PBMs may use mechanisms such as formularies and pharmacy networks to achieve greater savings for their clients. PBM-owned central-fill mail pharmacies are also a significant presence on the pharmacy side of the supply chain. PBMs earn revenue through sources such as fees charged to and collected from the entities they represent, a portion of the savings from rebates negotiated with manufacturers, or shared savings and fees from the maintenance of pharmacy networks.[8] In 2014, the top three PBMs managed pharmacy benefits for 80 percent of the marketplace.[9]

### D. Insurers

Insurers such as Medicare, Medicaid and private insurance companies reimburse pharmacies, hospitals, long-term care facilities and other healthcare entities for the amount paid to purchase the drug and related fees. The actual amount paid by these entities is confidential, therefore insurers generally can only estimate the reimbursement amount. Private insurers generally contract with PBMs to manage their prescription drug benefit, process prescription drug claims, and set drug formularies. Insurers use a range of strategies to hold down drug costs, including varying cost-sharing to incentivize preferred or low-cost generic drugs ("tiering") and prior authorization (a requirement that the ordering physician obtain approval from the insurer prior to prescribing a particular medication).

### E. Hospitals

Hospitals dispense drugs to patients through both inpatient and outpatient settings. Dispensing and reimbursement of a drug varies considerably depending on where a patient receives the drug. For instance, a drug that is dispensed in the inpatient setting to a Medicare patient, as compared to a commercially insured patient at an outpatient clinic as part of a bundled episode of care. Hospitals will often purchase large volumes of drugs through the use of Group Purchasing Organizations (GPOs), entities that help hospitals aggregate purchasing volume to negotiate discounts with manufacturers and distributors.

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[7] Medicare Payment Advisory Commission (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).

[8] Health Affairs, *Prescription Drug Pricing #12*: *Pharmacy Benefit Managers* (Sept. 14, 2017) (https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/).

[9] *Id*.

### F. Physicians

Under the Medicare Part B program, physicians are part of the drug supply chain. Part B uses a buy-and-bill model, meaning that providers purchase the drug first, then bill for it after it is administered. Medicare reimburses physicians at the Average Sales Price (ASP) + 6 percent, a statutory formula set as part of the Medicare Modernization Act in 2003. Physicians, like hospitals, may purchase drugs through GPOs.

### G. 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 payer stakeholders. In addition to reimbursement for the cost of the drug, pharmacies will also receive a dispensing fee, which varies based on the payer.

### H. Patients

When patients purchase a drug, they are only aware of the price they pay and the original list price. Whether or not the patient is insured can significantly impact the cost of the drug. Manufacturers sometimes administer patient assistance programs or offer coupons to lower out-of-pocket costs for patients who cannot afford the treatment. Patients with insurance may also have cost-sharing obligations, such as co-payments, coinsurance, or a prescription drug deductible.

## II. WITNESSES

**Lori M. Reilly**
Executive Vice President, Policy, Research & Membership
Pharmaceutical Research and Manufacturers of America

**Tom DiLenge**
President, Advocacy, Law, and Public Policy Division
Biotechnology Innovation Organization

**Chip Davis**
President and CEO
Association for Accessible Medicines

**Elizabeth A. Gallenagh**
Senior Vice President, Government Affairs and General Counsel
Healthcare Distribution Alliance

**David Mitchell**
President and Founder
Patients for Affordable Drugs

**Mark Merritt**
President and CEO
Pharmaceutical Care Management Association

**Matt Eyles**
Senior Executive Vice President and Chief Operating Officer for Policy and Regulatory Affairs
America's Health Insurance Plans

**B. Douglas Hoey**
CEO
National Community Pharmacists Association

**Gerald Harmon, M.D.**
Chair, Board of Trustees
American Medical Association

**Tom Nickels**
Executive Vice President for Government Relations and Public Policy
American Hospital Association