

# POLICY NOTE

#### **Key Findings**

- There is a great deal of confusion and misunderstanding in the United States about drug pricing, manufacturing, marketing, and the impact of government regulations.
- 2. There is a growing opinion that the government should place a price ceiling on drugs.
- 3. The average cost of bringing a drug to market today is \$2.5 to \$5 billion and takes 10 to 15 years to get through the government regulatory process.
- 4. Over 90 percent of research on new drugs fails to produce treatments and lose money.
- Specialty drugs accounted for one percent of all prescriptions, but
  percent of all prescription drug costs.
- Pharmaceutical pricing is complex and goes through a series of steps, using wholesalers and pharmacy benefit managers, before drugs actually reach patients.
- In economics, setting price limits on goods and services always results in scarcity, with fewer of the price-controlled products being produced and made available to consumers.

### Prescription Drug Pricing – A Complex, Poorly Understood Issue

Pharmaceutical pricing goes through a series of steps before drugs actually reach patients

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#### Introduction

There is a great deal of confusion and misunderstanding in the United States about drug pricing, manufacturing, marketing, and the impact of government regulations. This confusion has been made worse by the recent egregious behavior of several pharmaceutical manufacturers that raised the prices of some drugs by up to 5,000 percent.<sup>1</sup>

There is a growing opinion that the government should place a price ceiling on drugs. In 2014, prescription drug costs accounted for 9.8 percent of overall health care expenses.<sup>2</sup> In economics, setting price limits on goods and services always results in scarcity, with fewer of the price-controlled products being produced and made available to consumers. This has been confirmed by the disastrous centrally-planned economies of communist countries. Similar distorting effects and shortages would occur if government officials sought to control prescription drug prices.

#### Most drug research does not pay off

Only seven percent of possible drugs survive the research phase, make it through clinical trials, and go on to be marketed and make money for their manufacturers.<sup>3</sup> Over 90 percent of research on new drugs fails to produce treatments and lose money. The final pricing of the few successful drugs must make up for all the money spent on the research and development (R&D) of all the previous failures.

In 2015, the ten largest drug manufacturers spent 18 percent of their total revenue on R&D.<sup>4</sup> A better comparison across industries is the percent of sales spent on R&D. According to the National Science Foundation, in 2014 the average of sales profit across all industries spent on R&D was 3.5 percent. The pharmaceutical industry spent 13.4 percent of total sales profit on R&D, a higher percent than the computer and electronic industry, which spent 10.2 percent.<sup>5</sup>

<sup>1 &</sup>quot;Here's why Turing Pharmaceutical says 5,000% price bump is necessary," by Laura Lorenzetti, *Fortune Health*, September 21, 2015 at http://fortune.com/2015/09/21/turing-pharmaceuti-cals-martin-shkreli-response/

<sup>2 &</sup>quot;Health expenditures," Centers for Disease Control and Prevention, October 7, 2016 at https:// www.cdc.gov/nchs/fastats/health-expenditures.htm

<sup>3 &</sup>quot;Success rates for experimental drugs falls: study," by Bill Berkrot, Reuters, February 14, 2011 at http://www.reuters.com/article/us-pharmaceuticals-success-idUSTRE71D2U920110214

<sup>4 &</sup>quot;Top 50 pharmaceutical companies by prescription sales and R&D spending in 2015," The Statistics Portal, 2016 at https://www.statista.com/statistics/273029/top-10-pharmaceutical-companies-sales-and-rundd-spending-in-2010/

<sup>5 &</sup>quot;Businesses spent \$341 billion on R&D performed in the United States in 2014," by Raymond M. Wolfe, National Science Foundation, August 25, 2016 at https://www.nsf.gov/statistics/2016/nsf16315/

Drug companies are criticized for their large advertizing budgets. However, research shows that there is a substantial range for what pharmaceutical manufactures spend on marketing. In 2013, the ten largest drug companies spent between 17.9 percent and 28.4 percent of total revenue on advertizing.<sup>6</sup> The average was 23 percent. Compare those levels with the 20 percent that Oracle and Microsoft spend on marketing their products. The company Salesforce actually spends over 50 percent of its revenue on marketing.<sup>7</sup>

Just as professional athletes receive large salaries because of their time-limited careers, innovative drug manufacturers have a limited amount of time to earn a profit on a drug before its patent expires. Once a drug goes "off patent," it must compete with generic drugs. Generic manufacturers have a definite role in the health care system and can offer good prices, but they don't have the added expense of R&D. The sale of generic drugs cannot fund the discovery of new pharmaceuticals.

#### **Price controls limit investment**

Government price controls not only limit the supply of a product, they also limit the interest of financial investors in a company. Fewer investors mean less money for life-saving new drugs and less competition in developing those drugs.

#### **Specialty drugs**

Over the past few years, the increase spending on prescription drugs has largely been due to the increase use of drugs for very special and rare diseases. The Department of Health and Human Services recently released a study that found that specialty drugs accounted for one percent of all prescriptions, but 32 percent of all prescription drug costs.<sup>8</sup>

The high prices of these new and special pharmaceuticals must be weighed in comparison to the cost of treating a patient without that drug. For example, Sovaldi is a drug that treats hepatitis C and costs \$84,000 for a curative three month treatment. The alternative, a liver transplant, costs over \$500,000 and is associated with a great deal of pain and suffering, assuming a donor liver is even available.<sup>9</sup> Though it appears expensive in terms of price, Sovaldi is much more affordable than the alternative.<sup>10</sup>

#### Drug pricing is overly complex

Manufacturers do not set the final price of their drugs. Pharmaceutical pricing goes through a series of steps before drugs actually reach patients. Depending on whether people buy their drugs directly from a pharmacy or through their insurance, several transactions and multiple layers of profit are built into the system. The complicated pricing structure is shown in the graphic representation on page 3.

<sup>6 &</sup>quot;Pharmaceutical industry gets high on fat profits," by Richard Anderson, BBC News, November, 2014 at http://www.bbc.com/news/business-28212223

<sup>7 &</sup>quot;What percent of revenue do publically traded companies spend on marketing and sales?", by Sarah Brady, Vital Designs.com, 2015 at https://vtldesign.com/digital-marketing/content-marketing-strategy/ percent-of-revenue-spent-on-marketing-sales/

<sup>8 &</sup>quot;Prescription drugs: innovation, spending and patient access," U.S. Department of Health can Human Services, December 7, 2016 at http://delauro.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf

<sup>9 &</sup>quot;Sovaldi costs less than other treatments," by F. Jason Harris, *Modern Healthcare*, May 1, 2014 at http://www.modernhealthcare.com/article/20140501/NEWS/305019929

<sup>10</sup> Of course in economic terms, the death of a patient is an even cheaper outcome. This raises important ethical concerns not addressed in this policy paper.

## DISTRIBUTION AND FINANCIAL FLOW FOR RETAIL BRAND DRUGS





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In general, manufacturers sell to wholesalers who then sell to pharmacies. Most, if not all, insurance companies use pharmacy benefit managers (PBMs) to negotiate the best pricing from manufacturers. As shown, drug wholesalers and PBMs provide a service, but this comes at an added cost to the consumer. Wholesalers and PBMs will argue that they obtain better prices from manufacturers, but these contracts and the supposed benefits are not transparent. Actual contract pricing and rebates are usually closely guarded and not readily available to the public. What is known is that PBM companies, in general, have higher profit margins than drug manufacturers.<sup>11</sup>

Drug wholesalers and pharmaceutical benefit managers may have a role in the drug market, but only if they add value for patients. Their contracts and pricing should be transparent, so consumers can decide the amount of value added.

#### **Streamline regulation**

If public officials really want to bring prices down and increase competition in the drug industry, they should focus on streamlining the government drug approval process to decrease the time and money manufacturers devote to bringing a new drug to market. Depending on the study, the average cost of bringing a drug to market today is \$2.5 to \$5 billion and takes 10 to 15 years to get through the government regulatory process.<sup>12</sup> There is even a backlog of generic drugs awaiting government approval.<sup>13</sup>

#### Conclusion

Putting price controls on drugs would not solve the fundamental problem of our health care delivery system. Unlike the electronics or computer markets, in health care a third party, either the government through Medicare, Medicaid and Obamacare, or employers through insurance companies, pays for the majority of health care in the United States. Drug wholesalers and pharmaceutical benefit managers may negotiate better drug pricing, but this comes at a cost that is not readily transparent. Patients, as consumers of health care, and doctors as providers, are isolated from the actual costs of drugs and treatments.

Throughout our economy, a vigorous and creative free market, without third party interference, results in better products at cheaper prices every day with constant improvement. Allowing patients, in consultation with their providers, to decide which drugs are best clinically and financially for them should be the goal of health care reform, not damaging price controls.

<sup>11 &</sup>quot;Profits in the 2016 Fortune 500: Manufactures vs. wholesalers, PBMs, and pharmacies," by Adam J. Fein, Drug Channels, June 21, 2016 at http://www.drugchannels.net/2016/06/profits-in-2016-fortune-500.html

<sup>12 &</sup>quot;Cost to develop new pharmaceutical drug now exceeds \$2.5 B," by Rick Mullen, Scientific American, November 24, 2014 at https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceuticaldrug-now-exceeds-2-5b/

<sup>13 &</sup>quot;FDA still struggling with backlog of generic drug applications," by Ed Silverman, STAT Pharmalot, March 2, 2016 at https://www.statnews.com/pharmalot/2016/03/02/fda-generic-drugs/