

Measuring Prescription Drug Prices: A Primer on the CPI Prescription Drug Index

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Executive Summary

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Policymakers are currently considering and debating a range of proposals intended to reduce prices and increase consumer options in the prescription drug marketplace. Data on drug prices over time provide useful insights when evaluating the need for new policies and assessing policy effects. However, measuring how drug prices are changing can be difficult because of the market's basic measurement challenges and complexities.

In an effort to inform the public debate, the purpose of this primer is to review different measures of prescription drug price changes and discuss their strengths and limitations. A large body of economic research has developed a standard approach to measure price changes. In light of this research, we conclude that the Bureau of Labor Statistics' (BLS) CPI Prescription Drug Index (CPI-Rx) is the best available summary measure of the price changes of prescription drugs. Understanding how the CPI-Rx addresses the issues and challenges of measuring prescription drug inflation highlights the shortcomings of other measures that fail to address the measurement challenges. According to the CPI-Rx, not only are drug prices increasing more slowly than general price inflation; in the most recent period, drug prices have been decreasing. As of August 2019, the CPI-Rx has declined by 0.7 percent over the previous 12 months.

The CPI-Rx has important strengths compared with other measurements of drug prices, including measurements cited in the media. One of the goals of this primer is to explain the apparent discrepancy between the CPI-Rx and the measurements cited in the media. One strength of the CPI-Rx is that it provides a summary measure of how prices are changing in a market with a large number of prescription drugs. A second strength is that it accounts for the fact that lower-cost generic versions of many prescription drugs are widely available and purchased. A third strength is that it uses transaction prices, which reflect any negotiated price discounts. A limitation of the CPI-Rx is that posttransaction rebates are not reflected in the transaction price. The most informative measure of prescription drug prices would be based on net prices and would reflect all discounts and rebates. However, due to the difficulty in obtaining information on rebates, no such measure exists.¹ The CPI-Rx has several additional limitations. In situations where there is a known bias in the CPI-Rx, the bias generally causes the CPI to overstate the true level of inflation, and no measure of inflation exists that corrects for the sources of bias in the CPI-Rx. One of the main limitations of the CPI-Rx is that it does not account for the improvement in consumer value that occurs with the entry of new goods, particularly when they are of a higher quality than existing goods. The

¹ Some measures, which we discuss in this report, estimate net prices.

new goods and quality change bias is widely believed to cause the CPI-Rx to overstate the true level of prescription drug inflation, and has been estimated to be as high as 2 percentage points per year (Boskin et al. 1996), although the current magnitude of this bias is unknown. Another limitation to the CPI for prescription drugs—and, for that matter, to all measures of average drug prices—is that averages do not speak to individual cases (i.e., prices of individual products or the treatments for specific diseases). Thus, even if the CPI-Rx for drug prices indicates reasonable increases or declines, there may be some drug products, either new or old, for which price changes can appear extreme.

In recent years, there has been a large increase in approvals by the Food and Drug Administration (FDA) of new brand name and generic drugs (CEA 2018b). The large increase in drug approvals will likely cause an increase in the magnitude of the new goods bias in the CPI-Rx. We estimate that if the increase in drug approvals that occurred in 2017 and 2018 continues, it will produce cumulative benefits for consumers of between \$175.6 billion and \$300.1 billion (in 2016 dollars, at present discounted value) through 2027.

Introduction

Policymakers are currently considering and debating a range of proposals intended to reduce prices and increase consumer options in the prescription drug marketplace. Data on drug prices over time provide useful insights when evaluating the need for new policies and assessing policy effects. However, measuring how drug prices are changing can be difficult because of the market’s basic measurement challenges and complexities.

In an effort to inform the public debate, the purpose of this primer is to review different measures of prescription drug price changes and discuss their strengths and limitations. A large body of economic research has developed a standard framework to measure price changes (Boskin et al. 1996; National Research Council 2002). In light of this research, we conclude that the Bureau of Labor Statistics’ (BLS) CPI Prescription Drug Index (CPI-Rx) is the best available summary measure of the price changes of prescription drugs. According to this measure, not only are drug prices increasing more slowly than general price inflation; in the most recent period, drug prices have been decreasing. From the peak in June 2018 through August 2019, the CPI-Rx has declined by 1.9 percent. Figure 1 plots the year-over-year percentage change in the CPI-Rx. Through August 2019, the year-over-year change in the index has now been negative for 8 of the previous 9 months.

Figure 1. CPI-U for Prescription Drugs, 1970–2019

Year-over-year change (percent)



Sources: Bureau of Labor Statistics; CEA calculations.

Note: Data are seasonally adjusted.

In contrast to figure 1, during 2019 there have been numerous media reports that prescription drug prices are increasing. “Drug prices keep climbing” and “drug prices rose four times faster than inflation in the past six months alone,” according to the *New York Times* editorial board.

Many similar articles have recently been published. One of the goals of this primer is to explain the apparent discrepancy between the CPI-Rx and the measurements cited in the media. Because it is based on a well-established economic framework for measuring price changes, the CPI-Rx has important strengths compared with the measurements cited in the media.

One strength of the CPI-Rx is that it provides a summary measure of how prices are changing in a market with a large number of prescription drugs. For the CPI-Rx, the BLS takes the same approach as it takes for the general CPI, and it thus measures the prices of a random sample of prescription drugs. The CPI-Rx is a weighted average of the price changes of the sampled drugs that provides a measure of the average price change experienced by a typical household. In contrast, some recent news stories simply compare the number of drugs that have had price increases with the number that have had price decreases. But these comparisons can be misleading, because some drugs are widely used and others are rarely used. For the typical household, what matters are the changes in the prices of the most commonly prescribed drugs. For example, even if prices are increasing for a large number of rarely prescribed drugs, the CPI-Rx can show an average decrease if the prices of the most commonly prescribed drugs are decreasing.

A second strength of the CPI-Rx is that it accounts for the fact that lower-cost generic versions of many prescription drugs are widely available and purchased. Generic price increases are often much lower than brand name price increases, and generic drug prices often decrease (Frank, Hicks, and Berndt 2019). A particularly important case is when a new generic drug enters the market when patent (or exclusivity) barriers of a brand name drug are cleared. Because the FDA determines that a generic drug has the same active ingredient as the brand name drug and is bioequivalent to the brand name drug, typically many consumers switch to the generic version and pay a much lower price (Aitken et al. 2013). The CPI-Rx includes generic drug prices, and it captures a new generic entry as a price decrease. In contrast, some recent news stories focus solely on brand name drugs and miss the moderating effect of generics in general and the impact of a new generic entry in particular.

A third strength of the CPI-Rx is that it uses transaction prices instead of list prices. There can be many different prices for the same drug, and the price paid by a given consumer depends on a complex series of negotiations, which can involve drug manufacturers, health insurance companies, and pharmaceutical benefit managers. The BLS collects the transaction price, which corresponds to the negotiated price and reflects discounts. The transaction price includes all payments received by the pharmacy, which includes out-of-pocket payments from the patient and payments from third parties such as insurance companies; but it does

not include rebates.² In contrast, some recent news stories rely on list prices, which, as we discuss in more detail below, are a less meaningful measure of prescription drug prices.

The CPI-Rx has several limitations; in situations where there is a known bias in the CPI-Rx, the bias generally causes the CPI to overstate the true level of inflation. One of the main limitations of the CPI-Rx is that it does not account for the improvement in consumer value that occurs with the entry of new goods, particularly when they are of a higher quality than existing goods. Put simply, a new drug that cured cancers would greatly reduce the price of what consumers value—better health—even if the new product was more expensive than existing treatments, but the introduction of the new product would have no effect on the CPI-Rx. The new goods and quality change bias is widely believed to cause the CPI-Rx to overstate the true level of prescription drug inflation, and has been estimated to be 2 percentage points per year (Boskin et al. 1996). In recent years, there has been a large increase in FDA approvals of new brand name and generic drugs (CEA 2018b). The large increase in drug approvals will likely cause an increase in the magnitude of the new goods bias in the CPI-Rx. We estimate that if the increase in drug approvals that occurred in 2017 and 2018 continues, it would produce cumulative benefits to consumers of between \$175.6 and \$300.1 billion (in 2016 dollars) through 2027 in terms of present discounted value.

In the following sections, we discuss the conflicting measures of prescription drug inflation, how the CPI-Rx is constructed, and how it accounts for particular difficulties of measuring prescription drug prices, including tracking transaction prices rather than list prices and accounting for generic drug entry. Understanding how the CPI-Rx addresses the issues and challenges of measuring prescription drug inflation highlights the shortcomings of other measures that fail to address the measurement challenges. Finally, we discuss some well-known limitations and biases of the CPI-Rx. However, these biases generally cause the CPI-Rx to overstate prescription drug inflation compared with a true cost-of-living index. In particular, the new goods bias in the CPI-Rx likely grows as a larger number of branded and generic drugs enter the market, which will cause the CPI-Rx to overstate inflation by even more. In the final section of the paper, we calculate the value to consumers associated with this increase in the new goods bias.

² The price of medical goods and services in the CPI includes out-of-pocket payments and payments from insurers. Although the CPI only includes out-of-pocket spending by the household, this includes the medical goods and services purchased by insurers due to how health insurance is handled in the CPI. The CPI uses an indirect method to price health insurance, which reassigns the household payments for health insurance to the categories of medical goods and services for which the insurance pays (BLS 2019a). The CPI health insurance index is not a measure of premium inflation, as it only includes the retained earnings of insurance companies.

Conflicting Measures of Prescription Drug Inflation

A large body of economic research has developed a standard framework to measure price changes (Boskin et al. 1996; National Research Council 2002). The framework uses the economic theory of the consumer to measure how changes in the prices of goods and services over time affect the cost of living. When a price changes, the change in a consumer's cost of living is defined as the change in income needed to make her as well off after the price change as she was before. The CPI is designed to provide an empirical measure of the impact of price changes on the cost of living. The CPI-Rx is a component of the general CPI.

As of the most recent release of the CPI for August 2019, the CPI-Rx has declined by 0.7 percent over the previous 12 months. Other sources tell a story similar to the CPI-Rx. Express Scripts, one of the largest pharmacy benefit managers, reported that even though list prices increased in 2018, the prices paid by their clients fell. Some drug companies have themselves warned investors that increased discounts and rebates would offset any list price increases and that net prices would either be flat or fall in 2019 (*Wall Street Journal*; Hopkins 2019).

In contrast to the CPI-Rx, during 2019 there have been numerous news reports that prescription drug prices are increasing. “Drug prices keep climbing” and “drug prices rose four times faster than inflation in the past six months alone,” according to the [New York Times editorial board \(2019\)](#). Many similar news articles have recently been published, including “Drug prices in 2019 are surging with hikes at 5 times inflation” ([CBS News](#); Picchi 2019), “Drug prices persistently rising despite Trump efforts” ([Politico](#); Oweremohle 2019), and “Drugmakers push their prices higher” ([Wall Street Journal](#); Hopkins 2019). These stories all cite a study from the company Rx Savings Solutions, which says that 3,400 drugs have increased their prices in 2019 with an average price increase of 10.5 percent, which is the average only among the drugs with a price increase. The raw count considers different dosage forms and strengths as different products, and the price measured is the list price. An Associated Press [study](#) found that there were 96 list price increases for every decrease (Johnson and Forster 2018). The claim that prescription drug prices have fallen was rated as “mostly false” by the fact-checking website [Politifact](#) (Luthra and Sherman 2019).

Whether the price of prescription drugs is increasing or decreasing can be a difficult question to answer because of the market's measurement challenges and complexities. The measurement objective must also be clearly defined. A common objective of a price index is to measure the experience of the typical consumer and how much his or her cost of living has changed. Over the course of a typical year, the prices of some drugs increase, while the prices of other drugs stay constant or decrease. Because some drugs are widely prescribed and other drugs are only for rare diseases, it is not enough to compare the total number of drug price increases with decreases; what matters are the prices of the drugs purchased by the

typical consumer. Answering the question of what happens to drug prices becomes more complicated when manufacturers introduce low-price generic versions of previously available drugs, and when manufacturers introduce novel new drugs that provide improved treatment and/or have fewer side effects. Finally, overall spending (defined as the price times the quantity) on drugs can increase even if overall drug prices are decreasing, as long as there is a sufficiently large increase in utilization (quantity).

The studies behind the news stories suffer important limitations compared with the CPI-Rx. The news stories rely on studies that make claims about overall prescription drug prices based on list price changes of brand name drugs.³ The first limitation, as we explain in more detail below, is that list prices are perhaps the least important measure of price for prescription drugs. Second, lower-cost generic versions of many prescription drugs are widely available. Generic price increases are often much lower than brand name price increases, and generic drug prices often decrease. Third, the magnitudes of the reported price increases are themselves misleading, given that they are the average price increases conditional on there being an increase. That is, the reported average price increases fail to take into account those drug prices that did not increase or those that decreased. In the appendix, we summarize the methodology of the various price measures discussed in this report and highlight their strengths and weaknesses as measures of overall prescription drug inflation.

Box 1 presents a simple numerical example, showing why these measures presented in media accounts can be misleading as measures of overall drug price changes.

Box 1. An Example of How to Calculate Drugs' Average Price Changes

To illustrate some of the difficulties in measuring prescription drug prices, table i presents an example where, in the second year, most consumers pay lower prices. In the first year, there are four brand name drugs and one generic drug on the market. In the next year, the prices of some of the drugs change, and a new generic drug enters that competes with Brand B. Generic B enters at 75 percent of the price of Brand B and takes half the market share of Brand B. Because of these changes, in the second year most consumers pay lower prices for their prescription drugs. Consumers of Brand A pay 5 percent less, and consumers of Generic A pay 10 percent less. In addition, those consumers who purchased Brand B and switch to Generic B pay 25 percent less. Taken together, consumers who pay less in year 2 make up 73 percent of the market. For another 20 percent of the market—the consumers of Brand B who did not switch to the generic—the price of their drug does not change. Only consumers of Brand C and Brand D, who together make up 7 percent of the market, pay more in year 2.

³ Also, the studies do not always contain transparent methodology. All the information about the CPI-Rx presented in this report is available on the BLS website.

Although most consumers of prescription drugs pay lower prices in year 2, the measures used in some media reports would tend to suggest the opposite. The various measures sometimes reported in the media include the counts of price increases versus decreases for brand name drugs and the average increase among the brand name drugs whose price increased. Among brand name drugs, there are more price increases (Brands C and D) than decreases (Brand A). And the average price increase among those with price increases is 30 percent. These statistics tend to give a misleading picture of the price changes of brand name drugs because the drugs with price increases have small market shares. Moreover, the statistics about the price changes of brand name drugs do not capture the price decrease in Generic A or the impact of the entry of Generic B.

Table i. Drug Pricing Example

Drug	Share in year one (percent)	Price change (percent)
Brand A	33	-5
Brand B	40	0
Brand C	2	50
Brand D	5	10
Generic A	20	-10
Generic B	Introduced in year 2, taking half of Brand B's share	75 % of the price of Brand B

Source: CEA calculations.

Taking a weighted average using the market shares, which is similar to the calculation of a price index, shows that the weighted average prescription drug price decreased by 7.15 percent. The weighted average captures the fact that most consumers pay lower prices in year 2 and reflects the sizes of the price decreases and increases. The weighted average also treats the entry of Generic B as a price decrease for the 20 percent market share that switches from Brand B to Generic B. A price index that only included branded drugs would miss much of the price decrease in this example and provide a misleading measure of prescription drug inflation for the overall market.

Although the example in table i is simplified and hypothetical, real-world prescription drug markets can share its key features—a variety of price changes among drugs with differing market shares, the importance of generic drugs, and the entry of new generic drugs. Unlike the measures in some media reports, the CPI-Rx calculates a weighted average price that includes both branded and generic drugs. The CPI-Rx also incorporates the price decrease associated with the substitution to new generic drugs.

What Does the CPI Prescription Drug Index Measure?

Construction of the Index

The Consumer Price Index (CPI), as defined by BLS, “is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services” that is “developed from detailed expenditure information provided by families and individuals on what they actually bought.”⁴ The CPI methodology is guided by the economic theory of the consumer and the concept of a cost-of-living index. The CPI-U, which covers 93 percent of the U.S. population, measures the overall price changes associated with the consumption patterns of the average urban household.⁵ There are 211 basic categories for all of the goods and services purchased by households, and prescription drugs is one of the basic categories.⁶ The prescription drug category includes all retail prescription drugs, including mail order pharmacies. The overall index is constructed in 2 stages: in the first stage, basic indexes are created for the 211 product categories in each of the geographical areas included in the index; the second stage aggregates over both geography and item category to form the all-item index.⁷ The CPI-Rx is an intermediate level of aggregation that is formed by aggregating the prescription drug category over all geographic areas.

The sample of items in the CPI is selected in a two-stage sampling procedure. First, the retail outlets are selected randomly based on responses to the Telephone Point of Purchase Survey (known as TPOPs). Then, a BLS analyst goes to the outlet and randomly selects items. For prescription drugs, the item selection is based on a random sample of the last 20 prescriptions filled, with more expensive prescriptions assigned a larger sampling weight. Once the item is selected, the price is recorded. For prescription drugs, the price that is measured is the transaction price (all payments received by the pharmacy from the patient and third-party payers), and the analyst records all relevant price determining characteristics

⁴ See https://www.bls.gov/cpi/questions-and-answers.htm#Question_1.

⁵ The BLS also constructs measures of the prices received by the producers. The producer price index (PPI) includes a prescription drug component that measures the price the drug manufacturers receive and includes discounts (but not rebates). The PPI only includes domestic production but excludes Puerto Rico and the other territories. A large share U.S. of pharmaceutical production occurs in Puerto Rico. Excluding foreign and Puerto Rican production is a major limitation of the PPI as a measure of prescription drug inflation, particularly as many generic drugs are manufactured outside the United States.

⁶ The Bureau of Economic Analysis uses price indexes for the basic categories in the construction of the Personal Consumption Expenditures (PCE) Price Index (in addition to other sources). The prescription drug component of the PCE Price Index is the CPI-Rx.

⁷ The items are weighted in the first stage proportional to the item sampling probabilities (which is a combination of outlet sampling and sample of the item within the outlet). When the sample is refreshed, the new items enter with new weights. The second stage weights are based on the Consumer Expenditure Survey and is proportional to the share of total consumption for each of the item categories (BLS 2019b). The weights are formed using a two-year average of Consumer Expenditure Survey data.

(e.g., insurance company, copay amount, prescription size). In the subsequent months, the BLS analyst returns to the pharmacy and receives a price quote for an identical prescription.⁸ From the point of view of the consumer with insurance, the relevant price is the transaction price, which represents the direct payment in the form of out-of-pocket cost and the reimbursement from the insurance company that comes out of the payments the consumer makes to the insurance company in the form of insurance premiums.⁹

Benefits and Limitations of Measuring Transaction Prices

There can be many different prices for the same drug, and the price paid by a given consumer depends on a complex series of negotiations between multiple agents. Companies and health insurers pay pharmacy benefit managers (PBMs) to manage their health plan formularies. Drug manufacturers set a list price, and PBMs negotiate with the drug manufacturers for up-front discounts and rebates in exchange for placing the drugs in a more favorable position on the formulary. Figure 2 shows a simplified model of the prescription drug market for those with insurance. The consumer purchases the drug from a pharmacy, which acquires the drug from a wholesaler. The PBM pays the pharmacy a negotiated price. The negotiated price (with discounts) corresponds to the transaction price and is the price paid to the pharmacy. The negotiated price is typically determined as a function of the list price (CBO 2007). The customer pays any copay and coinsurance amounts, and the PBM pays the difference between the negotiated price and the out-of-pocket payments.

Rebates are handled differently, in that they are given after the transaction occurs and may not be applied when determining the transaction price.¹⁰ The price after all rebates have been applied is the net price. PBMs pass the rebates from drug manufacturers on to the insurance companies, which pass them on to the consumer in the form of lower premiums, and the impact will appear elsewhere in the CPI.¹¹ In a study of Medicare Part D plans, the Government Accountability Office found that over 99 percent of rebates were passed on to the insurance plan sponsors by the PBMs, although this result may not apply to non-Part D plans (GAO 2019).

⁸ Since 2015, these manually collected data have been supplemented with transaction data provided directly from a pharmacy chain, which had previously refused to participate in manual data collection (Konny, Williams, and Friedman 2019).

⁹ Government prescription drug coverage that does not charge a premium is excluded from the CPI (e.g., Medicaid).

¹⁰ For simplicity of terminology, we consider rebates that are reflected in the transaction price to be discounts.

¹¹ Specifically, this is in the health insurance component of the index; this component of the CPI is difficult to interpret because it is not a measure of premium inflation. Most of the premium expenditure is reallocated to the medical services for which the insurance pays.

Measuring list prices can be misleading because drug manufacturers can increase list prices while simultaneously increasing discounts and rebates. In the face of new competition, drug makers may respond by offering increased price concessions or rebates rather than decreasing the list price. However, this does not mean that the list price is meaningless. In some situations, the transaction price will be the list price with a wholesale and pharmacy markup, such as when individuals lack prescription drug coverage.¹² Also, out-of-pocket payments can be a function of the list price. Transaction prices are often a function of the list price; however, list price increases are generally not fully passed through to the transaction price.¹³

Generic Substitution

After certain patent protection (and/or exclusivity) is no longer a barrier to generic drug approval, there is the potential for generic competitors to enter the market. The FDA approves generics if, among other things, the active ingredient is the same as the branded drug and the generic drug is bioequivalent to the brand name drug. As a result, generic drugs are considered substitutable (in fact, almost a perfect substitute) for the branded version but typically have a lower price, and many consumers switch from the branded version to the generic version shortly after the generic version becomes available. This switch is a price decline (lower price for an identical product) that is not captured by tracking the branded drug or the generic drug's price over time. The CPI-Rx accounts for generic substitution by tracking the initial entry of a generic drug. After roughly 6 months after patent expiration (enough time for the generic to establish market share), the branded drug is randomly replaced with the generic drug, with a probability equal to the generic's market share, and the price difference is recorded as a price decrease. With a probability equal to the branded drug's market share, it is not replaced and continues in the sample.¹⁴ This methodology was incorporated into the CPI-Rx in response to research showing that there was substantial bias associated with ignoring the substitution that occurs with generic entry (Griliches and Cockburn 1994; Fisher and Griliches 1995). Box 2 presents how the competitive dynamics

¹² The vast majority of individuals with insurance have prescription drug coverage. It is one of the essential health benefits for plans on the exchanges, and almost all the larger group plans that are exempt from the minimum coverage rules provide prescription drug coverage. Those without prescription drug coverage include those who are uninsured (about 8.5 percent of the population in 2018, according to the Current Population Survey), and a relatively small number of Medicare enrollees who opt out of part D coverage.

¹³ This is due to changes in discounts and rebates that accompany the list price increase. Transaction prices are typically defined as a percentage of the list price (with a dispensing fee for the pharmacy). For example, if the negotiated transaction price is 85 percent of the list price and the list price increases by 10 percent, the negotiated price will only increase by 8.5 percent.

¹⁴ Branded drug manufacturers rarely cut list prices in response to generic entry, but do increase discounts and rebates (Aitken et al. 2013).

have affected the price in the market for insulin and the prospect of nonbranded competition in the future.

Box 2. The Price of Insulin and Barriers to Competition

There is limited competition in the U.S. insulin market as there are only three manufacturers. Insulin was discovered almost 100 years ago, and was derived from animal sources until the development of biopharmaceutical production processes, which allowed for the production of human insulin and human insulin analogs in the 1980s and 1990s. In recent years, the list price of insulin has increased dramatically. Research by the American Diabetes Association found that the list price of insulin increased at a rate of between 15 and 17 percent per year from 2012 to 2016. For many drug products, however, the net price of insulin after discounts and rebates has remained relatively constant or has even decreased (Cefalu et al. 2018). The observed price changes for insulin mirror those observed for prescription drugs overall. Large list price increases do not always correspond to large net price increases. High list prices can create a financial burden for those without insurance and for those with certain high-deductible health plans. Low-cost nonbranded versions are not yet available in this market, but they may be on the horizon.

Many of the current insulin products have been on the market for 20 or 30 years, and their patents have expired, yet they face limited generic competition due potentially to challenges obtaining approval for follow-on versions of insulin. (Note: proteins, including insulin, were added to the definition of a “biological product” by the Biologics Price Competition and Innovation Act of 2009, the BPCI Act.) The abbreviated pathway for follow-on versions of biologics, known as biosimilars, was created by the BPCI Act. Biosimilars can be approved upon a demonstration that they are highly similar to the reference product and have no clinically meaningful differences from the reference product in terms of safety, purity, or potency. Biosimilars can be licensed as interchangeable with the reference product if it can be shown that the biosimilar can be expected to produce the same clinical result in any given patient, and for biological products administered more than once, the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than continuing on the reference product without such switching. Interchangeable biologics can be substituted for the reference product without the intervention of the healthcare provider that prescribed the reference product. An interchangeable biologic may put more price competition on the original product than a biosimilar, as substitution is possible without the intervention of a prescribing health care provider. After March 23, 2020, insulins will be regulated under the Public Health Service Act as biologics. This transition will allow for approval of biosimilar and interchangeable insulin products through the biosimilar pathway (White and Goldman 2019).

Limitations of the CPI-Rx

Although the CPI-Rx is the best measure of overall prescription drug inflation, it is not a perfect measure. The limitations of the CPI-Rx take two general forms. First, there are sampling and measurement challenges that could cause the sample of items to not be representative of the average household’s purchases. The conceptual framework of the CPI is

the cost-of-living framework. The CPI differs from a true cost-of-living index due to a number of well-known (and difficult to fix) issues, which form the second set of issues. These issues are generally thought to be more pronounced in the CPI-Rx than in many of the other product categories, and they all cause the change in the CPI-Rx to be biased upward (i.e., they cause it to overstate inflation).

Potential Sampling and Measurement Biases

The CPI sample is designed to be representative of the retail outlets and the individual prescriptions, but there are many reasons why it may not be. Outlet sampling is based on a survey with a relatively high rate of nonresponse (BLS 2019c). Once an outlet is chosen, it does not always cooperate. In some cases, the outlet can be reluctant or unable to provide transaction prices for customers with insurance, which leads to cash quotes being overrepresented (given that a small number of customers without insurance tend to pay list prices). This means that list prices are overrepresented in the CPI sample, which will generally bias the prescription drug index up, although the recent introduction of corporate data has increased the amount of insurance prices in the CPI-Rx (Konny, Williams, and Friedman 2019).

The CPI-Rx is limited to retail prescription drugs, so hospital- and doctor-administered drugs are not included. In the BLS's CPI methodology, hospital- and doctor-administered drugs are viewed as inputs into hospital or physician services and are implicitly captured in those price indexes. Finally, the nature of the sampling procedure means that drugs for relatively rare conditions are unlikely to be included in the sample and thus may be underrepresented relative to their share of overall expenditures. Many of these sampling and measurement limitations are due to the need to produce an accurate and timely measure of inflation subject to a limited budget. Increasing the sample size would lower the sampling error but would increase the cost of data collection. There are alternative sources of data, such as claims data, that could be used to construct price indexes. Claims data are only available after a lag, but they contain much larger samples (millions of observations versus hundreds or thousands in the CPI-Rx).

Bosworth and others (2018) attempt to replicate the CPI-Rx methodology using prescription claims data and find higher levels of inflation in the claims data but are unable to determine the source of the discrepancy.¹⁵ Other studies use claims data to calculate prescription drug inflation, but they do not try to replicate the BLS methodology and are therefore not as comparable to the CPI-Rx. For example, AARP calculates a prescription drug index for medications that are commonly used by seniors using claims data. They find that branded drug prices increased 8.4 percent in 2017 and that generic drug prices decreased by 9.3

¹⁵ Bosworth et al. (2018) conclude that “we are left with some puzzlement about explanations for the differences between the indexes constructed from IQVIA and CPI data sets.”

percent (Schondelmeyer and Purvis 2018, 2019). IQVIA also constructs measures of prescription drug prices. It found that net price growth of branded drugs increased 0.3 percent in 2018, compared with a 5.5 percent increase in list price (IQVIA 2019).

Although rebates are implicitly captured elsewhere, the net prices themselves (the transaction price less all rebates) are not observed because the terms of the agreements between PBMs and the drug manufacturers are treated as trade secrets and not disclosed. The net price would provide the most meaningful measure of prescription drug price. Rebates have been increasing over time, from \$39.7 billion in 2012 to \$89.5 billion in 2016 (Pew 2018). The growth of rebates implies that net prices are growing more slowly than transaction prices (which are growing more slowly than list prices, which in turn are growing more slowly than the average increase in list price among drugs with list price increases).¹⁶ The research firm SSR Health estimates that the net prices of prescription drugs fell in 2018 by 4.8 percent.

CPI-Rx Biases Relative to a Cost-of-Living Index

The CPI follows a fixed basket of items over time that have constant weights, with the implicit assumption that individuals purchase the same items over time. The degree to which purchasing behavior changes over time generates bias in the index. To minimize this bias, the BLS periodically updates the sample of products and aggregation weights. Product substitution bias within a category (called lower-level substitution bias) occurs when individuals substitute to a different product because of a relative price change (e.g., the price of Gala apples declines, causing some individuals who used to purchase Red Delicious apples to purchase Gala apples instead). In a true cost-of-living (COL) index, this substitution would cause the item with the price decline to receive more weight, resulting in a lower value for the price index. In most product categories, lower-level substitution bias has been addressed by switching from a weighted arithmetic mean in the index calculation to a geometric mean. The geometric mean overstates substitutability in medical categories because it assumes that all products within the category are substitutable. If a patient is taking a statin for high cholesterol, no matter what happens to the price of insulin, they will not substitute from the

¹⁶ The definition of price as the transaction price is consistent with how prescription drug expenditures are measured by the Bureau of Economic Analysis as a part of Personal Consumption Expenditures (PCE) in GDP. Manufacturer rebates are included in consumption and are netted out elsewhere in the calculation of GDP. For this reason, prescription drug expenditures (and expenditure growth) tend to be overstated in the PCE. The National Health Expenditure (NHE) data, released by the Centers for Medicare & Medicaid Services, net out manufacturer rebates and show much lower spending on prescription drugs (\$414 billion vs. \$333 billion in 2017) and much lower spending growth (4.7 percent vs. 0.4 percent in 2017). See Hartman, Kornfeld, and Catlin (2010) for the difference in measurement between the NHE and GDP. The difference between the PCE and NHE prescription drug expenditures has been growing over time, reflecting the growth in rebates. This implies that a price index based on the net price (accounting for manufacturer rebates) would show slower price growth than the CPI-Rx.

statin to insulin because insulin treats diabetes, not high cholesterol. However, the arithmetic mean formula, known as a Laspeyres Index, will have some substitution bias, as it assumes zero substitution and some drugs are substitutes (e.g., drugs that treat the same condition).¹⁷

New goods bias arises when additional products enter the market. Generally, new goods enter the CPI when the sample of items in the index is refreshed. Refreshing the sample also takes into account changes in the amounts of expenditures on different items and changes in consumer shopping behavior (outlet bias). The price changes for the new item are tracked after it enters the sample. However, with differentiated products, the new items have value to some consumers that exceed the price at entry (consumer surplus). A true COL index will account for this gain in consumer surplus and treat it as a price decrease.

Quality change bias typically arises when a product is replaced by a similar product, say, a new version of the product. New features, improved efficacy, and other quality improvements occur at these version changes, and the price may or may not increase. If the price does not change, then the consumer is paying the same amount for a better product (that the consumer values more). This surplus should be reflected as a price decrease in a COL index. If the price increases, the question is how much of the increase is justified by the quality change and how much is inflation. The CPI-Rx makes no quality adjustments, so the implicit assumption is that the price of entering drugs fully captures the quality change relative to existing drugs.

New goods and quality change bias for medical goods and services account for the fact that what matters to consumers is the price of health rather than the spending on healthcare. Before the entry of a treatment for a serious disease, the price of better health could be prohibitively high or even unobtainable at any price. The entry of new treatments can lead to a large decrease in the price of health, even if the treatments themselves are relatively expensive. For example, before the introduction of HAART in 1996, a longer life was not possible for people with HIV/AIDS, and the cost of achieving a longer life fell dramatically once it entered.

Estimates of new goods and quality change bias generally find that the CPI-Rx overstates the true level of inflation as measured by a COL index. This means that, generally, the higher price of entering drugs relative to existing drugs is more than justified by their higher quality, although this does not imply that this is the case for every entering drug. The Boskin Commission estimated that the new goods and quality bias in the CPI prescription drug

¹⁷ Upper-level substitution bias occurs when the substitution occurs across product categories (e.g., the price of gasoline goes up and individuals spend less on cars). The CPI-U uses the Laspeyres formula to aggregate the basic indexes, and is therefore biased upward due to the upper-level substitution bias. The chained CPI-U uses a formula that corrects for this bias.

indexes is 2 percentage points per year (Boskin et al. 1996).¹⁸ In a study of anticholesterol drugs, Dunn (2012) finds that the quality adjusted price of these drugs fell from 1996 to 2007 despite the unadjusted prices increasing. For colorectal cancer drugs, Lucarelli and Nicholson (2009) find that quality-adjusted prices were roughly constant from 1993 to 2005, even though the average cost of treatment increased from \$100 to \$36,000 over the same period due to the entry of new higher-cost treatments.

The Estimated Value of Increased Drug Entry

As discussed in the previous section, the CPI-Rx tends to overstate prescription drug inflation by not taking into account the value to the consumer of new goods and quality change. Unlike products in other markets, the government completely regulates the entry of new products into the prescription drug market. Therefore, the magnitude of the new goods bias for prescription drugs will depend on government regulatory policies. The rate of drug approvals increased in 2017 and 2018, due in part to policies of the Trump Administration to expedite the drug approval process (CEA 2018b). The benefits to consumers of these additional approvals are not fully captured by traditional price indexes such as the CPI-Rx, but would be captured by a true COL index. Efforts by the FDA to speed up review times and eliminate the backlog of applications should have the effect of shortening approval times, which lower the cost to drug companies of developing new drugs, leading to the development of more drugs in the future, all else being equal. In this section, we conduct a simple empirical exercise to estimate the impact of increasing the rate of new drug entry on prices and the real output of prescription drugs, using the concept of the new goods bias in the prescription drug index. If investments in new drugs are able to sustain a higher rate of entry, the cumulative benefit to consumers of the increased rate of drug approvals through 2027 is estimated to have a present discounted value of between \$175.6 billion and \$300.1 billion (in 2016 dollars).

Methodology

The years 2017 and 2018 saw a substantial increase in the number of new drugs and generics approved. Average annual new drug approvals increased by 71.6 percent in 2017 and 2018 relative to the period 2008–16, and average annual generic drug approvals increased by 69.3 percent (table 1).¹⁹ This analysis proceeds, assuming that 2017 and 2018 represent a trend break in the number of new drug approvals. Some of the increase in 2017 and 2018 represents drugs that would have been approved at a later date in the counterfactual where the 2016

¹⁸ The Boskin Commission was a group of experts convened by the Senate Finance Committee to study biases in the CPI.

¹⁹ New drug approvals include applications for New Molecular Entities (NMEs) and Biologics License Applications (BLAs). Generic approvals are measured as the number of Abbreviated New Drug Applications (ANDAs) approvals.

policies persisted. This represents a one-time boost in the number of drugs approved at the expense of drug approvals in future years. The shorter approval times, however, lower the cost of drug development, which should lead to a greater number of drugs being developed and a sustained increase in the number of new drugs being approved each year. Although the new equilibrium rate of drug entry will likely be higher than the pre-2017 rate, the 2017 and 2018 rate may not be sustainable in the longer term.

Table 1. Drug Approvals and Inflation

Aspect	2008–16	2017–18
New drug approvals (annual average)	30.6	52.5
Generic approvals (annual average)	491.6	832.5
Average annual prescription inflation (CPI-Rx)	3.5%	2.5%
Average annual prescription drug inflation relative to general inflation (CPI)	1.8%	0.2%

Sources: Bureau of Labor Statistics; Food and Drug Administration; CEA calculations.

We estimate the COL index (adjusting for new goods and quality bias) for prescription drugs for 2017–27 under the assumption that new drug approvals continue at the 2017–18 rate and under the counterfactual scenario that drug entry continued at the 2008–16 rate from 2017 on. We assume that the new goods and quality bias in the CPI prescription drug index is 2 percentage points per year in the period 2008–16 and that the higher number of new drugs in 2017–18 causes the new goods and quality bias to increase by between 18 and 36 percent (to 2.36 and 2.72 percent per year).²⁰

There is a small negative relationship between the number of new drug approvals and measured prescription drug inflation based on data from 2008 to 2018. This correlation between new drug approvals and prescription drug inflation is used to predict the future level of inflation for the case where the average number of new drugs approved persisted at the

²⁰ The baseline estimate of 2 percent is from the Boskin Commission. The exact relationship between the percentage increase in approvals and percentage increase in new goods bias is unknown and the subject of ongoing research. The number of entering products is an imperfect proxy for the magnitude of the new goods bias. A single drug that enters with high sales could have a larger new goods bias than many drugs that enter with very little sales. The change in new goods bias uses the assumption that the average marginal new goods bias of the drugs that enter under the policy change is 50 percent of the average new goods bias of the drugs that otherwise enter. The upper-bound estimate assumes that the 2017–18 rate of drug entry persists, while the lower-bound estimate assumes that the new equilibrium rate of drug entry is halfway between the original rate and the 2017–18 rate. Because the benefit of the policy is defined as a percentage of the baseline new goods bias, changing the baseline estimate will change the estimated benefit by a similar proportion.

2008–16 annual rate and for the higher rate of new drug entry observed in 2017 and 2018. Nominal prescription drug expenditure data are from the National Health Expenditures (NHE) projected prescription drug spending through 2027.²¹

The value to the consumer of the higher rate of drug approvals is calculated as the difference in the value of real output calculated using the COL index for the higher rate of drug approvals (actual rates of inflation in 2017 and 2018, lower projected future inflation, and a larger correction for new goods) compared with the counterfactual estimate based on the lower pre-2017 rate of drug approvals. The difference in real output, which is calculated using the different COL indexes, is the amount that consumers would need to be compensated in order to be just as well off given a lower rate of drug approvals.

Results

All the price and COL indexes are normalized to equal 100 in 2016, and all real values are presented in terms of 2016 dollars. Table 2 presents the projected value of the price indexes in 2027. The increase in the rate of drug entry is predicted to lower the measured inflation rate from 3.4 percent per year to 2.93 percent. By 2027 the actual price index is projected to increase between 36.4 percent and 39.2 percent from 2016 to 2027. Under the counterfactual of the lower rate of drug entry, the measured price index is predicted to have increased 44.5 percent. The COL index under the counterfactual increases by 16.5 percent, and the COL index with the higher rate of new drug entry is projected to grow very little (between 1.6 and 7.9 percent). The new goods bias causes the cumulative price growth under the COL indexes to be much lower than under the price indexes.

Table 2. Projected Price Indexes in 2027 (2016 = 100)

2.0 pp new goods adjustment scenario		2.36 pp new goods adjustment scenario		2.72 pp new goods adjustment scenario	
Counterfactual price index	Counterfactual COL index	Actual price index	COL index	Actual price index	COL index
144.5	116.5	139.2	107.9	136.4	101.6

Source: CEA calculations.
Note: pp = percentage point.

The higher rate of new drug entry is estimated to generate between \$221.8 billion and \$381.1 billion (in 2016 dollars) in benefits for the consumer from 2017 to 2027 (table 3). The benefit in

²¹ The NHE data are produced by the Centers for Medicare & Medicaid (CMS). Actual expenditures are available through 2017, with projected amounts for 2018–27.

2017 and 2018 of the increase in new goods is estimated to be between \$9.3 billion and \$13.0 billion. The overall value of the new goods is estimated to be between \$23.1 billion and \$26.8 billion for 2017 and 2018. The cumulative present value of the increase in the number of new drugs is estimated to be between \$175.6 billion and \$300.1 billion (an average of between \$16.0 billion and \$27.3 billion per year).²² Of the total, between \$78.9 billion and \$109.2 billion represents direct cost savings in the form of lower measured inflation, while the value of the higher number of approved drugs is between \$96.7 billion and \$190.9 billion.

Table 3. Value of the Increase in Drug Approvals, 2017–27

Aspect	Lower-bound estimate	Upper-bound estimate
Cumulative benefit (\$ 2016, billions)	221.8	381.1
Present discounted value (\$ 2016, billions, 3% discount rate)	175.6	300.1

Sources: National Health Expenditure Projections; CEA calculations.

²² Under the much more conservative assumption that the increase in new drugs has no effect on the prices of existing drugs and that the increase in new drugs causes the new goods bias to only increase to 2.2 percentage points (a 10 percent increase), the present discounted value of the increase in the rate of new drug approvals through 2027 is estimated to be \$44.2 billion.

Appendix: Summary of Methodologies

In this appendix, we summarize the methodology of the various measures of prescription drug prices that are referenced in the report. Table A1 lists the main benefits and limitations of each measure.

Rx Savings Solutions price increase measure: Many of the news stories cited use a measure constructed by the company Rx Savings Solutions. The study is not available on the company's website, and it did not respond to our email inquiry. According to the news reports on the study, 3,400 drugs have increased their prices in 2019, with an average price increase of 10.5 percent, or approximately five times the rate of inflation. The raw count is inflated because Rx Savings Solutions considers different dosage forms and strengths as different products. The price increases are list price increases. The reported price increase appears to be a simple average across all of the drugs with a price increase. Finally, it includes nonretail prescription drugs (doctor- and hospital-administered) in its measure that are not included in the CPI-Rx.

Associated Press: It analyzed the list price changes that occurred in the first seven months of 2018, as well as the first seven months of prior years for comparison, using data provided by Elsevier. In 2018 there were 96 list price increases for every decrease. The limitations of the study are that it focused on brand name drugs only and on list prices. Also, a simple count of increases versus decreases does not take into account that not all drugs are equally important in determining the overall price change.

AARP: It develops price indexes of drugs commonly used by seniors for branded, generic, and specialty drugs. The price data are from the Truven MarketScan database, which is a large claims database for employer group plans, and they are transaction prices. The price changes for the individual drugs are weighted by the 2014 expenditures to form the indexes.

Express Scripts: It forms a list price index for a fixed basket of prescription drugs, but also calculates unit cost indexes using data from its plan members. The unit cost is the cost per day of medication and is defined so that total spending growth can be decomposed into utilization growth (number of prescription days) and unit cost growth. Unit cost measures changes in price, but also changes in the mix of drugs. In the case of generic substitution, a unit cost measure will capture it as a decrease in price.

IQVIA: It uses proprietary data to estimate net prices for a sample of manufacturers, which are then used to estimate overall net price changes. It is not clear from the report how the price changes for individual drugs are aggregated. Some of its proprietary databases have complete coverage of the U.S. pharmaceutical market.

SSR Health: Proprietary estimates of prescription drug inflation based on estimated net prices. Its published reports are not publicly available, and the methodology is unknown.

Table A1. Drug Price Comparison

Source	Measure type	Measure price	Coverage	Includes generics	Generic substitution captured as price decrease	Representative
BLS CPI-Rx	Price index	Transaction price	All retail prescription drugs	Yes	Yes	Yes
BLS PPI-RX	Price index	Producer sales price	Domestically produced drugs	Yes	Yes	No. Imports are not included.
Rx Savings Solutions	Simple average	List price	Drugs with price increases	No	No	No
Associated Press	Count	List price	Drugs with price changes	No	No	No
AARP	Index	Transaction price	Drugs commonly used by seniors	Yes, as separate index	No	No
Express Scripts	Index	Transaction price	All drugs	Yes	Implicitly in the unit cost indexes	No, only their clients
IQVIA	Index	Estimated net price	All drugs	Yes	No	Maybe
SSR Health	Unknown	Estimated net price	Unknown	Unknown	No	Unknown

Sources: Bureau of Labor Statistics; Associated Press; Scripts; IQVIA; SSR Health; American Association of Retired Persons.

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