

The pharmaceutical industry: an overview of CPI, PPI, and IPP methodology

Introduction

The pharmaceutical industry plays a major—and growing—role in the United States economy, with both the consumption and the production of its products. Total value of U.S. consumption of pharmaceutical drugs in 2009 was \$300 billion, or about 40 percent of the worldwide market share, and reflected a 37-percent increase since 2003.¹ The total value of shipments by domestic producers in 2009 was \$142 billion, with \$46 billion in estimated exports. The 2009 value of U.S. imports was \$81 billion, and represented a 65-percent jump over the value in 2003.² Less expensive generic equivalents account for three-quarters of prescriptions filled, a figure that is climbing quickly because of a wave of patent expirations. Despite the high volume, generics account for only one-quarter of sales in the U.S. drug market.

The United States relies on imports to meet the demand for prescription drugs. By volume, 40 percent of the finished pharmaceuticals consumed in the United States are imported; this figure is close to 80 percent for active and bulk pharmaceutical ingredients in these finished drugs. By value, the United States still leads the world in pharmaceutical production, accounting for 39 percent of world production, followed by the United Kingdom, Germany, France, and Japan.

The Consumer Price Index (CPI), Producer Price Index (PPI), and Import/Export Price Index (IPP) all have pharmaceutical indexes, but there are fundamental differences in the form and function of each index. These differences include the composition of the set of drugs sampled and the types of price collected. The CPI records drug price changes from the perspective of the retail consumer. The PPI tracks the first price received by the manufacturers themselves. The IPP measures changes in the U.S. import and export prices of pharmaceutical products. These indexes collectively span the value chain, complementing one another and providing insight into a dynamic and complex industry.³

Comparison of CPI-PPI-IPP pharmaceutical indexes

This summary briefly describes the three BLS price programs and their respective methods for calculating the pharmaceutical inflation monitors. The following table highlights some of the main characteristics of the three programs' approaches to constructing drug price indexes. The table is followed by a more detailed narrative.

¹ IMS Health MIDAS report, Sept 2009, via Generic Pharmaceutical Association (GPhA). www.gphaonline.org.

² The value of 2009 domestic production comes from the Census Bureau's Annual Survey of Manufactures, while the value of imports and exports is reported by the Census Bureau's Foreign Trade Division. For more information, see http://www.census.gov/foreign-trade/Press-Release/2009pr/final_revisions/exh7.pdf and http://factfinder.census.gov/servlet/IBQTable?_bm=y&-NAICSASM=325412&-ds_name=AM0931GS101&-ib_type=NAICSASM&-industry=325412&-lang=en.

³ PPI also publishes an index that measures the cost of the service that retail pharmacies provide in disseminating pharmaceuticals to customers. This margin index measures the retail service, not the prices of prescriptions or over-the-counter drugs themselves (the main subject of this document). For more information on retail trade PPIs, see <http://www.bls.gov/ppi/ppiaddretail.htm>.

Table 1. Comparison of CPI, PPI, and IPP Pharmaceutical Indexes⁴

Characteristic	CPI	PPI	IPP
<i>Official publication title</i>	Prescription drugs	Pharmaceutical preparations	Pharmaceutical products
<i>Relative importance values</i>	1.253 percent of CPI-US All Items	2.358 percent of PPI 5.158 percent of Finished Goods PPI	3.073 percent of all imports; 3.862 percent of all exports
<i>Does the program produce an index exclusively for prescription drugs?</i>	Yes	Yes	No
<i>Index break outs below the prescription drug level</i>	None currently available	8 broad therapeutic categories as well as 28 detailed therapeutic class indexes	N/A
<i>Average time between new samples</i>	4 years ⁵	5–7 years	2 years
<i>Are supplemental samples used to introduce new products?</i>	No	Yes, annually	No
<i>Type of price</i>	Transaction price received by the pharmacy	Manufacturer’s first transaction price	Import/export transaction price at the U.S. border
<i>Coverage/Scope</i>	Physician-prescribed prescription and nonprescription drugs dispensed via U.S. pharmacies (excludes physician and hospital administered drugs)	Prescription and nonprescription drugs produced in the U.S. (excluding Puerto Rico) for all channels of distribution	Pharmaceutical products imported/exported from the United States (including Puerto Rico), inclusive of prescription and non-prescription drugs, as well as other medicaments
<i>Index focal point</i>	Consumer	Goods-producing industry	U.S. international trade
<i>Is there a revision period for index data?</i>	No	Yes – Final indexes are released 4 months after preliminary publication	Yes – Final indexes are released for up to 4 months after preliminary publication

⁴ New outlets and drugs are initiated twice a year, constantly refreshing the prescription drug sample. Roughly 25 percent of the item and outlet sample is refreshed each year. For more information, refer to the “Item Sampling” section on page 9.

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The main responsibilities of the CPI, PPI, and IPP

This section briefly highlights the purpose, high-level design, and uses of the data produced by the CPI, PPI, and IPP.

CPI

The CPI is a measure of the average change over time in the prices of consumer items that people purchase for day-to-day living, such as food, clothing, shelter, and medical services. The monthly movement in the CPI derives from weighted averages of the *price changes* of the items in its sample.

In the CPI, the urban portion of the United States is divided into 38 geographic areas called *index areas*, and the set of all goods and services purchased by consumers is divided into 211 categories called *item strata*. This results in 8,018 item-area combinations (38 geographic areas multiplied by the 211 item strata).

The CPI is calculated in two stages. The first stage is the calculation of *basic indexes*, which show the average price change of the items *within* each of the 8,018 CPI item-area combinations. For example, the prescription drug index for the Boston CPI area is a basic index. The weights for the first stage come from the sampling frame for the category in the area. At the second stage, *aggregate indexes* are produced by averaging *across* subsets of the 8,018 CPI item-area combinations. The weights for the second stage are derived from reported expenditures from the Consumer Expenditure Survey (CE), which are updated every 2 years. The aggregate indexes are the higher level indexes; for example, the all-items index for Boston is an average of all of the area's 211 basic indexes. Similarly, the aggregate index for prescription drugs is an average of the basic indexes for prescription drugs in each of the 38 index areas. The U.S. city average—all items CPI—is an average of all basic indexes.

The prescription drug index accounts for about 1.25 percent of the U.S.-level All Items CPI. This 1.25-percent relative importance derives from the Consumer Expenditure (CE) survey. The CE survey collects detailed expenditure data from families and individuals on the items they actually purchased. Their spending habits are surveyed and aggregated over a 2-year period. These aggregate figures provide the CPI with a good estimate of the share of total expenditures that households spend on certain items. The current CPI index for 2011 uses expenditure data collected for the 2-year period from 2007–2008. New CE data from 2009–2010 will become available for CPI index use at the start of 2012.

The CPI is a principal federal economic indicator (PFEI), providing information about price changes in the nation's economy to government, business, labor, and private citizens. People use the PFEIs to help make economic decisions. The CPI and its components also are used to adjust other economic series for price changes and to translate these series into inflation-free dollars. Examples of series adjusted by the CPI include retail sales, hourly and weekly earnings, and components of the National Income and Product Accounts. The CPI is often used to adjust consumers' income payments (for example, Social Security), to adjust income eligibility levels for government assistance, to automatically provide cost-of-living wage adjustments to millions of American workers, and to index the federal income tax structure.

PPI

The PPI measures the change over time in the prices received by domestic producers of goods and services.

Most of the information used in calculating producer price indexes is obtained through the systematic sampling of virtually every industry in the U.S. mining and manufacturing sectors, as well as 77.4 percent of the service sector and 28.6 percent of the nonresidential construction sector. The PPI program currently calculates price indexes for roughly 500 mining and manufacturing industries (including more than 7,000 indexes for specific products and product categories), more than 3,000 commodity price indexes, nearly 1,000 indexes covering the services sector of the economy including wholesale and retail trade margins, as well as stage-of-processing (SOP) classification schemes.

Thus, the PPI family comprises a variety of price measures, which can be used independently or collectively to gauge inflation in the U.S. economy. The PPI industry indexes are based on the North American Industry Classification System (NAICS).

The PPI also publishes commodity indexes for pharmaceuticals, which include all pharmaceutical products in the PPI survey, regardless of industry of origin. This means that in addition to pharmaceutical products produced by the pharmaceutical industry, the PPI Pharmaceuticals Commodity Index includes pharmaceutical products that are manufactured by establishments whose plurality of revenue comes from some other industry, for example, medicinal and botanicals or biological products.

By commodity, the pharmaceutical index accounts for 2.358 percent of the total PPI and 5.158 percent of the PPI for finished goods. Unlike the CPI, which uses CE expenditure data to weight the index, the PPI derives its weighting from the value of shipments (VOS) figure available from the Census Bureau, which is a more meaningful size measure when tracking prices at the producer level. PPI weights are updated every 5 years, reflecting the latest Census VOS figures—for example, PPI will update its weights in January 2012 to reflect 2007 Census VOS data.

The PPI is primarily used as a PFEI; more detailed indexes are used as sources for industry analysis and contract escalation in the public and private sectors. PPI data are critical inputs into the development of sensitive economic indicators, including estimates of gross domestic product and industrial productivity.

IPP

The IPP import and export price indexes measure the change over time in the prices of goods and services traded between the United States and the rest of the world.

The import and export price indexes cover product groups accounting for nearly 100 percent of U.S. commodity imports and exports, by value, excluding goods exclusively for military use, works of art, and selected special miscellaneous exports. The source of data for weighting and item selection is derived from export declarations of U.S. shippers (as well as data from the Canadian Customs Service for exports to Canada) and the consumption entry documents of U.S. importers. IPP also produces services indexes covering air freight and air passenger fares.

The import and export price indexes are PFEIs used to deflate trade statistics, measure import and export price trends, and analyze terms of trade, exchange rates, and price elasticities that reflect changes in the volume of trade in response to changes in prices or income.

The special case of Puerto Rico

The price programs within the Office of Prices and Living Conditions (OPLC) have varying methodologies that dictate which drugs are considered in scope for the index. The PPI considers any pharmaceutical manufactured in the 50 United States, plus the District of Columbia, in scope for eligibility in the index. Note that this scope definition excludes pharmaceuticals manufactured in Puerto Rico or other American territories; additionally, the U.S. Economic Census, which PPI uses as a source for its weights, excludes Puerto Rico and other territories, and conducts a separate survey for those areas. Conversely, the Import and Export Price Indexes consider Puerto Rico to be an extension of the United States, so that goods going into and out of the island considered U.S. imports and exports. Essentially, IPP treats Puerto Rico as another state. This is in keeping with the Census Bureau's policy that "Puerto Rico is a Customs district within the U.S. Customs territory and its trade with foreign countries is included in the U.S. export and import statistics."⁶ Consequently, the price trends of pharmaceuticals manufactured in Puerto Rico and shipped to the United States are excluded from both the PPI and the Import Prices Indexes. The Consumer Price Index ignores the production location of drugs altogether and considers them eligible regardless of where they are manufactured.

The difference between the three programs' methodologies concerning Puerto Rico is important because of the significance of the pharmaceutical industry in the territory and in shipments to the United States. The pharmaceutical industry represents about 26 percent of the island's gross domestic product and 13 of the top 20 prescription medications sold in the United States are manufactured in Puerto Rico.⁷ In addition, according to the Census Bureau, shipments from Puerto Rico into the United States under Harmonized System Chapter 30 *Pharmaceutical products* were valued at approximately \$27 billion in 2009.⁸

Many pharmaceutical companies established manufacturing facilities in Puerto Rico because of historic tax advantages. Enacted in 1976, Section 936 of the U.S. Internal Revenue Code provided tax incentives to U.S. firms that established wholly owned manufacturing subsidiaries in U.S. possessions. This provision allowed for a tax credit against U.S. income taxes imposed on the income earned by the "Possession Corporation." The Section 936 tax credit was phased out over a period of 10 years, beginning in 1996. Since the phaseout of Section 936, Puerto Rico has struggled to maintain its position as a top manufacturer of pharmaceuticals, and the island's manufacturing sector has shrunk from 157,000 jobs to 90,400 jobs over the past decade.⁹ Many corporations left the island while others restructured as Controlled Foreign Corporations (CFCs) to obtain more favorable tax treatment from Puerto Rico.¹⁰ Several large

⁶ The U.S. Census Bureau. "Guide to Foreign Trade Statistics – Description of the Foreign Trade Statistical Program," <http://www.census.gov/foreign-trade/guide/sec2.html#possessions>.

⁷ Karl Schmider. "Will New Legislation Shatter The Pharma Industry's Tropical Dreams?," *Life Science Leader*, December 2010, http://www.lifescienceleader.com/index.php?option=com_jambozine&layout=article&view=page&aid=4152&Itemid=56&wwparam=1300114300.

⁸ The U.S. Department of Commerce, Economic and Statistics Administration Foreign Trade Division. "U.S. Trade with Puerto Rico and U.S. Possessions, 2009," <http://www.census.gov/prod/2010pubs/ft8952009annual.pdf>.

⁹ "Pfizer closures another blow to Puerto Rico economy," Reuters, May 18, 2010, <http://www.reuters.com/article/2010/05/18/pfizer-jobspuertorico-idUSN1816074320100518?wwparam=1300285125>.

¹⁰ The Internal Revenue Service. "IRS Directive, Tier I Issue – Industry Director Directive on Section 936 Exit Strategies #3," <http://www.irs.gov/businesses/article/0,,id=212139,00.html>.

pharmaceutical companies have closed plants in recent years in an attempt to find greater efficiencies, prompted by the changing tax structure and increased production costs (including the higher costs of electricity produced by oil-fired power plants).¹¹ These costs have also affected the growth of contract manufacturing and generic manufacturing. Unlike branded pharmaceuticals, Puerto Rico is not as competitive on cost for the production of cheaper generic pharmaceuticals, which are rapidly taking market share from branded pharmaceuticals. Branded pharmaceuticals are currently in the midst of a patent cliff as a number of blockbuster drugs are facing expiring patents and new competition from lower cost generics. In October of 2010, Puerto Rico's governor enacted a new law changing the way Puerto Rico will tax certain foreign corporations, possibly resulting in the imposition of new excise taxes on biopharmaceutical companies. The law drew complaints from both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO).¹²

Pharmaceutical structure and design

This section explains in more detail the structure and design of the pharmaceutical price series produced by the CPI, PPI, and IPP. This section also addresses common questions such as what items are included in the index and where are prices captured and what kinds of data are published?

CPI

The CPI for prescription drugs is part of the Medical Care major group. (There are 8 major groups in the CPI—food and beverages, housing, apparel, transportation, medical care, recreation, education and communication, and other goods and services.) The two main categories within the Medical Care (MC) major group are Medical Care Commodities (MCC) and Medical Care Services (MCS). MCS account for about 75 percent of the weight within MC, while MCC make up the remaining 25 percent of the weight in MC. Within the MCC component, the prescription drugs sample represents the bulk of its weight, roughly 75 percent of the total expenditure for MCC.

The CPI collects transaction prices received by the retail pharmacy. If a particular prescription observation is paid for by a third-party payer, then the total price used in index calculation will include both the patient's copayment as well as the insurance reimbursed portion. The three eligible types of payers are: 1) cash, 2) insurance, and 3) Medicare part D. Medicaid is not eligible because there are typically no insurance premiums required to obtain care as a Medicaid beneficiary.

Over-the-counter (OTC) drugs may appear in the CPI prescription drug index if they were prescribed by a doctor, dispensed by a selected pharmacy, and then selected for pricing at the time of initiation. Spending on prescription-dispensed OTC drugs is relatively small, and, consequently, the CPI sample for prescription drugs typically has few, if any, OTC products.

¹¹ Michael Melia. "Puerto Rico's Pharmaceutical Industry 'Terminally Ill'," *Manufacturing.NET*, November 19, 2007, <http://www.manufacturing.net/Pharmaceuticals-Leaving-Puerto-Rico.aspx>.

¹² *PhRMA Statement Regarding Puerto Rico Law 154* (Pharmaceutical Researchers and Manufacturers of America, October 25, 2010), <http://www.phrma.org/media/releases/phrma-statement-regarding-puerto-rico-law-154>; The Pharmaceutical Researchers and Manufactures of America. "BIO Opposes Puerto Rico's Newly Enacted Tax on Foreign Corporations," http://bio.org/news/pressreleases/newsitem.asp?id=2010_1027_01.

Prescription drugs that are administered in a hospital setting and billed by the hospital as a component part of a larger service will not be priced in the CPI prescription drug index. Such prices will instead be captured in the hospital index as part of a priced hospital service. (This is one area in which the PPI would pick up some drugs that the CPI would not, because the PPI ignores channel of distribution. Drugs that are used mostly in a hospital setting will be missing from the CPI sample.)

Internet- and catalog-based prescription drug channels of distribution to U.S. consumers are eligible to be priced in the CPI.

The CPI for prescription drugs is a U.S.-level aggregate index and is the only published index at the present time with no further breakdown or classification structure. The CPI, unlike the PPI, does not calculate or publish prescription drug indexes based on therapeutic classes. Various therapeutic classes are captured however, as the CPI sample consists of approximately 350–400 distinct molecules.

Prior to January 1999, all CPI price relatives used a modified Laspeyres index number formula. This is a ratio of a weighted arithmetic mean of prices in the current period to the same average of the same items' prices in the previous period, with estimated quantities of the items purchased in its sampling period serving as weights. In January 1999, the price relatives used for most of the item strata (including prescription drugs) converted to the geometric mean index formula, which is a weighted geometric mean of price ratios (an item's current price divided by its previous price) with weights equal to expenditures on the items in their sampling periods. More information on this can be found on page 4 of the following publication:
<http://www.bls.gov/opub/mlr/1998/10/art1full.pdf>.

The CPI calculates, but does not publish, brand and generic drug indexes as subcomponents of the prescription drug index. One reason these figures are not published is that there is some debate over how to include drugs that are going off patent protection. Presently, the CPI holds out these transitioning drugs in the calculations of brand and generic indexes, but these price changes are reflected in the overall prescription drug index.

PPI

The PPI commodity indexes for pharmaceuticals are categorized under the Chemicals and allied products commodity grouping (06). There are 15 major commodity groupings (01 through 15) in the PPI commodity series. Each major commodity grouping includes (in descending order of aggregation) subgroups (three-digit level), product classes (four-digit levels), subproduct classes (six-digit level), and individual items (eight-digit level). The PPI for pharmaceuticals is found in the Drugs and pharmaceuticals subgroup (063), in its own product class, Pharmaceutical preparations (0638). The index is further broken out at the 6-digit level to provide detail for eight major therapeutic categories found in the Pharmaceutical Preparations product class (for example, neoplasms, endocrine & metabolic disease—063801; central nervous system and sense organs—063802, etc.) There is also further detail beyond the six-digit commodity. Other product classes within the Drugs and Pharmaceuticals subgroup include medicinal and botanical chemicals (0631) and veterinary preparations (0634). Additionally, biologics and vaccines are classified within biological products (0637).

The PPI for pharmaceutical preparations is a national index, not broken out by geographic regions. The scope of the sample for pharmaceutical preparations lies within the 50 United States plus the District of Columbia; therefore products manufactured overseas (including Puerto Rico) are not eligible for sampling. This is an example of sampling difference with the

CPI and IPP. The PPI sample is open to all products classified as pharmaceutical preparations, regardless of distribution channel, and includes drugs for export. This includes drugs sold to and administered by health practitioners in hospitals, such as cancer therapy products, or other products not sold in the retail channel. Prescription drugs as well as OTC drugs are found in the sample.

In addition to the product class break out in the pharmaceuticals PPI by therapeutic category, the program offers a special aggregation for a look at prescription drug prices (SI07003) versus OTC drug prices (SI07006). Currently, the PPI does not publish indexes for brand name drugs compared with generic drugs. However, work is in progress to achieve this goal. For more information, see the “Supplemental sample design and methodology” section.

The desired type of price collected is a net transaction price, followed by the wholesale acquisition cost (WAC). Net transaction prices are preferred because they include discounts, surcharges, chargebacks/rebates, or adjustments to payment often employed by manufacturers. Average prices are discouraged for use in index calculation, as price fluctuations are often the result of volume fluctuations of the product and not representative of “pure price change” on the good. Medicaid and Medicare rebates are eligible to be used in establishing a price basis for a drug during the item collection phase of the sample. Types of buyers for these pharmaceutical quotes include wholesalers, distributors, hospitals, pharmacies, pharmacy benefit managers, and essentially any direct customer in business with the manufacturer.

The PPI uses a modified Laspeyres Price Index formula, which compares values of base period quantities at current period prices against values of base period quantities at base period prices. Weights for the PPI are derived from value of shipment measures collected by the Census Bureau through Economic Censuses, which are taken every 5 years and are representative of total value of domestic output in the economy. The reason the PPI is considered a modified Laspeyres Price Index (and not a pure Laspeyres Price Index) is that quantities are updated roughly every 5 years to account for changing market trends that can significantly affect pricing trends and the weight attributed to certain products and industries. The actual computation deviates slightly from the standard formula, with the final index ending up as the weighted average of item price relatives. The indexes are generally kept continuous amidst these updates through a “linking” procedure so that the program can provide pricing trends covering decades of economic activity. Please see Chapter 14 of the *BLS Handbook of Methods* for more information. (A link is provided in the “Conclusion” section of this document.)

IPP

The IPP produces commodity-based import and export price indexes based on the U.S. Harmonized Tariff Schedule (imports) and Schedule B manual (exports). The Pharmaceutical Products indexes (import P30 and export D30) are found under Section VI: Products of the Chemical or Allied Industries of the Harmonized Tariff Schedule/Schedule B manual.¹³ The import Pharmaceutical Products index contains two substrata: P3004—Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or packings for retail sale, and P30R—other pharmaceutical products, an unpublished residual index. The export Pharmaceutical Products index is comprised of three substrata: D3002—human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera

¹³ The U.S. International Trade Commission. “By Chapter, Harmonized Tariff Schedule of the U.S.,” <http://www.usitc.gov/tata/hts/bychapter/index.htm>; The U.S. Census Bureau. “Schedule B,” <http://www.census.gov/foreign-trade/schedule/b/>.

and other blood fractions and modified immunological products; vaccines, toxins, cultures of microorganisms (excluding yeasts) and similar products, D3004—medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or packings for retail sale, and D30RR—other pharmaceutical products, an unpublished residual index. Prescription pharmaceuticals are housed within the P3004 and D3004 Medicaments indexes; however, IPP does not have further breakouts for brand versus generic, prescription versus OTC, or by therapeutic class. The other pharmaceutical products indexes contain, among other things: glands and organs including their extracts; unmixed medicaments not in measured doses/packaged for retail sale; wadding, gauze, and bandages; blood grouping reagents; and dental cements.

The scope of the IPP pharmaceutical indexes covers all pharmaceutical products under Chapter 30 of the Harmonized Tariff Schedule and Schedule B manuals imported into and exported from the 50 United States as well as U.S. territories and possessions considered to be part of the U.S. under the Balance of Payments definition (for example, Puerto Rico, the Virgin Islands), U.S. customs bonded warehouses, and U.S. foreign trade zones.

The desired type of price collected for physical goods is the net transaction price between the importer and exporter at the border. Average prices are generally discouraged for use in index calculation due to the possibility of differing product characteristics, number of units traded, class of buyer or seller, discounts or region of transaction, and a number of other factors which may lead to values unrepresentative of a pure price change. IPP accepts prices associated with intracompany transfers—typically items that are traded between affiliates or entities of the same multinational company; however, IPP only accepts transfer prices that are market-based or market-influenced. IPP also accepts prices associated with production sharing, which occurs when two or more independent companies or various affiliated units of the same company located in different countries share the production responsibilities for a particular product.

The import and export price indexes are modified Laspeyres formulas and use two aggregation methodologies, item level and index level. At the lowest level, items are weighted within establishments (or detailed categories). These relatives are combined across establishments and then aggregated to lowest level stratum indexes. The weights used for the lowest level stratum indexes are based on data from several samples and are derived from the dollar values on the sampling frames. These dollar figures are divided by the corresponding probabilities of selection determined by the sample design. Each establishment/detailed category pair (collectively called the "weight group") is considered to be a relatively homogeneous collection of items. Therefore, each set of items selected within a weight group also represents nonselected items within the weight group.

At the next step, lowest level stratum indexes are aggregated to successive upper index levels. The quantity weights are based on trade value figures compiled by the Bureau of the Census for the base year. The weights are updated annually with a 2-year lag. For example, the 2011 indexes are based on trade weight values from 2009. This index formula is very similar to that used in the two other price programs in BLS.

Pharmaceutical sampling methodology

This section explores how companies and items are selected for pricing.

CPI

Outlet Sampling. The CPI outlet sample of retail pharmacies is drawn from a panel of outlets that were selected based on the results of the Telephone Point of Purchase Survey, whereby consumer units (in the areas in which the CPI is priced) report where and how much they spend on prescription drugs. The retail outlets where consumers report prescription drug expenditures are where the CPI records prices for index calculation, including stand-alone pharmacies, grocery/big box store pharmacies, and internet- and catalog-based pharmacies. Any given retail pharmacy outlet in the CPI sample is typically priced for approximately 4 years.

Item Sampling. The sample of prescription drugs is drawn based on revenue streams at selected retail pharmacies. More specifically, the sample is selected at the time of initiation from a panel of drugs that consists of the last 20 prescription drugs dispensed at the selected pharmacy. The probability of any drug's selection during this "disaggregation" process is proportional to that drug's revenue as a share of the total revenue generated by the last 20 drugs. The CPI employs this particular methodology for initiating prescription drugs because obtaining revenue information for the complete set of drugs dispensed at a retail pharmacy would be too time-consuming to the respondent and would unnecessarily jeopardize respondent cooperation. Typically, about five or six observations are selected for pricing at each retail pharmacy by CPI field representatives.

The CPI initiates new samples of outlets and drugs twice a year, thus constantly refreshing the prescription drug sample. Individual observations are priced for approximately 4 years before they are rotated out and new observations replace them. These item rotations occur concurrently when new outlets are selected to be priced.

PPI

Samples for the pharmaceuticals PPI are taken from both a products-based frame (for the majority of the prescription and over-the-counter drug market) as well as an establishment-based frame (representing the remainder of drugs for human use, as well as veterinary preparations). Prescription pharmaceuticals are sampled based on probability proportionate to size (dollar value). This is similar to the program's general index methodology that gives establishments (or products, depending on the type of frame) a chance of selection based on their market share. However, there is no predetermined quote target for the manufacturers that are sampled. Companies could be furnishing 3 quotes or 30 quotes, depending on their product portfolios.

Collecting producer prices forces the PPI to rely on the manufacturers themselves to provide timely price reports. Pricing forms for each item are sent to participating companies each month. The pricing forms are unique for each item in the index, and contain information identifying the item and price basis, including terms of transaction, adjustments to price, etc. For pharmaceutical items, a typical item description will include the drug's active ingredient and unique National Drug Code (NDC), as well as other identifying characteristics, such as whether it is a brand or generic product, its form and strength, the size of its container, and the type of buyer. The Industry Analyst within PPI monitors the returned forms and may make frequent contact with company respondents for data quality control.

A sample cycle generally lasts between 5 and 7 years for the pharmaceuticals index. A new sample cycle will refresh the entire sample of products, allowing entirely new products or new trends in the market to be incorporated into the sample. Considering the amount of effort expended, both on the part of the program and the reporting companies, it is generally not feasible to resample each industry in a shorter time frame. However, to address the continuous introduction of new products in the pharmaceutical industry, the PPI augments its sample annually. This supplemental sample is drawn from the FDA *Orange Book*, which lists all drugs approved for marketing in the United States. Through the supplemental sample, the PPI is able to obtain pricing data for new drugs, both branded and generic, in order to better represent the current U.S. pharmaceutical industry.

IPP

Samples for the IPP pharmaceutical import and export price indexes are taken from the universe of data provided by Census's Foreign Trade Division. The data are comprised of records of export transactions from the U.S. Census Bureau and import transactions from U.S. Customs and Border Protection. All pharmaceutical products imported or exported under Chapter 30 of the Harmonized Tariff Schedule of the United States/Schedule B manual¹⁴ are eligible for sampling. The IPP uses a multistage sample design to select specific import and export items that can be repriced over time. The first stage selects establishments independently within each broad product category (stratum). Establishments are eligible to be selected in more than one category. The second stage selects Sample Classification Groups (SCGs), which are based on the 10-digit Harmonized Tariff Schedule and Schedule B codes, within each establishment/stratum pair. This stage is designed to support all of the IPP classification systems. An establishment/stratum pair can be sampled multiple times, allowing for more quotes to be selected from SCGs with larger representations of the stratum value traded by the establishment. These first two stages are conducted at BLS headquarters using the sample frame. Subsequent stages of disaggregation are completed by Field Economists until a unique item is selected.

The IPP separates the import and export merchandise universes into two panels. Samples for one import panel and one export panel are fielded every year, resulting in a full sample cycle every 2 years. Each item sampled has a life cycle of approximately 5 years, and then they are replaced by a newly sampled item in its respective panel.

Both the IPP and PPI programs rely on respondents to provide timely price reports, as access to prices is not readily available for field economists. Respondents have the option of reporting prices via direct mail, fax, telephone, or the Web-repricing method. The production period allows roughly 2 weeks for the forms to be filled out and returned before the monthly indexes are calculated. The Industry Analysts within BLS monitor the returned forms in each program and may make frequent contact with company respondents and field collectors for data quality control. The size of samples and sampled companies for all BLS indexes are not disclosed to the public because of confidentiality safeguards needed for BLS to collect proprietary prices from volunteering companies.

¹⁴ The U.S. International Trade Commission. "By Chapter, Harmonized Tariff Schedule of the U.S.," <http://www.usitc.gov/tata/hts/bychapter/index.htm>; The U.S. Census Bureau. "Schedule B," <http://www.census.gov/foreign-trade/schedule/b/>.

Supplemental sample design and methodology

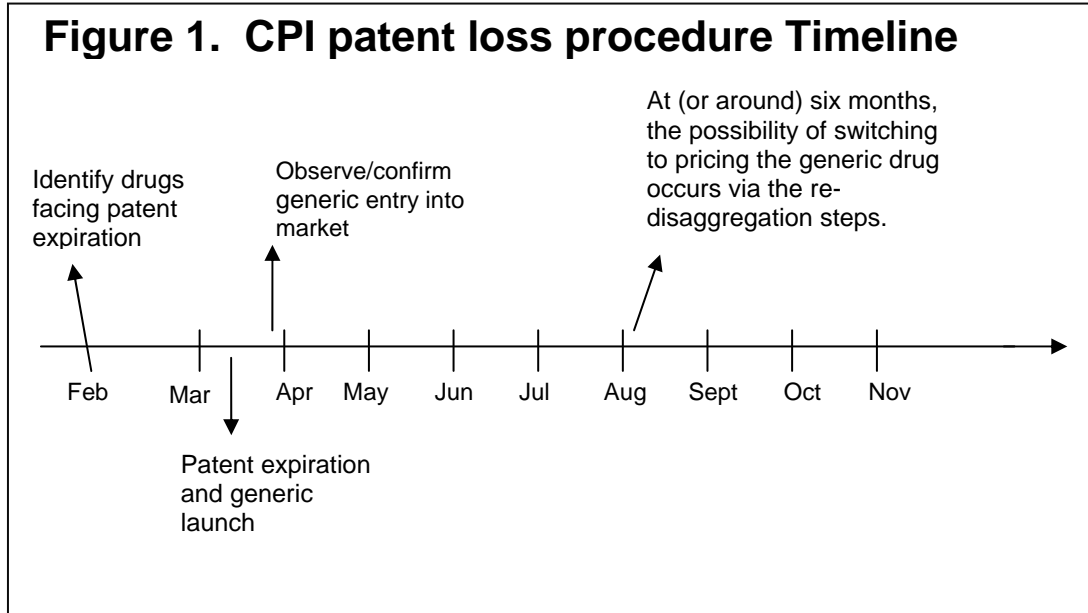
When a brand name drug goes off patent, consumers have the ability to switch to new generic drugs that offer deep price discounts. These generic companies (known as nonoriginators) subsequently capture a large portion of market share (in terms of number of prescriptions) away from the brand manufacturers (known as originators). Originators react in various ways to this phenomenon of dissipating revenues, including life cycle management strategies and follow-on products. The average price level for the drug (now brand and generic) is significantly lower, and both the CPI and PPI have developed methods to reflect the price decrease accompanying the transition of a single source to a multisource drug. The IPP does not currently augment its sample to account for patent expirations.

CPI

The CPI procedure for drugs going off patent protection involves a redisaggregation between the originally priced brand drug and the newly available generic equivalents on the basis of the number of prescriptions dispensed over a given time interval. Approximately 6 months after patent expiration of the priced drug and the introduction of generic penetration in the marketplace, the CPI data collector queries the respondent regarding the number of prescriptions for the two versions. The probability of selection is proportional to sales over the previous 3-month reference period. So, for example, if a drug goes off patent protection on March 1 and faces generic competition on this same date, then the CPI procedurally redisaggregates this active ingredient (between brand and generic) in September for the number of units dispensed from July to September (the last 3 months). The CPI allows a 6-month window for the generic drug to gain market share, though in the marketplace, the consumer shift to generics often occurs rather quickly. Six months after patent expiration, the *possibility* of switching to the generic occurs. That is, during redisaggregation, it is possible that the brand drug may once again get selected to price. However, because of this rapid change in market share, the patent loss procedure may occur before 6 months. It should be noted that although we target a period within 6 months for this redisaggregation step, the actual procedures may occur before or after, depending on respondent burden and cooperation.

The CPI employs a much simpler maneuver for prescription drugs which become available without a prescription while priced in the CPI sample—price the over-the-counter (OTC) price in the prescription sample and record any (adjusted) price changes between the previously prescription-priced drug and the now OTC-priced version. The OTC version will remain in the prescription drug sample until it rotates out. At the same time, this newly established OTC version is eligible to be initiated in the OTC samples.

Figure 1. CPI Patent Loss Procedure Timeline



PPI

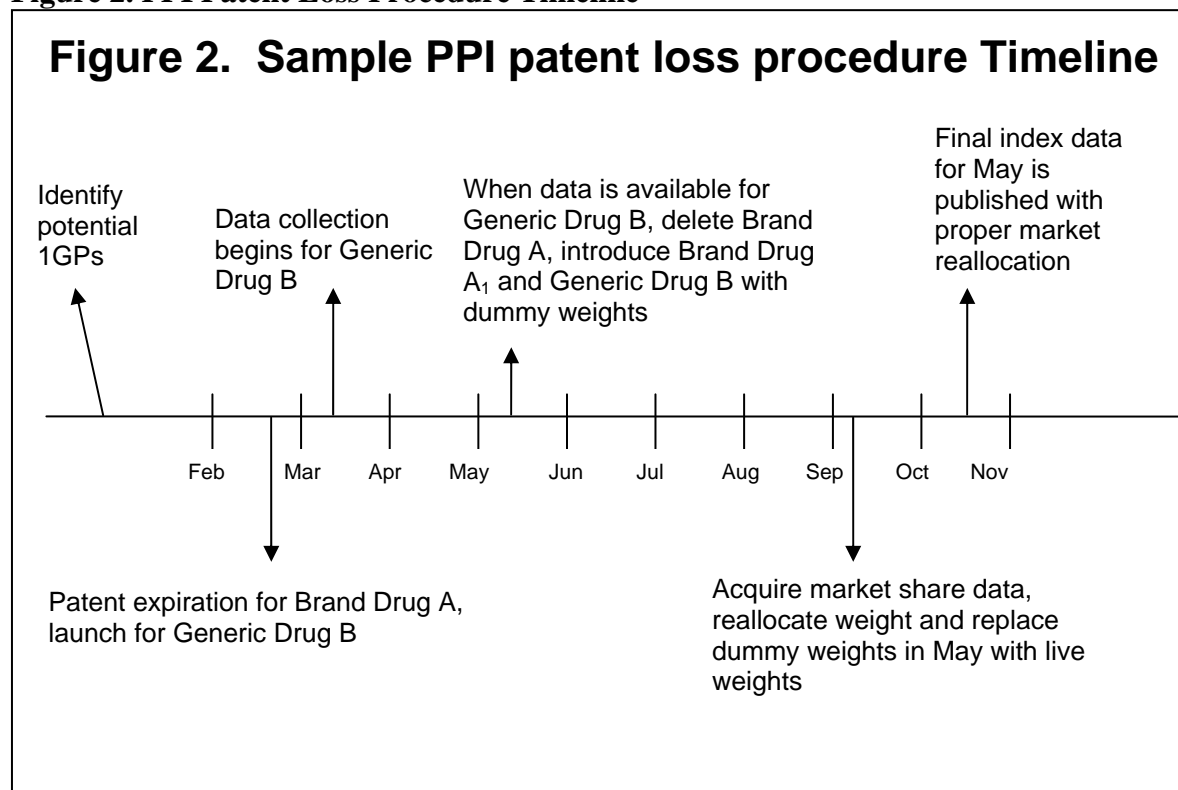
In the pharmaceuticals industry, a representative basket of products can change dramatically over the course of standard PPI sample intervals (roughly 5 to 7 years, as stated previously). To solve this problem, the program uses supplemental samples to augment the sample of drugs used in index calculation, including adding new products and making appropriate adjustments to brand name drugs going off patent protection.

Supplemental sampling for pharmaceuticals was introduced in the mid-1990s to help produce a better measure of new, in-scope pharmaceutical prices. The program conducts supplemental sampling on a yearly basis, giving every prescription drug receiving FDA approval a chance of selection and introduction into the index. Additionally, the program conducts rolling sampling for first generic drugs that have branded incumbents in the sample. This augmentation is performed through the introduction of the first generic product into the sample with a weight representative of that captured from the brand. The weight carried by the brand is reallocated, accomplishing a deflation of its own weight comparable to that of the drug's revenue stream as well as keeping the original weight constant (that is, the sum of the new brand weight and generic weight is equal to the old brand weight) in the products marketed off the active ingredient in question (both generic and brand forms of the drug).

For example, say Brand Drug A, included in the PPI, is expected to come off patent February 25. Its first-to-market therapeutic equivalent is represented in this example by Generic Drug B, referred to in the PPI as a "1GP" drug. Generic Drug B will be introduced into the sample as soon as data are collected for the drug, along with a "new" drug, Brand Drug A1. Brand Drug A1 is simply Brand Drug A, reweighted to reflect the postpatent market allocation. For the sake of this example, suppose data are collected for Brand Drug B in April, making the item eligible for inclusion in the May index. Beginning in May, both Generic Drug B and Brand Drug A1 are given temporary weights until accurate sales figures can be measured. Current PPI methodology allows 4 months to measure market reallocation after a drug goes off patent; PPI data are revised every 4 months, so when the weights are updated to reflect the reallocated

market value, they become retroactive for all months Brand Drug A1 and Generic Drug B are in the index. The following timeline shows the Generic Drug B introduction process:

Figure 2. PPI Patent Loss Procedure Timeline



International Price Program

The IPP program is not affected by the patent expiration issue. Imports and exports do not get broken down into a brand and generic level.

Indexes available to the public

Current CPI pharmaceuticals structure for SEMF—Prescription Drugs

Presently, the only published index available is the aggregate U.S.-level prescription drug index. The CPI program continues to explore the feasibility of publishing indexes for additional levels, such as by brand or generic and therapeutic class.

Current PPI pharmaceuticals commodity structure

The PPI publishes the following commodity structure:

Current PPI pharmaceuticals commodity structure	
0638	Pharmaceutical preparations
063801	Neoplasms, endocrine & metabolic disease
06380102	Cancer therapy products
06380103	Insulin/antidiabetes products
06380104	Other neoplasms, endocrine system, and metabolic diseases
06380105	Hormones and oral contraceptives
063802	Central nervous system and sense organs
06380202	Analgesics
06380202OC	Analgesics, over-the-counter
06380202RX	Analgesics, prescription
06380203	Psychotherapeutics
063802031	Antidepressants
063802032	Other psychotherapeutics, including tranquilizers
06380204	Anticonvulsants
06380205	Other central nervous system and sense organs
063803	Cardiovascular system
06380302	Anticoagulants
06380303	ACE Inhibitors
06380304	Calcium channel blockers and other vasodilators
06380305	Other cardiovascular preparations
063804	Respiratory system
06380402	Bronchial therapy
063804021	Antihistamines
063804022	Bronchodilators
06380403	Other respiratory preparations
06380403OC	Other respiratory preparations, over-the-counter
06380403RX	Other respiratory preparations, prescription
063805	Digestive and genito-urinary systems
06380502	Antispasmodic/antisecretory
06380503	Other digestive or genito-urinary preparations
06380503OC	Other digestive or genito-urinary preparations, over-the-counter
06380503RX	Other digestive or genito-urinary preparations, prescription
06380504	Antacids
063806	Skin preparations
06380602	Emollients and protectives, including burn remedies
06380603	Other pharmaceutical preparations acting on the skin
06380603OC	Other pharmaceutical preparations acting on the skin, over-the-counter
06380603RX	Other pharmaceutical preparations acting on the skin, prescription
06380604	Anti-acne preparations
06380604OC	Anti-acne preparations, over-the-counter
06380604RX	Anti-acne preparations, prescription

063807	Vitamins, nutrients & hematinic preps
06380702	Multivitamins
06380703	Other vitamins and nutrients
06380703OC	Other vitamins and nutrients, over-the-counter
06380703RX	Other vitamins and nutrients, prescription
06380704	Hospital solutions
063808	Parasitic and infective diseases
06380802	Broad and medium spectrum antibiotics
06380803	Systemic antivirals
06380804	Other parasitic and infective diseases

Current IPP pharmaceuticals commodity structure

Presently, the only Import and Export Price Indexes published for pharmaceutical products are:

30 Pharmaceutical products
3004 Medicaments

Additional pharmaceutical PPI industry data available

The PPI commodity index is made up of the same sample units and items used to calculate the industry index. The core structure of the industry-based pharmaceuticals PPI is based on the Census Bureau's North American Industry Classification System (NAICS). This PPI industry series carries the NAICS-based coding structure, whereas the PPI commodity series uses internally derived index codes.

The PPI industry structure includes veterinary pharmaceutical preparations (found in PPI 0634) and in-vivo diagnostics (classified in PPI 0637). The PPI industry structure uses weights representing both primary and nonprimary production for the industry. As a result, secondary products and miscellaneous receipts are included in the series and can affect price indexes at the six-digit industry level (325412). The six-digit subproduct classes found in the PPI commodity structure are derived from their seven-digit equivalents in the industry structure. Movements may be slightly different month to month because of distortions in the relative importance of the components in their respective structures.

As is shown in the structure, the industry series structure goes into detail within the product lines, breaking out therapeutic categories into detailed therapeutic classes (for example, within central nervous system preparations, one would find indexes on analgesics and psychotherapeutics). This extra detail is transferred over into the commodity index structure, effective January 2010.

Current PPI pharmaceuticals industry structure	
325412325412	Pharmaceutical preparation manufacturing
325412325412P	Pharmaceutical preparation manufacturing
3254123254121	Pharmaceuticals, affecting neoplasms, the endocrine system, and metabolic diseases
3254123254121111	Cancer therapy products
3254123254121112	Insulin/antidiabetes products

3254123254121113	Other neoplasms, endocrine system, and metabolic diseases
3254123254121114	Hormones and oral contraceptives
3254123254124	Pharmaceutical preparations, acting on the central nervous system and the sense organs
3254123254124111	Analgesics
3254123254124112	Psychotherapeutics
32541232541241121	Antidepressants
32541232541241123	Other psychotherapeutics, including tranquilizers
3254123254124113	Other central nervous system and sense organs
3254123254124114	Anticonvulsants
3254123254127	Pharmaceutical preparations, acting on the cardiovascular system
3254123254127111	Anticoagulants
3254123254127112	ACE Inhibitors
3254123254127113	Other cardiovascular preparations
3254123254127114	Calcium channel blockers and other vasodilators
325412325412A	Pharmaceutical preparations, acting on the respiratory system
325412325412A111	Bronchial therapy
325412325412A1111	Antihistamines
325412325412A1112	Bronchodilators
325412325412A112	Other respiratory preparations
325412325412D	Pharmaceutical preparations, acting on the digestive or the genito-urinary systems
325412325412D111	Antispasmodic/antisecretory
325412325412D112	Other digestive or genito-urinary preparations
325412325412D113	Antacids
325412325412G	Pharmaceutical preparations, acting on the skin
325412325412G211	Emollients and protectives, including burn remedies
325412325412G311	Other pharmaceutical preparations acting on the skin
325412325412G411	Anti-acne preparations
325412325412L	Pharmaceutical preparations, vitamin, nutrient, and hematinic preparations
325412325412L111	Multivitamins
325412325412L112	Other vitamins and nutrients
325412325412L113Y	Hospital solutions
325412325412Q	Pharmaceutical preparations, affecting parasitic and infective diseases (excluding diagnostics)
325412325412Q111	Broad and medium spectrum antibiotics
325412325412Q112	Systemic antivirals
325412325412Q113	Other parasitic and infective diseases
325412325412T	Pharmaceutical preparations, for veterinary use (excluding pet flea and tick products)
325412325412VY	In vivo diagnostic substances
325412325412SM	Secondary products and miscellaneous receipts

It is important to note that the pharmaceuticals PPI is not exclusively a measure of prescription drug prices. To isolate this important stratum (and to compare PPI statistics to other measures of prescription drug prices), the program provides the special aggregation structure below, which is drawn from the same sample used in calculation of both the industry and commodity indexes. To compare PPI and CPI prescription drug measures, the special index SI07003 should be used rather than the generally referenced pharmaceuticals PPI (0638).

SI07003 Pharmaceutical preparations, prescription
 SI07006 Pharmaceutical preparations, non prescription

Also of note is that the PPI produces an index that measures the cost of the service retail pharmacies provide in disseminating pharmaceuticals to customers. The PPI for retail pharmacies and drug stores (446110) shows the difference between the vendor price (the price a pharmacy pays for the drug) and the retail price (the price a pharmacy sells the drug); *it does not measure the out-of-pocket expense for prescription and over-the-counter drugs*. This price difference is also referred to as profit margin, margin price, or gross margin. All PPI retail trade industries use the margin price method of calculation. This index collects payments to the pharmacies from end-use customers, third-party insurance providers, and the government (through Medicare Part D, and previously through Medicaid). Therefore, this index provides insight into the service component of retail prescription drug cost.

The PPI Pharmacies and drug stores structure is as follows:

Current PPI pharmacies and drug stores industry structure	
446110446110	Pharmacies and drug stores
446110446110P	Primary services
4461104461101	Sales of prescription drugs
4461104461104	Sales of over-the-counter drugs and all other goods
44611044611041	Sales of over-the-counter drugs
44611044611042	Sales of all other goods

Additional pharmaceutical IPP data available

In addition to the product category indexes based on the Harmonized Classification System, the IPP also produces end-use indexes based on the Bureau of Economic Analysis System and industry indexes based on the North American Industry Classification System (NAICS). In the NAICS indexes (both imports and exports), items are classified by output industry, not input industry.

Bureau of Economic Analysis End-Use Indexes
 40100 Medicinal, dental and pharmaceutical preparatory materials
 NAICS Industry Indexes
 3254 Pharmaceuticals and medicines

Future direction of the pharmaceuticals industry

According to a recent survey of industry executives conducted by PricewaterhouseCoopers, the pharmaceutical industry will increase its international operations in the coming years. Brazil, Russia, India and China (the “BRIC nations”) continue to lead demand growth, with Mexico, Turkey, and South Korea also joining the ranks. Pharmaceutical executives expect to tailor their production operations to better serve these emerging markets. When asked for predictions specific to production, 76 percent of executives expected their overseas manufacturing presence to increase.¹⁵ Companies are expected to continue sourcing to countries in Asia Pacific, where there has been a strong tradition of pharmaceutical manufacturing, but will also look to less familiar locations, such as Eastern Europe and the Middle East.

Conclusion

This document was created to help BLS data users develop a better understanding of the similarities and contrasts between the three different price programs that track pharmaceutical price levels. Detailed explanations of how each program obtains and prepares its economic data can be found in the *BLS Handbook of Methods*. Please see the links below for additional information.

- *BLS Handbook of Methods*, Chapter 14. Producer prices: <http://www.bls.gov/opub/hom/homch14.htm>.
- *BLS Handbook of Methods*, Chapter 15. International price indexes: http://www.bls.gov/opub/hom/homch15_a.htm.
- *BLS Handbook of Methods*, Chapter 17. Consumer price index: <http://www.bls.gov/opub/hom/homch17.htm>.

Although the three programs track products at different stages of the value chain, there is potential for overlap of unique drugs in each of the three samples. Such instances of overlap provide avenues for further internal research and analysis on industry trends at various pricing points. It is also clear, however, that there are areas in which the three programs may not possess overlapping samples. For example, the CPI will pick up price changes for pharmaceuticals produced overseas, while the PPI pharmaceuticals indexes will not. This effect will, however, be captured in the PPI pharmacy services index. Conversely, the PPI pharmaceuticals indexes will pick up those types of prescription drug price changes that get recorded mostly in the hospital setting, while the CPI prescription drugs index will not. These changes will instead be captured in the CPI hospital services index.

As increased research efforts aim to disseminate analysis and insight into the industry, efforts are also being made to increase the qualitative aspects of the indexes produced by BLS. For the PPI pharmaceuticals index, opportunities include index breakouts for brand versus generic comparisons and potentially even single-source versus multisource brand name drugs. The PPI pharmacy services index is looking to expand coverage of prescription drugs and also provide breakouts for brand name drugs compared with generic drugs, and is also considering generic substitutions in the event of patent expirations on brand name products in the sample.

¹⁵ PwC Supply Chain report, 2010. (Requires free registration). <http://pwchealth.com/cgi-local/hregister.cgi?link=reg/achieving-global-supply-chain-visibility.pdf>.

The CPI program is exploring plans to release brand versus generic breakouts and is looking into the possibility of providing component indexes for the different therapeutic classes within prescription drugs. Additionally, the CPI program is continuing to study the issue of patent expiration and the transition phenomenon between brand name and generic drugs. Efforts are also aimed at studying new biopharmaceuticals (as well as follow-on biogenerics) and how they impact pricing trends throughout the industry.

Program staff work on these ongoing initiatives in an effort to increase public awareness of BLS and its products. By publicizing our data and processes to the business executives, government officials, academia and general public who use our data, we hope to enhance the quality of our existing products and open up the possibility of developing entirely new products

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