Improving the PPI sample for prescription pharmaceuticals

Frequent new product introductions make developing price indexes for this industry challenging; BLS updates its methodology to capture new products and make its sample more representative

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The prescription pharmaceutical industry, with its frequent product innovation and tightly regulated markets, poses unique challenges to the development of price indexes. This article describes the industry and the features that make it unique. It also discusses some of the problems confronting analysts as they develop price indexes for the industry, and the solutions implemented by the Producer Price Index (PPI) program of the Bureau of Labor Statistics to more accurately measure price change for prescription pharmaceuticals.[1]

About the industry

The pharmaceutical industry is characterized by frequent product innovation, with manufacturers continually developing and marketing new products. Some of these newly-developed products compete with existing products; others are completely new. The development of prescription pharmaceuticals requires costly and time-consuming research. After a product has been developed, it must undergo the rigorous approval process of the Food and Drug Administration (FDA). This process, which currently takes about 18 months, tests the product for safety as well as its efficacy in treating specific conditions.

To allow time to recoup the considerable investment costs associated with developing new products, manufacturers of FDA-approved new products are granted a period of patent/exclusivity protection. During this period, the company gaining approval has exclusive rights to the product's formulation. The new product competes against other products used to treat the same condition, but with different formulations and characteristics. When the protection period expires, other companies can gain approval to market "generic" versions of the product.[2]

Two new laws enacted since the early 1980s accelerate the approval process for new pharmaceutical products, both patented and generic. The Hatch–Waxman Act, passed in 1984, reduces the time between the patent expiration of a predecessor product and the approval of bioequivalent generic competitors.[3] The Prescription Drug User Fee Act, passed in 1992, significantly decreases the approval time for newly developed drugs. Both new drugs and generic versions of existing drugs now reach the market sooner and competition has increased within the therapeutic classes of drugs. Increased competition may help control inflation in the industry. Throughout the 1980s, prices for prescription pharmaceuticals increased much more rapidly than overall prices. Since 1992, however, inflation in the prescription pharmaceutical industry has slowed to less than one-half its 1980–92 average. (See chart 1.)

Price behavior and product age

Ongoing BLS research shows that prices of both new protected and generic drug products increase less rapidly (or even decline) in the 2 years following the products' introduction, than those of drugs on the market for more than 2 years. In one internal analysis, BLS researchers found that prices for drugs on the market for 2 or fewer years had decreased by 15.9 percent, while prices for the sample as a whole had increased by 3 percent. The same analysis also found that new protected products had a lower rate of inflation than

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the sample as a whole, while the rate for generic drugs declined.[4] (See table 1.)

In 1993, Ernst Brendt, Zvi Griliches and Joshua Rosset found similar results: less-than-average price increases in younger products, and higher-than-average price increases in medium-age products.[5] The authors tried to determine why the PPI for prescription pharmaceutical preparations grew faster than several pharmaceutical indexes they had constructed for the January 1984–December 1989 period, using a variety of methodologies. A key determination was that the PPI differed from their research indexes due partly to an underrepresentation of newly developed drugs in the PPI sample. The research was subsequently updated, using a larger database for the January 1987–December 1991 period. The findings were similar to those of the earlier study.[6]

Although it is unclear exactly why new drugs, both protected and generic, behave differently than older drugs, several causes are likely. New protected drugs must compete in established markets with drugs of the same therapeutic class. Short of significant product differentiation, price competition is a new entrant's most promising opportunity to gain market share. This provides the manufacturer with an incentive to minimize price increases in the first years following the new product's introduction. Conversely, older drugs supply established markets where demand is relatively price inelastic and thus less sensitive to price increases.

New generic drugs must compete with the predecessor product and other generic versions of the product solely based on price. Research shows that introduction prices for most generic products tend to be 30 percent to 50 percent lower than prices for predecessor products.[7] Following the introduction of a generic competitor, prices for predecessor products remain relatively unaffected because manufacturers of predecessor drugs generally do not enter into full-scale price competition with the generic versions.[8]

Price competition *among* generic versions of a drug is quite fierce. Research shows that each additional generic product entrant results in lower prices for all of the generic versions of that drug.[9] Therefore, because the majority of generic versions of a drug are introduced shortly after expiration of the predecessor's patent, most generic drug prices continually decline in the 2 years after introduction.

PPI sampling methods

The PPI measures average changes in selling prices received by domestic producers for their output. Traditional PPI methodology selects a first-stage sample of manufacturers from a

Chart 1. Annual percent change (December to December) in the producer price indexes for pharmaceutical preparations, prescription and finished goods, 1981–96

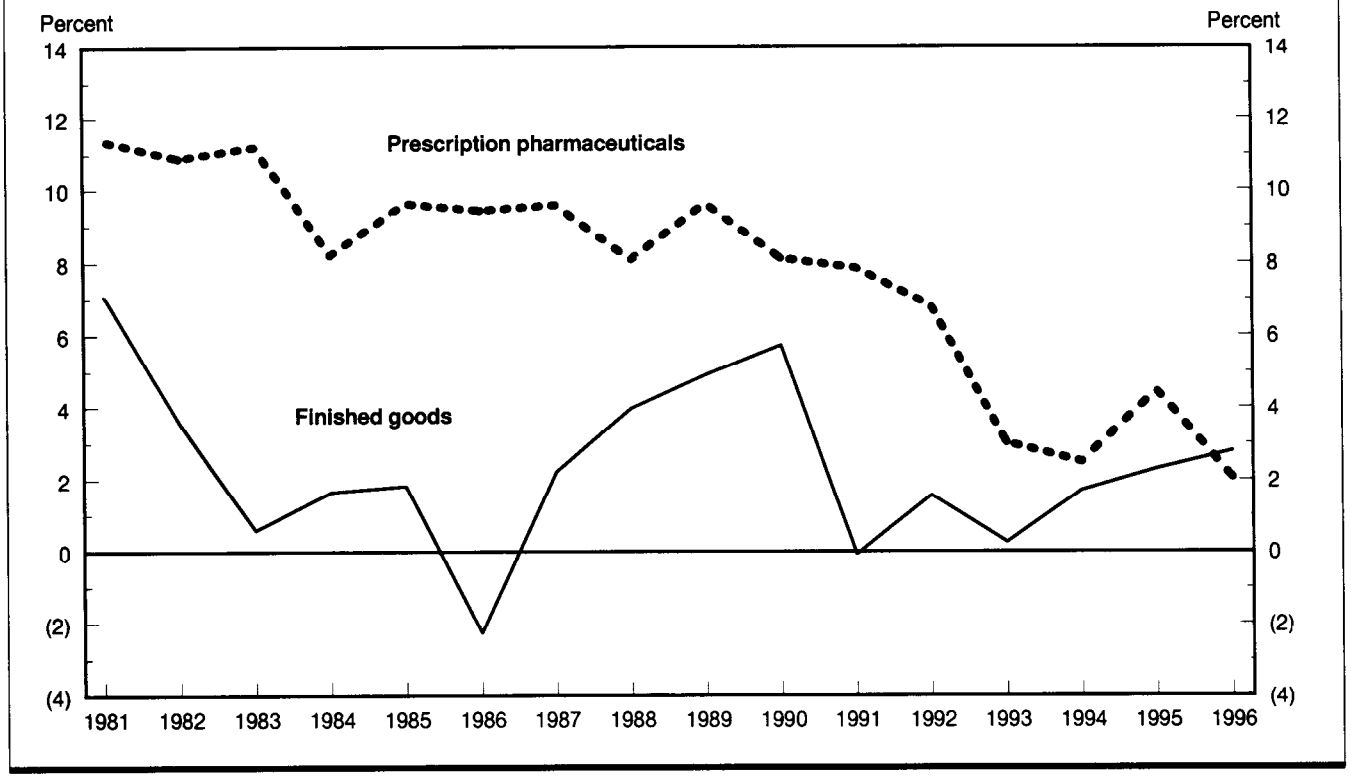


Table 1. **Percent change in the producer price index for prescription pharmaceuticals by product age class, 1993–96**

Product age class (in years)	December 1993 to December 1994	December 1995 to December 1996
≤2	−15.9	0.7
>2 to ≤4	1.3	−3.1
>4 to ≤6	4.1	4.7
>6 to ≤9	2.6	1.5
>9 to ≤24	6.7	3.4
>24	3.8	4.4
Total	3.0	2.9

NOTE: This table represents the price change of items by age class based on their importance to the PPI. Items were weighted by item weight and the weight their therapeutic class carries within the PPI for prescription pharmaceuticals.

database of all domestic manufacturers based on the Unemployment Insurance System.[10] Then, a second stage of sampling is conducted to select individual products and transaction data. A new sample for each industry included in the PPI is selected, on average, every 7 years. Within this framework, PPI methods for selecting a representative sample of prescription pharmaceuticals have continually evolved. Thus far, three complete samplings (Cycles A, B, and C) of the industry have taken place since 1981, when it was first included in the PPI. The main characteristics of each sample design are described below.

Cycle A (July 1981). At the first stage of sampling, 150 manufacturers were drawn from the universe of producers, with probability of selection proportional to employment. Producers were asked for an average of four price quotes, with a maximum of eight. For each sampled manufacturer, products were selected with probability proportional to value of shipments at the time of collection.

Cycle B (January 1987). To improve the statistical quality of the detailed price indexes published, while also reducing the number of manufacturers sampled, the previous methodology was modified. At the first stage, 82 manufacturers were selected from the universe of producers. The average number of price quotes per manufacturer was increased to 8, with a maximum of 16. The second stage of sampling used a special procedure that forced the selection of 1 quote from each therapeutic class in which the sampled company produced. A specific product within each class was then selected using normal procedures, based on probability proportional to current value of shipments.

Cycle C (January 1994). Cycle C represented a departure from traditional PPI sampling methodology. Instead of a company-based sample, a product-based sample was selected. Products were selected proportionate to size within therapeutic class, rather than proportionate to size within a manufacturer's product line. As a result, the chance of a product being selected depended only on its share of sales relative to other drugs of its class, rather than on its proportion of the manufacturer's sales. Thus, the Cycle C sample was more representative at the therapeutic class level. It also gave newer products, with a relatively lower value of shipments, a greater chance of selection. The product sample was obtained from a third-party database of prescription pharmaceutical sales at retail pharmacies in 1992. The database included the manufacturer, the products' form and strength, and the costs to the pharmacies for the drugs sold. The database covered 77 million prescriptions from 30,000 pharmacies.

The sampling universe was stratified into 34 separate therapeutic classes. Products were selected from each stratum in two stages, with probability of selection proportionate to dollar sales. In the first stage of sample selection, the product was selected. In the second stage of sampling, the specific dosage form and strength were selected. No restrictions were placed on the number of quotes per company. Specific product presentation and transaction variables were selected at the establishment in a third stage, with probability of selection again proportional to dollar value. The final sample consisted of 965 items from 124 manufacturers. Because the number of quotes per manufacturer was not restricted, many companies were asked to supply the PPI with more than 20 quotes, and some were asked for more than 30. BLS was able to obtain cooperation in repricing 511 items.

PPI standard sampling procedures call for selecting a new sample of products every 7 years, on average. Prices for selected products are then followed for the life of a sample. Naturally, these products age over the life of a sample, resulting in an age distribution shift. There was a significant shift in the age distribution of the Cycle C sample between 1993, when it was selected, and January 1994, when it was first used in the PPI. (See table 2.)

While the PPI sample for prescription pharmaceuticals is naturally aging, new products also are constantly being introduced in the market. Table 3 shows the number of new FDA-approved drugs brought to market each year since 1986. New drugs, both new generics and those whose active ingredients are available for the first time (new chemical entities), are being introduced at a rapid pace. The FDA reports that more new drugs were approved in 1996 than in any previous year.

For various reasons, the rapid rate of new product introduction in the prescription pharmaceuticals industry should continue in the near future. The growth of managed care, for example, has accelerated the use of drug therapy as a less

costly alternative to inpatient therapies, which in turn helps promote the development of new drugs. Managed-care organizations also encourage the use of generic versions of drugs, and, as a result, generic market penetration has grown considerably and is projected to continue. The share of the U.S. prescription drug market held by generic drugs more than doubled over the 1984–96 period, rising from 18.6 percent in 1984 to 41.6 percent in 1996.[11] Over the next 5 years, new medications generating more than $15 billion in annual sales will lose their patent protection, with generic versions of these drugs likely being introduced.[12] All of these factors should continue to put downward pressure on the average age of drugs in the marketplace.

Although each succeeding redesign of the PPI sample for prescription pharmaceuticals made it more representative of the industry, program resource constraints and the need to minimize respondent burden prevent BLS from shortening the resampling interval to fewer than 6.5 years. As mentioned earlier, with constant introduction of new products such a resampling interval ensures continual erosion in sample representation with respect to new drugs.

Regardless of the cause of the differences in drug age-group price movements, it appears that a drug's price behavior varies significantly over its life cycle. Between samplings, failure to include new drugs—which have been shown to have different price movement than older drugs—could lead to upward bias in the PPI. To compensate for this aging, in January 1996, BLS introduced an initial supplemental sample (Supplement I) of new items to the PPI prescription pharmaceuticals sample.[13] All new chemical entity drugs, generic versions of existing drugs in the PPI sample, and new versions of existing drugs produced by the same manufacturer (line extensions) that were approved by the FDA between December 1992 and April 1995 were eligible for the Supplement I sample.

The raw sampling frame contained 885 products, consisting of 284 unique active ingredients in multiple forms and strengths, and produced by 157 companies. The data were refined as follows:

- Companies that refused to cooperate in Sample C were eliminated from the sample under the assumption that they probably would refuse again.
- Products known to be produced in Puerto Rico or elsewhere outside the United States are considered out-of-scope and were excluded from the sample.
- The remaining products were assigned to one of three general classes: new chemical entities, generics, and line extensions. The generic group was further split into two subgroups: first generics (products available generically for the first time) and bandwagon generics (products already available generically). The line-extension group was further stratified by the nature of the change: new dosage form (such as tablet or injection), new strength, or new formulation (mix of ingredients). Some active ingredients fell into both the generic and line extension classes: the company with the original approval received approval to market a new form/strength/formulation, and during the same period, another company received approval to market a generic version.

Table 2. Weighted distribution[1] of the PPI sample for prescription pharmaceuticals by product age class, 1993–97

Product age class[2] (in years)	Year						
	1993[3]	1994	1995	1996[4] (without supplement I)	1996	1997[5] (without supplement II)	1997
≤2	8.7	4.4	0.1	0.0	7.2	2.4	5.8
>2 to ≤4	11.0	7.1	8.7	4.4	6.3	7.1	6.9
>4 to ≤6	15.6	14.2	11.0	7.1	6.4	7.8	7.5
>6 to ≤9	19.1	20.0	20.0	23.7	21.6	15.5	14.9
>9 to ≤24	40.7	49.3	55.2	59.4	53.8	62.1	60.0
>24	5.0	5.0	5.1	5.3	4.8	5.1	4.9

[1] Weights were calculated to represent the item's weight within the PPI for prescription pharmaceuticals. Age weight = collected item weight * ((therapeutic class of PPI for prescription pharmaceuticals in the sampling period) + (therapeutic class of PPI for prescription pharmaceuticals in the current period)) / 2. Age weights were then summed by age class and for the industry. The figures in table 2 represent the percent the age class' age weights are of the industry's age weights.

[2] Number of years product had been on the market in January of the indicated year.

[3] These data represent the age of the Cycle C sample when it was drawn. Cycle C was not introduced until January 1994. The data used in the PPI prior to January 1994 were from Cycle B and no age data have been calculated for that sample.

[4] These data represent the age of the Cycle C sample without Supplement I. The data used in the PPI from January 1996 forward include Cycle C and Supplement I.

[5] These data represent the age of the Cycle C sample with Supplement I, but not Supplement II. The data used in the PPI from January 1997 forward include Cycle C and Supplements I and II.

After the refinement steps described above, the frame included 566 products, comprising 192 unique active ingredients from 106 manufacturers. Although there were only 192 unique active ingredients, the final sampling universe consisted of 204 products. Some active ingredients fell into both the generic and line extension classes, and were given a chance of selection in each class. A sample of 99 items was selected. The first stage sample was selected as follows:

- All new chemical entities were certainty-selected;
- All first generics were certainty-selected;
- A simple random sample of all remaining new products was selected.

In the second stage, the specific manufacturer (if there was more than one for the sampled active ingredient) was randomly selected. All the remaining product detail not implicit in the above (strength, presentation, and transaction variables) was sampled during the interview with the respondent.

The final sample consisted of 99 items produced by 57 companies. Forty companies overlapped with Cycle C, and the remaining 17 were new to the PPI. BLS economists obtained company cooperation in repricing 49 additional products, bringing the total number of observations in the PPI prescription pharmaceuticals sample to 544.[14] Collected Supplement I items fell into 21 of the 50 detailed price indexes for prescription pharmaceuticals. (See exhibit 1.) The therapeutic class with the largest number of Supplement I items was miscellaneous pharmaceutical preparations, followed by antihypertensive drugs, systemic antihistamines, and ophthalmic and otic preparations. No other therapeutic class had more than two items added from Supplement I. The average age of the items included in Supplement I when they were introduced in January 1996 was 22 months, and the range of ages was 9 months to 37 months.

Following normal PPI methodology, weights for Supplement I items were derived from revenue figures provided by the manufacturer during the selection interview, with two exceptions: first generics for which the brand-name version was already included in the index, and line extensions for which the earlier version was already included in the index. For line extensions in which the route of administration remained the same as in the earlier version, it was assumed that, at least in the short run, the overall size of the market for that formulation does not change with the introduction of another version. Therefore, the item weight for the original version in the Cycle C sample was re-apportioned between the original and new versions based on sales data provided by the respondent.

First generics were handled similarly. The current item weight for the branded version was reapportioned between the branded and generic versions. The rationale is that, at least in the short-run, availability of generics will not lead to an increase in the number of prescriptions written for that drug, but instead will lead to a reallocation of sales dollars between the branded and generic versions. All first generics introduced in Supplement I were apportioned 64.2 percent of the predecessor branded product's item weight.[15]

Table 3. Number of new drugs approved by the FDA, 1986–96

Year	Number	Year	Number
1986	20	1992	26
1987	21	1993	25
1988	20	1994	22
1989	23	1995	28
1990	23	1996	53
1991	30		

SOURCE: U.S. Food and Drug Administration.

Supplement I items fell into two classes: those new drugs with predecessors in the existing sample and those without. New drugs without predecessors, including new chemical entities, were introduced using standard PPI sample rotation methodology. No price comparisons were made between items in the existing and supplemental sample.

New drugs with predecessors include line extensions featuring unchanged routes of administration. These drugs were introduced by splitting the predecessor drug into two items. One comparison was made between the December and January prices of the predecessor, with its item weight reset to reflect the proportion of sales retained by the predecessor. A second comparison was made between the December price of the predecessor and January price of the successor line extension product, with its item weight corresponding to the sales captured by the latter. If production cost information for the predecessor and successor drugs had been provided by the manufacturers, BLS analysts would have adjusted the comparison to account for any production cost differences. In practice, the comparison was made showing the full price change between the predecessor and successor drugs.

New drugs with predecessors also include the first generics group. These drugs were introduced into the PPI in a manner similar to that for line extensions, except that the predecessor brand-name drug price and successor generic drug price were always directly compared without adjusting for qualitative changes. The direct comparison captures any difference between the predecessor's price and the successor generic drug's price for the portion of the market captured by the successor generic drug. The direct comparison is predicated on the assumption that the two products are of equal quality, given that the FDA has determined them to be bioequivalent[16]

Impact of Supplement I

The impact of Supplement I on the product age distribution of the PPI sample for prescription pharmaceuticals is shown in table 2. With the inclusion of Supplement I items, the younger age classes had greater representation in the PPI than when Cycle C was introduced in January 1994. The published index for prescription pharmaceuticals from January 1996 forward includes the Supplement I items. The index for prescription pharmaceutical products rose 2.1 percent during 1996. If Supplement I had not been introduced, the index would have risen 2.7 percent. Chart 2 and table 4 compare the PPI for prescription pharmaceuticals with an unpublished research index for the same industry. (The research index excludes 211 Supplemental items.)

Approximately half of the cumulative impact of Supplement I on the published PPI occurred when it was introduced in January 1996.[17] In that month, the direct price comparisons were made between branded items in the Cycle C sample and generic versions in Supplement I. The Supplement I items continued to put downward pressure on the published PPI throughout the calendar year, as evidenced by the widening disparity in the index levels. (See table 4.) Items in Supplement I registered a lower rate of inflation than older items already in the sample: simple average prices for Supplement I items decreased 1.5 percent in 1996, while prices for Cycle C items increased 2.7 percent over the same period. It should be noted, however, that the price differential between the research and published indexes has varied. In 3 of the 14 months since the introduction of the supplements, price changes in the published index exceeded those of the research index.

Current price trends for the various age categories differ from those in the 1994 study, largely due to the average age of the drugs in Supplement I. Because Supplement I included nearly 3 years of product introductions, the average age of drugs in the sample was 22 months when the sample was introduced. Supplement I included four generic drugs, with three falling in the 2- to 4-year age category when introduced, and two of these showing significant price declines. (The branded-to-generic price comparison was made when the drug was in that age class.)

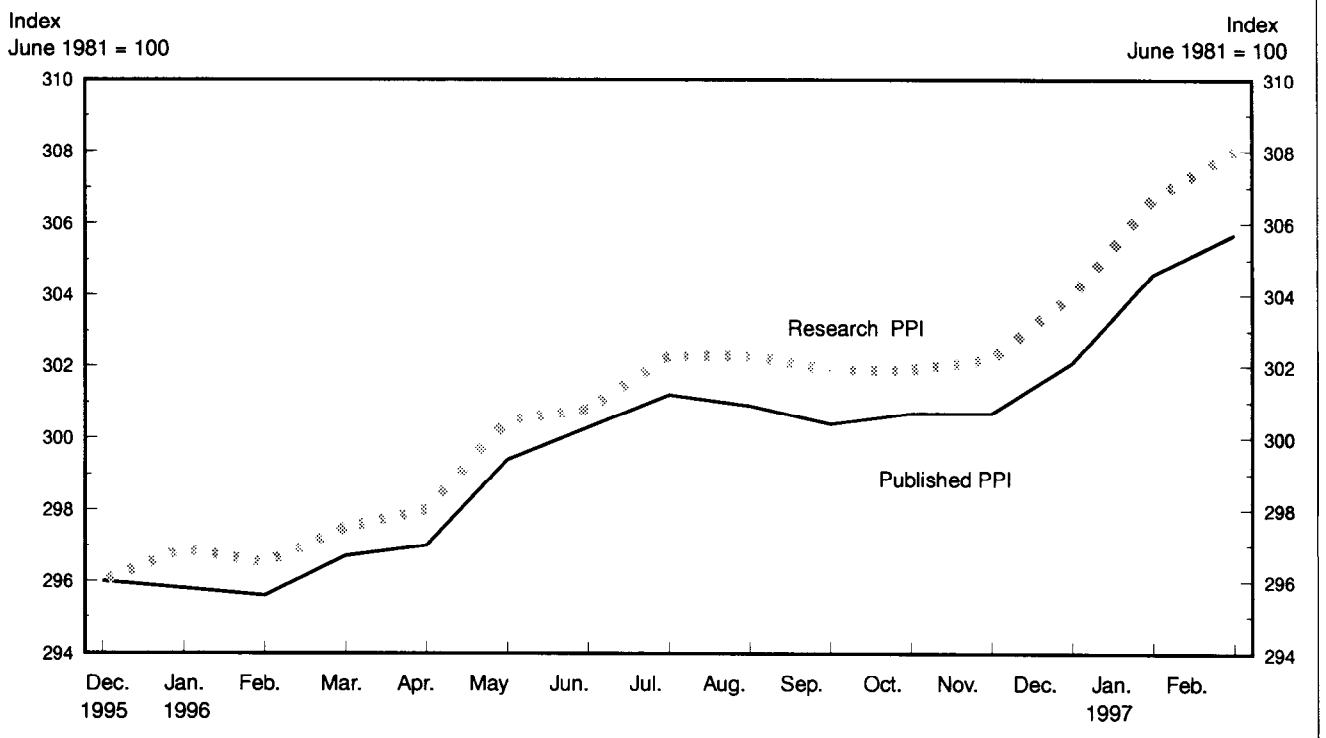
Supplement II

Because newer and older drugs have different price movements and product introductions are accelerating, BLS now supplements the PPI prescription pharmaceuticals sample annually. The second supplement was introduced in January 1997 (Supplement II). Eligible products included all those approved by the FDA between May 1995 and May 1996. There were 507 products in the raw sampling frame, consisting of

Exhibit 1. Detailed producer price indexes for pharmaceutical preparations, prescription

Product code	Product
2834-	Pharmaceutical preparations,prescription
102	Analgesics
1021	Narcotic analgesics
1022	Non-narcotic analgesics
1023	Synthetic, including acetaminophen and anti-migraine
10229	Aspirin, APC and related
104	Antacids
105	Antiarthritics
106	Anticoagulants
107	Anticonvulsants
109	Systemic antihistamines
111	Systemic anti-infectives
1111	Broad and medium spectrum antibiotics
11111	Cephalosporins
11112	Broad spectrum penicillins
11113	Erythromycins
11114	Tetracyclines
11119	Other broad and medium spectrum antibiotics
11129	Systemic penicillins
11139	Urinary antibacterials
11199	Other systemic anti-infectives
116	Antispasmodic/antisecretory
118	Bronchial therapy
119	Cancer therapy products
121	Cardiovascular therapy
12119	Antihypertensive drugs
12129	Vasodilators
12191	Other cardiovasculars
123	CNS stimulants/antiobesity preparations
124	Contraceptives (excl. devices, kits, implants, etc)
125	Cough and cold preparations
12511	Oral cold preparations
12512	Nasal decongestants
12513	Decongestant/antihistamine combinations
12519	Other cough and cold preparations
126	Dermatological preparations
12611	Acne preparations
12619	Fungicides
12631	Topical anti-infectives
12641	Antipruritics
12691	Other dermatological preparations
127	Diabetes therapy
128	Diuretics
135	Hormones
136	Hospital solutions
139	Muscle relaxants
141	Nutrients and supplements
142	Ophthalmic and otic preparations
144	Psychotherapeutics
1441	Tranquilizers
14411	Major tranquilizers
14412	Minor tranquilizers
1442	Antidepressants
145	Sedatives
147	Tuberculosis therapy
148	Vitamins
14819	Adult multivitamins
14829	B-complex
14839	Other vitamins
198	Miscellaneous prescription pharmaceutical preparations

Chart 2. Published producer price index and unpublished research index (excluding supplements) for pharmaceutical preparations, prescription, December 1995–February 1997



194 unique active ingredients in multiple forms and strengths, produced by 132 companies.[18]

Supplement II data were refined as in the first supplement. After refinement, the sampling frame included 139 products, comprising 87 unique active ingredients from 57 manufacturers. First-stage sampling proceeded as in Supplement I. The second stage of sampling, however, differed from Supplement I in that all generic versions of a sampled drug were selected.

The final sample consisted of 46 items—29 new chemical entities, 7 first generics, and 10 line extensions. The items were produced by 30 companies, with 24 being current PPI reporters; the other six were new to the PPI. BLS obtained company cooperation for 17 items, bringing the total number of observations in the prescription pharmaceutical sample to 561. The therapeutic class with the largest number of Supplement II items was miscellaneous pharmaceutical preparations, followed by cancer therapy drugs. No other therapeutic class had more than two items added from Supplement II.

Items in Supplement II were added to the existing sample in a manner similar to that used in Supplement I, with one significant exception. The weight of predecessor-branded drugs reallocated to the generics was based on the actual percentage of

Table 4. Index levels and percent change over the month for published PPI and unpublished research PPI for prescription pharmaceuticals, December 1995–February 1997

Year and month	Published producer price index		Unpublished research producer price index	
	Index level	Percent change	Index level	Percent change
1995: December	296.0	....	296.0	....
1996: January	295.8	–0.068	296.9	0.304
February	295.6	–.068	296.5	–.135
March	296.7	.372	297.5	.337
April	297.0	.101	298.0	.168
May	299.4	.808	300.5	.839
June	300.3	.301	300.8	.100
July	301.2	.300	302.3	.500
August	300.9	–.100	302.3	.000
September	300.4	–.166	301.9	–.133
October	300.7	.100	301.9	.000
Noveber	300.7	.000	302.2	.100
December	302.1	.466	304.0	.597
1997: January	304.6	.828	306.7	.890
February	305.7	.361	308.0	.425

dollar value sales captured by the generic versions. BLS purchased data from IMS America to calculate these reallocations. The data represent dollar sales to retail pharmacies and hospitals—an estimated 89 percent of the total market. The data are for March 1997, and represent the most current data available when the weight re-allocations were made. Price comparisons for Supplement II were done in the same way as in Supplement I.

The impact of Supplement II on the age distribution of prescription pharmaceuticals priced for the PPI is shown table 2. As with Supplement I, the younger age classes had greater representation in the PPI than they did prior to the introduction of Supplement II. Since the inclusion of Supplement II items in January 1997, the published index has continued to show smaller price increases than in the unsupplemented research index. The simple average price change in January 1997 for drugs in Supplement II was a 4.5-percent decline. The published index increased 0.8 percent. In the 14 months since January 1996, the published index has risen 3.3 percent. Had Supplements I and II not been introduced, the index would have risen 4.1 percent.

BOTH THE FIRST AND SECOND SUPPLEMENTS had predictable effects on the PPI for prescription pharmaceuticals, given prior research by BLS researchers and others. The unpublished research index will continue to be calculated to track the cumulative impact of this methodological change on price measures for the industry. BLS plans to introduce additional supplements in January 1998 and January 1999. A completely new sample will be introduced in the year 2000. □

Footnotes

[1] For more information on the Producer Price Index, including background and methodology, see "Producer Prices," *BLS Handbook of Methods*, Bulletin 2490 (Bureau of Labor Statistics, 1997), pp. 130–43.

[2] Generic drugs are new versions of existing (predecessor) drugs that use the same active ingredient and are rated as bioequivalent to the predecessor drug by the FDA. The FDA's bioequivalence criteria requires that the absorption rate and peak concentration in the bloodstream of the generic drug does not vary significantly from the predecessor drug.

[3] The act is titled Drug Price Competition and Patent Term Restoration Act of 1984.

[4] A variety of internal research is conducted by PPI analysts on a continual basis.

[5] Ernst Berndt, Zvi Griliches and Joshua Rossett, "Auditing the Producer Price Index: Micro Evidence from Prescription Pharmaceutical Preparations," *Journal of Business and Economic Statistics*, July 1993.

[6] Ernst Berndt and Paul Greenberg, "An Updated and Extended Study of the Price Growth of Prescription Pharmaceutical Preparations," in Robert B. Helms, ed., *Competitive Strategies in the Pharmaceutical Industry* (Washington, The AEI Press, 1995), pp. 35–48.

[7] Zvi Griliches and Iain M. Cockburn, "Generics and the Producer Price Index for Pharmaceuticals," in Helms, ed., *Competitive Strategies*.

[8] Richard Caves, Michael Whinston and Mark Hurwitz, in "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers: Microeconomics* (Washington, 1991), showed that branded drug producers sacrifice significant market shares to low-priced generic substitutes, but the reductions are fairly small given the price differentials. They presented an example with five generic competitors showing a generic/branded price ratio of 0.456, but the branded drug's market share falling only to 0.748.

[9] Caves and others also showed that entry of additional generic producers depressed the price of existing generic products much more severely than the price of the branded drug. They showed ratios of generic to branded drug prices of 0.558 with 1 generic on the market, 0.496 with 3 generics on the market, 0.294 with 10 generics on the market and 0.171 with 20 generics on the market.

[10] For more information on these programs, see the following in the *BLS Handbook of Methods*, Bulletin 2490 (Bureau of Labor Statistics, 1997): "Producer Prices," pp. 130–43; and "Employment and Wages Covered by Unemployment Insurance," pp. 42–47.

[11] Represents share of countable units, such as tablets. Pharmaceutical Research and Manufacturers of America (PhRMA), *1997 Industry Profile* (Washington, March 1997).

[12] Standard and Poor's, *Industry Surveys, Healthcare: Pharmaceuticals May 29, 1997* (New York, McGraw-Hill, 1997).

[13] The initial impact of Supplement I and future supplements is seen in May of the year of introduction, when final January indexes are published. Due to the PPI calculation methodology and its N–4 month revision period, the weight changes of the predecessor drugs discussed below are not seen until the final indexes are published. For more information on the supplements, see Douglas Kanoza, "Age Distribution and Price Movements of Drugs in the 1994 PPI Prescription Drug Sample," *Producer Price Indexes*, May 1995; and Douglas Kanoza, "Supplemental Sampling in the PPI Pharmaceuticals Index' *Producer Price Indexes*, January 1996. The data source for Supplement I items covering the December 1992–April 1995 period was Food and Drug Administration, Center for Drug Evaluation and Research, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 15th ed. and Cumulative Supplements (For sale by the Superintendent of Documents).

[14] This number is lower than would be expected from previously provided information due to attrition of Cycle C items. Attrition can be due to a manufacturer's discontinuation of an item or refusal to continue to provide price data.

[15] This percentage was based on an estimate of maximum generic penetration. Data released by Pharmaceutical Research and Manufacturers of America (PhRMA) showed a 57.2-percent to 42.8-percent ratio of prescriptions filled by branded and generic drugs, respectively. The percentage assigned to brand-filled prescriptions was reduced by an estimate of the single source brand drugs—that is, prescriptions filled by branded drugs because only branded drugs are on the market. The ratio of single source to multiple source active ingredients from *Approved Drug Products with Therapeutic Equivalence Evaluations* was used for this purpose. Ernst Berndt, Iain Cockburn, and Zvi Griliches, in "Pharmaceutical Innovations and Market Dynamics: Tracking Effects on Price Indexes for Antidepressant Drugs," *Brookings Papers: Microeconomics* (Washington, 1996), found the estimate to be realistic based on their research of one therapeutic class of drugs.

[16] The Food and Drug Administration, in *Approved Drug Products with Therapeutic Equivalence Evaluations*, 15th ed. (For sale by the Superintendent of Documents, 1995), states: "A major premise underlying the 1984 law is that bioequivalent products are therapeutically equivalent and, therefore, interchangeable."

[17] As mentioned previously, Supplement I includes drugs approved by the FDA between December 1992 and April 1995, and its initial impact was not seen until the final January indexes were published in May.

[18] The data source for Supplement II was Food and Drug Administration, *Approved Drug Products with Therapeutic Equivalence Evaluations*, 16th ed. and Cumulative Supplements.