

GAO

Report to the Chairman, Special
Committee on Aging, U.S. Senate

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PRESCRIPTION DRUG PRICES

Official Index Overstates Producer Price Inflation



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**Health, Education, and
Human Services Division**

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April 28, 1995

The Honorable William S. Cohen
Chairman, Special Committee on Aging
United States Senate

Dear Mr. Chairman:

During the 1980s and 1990s, the prices of prescription drugs rose on average at triple the rate of economywide inflation, according to federal government statistics. As the Congress debated whether to curb drug price increases, however, research questioning the accuracy of the price statistics—especially the producer price index for prescription drugs (PPI-Drugs) published by the Bureau of Labor Statistics (BLS)—was in its early stages. Today, a body of research has accumulated that emphasizes the need to examine the accuracy of PPI-Drugs.

As you requested, this report (1) reviews the accuracy of PPI-Drugs as a measure of drug price inflation, (2) describes whether PPI-Drugs could be changed to provide a more accurate measure of changes in the cost of purchasing drugs, and (3) provides guidance on appropriate uses and common misuses of price indexes.

To address these objectives, we reviewed BLS policies, methodology, and procedures. We also reviewed the research literature that discusses the disagreements over the computation of PPI-Drugs. We discussed BLS procedures and the relevant research with BLS officials, industry representatives, and academic researchers who study BLS price indexes.

Results in Brief

Recent research indicates that PPI-Drugs, the official wholesale level index of U.S. drug prices, has overstated drug price increases substantially since at least 1984. This overstatement has three causes. First, before 1994 BLS used a market basket (sample) of drugs that underrepresented new and recently introduced drugs in the market. This sampling problem alone led PPI-Drugs to overstate drug inflation between 1984 and 1991 by an estimated 23 to 36 percent. Second, the index does not account for the cost savings incurred when consumers switch to lower priced substitutes, such as generics. (Probably to a lesser extent, the index also understates drug inflation by its similar treatment of cost increases incurred when consumers switch to higher priced drugs.) Third, PPI-Drugs does not adequately separate pure price changes, which constitute inflation, from

price changes that reflect different product characteristics, such as fewer side effects.

Some progress has been made in addressing the causes of the overstatement. First, BLS recently revised its methodology for sampling drugs. The revisions are expected to reduce but not eliminate future overstatement of drug price inflation. Specifically, to improve the representativeness of its PPI-Drugs, BLS initiated (in January 1994) more frequent and comprehensive sampling of prescription drugs. Concerning the second cause of the overstatement of PPI-Drugs—switching to substitute drugs—BLS has not acted because it disagrees with researchers' proposed criteria for identifying substitutes for brand-name drugs. A compromise might be to create an additional index. It is unclear, however, whether an additional index consistent with the researchers' criteria would be worthwhile, given the expense of BLS' acquiring needed data. Concerning the third cause of overstatement of PPI-Drugs, BLS and researchers agree that the methods for adjusting drug price changes for different product characteristics are not yet refined enough to be implemented.

Regardless of the outcome of the PPI-Drugs debate, users should be aware of four potential misuses of all price indexes. First, because price indexes measure price changes rather than price levels, they can be used to determine whether prices rise rapidly, but not whether they are excessive. Second, comparing price indexes for wholesale and retail markets generally does not help determine which market level is more competitive. Third, price indexes cannot be used to determine whether introductory prices of new drugs are higher now than in the past. Finally, price indexes like PPI-Drugs measure prices of products in a specific industry only and do not incorporate the prices of potential alternative products that may have similar uses but are classified as belonging to another industry.

Background

BLS, a branch of the Department of Labor, regularly produces statistics that measure the health and performance of the U.S. economy. The frequently cited consumer price index (CPI) and producer price index (PPI) measure economywide inflation in retail and wholesale markets. These two broad measures of inflation incorporate thousands of narrower indexes that measure price changes in various industries. For example, the BLS producer price index for prescription drugs—PPI-Drugs—measures the rate of price change in the prescription drug industry.¹ PPI-Drugs in effect summarizes separate indexes for drugs in 43 different therapeutic

¹The standard industrial classification (SIC) code for this industry is 28341.

categories and subcategories, such as antiarthritics and cardiovascular drugs.² In public policy debates, PPI-Drugs is frequently used to evaluate the reasonableness of the drug industry's pricing decisions.

As currently constructed, PPI-Drugs tracks price changes for a sample of products, known as a market basket. The index tracks these price changes for a period of time, known as a cycle, which, before 1994, was typically between 5 and 7 years. Beginning in 1994, BLS reduced the cycle to 4 years with an intermediate update scheduled for every 2 years. During a cycle, the products in the market basket and the weights (market shares) of each product in the market basket remain largely unchanged. However, within any cycle, BLS frequently makes minor modifications to the sample. The modifications occur when a company no longer manufactures or ships a product and is then asked to provide a replacement product for the index. In addition, in cases in which a manufacturer of brand-name drugs also has introduced an equivalent generic drug, BLS redistributes the sample weight between the brand-name and generic drug. In general, an index such as PPI-Drugs is relatively simple and inexpensive to construct, but, because of its fixed-weight design, its most appropriate use is generally for industries with little product innovation over time.

From 1980 through 1992, PPI-Drugs rose about 9.4 percent per year on average, while the economywide rate of inflation averaged 4.3 percent annually at the retail level and 2.8 percent annually at the producer level. Compared to their 1980-1992 history, drug prices recently have been rising much more slowly, although still faster than prices in the economy as a whole. PPI-Drugs rose 4.5 percent from 1992 to 1993 and 2.5 percent from 1993 to 1994—both big declines in the rate of drug price inflation—but still faster than the overall rate of producer inflation of 1.2 and 0.6 percent during the same years.³ That is, the producer price inflation for drugs during the past 2 years outpaced the economywide producer price inflation by 2 to 3 percentage points per year.

²BLS also constructs a consumer price index for prescription drugs (CPI-Drugs). This index is constructed from information about consumers' direct purchases, such as retail purchases of prescription drugs. It does not account for indirect purchases of drugs through hospitals or managed care pharmacies. As a result, CPI-Drugs is limited as a comprehensive measure of the effect of price increases on consumers. However, in recent years CPI-Drugs and PPI-Drugs have tended to track each other closely.

³Researchers have not identified whether PPI-Drugs overstates actual drug price inflation by a fixed amount or whether the overstatement depends on the inflation rate. As the inflation rate changes, this distinction becomes important. For example, if PPI-Drugs overstated inflation by 3 percentage points annually, then as PPI-Drugs fell from, for example, 9 to 3 percent, actual inflation would fall from 6 to 0 percent. Alternatively, using the same example, if PPI-Drugs overstated inflation by 50 percent, then a decrease in the growth of PPI-Drugs from 9 to 3 percent would imply that actual inflation would fall from 6 to 2 percent.

Four factors may have contributed to the recent moderation of drug price inflation. First, the overall rate of producer inflation slowed during the same period, which put less pressure on drug companies to raise their prices. Second, purchasers increased their bargaining power against drug manufacturers through the growth of managed care, greater use of drug formularies, and other industry developments. Third, some drug companies restrained price increases voluntarily to reduce the public and political pressure to impose controls on drug price increases. Fourth, in January 1994, BLS changed its methodology in ways intended to reduce PPI-Drugs' overstatement of drug price inflation.

We conducted our work from October 1994 through February 1995 in accordance with generally accepted government auditing standards.

Methodological Weaknesses of PPI-Drugs Lead to Overstatement of Drug Price Inflation

Rapid introduction of new drugs during the past decade has helped expose several weaknesses of PPI-Drugs. This pace of change in drugs has made it difficult for BLS to obtain a sample that represents the marketplace. Moreover, rapid innovation highlights index weaknesses in both product substitution and quality changes. These weaknesses in sampling, substitution, and quality changes affect the accuracy of PPI-Drugs. After examining these weaknesses, researchers have recently concluded that PPI-Drugs has overstated drug inflation in recent years.

Rapid Innovation in Drug Products Means PPI-Drugs Is Not Properly Representative

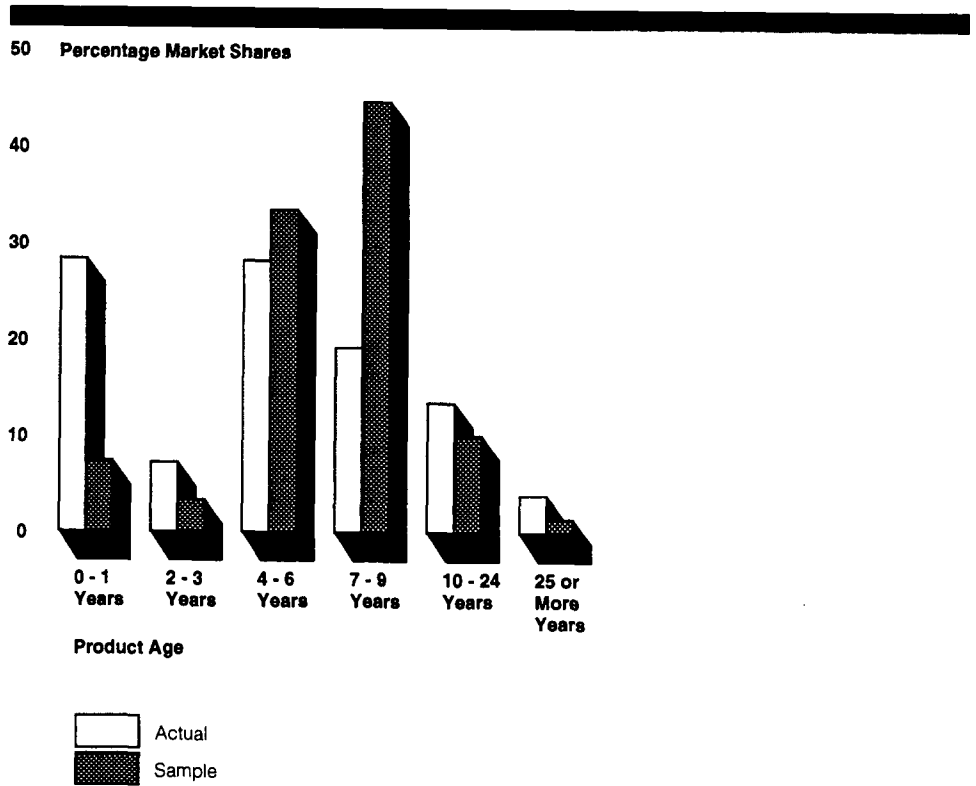
For at least a decade before 1994, the market basket of drugs used to construct PPI-Drugs did not represent accurately the actual proportions of new, old, and "middle-age" drugs, which caused the index to overstate drug price inflation.⁴ Research data show that, before 1994, the BLS market basket included too many middle-aged drug products (drugs on the market between 4 and 9 years) compared to the proportion of such drugs in the marketplace. By the same token, the BLS sample used to contain too few new drugs, and too few old drugs, as well. In effect, pharmaceutical innovation outpaced the ability of BLS sampling updates to keep PPI-Drugs properly representative of the prescription drug marketplace.

The details of the differences between the BLS sample and the full range of drugs in the marketplace appear in figure 1. In 1989, new drugs—those less than 2 years old—generated 28 percent of prescription drug revenues in the actual market, while similarly aged drugs in the BLS sample accounted

⁴Ernst R. Berndt, Zvi Griliches, and Joshua G. Rosett, "Auditing the Producer Price Index: Micro Evidence From Prescription Pharmaceutical Preparations," *Journal of Business and Economic Statistics*, 11 (1993), pp. 251-264.

for only 7 percent of revenues. By contrast, drugs that had been on the market for 7 to 9 years comprised only 19 percent of the full market but 45 percent of the revenues for the BLS sample.

Figure 1: Actual and Sample Percentage Market Shares for 1989



Source: Based on data from "Auditing The Producer Price Index: Micro Evidence From Prescription Pharmaceutical Preparations" by Ernst R. Berndt, Zvi Griliches, and Joshua G. Rosett in the *Journal of Business and Economic Statistics* (1993), pp. 251-264.

The disparity between the combination of older and newer drugs in the index's market basket and that of the market matters because prices rise faster during some phases of a product's life cycle than others. The prices of brand-name drugs in the middle of their product life cycle inflate more quickly than the prices of drugs at either end of the product life cycle. This pattern, combined with the overrepresentation of 4- to 10-year-old drugs in the PPI-Drugs market basket, caused the index to overstate drug price

increases. One study examined data on 2,090 products, accounting for 24 percent of industry sales from 1984 to 1989 and found that PPI-Drugs overstated average annual price growth by 36 percent.⁵ A subsequent study, which examined data on 6,150 products, accounting for 80 percent of industry sales, found that from 1987 to 1991 PPI-Drugs overstated average annual drug price growth by 23 percent.⁶ Whether this smaller estimate of overstatement results from the larger sample, the more recent data (1990 and 1991), or some other factor is not known.

PPI-Drugs Does Not Treat New Drugs as Substitutes for Existing Drugs

Sampling aside, researchers have suggested a second reason for PPI-Drugs' overstatement of drug inflation: the index does not account for the potential cost savings to consumers who substitute a new product for an existing one, usually a brand-name drug for a less expensive generic. BLS disagrees with this critique for two reasons: (1) by design, PPI-Drugs measures the change in prices charged by manufacturers, not the change in consumers' well-being, and (2) differences in quality between brand-name products and generics justify their current treatment in the index.⁷ We find, however, that treating new drugs as potential substitutes for existing drugs should be incorporated in measuring the change in prices received by drug manufacturers.

Two Views of Switching to Generics

Researchers argue that PPI-Drugs would be more useful if it accounted for the cost savings that result when consumers switch to generic drugs. Under current BLS procedures, a generic drug introduced into the market in one year, for example, 1994, would not be included in the PPI-Drugs market basket until it is next updated—as much as 4 years later. By contrast, these cost savings could be recognized immediately, according to one study, by including in the index the price of the generic drug when it becomes available.⁸ Under the researchers' proposal, the generic drug would be partially substituted in the index for the brand-name drug. The higher the percentage of consumers switching to the generic, the greater the importance of the generic in the revised index. By including the lower priced generic product, a revised PPI-Drugs would be reduced, compared to the current index that only captures the brand-name price.

⁵Berndt, Griliches, and Rosett, pp. 251-264.

⁶Ernst R. Berndt and Paul E. Greenberg, "Price Growth of Prescription Pharmaceutical Preparations: An Update and Extension," American Enterprise Institute conference paper (Oct. 1993).

⁷Product quality refers to characteristics or attributes rather than effectiveness. For example, a new drug with fewer side effects is considered to be a higher quality drug even though it may or may not be more effective as defined by the Food and Drug Administration (FDA).

⁸In this case, we assume that the price of the brand-name drug is already included in the index.

BLS' reasoning for its current practice—treating generics and other new products as distinct products, not substitutes—centers on two arguments. First, by design PPI-Drugs measures manufacturers' prices, not consumers' well-being. BLS relies on a theoretical argument that the design of producer level price indexes should be guided by the process by which a product is manufactured, not by the product characteristics that the consumer values.⁹ As a result, when brand-name and generic drugs are manufactured by different companies, BLS argues that the different production processes justify their treatment in the index as different products.¹⁰ Second, according to BLS, the price of brand-name drugs should not be directly compared to generic drugs, in any event, because of potential differences in quality. A generic drug, for example, amoxicillin, may be a less than perfect substitute for the brand-name drug, Amoxil.¹¹ To deal with this possibility, BLS would have to adjust drug prices to reflect quality differences between brand-name and generic drugs before comparing them. To date, the information needed to perform this adjustment has not been available. However, BLS is currently examining alternative methods for making quality adjustments so that brand-name and generic drug prices can be directly compared.

Although choosing between the researchers' and BLS' views is a matter of judgment, not of logic, we find the researchers' view more compelling. A price index can measure manufacturers' prices while recognizing that, in the marketplace, consumers treat two products as close substitutes. To do otherwise means that two identical products (for example, two ears of corn or two aspirin tablets) must be treated as distinct products simply because their production processes somehow differ. How users of price indexes gain better information when this production process rule is followed is hard to discern.

Evidence on Savings From Switching to Generics

While estimates of the cost savings derived from switching to generics are not comprehensive, results from a study of two generic products—cephalexin and cephadrine—and their brand-name counterparts suggest

⁹Robert B. Archibald, "On the Theory of Industrial Price Measurement: Output Price Indexes," *Annals of Economic and Social Measurement*, 6 (1977), pp. 57-72.

¹⁰BLS treats brand-name and corresponding generic drugs as equivalent (and averaging their prices in calculating the index) but only in those cases in which both are produced by the same manufacturer.

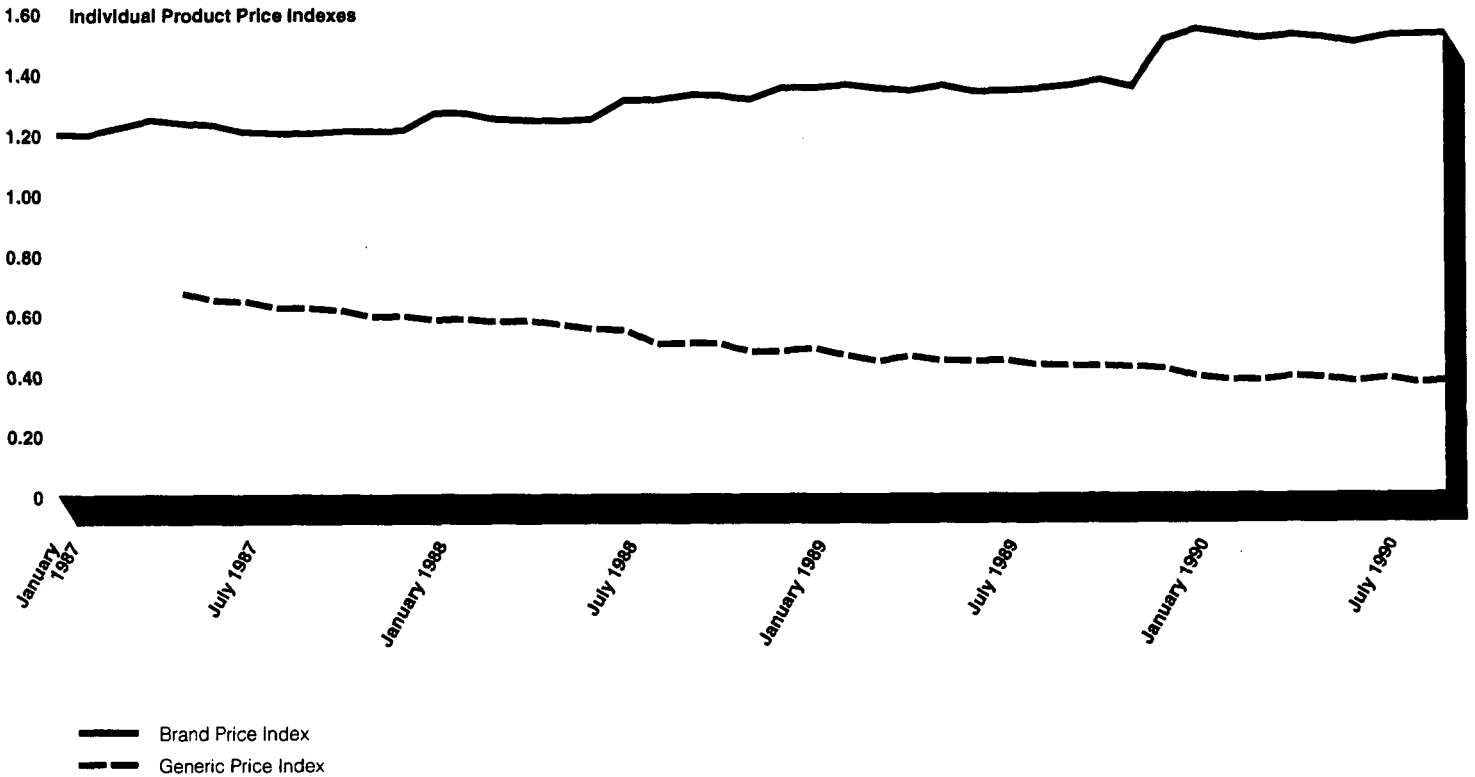
¹¹As evidence that they are not perfect substitutes, BLS points out that brand-name drugs typically retain significant market share after the introduction of the much lower priced generic alternatives. Therefore, BLS contends that quality difference must exist between the two products that supports the existence of a higher priced brand-name product. Alternatively, some analysts argue that brand-name and generic versions of the same product should be treated as perfect substitutes because the FDA certifies them to be therapeutically equivalent.

that the overstatement could be substantial. When the generic and brand-name drugs were treated as distinct products (the BLS approach), price increases from the brand-name product, in one case, increased the index, and, in the other, held it constant. However, when the products were treated as potential substitutes, the index fell by 53 and 30 percent for the two individual products during the 3 years after introduction of the corresponding generic drug.¹²

Examining the pattern of the prices of brand-name and generic cephalexin over time helps to understand the source of overstatement. (See fig. 2.) The brand-name version of cephalexin exhibits generally rising prices. After the patent for cephalexin expired, generic alternatives became available at lower and generally falling prices. As a measure of average drug price changes, PPI-Drugs captured only the rising price of the brand-name product but omitted the impact on average prices of (1) the lower prices of generic alternatives, compared to the brand-name cephalexin, and (2) the increasing importance of generics as consumers switched to them.

¹²Zvi Griliches and Iain Cockburn, "Generics and New Goods in Pharmaceutical Price Indexes," *American Economic Review*, 84 (1994), pp. 1213-1232.

Figure 2: Comparison of Brand and Generic Prices for Cephalexin



Note: Generic drugs were introduced in 1987 after the patent for Keflex expired.

Source: Table 1, "Generics and New Goods" by Zvi Griliches and Iain Cockburn as published in the 1994 *American Economic Review*, p. 1216.

Although these results on only two drugs are not statistically generalizable to the entire industry, no obvious reason exists to consider the results atypical.¹³ Furthermore, any overstatement of drug price inflation due to inappropriate treatment of generics in the index could be increasing. The market share of generic drugs, which has grown markedly, is expected to keep growing. From 1984 to 1993, the generic segment of the prescription drug market nearly doubled, increasing from 19 to 37 percent of all prescriptions written, according to the Pharmaceutical Research and

¹³Additional research is forthcoming that is expected to help determine whether the patterns exhibited by these two drugs are observed regularly.

Treatment of New Brand-Name Versions

Manufacturers of America.¹⁴ The impending movement of more than 200 drugs off patents during the 1990s will likely increase the market share of generics further.¹⁵ Reinforcing this growth will be the efforts of managed care plans to control drug costs by encouraging the use of generics.

Although researchers have focused on whether generic drugs should be included as substitutes in PPI-Drugs—which would tend to lower the price index—researchers have also debated whether to include newer versions of the brand-name drug, or therapeutically similar products, as substitutes—which would likely increase the price index. As a hypothetical example, the manufacturer of a drug whose patent is about to expire may introduce a more expensive time-release version of the same drug that is taken once a day rather than twice a day. Drug manufacturers often introduce new products, known as “line extensions,” that have similar therapeutic effects on patients as existing drugs. (Line extensions are often considered to represent only minor improvements in therapeutic value or quality.)

Like generic drugs, line extensions often substitute for brand-name drugs and, in PPI-Drugs, are treated as new products.¹⁶ Unlike generic drugs, which often are introduced at a price below that of the equivalent brand-name drug, line extensions are often introduced at a substantially higher price even if their therapeutic advantages are minor. As a result, in the case of line extensions, PPI-Drugs would understate inflation. After adjusting for any increases in product quality, the index would ignore the cost-increasing effect of consumers’ switching to the more expensive line extension product.¹⁷ Unfortunately, the extent to which PPI-Drugs understates drug price increases due to the treatment of line extension drugs has not been estimated. Some researchers believe, however, that any understating

¹⁴This activity is, in part, a consequence of the Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417, also known as the Waxman-Hatch Act, which made gaining FDA approval for generic drugs easier.

¹⁵The U.S. Market for Generic Drugs, Vol. II, Frost and Sullivan, Inc., 1991, cited in “The Changing Environment for U.S. Pharmaceuticals,” The Boston Consulting Group, April 1993, p. 15.

¹⁶BLS treats line extension products like other new products whenever a company continues to manufacture and ship the original product. In other cases in which the original product is discontinued and BLS can identify a successor product, the successor product replaces the original product in the index after BLS attempts to adjust its price for quality changes between the original product and the line extension.

¹⁷Even though line extensions often provide some additional therapeutic value, the overall effect of line extensions may be inflationary. New drugs qualify for new patents and may be marketed aggressively to patients and doctors who do not always bear all of the additional cost of the new therapy. Because the doctors and patients who make the decisions do not face the full impact of their decisions, they may tend to favor more expensive, state-of-the-art drugs even when the benefits may not justify the increased cost of the new drug. Any price increases associated with the new drug that exceeded those associated with improvements in quality would be inflationary.

effect of line extensions on the index is smaller than the overstating effect of generic substitutes.

PPI-Drugs Does Not Adequately Adjust for New Product Quality

Price index accuracy requires that price changes be adjusted for changes in product quality. New drug products typically differ in quality (for example, side effects or dosage frequency) from drugs or therapies that they might replace or compete with. Similarly, the perceived quality of an established drug can change as all of its benefits or side effects become known. As physicians and patients respond to new information by adjusting their prescribing and purchasing, prices are likely to change as well. However, price changes that reflect quality changes do not constitute inflation (or deflation), and measures of drug price inflation should exclude them. While the current methodology for PPI-Drugs allows for quality adjustments to prices, the state-of-the-art—and hence the current BLS approach—is not sufficiently refined to avoid understating drug price adjustments required by quality improvements. Consequently, the current approach cannot fully eliminate the overstatement of drug price inflation from this source.

Research on adjusting drug prices for quality changes is relatively new and ongoing, but it suggests that the current treatment of quality changes in PPI-Drugs may cause drug inflation to be overstated. One study that examined ulcer drugs for the 1978-1989 period suggests that a constant quality price index would show only about half of the price inflation of the official index that was measured without quality adjustment.¹⁸ The bulk of quality adjustments occurred in the most recent years of the sample, 1985 to 1989. However, that failure to adjust for quality could result in a price index's understating, rather than overstating, price inflation for some products. Understating would occur if average quality were to deteriorate rather than improve. Nonetheless, as the results of this study suggest, for drugs that retain or gain market share, most quality changes will be considered improvements. Consequently, failure to adjust for quality changes is perhaps more likely to result in the index's overstating inflation.

¹⁸Valerie Y. Suslow, "Are There Better Ways to Spell Relief? A Hedonic Pricing Analysis of Ulcer Drugs," American Enterprise Institute conference paper (Oct. 1993), p. 36.

A Revised Index Could Better Measure Drug Price Changes

As evidenced by the research literature, BLS could develop the analytical and practical capability to address the three innovation-related methodological weaknesses of PPI-Drugs. So far, however, BLS has instituted changes that address only the first—sampling problems. This response stems from BLS' disagreement with the proposed revision of the index's treatment of generics. In addition, although the general method to adjust for quality in price indexes is well established, its application to prescription drugs has not yet been researched thoroughly. The changes implemented by BLS are expected to reduce but not eliminate the index's overstating of drug price inflation. Nonetheless, the methodological changes will necessarily disrupt the index's continuity to some extent.

BLS Has Revised PPI-Drugs to Address Sampling Problems

Effective in 1994, BLS implemented three changes to the sampling procedures for PPI-Drugs. Each change is expected to help reduce the extent to which PPI-Drugs overstates drug price inflation. Future reviews will be needed, however, to assess how much these changes reduce the overstatement. Following are the three changes:

- First, BLS will now update the sample of products, or market basket, used to construct PPI-Drugs every 4 years. Intermediate adjustments will be made every 2 years—midway through the 4-year period. Until 1994, the sample was updated only every 5 to 7 years. The new procedure makes the PPI-Drugs market basket more representative of the range of drugs on the market. New products will be introduced into the market basket more rapidly now.
- Second, BLS has begun sampling a broader and more representative group of drug manufacturers. It previously sampled 542 products made by 53 manufacturers; it now samples 762 products made by 125 manufacturers.
- Third, BLS has strengthened its efforts to ensure that drug manufacturers provide prices from actual transactions rather than list prices. An index based on transaction prices represents a truer picture of drug prices because it includes negotiated discounts or rebates, whereas an index based on list prices does not.¹⁹ Before January 1994, only 30 percent of the prices used by BLS to construct the index were considered actual transaction prices. Since January 1994, however, 86 percent of the prices used by BLS in the index have been transaction prices.

¹⁹For any period of time, transaction prices need not change in the same direction or magnitude as list prices. An index that relies heavily on list prices may then overstate (understate) actual price inflation if transaction prices are decreasing (increasing) relative to changes in list prices. Some researchers contend that, in recent years, efforts by health plans to control costs have resulted in pharmaceutical manufacturers' giving broader and deeper discounts than previously. This would suggest that PPI-Drugs overstated drug price inflation in the few years before 1994 because too many list prices were used to construct the index.

Previous Version of PPI-Drugs Is Not Directly Comparable to Improved Version

Users of PPI-Drugs should realize that, because BLS changed the sampling procedures beginning in 1994, the index values before 1994 will not be directly comparable to later index values. This discontinuity is an unavoidable consequence of making needed improvements in the index methodology. The size of this discontinuity is probably substantial but cannot be precisely estimated yet. Existing research demonstrated a 23-percent overstatement due to sampling problems for a period ending in 1991. However, further research is needed to determine whether the earlier overstatement has persisted and to what extent the new procedures have reduced it.

Compromise Might Sidestep BLS-Researcher Dispute Over Treatment of Substitute Products

BLS has not adjusted PPI-Drugs significantly to address any over- or understatement of drug price inflation caused by the index's treatment of substitute products. BLS has not done more partly because it disagrees with researchers on the appropriateness of modifying or revising the methodology and partly because it lacks data to modify the methodology according to researchers' proposals.

A compromise solution might have BLS supplement PPI-Drugs with an additional index—consistent with the definition and treatment of substitute products proposed by researchers. Index users could then select the version of the index best suited to their needs. For BLS to implement this solution would likely entail some extra cost, however, because it would need to acquire more data. Whether the benefits of an additional index would justify its added costs is not known.

Changing the index to reflect these cost savings would involve redistributing the sample weights—essentially averaging the prices—between the generic product and its brand-name counterpart upon including them in the index. (Currently, the brand-name and generic prices are entered separately.) Similarly, changing the index to reflect cost increases would involve the same treatment for the prices of a line extension drug and its brand-name counterpart, depending on their equivalence.

Although BLS Recognizes the Need for Quality Adjustments, Technical Obstacles Remain

BLS has some procedures in place to adjust the prices of new products included in PPI-Drugs for their quality changes. More sophisticated methods of quality adjustment could be developed for PPI-Drugs. (BLS has developed such methods for some other industries.) At this time, however, both BLS and outside experts do not believe that applying these sophisticated

methods to a price index for prescription drugs has been researched thoroughly.

The current BLS procedure uses changes in production costs to approximate the component of a new product's higher price that is the result of changes in quality. In many instances, however, data on resource costs are not available or may in fact be a poor indicator of quality change. When the data are unavailable, BLS may attribute either all or none of any price difference (from the previous version of the drug) to a quality change.²⁰

In other rapidly changing industries, such as the computer industry, BLS uses a more sophisticated approach, known as hedonic pricing, to adjust prices for quality. The hedonic approach isolates the individual contributions to price of a product's many distinct characteristics. For example, two cardiovascular drugs will not have the same price because of the different side effects they cause and because one must be taken once a day and the other four times. Although hedonic-based indexes are more difficult and costly to construct, they more closely approximate the theoretical ideal of a price index that excludes quality-driven price changes from measured inflation. Nonetheless, BLS and outside experts agree that more research on applying hedonic pricing to prescription drugs is needed.

Users Should Interpret Indexes Cautiously

Price indexes provide valuable information about inflation, although users should avoid four potential misuses of all price indexes, including PPI-Drugs. These potential misuses reflect difficulties in measuring inflation rather than shortcomings of BLS index methodology.

PPI-Drugs Measures Price Changes Rather Than Price Levels

Price indexes measure price changes, not price levels. BLS tracks prices of individual drug products from month to month and computes an average price change for these products.²¹ However, BLS has no objective standard to which the average level of drug prices can be compared. Because no objective reference point exists, BLS arbitrarily sets the initial value, or base year, of each of its indexes, without regard to the type of product or

²⁰BLS only substitutes new products for old if the old products are no longer shipped or manufactured. In these cases, BLS tries to obtain similar products to substitute for the missing product. In some cases, BLS tries to adjust the price of the new product for quality changes that may have occurred between the old product and the new.

²¹PPI-Drugs averages the inflation rates for hundreds of individual drugs. The price of any particular drug may change more quickly or more slowly than the index.

any benchmark for its price level. Consequently, the index should not, for example, be used to compare drug price levels with price levels in other markets, such as food or consumer electronics. Nor does the index contain or incorporate a comparison of actual price levels to those prices that would prevail in a fully competitive market for prescription drugs. PPI-Drugs can be used to compare the rate of drug price inflation to a standard, such as the overall inflation rate, or the inflation rate in the markets for chemicals, health care, or other products. Thus, one cannot correctly say that, on the basis of PPI-Drugs, “drug prices are high or low,” but one can say that “drug prices are rising relatively quickly or slowly.”

PPI-Drugs Does Not Measure Competition in Prescription Drug Markets

Differences between inflation in wholesale and retail markets, as measured by PPI-Drugs and CPI-Drugs, provide little insight into which market is more competitive. Between 1989 and 1993, CPI-Drugs increased at an average rate of 7.9 percent per year while PPI-Drugs increased at an average rate of 7.2 percent per year. This does not mean that retail markets are less competitive than wholesale markets because PPI-Drugs and CPI-Drugs measure drug price inflation in different market segments.²² PPI-Drugs measures prices of drugs that eventually reach all paths of distribution, such as hospitals, managed care pharmacies, and retail pharmacies. Large purchasers, such as hospital buying groups and managed care organizations, often can use their market power to obtain lower prices than are available to small pharmacies. In contrast, CPI-Drugs focuses primarily on drugs sold through retail pharmacies—a segment of the market that, in some cases, has had little ability to negotiate for lower prices. Thus, PPI-Drugs includes market segments that are not represented in CPI-Drugs. As a result, the two indexes would not be expected to increase at the same rate.

PPI-Drugs Is Not Designed as an Index of Introductory Prices

PPI-Drugs is not designed as an index of introductory (or launch) prices and does not measure whether introductory prices have been increasing. Therefore, PPI-Drugs cannot be used to evaluate how prices of new drugs may have grown over time, how these introductory prices compare with those of drugs that the new drugs may replace, or whether these prices may be set by manufacturers to influence public opinion. BLS generally does not compare new, but therapeutically similar, drugs to the existing products that may be replaced. As a result, PPI-Drugs does not measure

²²On a more fundamental level, the level of competition in a market and inflation in that market are generally unrelated. Markets may be competitive and still experience high inflation or noncompetitive and experience little or no inflation.

price differences between existing and newly introduced drugs.²³ Finally, drug manufacturers often adjust their prices as they gain experience with the marketability of their new products. Manufacturers may choose a strategy of introducing new products at a relatively high price, and later lowering them because drug price indexes measure price changes, not the introductory price for new drugs. As a result, the public might view modest drug price increases favorably.

PPI-Drugs Measures Drug Prices but Not Prices of Alternatives in Other Industries

PPI-Drugs cannot be used to determine whether the value of a product justifies its price. The value of a drug to the consumer depends on the drug's effect on the well-being of the consumer and is often related to the price and availability of alternatives. However, the index does not account for either the price or availability of those alternatives and, as a result, cannot be used to determine whether drug prices rise quickly or slowly when compared with the price of other medical alternatives. The index cannot, for example, measure the effect on consumers' costs or well-being of an antibiotic that allows patients to return home quickly after a hospital stay or of a drug that substitutes for a painful or risky surgical procedure.

Conclusions

The evidence is strong that PPI-Drugs substantially overstated actual drug price increases for many years. In 1994, BLS addressed one source of the overstatement—sampling problems—by updating its procedures for sampling drugs to be included in the index. We believe this action was appropriate. A second source of overstatement—the index's treatment of generic and other therapeutically similar drugs—has not been addressed because BLS and researchers disagree. Until a consensus is reached, BLS could produce an additional index consistent with the methodology proposed by the researchers. At this time, however, it is unclear whether such a solution would be worthwhile given the additional resources BLS would have to spend for data acquisition. A final source of overstatement—inadequate adjustment for product quality changes—also has not been addressed but only because technical problems have not been solved.

Because of the problems identified with PPI-Drugs, users of the index should be aware of its historical overstatement of actual drug price inflation. They

²³If BLS were to link the prices of new and existing drugs, it would have to adjust the prices for differences in the value of the two products. For example, a new drug with fewer side effects would be expected to command a higher price than an existing drug with more side effects. BLS would face the difficult task of determining the market price of reducing side effects if it were to couple the two products.

should also recognize that, because of significant changes in the index methodology beginning in January 1994, index values before and after that date are not directly comparable. Although the research results do not permit either BLS or users to correct the index with simple mechanical adjustments, the recent as well as forthcoming research results can help users make qualitative allowances for the overstatement of drug price increases.

Finally, users should also avoid several potential misuses of PPI-Drugs. For example, because it measures inflation rather than price levels, the index can be used to determine whether prices have risen quickly but not whether they are excessive.

Agency Comments and Our Evaluation

BLS reviewed a draft of this report and provided written comments, which are reproduced in appendix I. In summary, BLS agreed that its past procedures did not ensure the accuracy of PPI-Drugs but suggested that estimates of the size of the problem may be overstated. We do not believe, however, that BLS provided sufficient evidence to dispute these estimates. BLS also disagrees with our treatment of quality adjustment issues; they suggest that we do not understand the theoretical foundation for PPI-Drugs. We believe we do understand the BLS theoretical position—we simply disagree with the appropriateness of that position for PPI-Drugs.

Disagreements About the Size of the Misstatement

BLS agreed that its past sampling procedures did not ensure that the market basket used to construct PPI-Drugs accurately represented the prescription drug market. However, BLS disputed the conclusion that the sampling problem alone caused inflation to be overstated by 23 to 36 percent. BLS argued that these estimates were based on segments of the industry that may not have represented the industry as a whole. However, BLS did not provide an alternative estimate of the past overstatement of inflation from inaccurate sampling procedures.

We agree that constructing a sample that represents the industry as a whole is critical to developing an accurate index; the researchers' critique of PPI-Drugs expressed that concern, which is also central to this report. While the figures cited in our report are estimates, we believe that they are accurate. In one study we consulted, the authors argued that their results were representative by demonstrating that their data were accurate for systemic anti-infectives, a subclass of drugs for which they had access to

the entire industry.²⁴ The other study, which covered 80 percent of the industry, reported that drug prices rose 6.9 percent per year from 1987 to 1991, while the BLS estimate for the same period was 8.4 percent per year.²⁵ For PPI-Drugs to be accurate during this period, the annual inflation rate for the missing 20 percent of the industry would have had to be 14.7 percent, more than double the rate of inflation in the rest of the industry.

BLS also disputes the estimates in the report because PPI-Drugs closely tracks CPI-Drugs. However, as cited in our report, PPI-Drugs measures a substantially different market segment than CPI-Drugs. As a result, we believe that the close relationship between the two indexes is a coincidence, rather than evidence of the accuracy of PPI-Drugs.

Disagreement About Quality Adjustment Issues

BLS disagrees with our treatment of quality adjustment issues by suggesting that we do not understand the theoretical basis for producer price indexes. We believe that we do understand this topic; we simply disagree with the relevance of the BLS conceptual framework for PPI-Drugs. The BLS framework is based on a theoretical model of the production process of a representative firm.²⁶ This framework arbitrarily defines a product as the output of a single firm—different firms produce different products regardless of whether the products are similar. For example, this framework would treat ears of corn from different farms as different products solely because they were grown on different farms. By discounting potential similarities in product characteristics, the framework does not take into account whether the market treats similar products manufactured by different firms as potential substitutes. We believe that this is inappropriate for the prescription drug industry because a large percentage of the market treats products of different firms as potential close substitutes.

We also believe that one of the basic assumptions underlying the BLS framework is not always appropriate for the pharmaceutical industry. As BLS indicates in their comments, their framework is based on the assumption that markets are competitive. However, many drugs are sold with patent protection which, by design, limits the level of price competition for that product. What effect violating this assumption has on the underlying framework of PPI-Drugs is unknown.

²⁴Berndt, Griliches, and Rosett, pp. 251-264.

²⁵Berndt and Greenberg, pp. 6, 8-9.

²⁶Archibald, pp. 57-72.

BLS also claimed that we incorrectly summarized its procedures for line extension drugs. To provide more detail about the BLS procedures, we added a footnote in response to this comment.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time we will send copies to the Secretary of Labor; the Commissioner, Bureau of Labor Statistics; congressional committees; and other interested parties. Copies also will be made available to others on request.

This report was prepared by Scott L. Smith, Assistant Director, and Joseph Kile, Senior Economist. If you have any questions about this report, please contact me at (202) 512-7107.

Sincerely yours,



Jonathan Ratner
Associate Director
Health Financing and
Public Health Issues

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Abbreviations

BLS	Bureau of Labor Statistics
CPI	consumer price index
CPI- Drugs	consumer price index for prescription drugs
FDA	Food and Drug Administration
PPI	producer price index
PPI- Drugs	producer price index for prescription drugs

Comments From the Bureau of Labor Statistics

U. S. Department of Labor

Commissioner for
Bureau of Labor Statistics
Washington, D.C. 20212



APR 5 1995

Mr. Jonathan Ratner
Associate Director
Health Financing and Public
Health Issues
General Accounting Office
Washington, D.C. 20548

Dear Mr. Ratner:

Thank you for the opportunity to comment on your draft report, "Prescription Drug Prices: Official Index Overstates Inflation" (GAO/HEHS-95-90).

I would like to comment generally on the sampling and quality change problems discussed in your report as potential sources of overstatement in the rate of prescription drug price change measured by the Producer Price Index (PPI). The latter topic encompasses the quality adjustment and new drug problems treated separately in your report.

I agree that, prior to the January 1994 resampling of prescription drugs, the PPI almost certainly under-represented new drugs. I do not, however, find compelling the report's estimate of the likely overstatement in the index between 1984 and 1991 due to this shortcoming. The estimated overstatement of 23 to 36 percent cited in the report comes from two studies that compared the PPI to Laspeyres indexes constructed with drug price data that excluded significant portions of industry sales. The first study, which produced an estimated 36 percent overstatement, was based on data for four companies accounting for just 24 percent of industry shipments. The second study, which produced an estimated 23 percent overstatement, was based on data for 17 companies and had substantially broader representation, but excluded 20 percent of industry shipments. Since there may be systematic differences in the pricing behavior of the companies included in and excluded from these studies, caution should be exercised in interpreting their results.

A comparison between the PPI and the Consumer Price Index (CPI) for prescription drugs suggests further reason for caution regarding the estimates in the report. The two prescription drug indexes tracked very closely over the 1984-91 period, with the PPI increasing at an average annual rate of 12.4 percent and the CPI at an average annual rate of 12.5 percent. Approximately 20 percent of the CPI

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prescription drug sample is reselected each year, which presumably means that new drugs are more fully represented there. Although there are other differences between the two indexes--most importantly, the PPI measures prices received by domestic producers whereas the CPI measures prices paid by consumers--the similarity in their movements calls into question the significance of new drug underrepresentation in the PPI as cited in your report.

Although I have questions about the specific estimates in the report, I agree that PPI procedures should be changed to ensure that new drugs are more fully represented. As a general matter, the ability of the Bureau of Labor Statistics (BLS) to accelerate the updating of PPI industry samples is constrained by budget limitations and the need to minimize respondent burden. As your report notes, however, BLS did implement a new PPI prescription drug sample in January 1994 to correct the problem of underrepresentation of new products. Our analysis of reported price change over the 12 months since the new sample was linked into the PPI indicates that the class of 1-2 year old drugs exhibited a significantly different price profile than did older drug classes. This result reinforces the importance of our planned 1996 interim augmentation of the PPI prescription drug sample aimed at restoring the representation of 1-2 year old drugs to its proper level.

The report correctly points out that changes in PPI prescription drug index values before and after the January 1994 resampling are not directly comparable. Although budget limitations generally preclude the development of rigorous parallel indexes, it clearly is important for BLS to carefully consider what steps we can take to gauge and fully inform users of the impact of methodological improvements on our measures. We are not yet certain what that will mean in this particular case.

The objective of the PPI is to measure pure price change for a fixed set of outputs of domestic producers. In practice, the set of outputs for which we collect price information is constantly changing as producers discontinue products, modify them, or introduce entirely new products. Although such sample content changes are necessary to maintain the representativeness of the products priced for the PPI, it is important to make substitutions in a way that distorts the measure of pure price change as little as possible. This requires that adjustments be made to preclude any index

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movement due to quality differences between the original and substitute products. The theoretical model underlying the PPI requires that the value for a given quality change equal the cost differential for producing the original and substitute products under the same production technology.

The report discusses three types of quality change in prescription drugs: the introduction of new generic varieties of existing drugs; line extensions; and the introduction of new chemical entities. It has not been practical to use the production cost methodology to make quality adjustments to generic drug prices because such an approach would require making cost comparisons across producers. As your report notes, PPI staff currently are studying alternative approaches for valuing the quality difference between branded and generic drugs. This work will be completed in time for the January 1996 prescription drug sample augmentation, which will include a selection of new generic drugs.

The report is incorrect in stating that line extensions are treated as new products in the PPI. When a drug producer sampled for the PPI reports that a line extension has replaced an older version of a drug, BLS staff telephone the company to request the production cost differential for the new product as compared to the older product it replaces. This information, which BLS staff typically are successful in gaining from pharmaceutical company respondents, then is used to make a quality adjustment before comparing the prices of the original and extended versions of the drug.

The emergence in production of an entirely new chemical entity presents the most difficult quality adjustment problem for the PPI. Using the production cost methodology to value quality changes embedded in new chemical entities is infeasible, as cited above for generic drugs, in that it may require making cost comparisons across producers. As your report states, some researchers have suggested that hedonic pricing methods hold promise for valuing the differences in characteristics between new chemical entities and previously available drugs. More research clearly is needed to confirm this potential. One major question pertaining to the use of hedonic methods is whether different models will be needed for each of the more than 30 prescription drug therapeutic classes. An equally vexing question pertaining to new chemical entities is how to identify the antecedent goods to which price comparisons should be made. Antecedents may be found in the same

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therapeutic class of drugs as the new entity, but they also may reside in a different therapeutic class or even in an entirely different category of products and services, e.g., medical and surgical hospital treatments.

One final comment I would like to make is that the report exhibits a seeming lack of understanding about the conceptual framework underlying the PPI. This is best illustrated in the first paragraph on page 9. The conceptual framework (or "logic") for the PPI, the theory of output price indexes, is based on the production process of the firm and the assumption that markets are competitive. Because the focus is on firm behavior, consumer considerations play a role only in terms of the demand for the product, over which the firm is hypothesized to have little or no control. Furthermore, firms are distinguished by their production processes, so that generic and branded drugs may not be qualitatively the same because of differences in the process by which they are produced. These qualitative differences may in part explain why the branded versions of drugs continue to be sold after the generic versions are introduced. The last sentence in the paragraph notwithstanding, the output price index concept has served users of the PPI rather well.

Please let me know if I can be of further assistance as you finalize the report.

Sincerely yours,



KATHARINE G. ABRAHAM
Commissioner

Now on p. 7.

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