Statement on

Extraordinary Price Increases in the Pharmaceutical Market

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Statement of

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Extraordinary Price Increases in the Pharmaceutical Market

Thank you, Chairman Schumer and other members of the Joint Economic Committee for this opportunity to provide information and insights regarding pricing trends in the pharmaceutical market.

I am Madeline Carpinelli and I serve as a Research Fellow with the PRIME Institute at the University of Minnesota. This Institute focuses its research on policy issues related to pharmaceutical economics and the distribution and management of drug expenditures at all levels in the marketplace. Prior to joining the PRIME Institute, I was a senior policy analyst at the Office of Inspector General (OIG) for HHS, where I managed a team of analysts in conducting evaluations of government drug price reporting and compliance issues. During my tenure at the OIG, I played a significant role in the development of the OIG's annual Work Plan related to identification of key issues in the pharmaceutical industry such as the role of AWP, AMP and the Public Health Services' 340B Drug Program. I also interfaced with the Department of Justice and the OIG Office of Prosecutions and Investigations.

These remarks present my own findings and views based upon my experience in studying the pharmaceutical marketplace for the past nine years and upon my observations and ongoing work in collaboration with Dr. Stephen W. Schondelmeyer, the Director of the PRIME Institute.

Today, I will provide an overview and preliminary findings from research we have been conducting on *extraordinary* price increases in the pharmaceutical market. Through our tracking of drug prices over time, we have become aware that certain drug products have experienced *extraordinary* price increases that are well beyond what would normally be expected in a competitive market. We found hundreds of cases of *extraordinary* price increases for branded drug products. We also found that the incidence of such extraordinary price increases has been rising sharply in recent years, and today is much higher than it was in the 1980s and 1990s.

Tracking Drug Prices and Related Trends

Tracking changes in the benchmark prices of prescription drugs is important since it provides an explanation of the role of price changes in drug expenditures over time. AARP and the PRIME Institute have routinely tracked the price changes experienced by the brand name and generic prescription drugs most commonly used by Medicare recipients. These price change reports are updated quarterly and the reports can be found on the AARP website (www.AARP.org). These price trend reports have shown that a representative market basket of the most commonly used brand name drugs has experienced price increases from 2006 to 2007 that averaged 7.4%. For the same time

period, the rate of general inflation, as measured by the Consumer Price Index for All Items, was 2.9%. In other words, brand name drug prices grew at more than two and one-half times the rate of general inflation.

Certain commonly used brand name drugs experience price increases that are substantially greater than other brand name drugs on average. For example, in 2007, Ambien (5 mg and 10 mg tablets) had an annualized price increase of 27.7% compared to the overall brand name inflation rate of 7.4%. Brand name prices that increase at a rate of two to three times the rate of general inflation have persisted for more than a decade. Each time the price trends are examined there are a handful of brand name prescription drugs that have price increases substantially greater than the overall brand name inflation rate. The impact of these prices growing faster than general inflation has been that prescription drugs have been growing as a share of national health expenditures and as a share of the gross domestic product.

While tracking the price changes of the most commonly used brand name and generic drugs, the prices of other drug products beyond the top 200 to 300 drugs have also been examined. In recent years, some of these less commonly used prescription drug products have had *extraordinary* price increases.

Extraordinary Drug Price Increases

What do we mean by an *extraordinary* price increase? *Extraordinary* is a term that can be understood in contrast to the ordinary. Ordinarily brand name price increases have been two to three times the rate of general inflation and this rate of price increase has become routine. This rate of inflation is not necessarily acceptable, or even reflective of an economically efficient pharmaceutical market, but it has come to be expected in recent years. Even the fact that certain brand name drugs have price increases that are two to three times the average rate of inflation for most brand name drugs has come to be expected. Price increases of these certain brand name drugs may be 10% to 30% on an annual basis.

We should not minimize the impact that these brand name price increases have on public and private drug expenditures each year, or the concern that these price increases raise for patients, payers, and policymakers. Recently, however, there have been other prescription drug products that have had *extraordinary* price increases which are far beyond these already substantial price increases observed for major brand name drug products.

In order to examine, and understand, the magnitude of these *extraordinary* price increases, the PRIME Institute has been conducting a study of such price increases. For purposes of this study:

Extraordinary price increases are:

'any price increase that is equal to, or greater than, 100% at a single point in time.'

A 100% increase in price means that the price of a drug has doubled overnight. In other words, a prescription that costs $100 today would cost $200 tomorrow. Other levels of price increases may well deserve the label as *extraordinary* price increases, but a price that more than doubles all at once is certainly *extraordinary*. A price increase of this magnitude could also be labeled as a *supra competitive price* indicating that the price is achieved through some real, or perceived, monopoly position in the market.

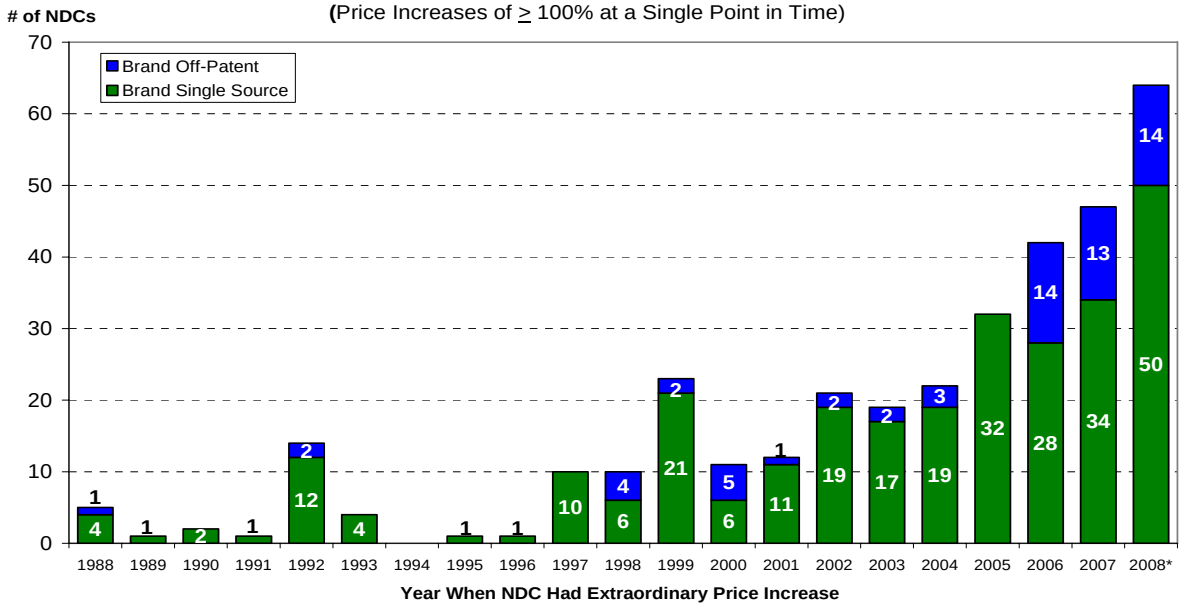
The benchmark prices known as AWP and WAC are set, or influenced, by the drug firm. These are publicly available prices and changes in these prices will lead to changes in expenditures of public and private drug programs. Our work on this study is ongoing, but we have preliminary descriptive data on the extent of *extraordinary* price increases.

The price history of each drug product, at the NDC (national drug code) level, was examined to determine the direction and amount of price change in both of the usual benchmark prices (i.e., AWP and WAC). There was a total of 35,143 NDCs that have been introduced to the market since 1987 and this set of NDCs was used as the data set for the study. More than one-half of these drug products (18,124 NDCs) were manufactured, or at least marketed, by the firm whose name is on the label. The remaining 17,019 NDCs are drug products that are sold by firms known as repackagers. An examination of the role, practices, and pricing of these repackagers will be the subject of a later analysis.

The drug products were grouped by their patent and exclusivity status into three broad groups: (1) brand single source drugs, (2) brand off-patent drugs, and (3) generic off-patent drugs. Price changes for brand name drug products have been the initial focus of our research. Across all drug product groups, 13.5% of all NDCs have had one or more *extraordinary* price increases in the period 1988 to 2008. One in twenty (5.3%) of the brand single source NDCs and one in forty-five (2.2%) of the brand off-patent NDCs had seen an *extraordinary* price increase.

The timing of when these *extraordinary* price increases occurred was examined over the twenty year period from 1988 to 2008. While there were a few *extraordinary* price increases in the decade of the 1990s, the vast majority have been seen since the year 2000. The number of *extraordinary* price increases has been growing, and especially for brand name single source and brand name off-patent NDCs, in the past four years (See Figure 1).

Figure 1. Extraordinary Price Increases of Drug Products: 1988 to 2008
Brand Single Source & Brand Off-Patent NDCs
(Price Increases of ≥ 100% at a Single Point in Time)



Source: Compiled by the PRIME Institute, University of Minnesota from data found in Price Chek PC (Wolters Kluwer Health, Inc., Indianapolis, IN, June 4 2008).
Extraordinary price increase at a single point in time for AWP or WAC reported in the year indicated.
Data does not include NDCs for drug products that are co-licensed, co-marketed or repackaged; or for drug ingredients used by pharmacists for compounding prescriptions.
* Data for 2008 was for January 1 through June 30. The number reported above was annualized by doubling the experience from the first 6 months.

A price increase of 100% or more at one point in time is remarkable in its own right, but the size of some of these *extraordinary* price increases is staggering. For the brand single source drug products there were 6 price increases of more than 1,000% with the largest being 3,436%. Another 6 brand single source NDCs had an increase between 500% and 999%. One of the brand off-patent NDCs had a price increase of 10,631% and another 10 NDCs had *extraordinary* price increases of greater than 500%.

Impact of *Extraordinary* Drug Price Increases

Obviously there have been some extremely high price increases for a large and growing number of drug products. Because of the magnitude of these *extraordinary* price increases, it is hard to imagine that there has not been a significant impact on the market. These observations raise questions and concerns.

The questions involve asking:

- Why have these *extraordinary* price increases occurred?
- What market forces have led to, or allowed, these *extraordinary* price increases?
- What patterns are there with respect to types of drug products involved?
- What patterns are there with respect to types of drug firms involved?
- What policy issues are raised by this pricing behavior?
- What policy approaches may be appropriate to mitigate or regulate this behavior?

The concerns raised by these *extraordinary* price increases include:

- What is the impact Medicare Part D and Part B drug expenditures?
- What is the impact on Medicaid drug expenditures?
- What is the impact on drug expenditures in other government programs such as the Veterans Administration, the 340 B program, Indian Health Service, the active military health system, and other programs?
- What is the impact on employer and private drug benefit programs?
- What is the impact on orphan drug products?
- What is the impact on access to medications?
- What is the impact on access and affordability to vulnerable patient populations?

Factors Driving *Extraordinary* Drug Price Increases

The pharmaceutical market is extremely complex and vexing to most observers. There are many unique institutional and structural features to the pharmaceutical market that influence the economic behavior of drugs and drug prices. The extent and magnitude of price increases seen in our preliminary study of this issue appear to indicate that the *extraordinary* price increases are not driven by the ordinary explanations for price increases such as the general inflation rate of the economy, the cost of materials, labor and distribution, or the costs of FDA required research for approval.

The magnitude of these *extraordinary* price increases is so great that these prices do not appear to be the product of an economically efficient competitive market. In fact, these prices may well be *supra competitive* prices, that is, prices above what can be sustained in a competitive market. Supra competitive prices are present when a firm has a unique position in a market with respect to intellectual property, legal status, barriers to entry, product features that offer a competitive advantage, or other factors. The number and magnitude of these *extraordinary* price increases also raises the possibility that antitrust issues may be present. Determination of the antitrust implications would require an assessment of the specific and unique market for each drug product to determine the circumstances and market forces that enabled these *extraordinary* price increases to be taken and sustained.

Most of the drug products with *extraordinary* price increases are not among the top 100 to 500 drug products on the market. In part, these drug products may have been able to implement these *extraordinary* price increases because these are low volume drugs that are not often tracked or noticed in the marketplace. In a sense, these drug products and their price increases have “flown below the radar” with respect to attention being given to their pricing behavior.

Many of these drug products are for conditions that have a relatively small volume of demand. Indeed, some of these drug products are even designated as orphan drugs—meaning that they are for conditions that have a small target population. Among the

drug products with *extraordinary* price increases are a number of products that are unusual dosage forms such as injections, gels, transdermal patches, sustained release tablets and capsules, and others. Some of these drug products may have such a small market that it would not be profitable for two competitors to survive. Other drug products with *extraordinary* price increases may have been in short supply either before or after the price increase was taken. The fact that some of these drug products are sold only through limited distribution channels (e.g., specialty pharmacies, mail order pharmacies, physician dispensers, dialysis care centers, and others) may also have played a factor in enabling *extraordinary* price increases.

The intellectual property and exclusivity status of these drug products may also have facilitated the *extraordinary* price increases. Among the drugs found to have these large price increases were old drugs that have a patent for a new use of the drug, thus providing a period of market exclusivity for the drug product. Other old drug products have been prepared in a new dosage form that may be the subject of a patent, thus preventing the expected generic competition that is usually seen. In other situations, certain drug firms have a large number of drug products with *extraordinary* price increases. This observation raises the issue of whether or not the extreme price increases are a matter of a particular corporate strategy. Firms may acquire drug products that have limited market competition, or that have high potential for monopoly power with or without intellectual property rights.

The PRIME Institute plans to continue research in this area to better understand and characterize the market conditions that have led to the growth of *extraordinary* price increases for prescription drug products. Our research will look for patterns across drug firms, therapeutic categories, market conditions, intellectual property and exclusivity status, dosage forms, distribution channels and other factors. The continued research will also examine how these *extraordinary* price increases have affected private and government drug programs, market entry and the market for drug products, and specific patient populations.

Summary

Extraordinary price increases for drug products have been observed in recent years. These *extraordinary* price increases are price changes of more than 100% at a single point in time with some ranging to more than a 10,000% increase in price. About one in every twenty brand single source drug products (5.3%) has had one or more *extraordinary* price increases. These enormous price increases certainly affect the individual patients who are using the medication and in aggregate these large price increases expand the ever-growing expenditures of private and public drug programs. The PRIME Institute will continue to study this issue to improve our understanding of the issues involved and to identify policy alternatives to address any societal concerns that may be present.