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The Impact of Pipeline Drugs on Pharmaceutical Spending

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Summary of Preliminary Results
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Overview

National expenditures on pharmaceuticals have risen at over 10 percent annually for the last several years. Advances in pharmaceutical technology are helping millions of Americans. This translates into innovative new drugs; some of which are more expensive than the drugs they replace, some of which will be used by more people, and others which represent entirely new therapies. Providing consumers with these therapies is placing increasing demands on the resources available for health care. As drug spending increases, it will affect consumers and public and private sponsors of health care. The future level of pharmaceutical spending is also important background information for Congress to consider as it develops legislation to help seniors with their drug purchases.

Our research indicates that total expenditures on pharmaceuticals are likely to increase by more than 15 percent annually over the next five years. This would cause prescription drug spending to double from an estimated $105 billion in 1999 to $212 billion in 2004. We attribute 40 percent of this increase to the cost of "pipeline" drugs. Some of this increased spending will be for breakthrough drugs for conditions for which no current treatment exists, and some will be for drugs that will replace existing therapies. We attribute the remaining 60 percent of the projected increase in expenditures to increases in prices and utilization of drugs already on the market.

Our study looks at a variety of factors that influence both the price (and price increases) of existing and new drugs and the quantity of pharmaceuticals that are purchased. The study also examines pipeline drugs and drug classes that may create demand for new treatments and may result in more patients receiving treatment.

Purpose

The purpose of this study is to project future levels of drug expenditures, paying particular attention to the impact of "pipeline" pharmaceuticals. "Pipeline" pharmaceuticals are those drugs that currently are in the development and approval processes. The study does not attempt to estimate any offsetting savings in non-drug expenditures.

Methodology

The model is based upon expenditure data for most frequently prescribed drugs from 1989 through 1998. We included a drug in the study if it was among the 100 most frequently prescribed drugs in any year during the study period, thereby focusing on the drugs that are most likely to be used rather than the most expensive. Drugs currently in the pipeline were examined, and drug classes expected to contribute most to increased spending were identified (see list below). Based on a comparison with recently approved drugs, we believe that those pipeline drugs that will receive approval over the next five years will target similar diseases and populations. We recognize that the pipeline includes dramatically new types of drugs based on pharmacogenomics, but argue that most of these drugs are still in the early stages of development (i.e., Phase I or II trials). Thus, it is unlikely that many of these drugs will be approved and marketed before 2004.

In estimating price increases, we used the average wholesale price (AWP). While managed care plans and other large purchasers receive discounts from the AWP, there is no evidence that the average level of discounts prevailing in the market has changed significantly in recent years. Because of this, it is reasonable to base projections of the general level of future price increases (although not expenditures) on an analysis of AWP data.

In estimating changes in the utilization of pharmaceuticals, we used annual survey data published in *American Druggist* on the overall number of prescriptions filled in the United States.

We examined data for both price and utilization for ten years from 1989 through 1998. The average annual rates of increase for the last five years of the study period were then used to project increases in price and utilization for the five-year projection period, 1999-2004. Price and utilization increases were estimated separately for existing products and pipeline drugs in order to distinguish the major determinants of overall drug expenditure increases.

Overall expenditures were projected for the years 1999 through 2004. These projections were made on a straight-line actuarial basis starting with current expenditure levels and using the projected future price and utilization increases for both existing and pipeline drugs.

What's in the Pipeline?

Drugs under development generally fall into three broad categories: "blockbuster" drugs (those that are likely to generate more than $500,000,000 in annual revenues), "me too" drugs (those that provide alternatives to existing therapies but provide little significant clinical advantage), and "lifestyle" drugs (e.g., Rogaine® and Viagra®). Drugs may fall into more than one of these categories.

Some of the classes of pipeline drugs that are most likely to contribute to increased spending include:

- Genetic therapies
- Anti-hypertensives

- Antidepressants
- Cancer therapies
- Oral diabetic agents
- Anti-arthritic agents
- Hormone replacement therapies
- Erectile dysfunction therapies
- Cholesterol lowering agents

Some classes of drugs are expected to contribute significantly to future drug expenditures because the cost of the therapy itself is predicted to be very high (e.g., genetic therapies often cost more than $1,000 per patient per month). In other cases, the anticipated cost increase is attributed to the large population targeted by the new drugs. For example, cardiac agents such as anti-hypertensives and cholesterol-lowering agents target Americans with heart disease, who comprise nearly one-quarter of the population. Certain drugs falling into the "lifestyle" category are expected to generate significant expenditures as well. For example, there are at least two drugs under development to treat erectile dysfunction. If Viagra® is any guide – with sales of over $1 billion since its introduction two years ago – these drugs, once introduced, will generate substantial expenditures.

Summary of Projections

We project overall spending on pharmaceuticals to increase at an annual rate of 15 to 18 percent over the next five years, doubling prescription drug spending from an estimated $105 billion in 1999 to $212 billion in 2004. These increases can be attributed to several sources: the introduction and use of new drugs, rising prices for existing drugs, and the increased use of existing drugs.

The introduction of new drugs currently in the pipeline accounts for 40 percent of projected increases, contributing 6 to 8 percent annually in increased spending. Some of these expenditures represent the replacement of older therapies, as was the case with cox-2 inhibitors (e.g., Celebrex®) replacing older non-steroidal anti-inflammatory drugs (NSAIDs). These new therapies may have significant benefits, such as reduced side effects or greater clinical effectiveness. However, they are often more expensive than the therapies they replace. In addition, the benefits of the newer therapies may lead to greater use. For example, when Lipitor®, a new cholesterol-lowering drug was introduced in the late 1990s, its sales skyrocketed to over 1.5 million prescriptions in the 13 months following its introduction into the marketplace. Some of these sales were generated by people who were already being treated with other cholesterol-lowering drugs, but some represented new patients as well. Other new drugs currently in the pipeline will be therapies for conditions, such as for non-Hodgkins lymphoma, for which no current treatment exists.

In addition to the 40 percent of projected increases in drug spending attributed to pipeline drugs, we attribute the remaining 60 percent to existing drugs. Price increases on existing drugs will contribute an additional 4 to 5 percent annually. Prices are not raised on every drug each year. However, over a third of all drug/dosage combinations experience a price increase in any given

year. This number increases to 70 percent when the focus is on the most frequently described dosage forms for newly introduced drugs.

As the population grows and ages, the number of individuals treated with pharmaceuticals rises. This leads to an increased use of existing drugs, which will contribute another 4 to 5 percent annually to drug expenditures.

Conclusion

Expenditures on pharmaceuticals will continue to rise at double-digit annual rates during the next five years (1989-2004). Several factors will contribute to these increases. The introduction of new drugs currently in the pipeline accounts for 40 percent of the projected increases. Price increases on existing drugs continue to be an important factor, as does increased use of existing drugs; together these factors account for the remaining 60 percent of projected increases.

Next Steps

A final report will be released in June of this year. As noted earlier, the results released today are projections based on past expenditure, price and utilization data. The estimates thus assume, that all things being equal, past trends will continue. However, we recognize that there are numerous factors that could influence future expenditures. For example, new drug approvals, the aging of the population, and continued direct-to-consumer advertising may well spur future spending beyond the range of the estimates provided today. On the other hand, factors such as increased use of generic drugs and cost management efforts by health plans and pharmacy benefit management (PBM) companies might be expected to moderate the upward trend in drug spending. In addition, there are factors whose likely impact on future spending is unclear, such as potential legislation, regulatory changes, or even mergers in the drug industry.

Over the next two months, we will conduct sensitivity analyses of these and other factors and refine our future expenditure estimates. However, we do not expect that our final results will vary from the projected 15 to 18 percent annual increase by more than a few percentage points. The final report will present these refined estimates as well as a more in-depth discussion of pipeline drugs and the University of Maryland pharmaceutical expenditure model.