

**WORKSHOP 2:****Budgeting and Financial Management of New and Emerging Pharmaceutical Technology***Lee Vermeulen, M.S., and Nilay Shah, M.S.*

Many factors, both external and internal, drive the cost of medications. Internal factors are somewhat controllable. External and higher-order influences are largely beyond the pharmacist's control. In this workshop, Mr. Vermeulen and Mr. Shah, from the Center for Drug Policy and Clinical Economics, University of Wisconsin, Madison, Wisconsin, focused on how to develop a plan for managing medication technology that responds to the complex external and internal factors driving costs. Constant vigilance is key to success.

**Drivers of Medication Costs**

Total health expenditures in the United States in 2002 will reach an estimated \$1.542 billion. Drug costs account for only 10 percent of this sum. Nonetheless, talk of health care cost containment often focuses on the price of drugs. The reason, Vermeulen proposed, is the disproportionately high inflation factor associated with drug costs. The cost of drugs is growing by 15 to 18 percent a year—around twice the rate of inflation in other areas. If the drug costs continue to increase at their current rate, they will account for 14 percent of the health care budget.

Price inflation is one of the factors driving drug costs. Nonetheless, even if prices were capped, the cost of medications would continue to rise. This is because of the impact of three other drivers—utilization, product mix, and a blend of the two.

- **Utilization.** Per-capita increases in prescription drug costs are high. There are many reasons. The population is aging, and the incidence of chronic disease is rising. Patients are demanding more drugs. Direct-to-consumer advertising is partly responsible for this trend. Another factor is increasing third-party coverage for drugs.
- **Product Mix.** Right or wrong, Americans often associate new technology or medications with better outcomes. Older products are often abandoned, to be replaced by newer, more expensive ones, even if their greater efficacy has not been proven. “Me too” drugs and patent extensions also have a role.
- **Utilization and Product Mix.** Medications are now being used for disorders that have not been treated with pharmacotherapy in the past. These products are often new and expensive entities. Left unchecked, this trend may give rise to major ethical dilemmas, including the prospect of rationing.

Of the drivers, utilization contributes most to price increases. The growth in utilization has other effects as well. For example, it is largely responsible for the pharmacist shortage. More pharmacists are needed because more drugs are being used. Increased utilization is also driving concerns about medication safety. We have designed a medication-use process around a certain volume of use, and use has increased beyond those the original bounds.

**The Challenges**

We have, Vermeulen proposed, an overburdened and wasteful medication use system and are experiencing unprecedented cost-containment pressure. Given this scenario, pharmacy must provide evidence supporting two claims:

1. Medications are good investments that provide more value than any other technology, and
2. Clinical pharmacy services and clinical pharmacists are good investments, providing value by maximizing the efficient use of medications.

Evidence to support both claims is mounting. Nonetheless, pharmacy will not have an opportunity to make these arguments until it has tackled the low-hanging fruit. Namely, pharmacy must

- Eliminate the waste associated with inefficient purchasing, distribution, and medication-prescribing practices; and
- Ensure and maximize reimbursement,

**External Factors Affecting Drug Costs**

Per-capita health care spending in the United States in 2001 grew by 10 percent—the highest percentage increase in a decade. Employers' health insurance premiums and employees' out-of-pocket expenses for health care grew at a similar rate. Hospital spending is a key driver of overall spending. Within this broad scenario, Shah presented reviewed the external factors affecting drug costs. Key points of his presentation are summarized here:

**Medication Expenditure Trends**

- The Centers for Medicare and Medicaid Services project an average annual growth in medication expenditures of 11.7 percent between 2003 and 2007. The annual percentage increases are, however, expected to move slowly downward during this time.
- An aging population and an increase in the number of individuals with chronic diseases, as well as the number of “blockbuster” drugs entering the market, will drive up costs.
- Patent expirations will help moderate the upswing in costs. Changing health plan designs will also affect demand.

- Drug volume is the key driver of hospital expenditures, and much of the increase in volume is attributable to the diffusion of new drugs. Pharmacy managers often give too much weight to monitoring the development of new products. The diffusion of pharmaceutical technology has more influence; this is where the impact on resource allocation patterns is strongest.

## Effects of Innovation

- New drugs have a powerful effect on medication costs. Of the projected 14.2 percent increase for the current year (2002), 10.6 percent is associated with pipeline drugs. Pipeline drugs are a “moving target, and monitoring them is essential.
- The number of new medical entity submissions is declining sharply—from a high of 42 in 1999 to a projected 16 in 2002. The chemical pipeline is by and large dry. It is on the biological side where growth is likely.
- The mean time for Food and Drug Administration (FDA) approval continues to decline across all phases. The recent renewal of the Prescription Drug User Fee Act is expected to further shorten approval times..

## Drug Pricing

The major factors affecting the price of a new drug are the characteristics of the product (new versus replacement), the characteristics of the disease it treats (chronic or acute, number of patients), company needs, and reimbursement. Compounds that represent a gain over existing therapies and those intended for acute illnesses tend to have higher launch prices. Company mergers also affect drug costs.

Generic drug products have a strong impact on the market. The first generic customarily captures 80 percent of the branded product's volume within the first year. The price of a generic product at that time is usually around 55 percent of that of the brand-name product. Several top-selling drugs are slated to come off patent in 2003 and 2004.

Shah made some general observations that may be useful to pharmacy managers in budget forecasting. First, with respect to costs, drugs may be categorized six ways:

- **Fast pays**, such as antipsychotics, bring about a quick decrease in drug costs.
- **Slow pays**, such as lipid products, have no immediate impact.
- **Narrow pays** benefit only a subset of the population.
- **Diffuse pays**, such as antimigraine products, bring increased medical costs that are offset by costs in other areas (e.g., decreased absences from the workplace).
- **Pay-me-laters**, such as antiretrovirals, may decrease short-term but increase long-term costs.

- **No pays** include lifestyle drugs such as products for erectile dysfunction.

Shah further noted that the spread of innovation tends to follow an S-shaped curve. Use begins with the innovators, who use the drug immediately, often because of their involvement in research. Next are the early adopters, followed by the later adopters. The rate of diffusion of innovation varies among specialties.

## Promotional Strategies

Promotional activities such as detailing, sampling, and professional and direct-to-consumer advertising have a strong impact on drug costs. Funds spent by the industry on direct-to-consumer ads, for example, mushroomed from \$13 million in 1989 to \$643 million in 1997 to \$2,538 million in 2001. Retail sales for the 50 drugs most heavily advertised through this means rose 32 percent in 2000; sales for all other drugs rose 13.6 percent. Legislation to regulate direct-to-consumer ads has been debated in 23 states, and FDA is reviewing its policy.

## 2003: What's in Store

Mr. Shah ended his presentation with five predictions for the coming year:

- Continued increase in the prevalence of chronic diseases, leading to increased drug use and more complex hospitalizations.
- Continued rise in drug costs, but at a lower annual rate than in the recent past.
- Increase in prices for innovative drugs.
- Unlikely passage of a Medicare drug benefit.

## A Model for Medication Technology Management

Dealing with the complexity of factors driving medication costs requires more than a simple budget. It requires a three-dimensional planning model (see illustration) that comprises financial considerations (the traditional budget) as well as strategic (programmatic) and tactical (policy) dimensions.

- **Financial planning** includes traditional budget-development activities. It requires an awareness of one's own situation and the overall gestalt as well as an ability to identify relevant trends and to factor in price inflation and policy and cost-containment strategies.
- **Strategic planning** includes programmatic decisions, product-line budgeting, and longer-term considerations. For example, new pharmacy programs, such as a specialty clinic staffed by pharmacists, will be needed to appropriately manage new medications. Pharmacy leaders must consider broadening their current strategic-planning efforts to include preparation for the introduction and diffusion of new pharmaceutical technologies.

- **Tactical planning** includes managing medication technology through policy and the use of traditional tools such as the formulary. It also entails consideration of innovative approaches such as pharmacist case management, prescriptive authority, and collaborative practice.

In their planning, pharmacy managers must bear in mind the following general categories of influence:

- **Provider Characteristics.** Pharmacists need to understand the needs and priorities of their own prescriber group and of differences among the members of that group. They need to know, within their institutions, who are the “fast adopters” and who are the “slow adopters.” Cost sensitivity of providers is another variable.
- **Payer Characteristics.** Pharmacists should know the extent of managed care penetration; they should also be aware of the structure of managed care organizations. An understanding of risk bearing and of an institution’s mission with respect to indigent care are other factors that need to be considered in the pharmacy’s tactical and strategic planning.

- **Patient Characteristics.** These include volume, case mix, acuity of illness, socioeconomic level, and insurance status.

- **Organization Characteristics.** Considerations include an institution’s size and location, and whether it is a teaching hospital. Other factors include leaders’ willingness to implement therapeutic interchange, strong formularies, and other practices that can help hold the line on costs.

- **Technology.** Organizations with strong research programs will have more innovators, which will drive up costs. Research, however, can produce a revenue stream. If some drug products are available free this may be a means of cost avoidance.

## Conclusion

We are entering a decade that promises technological advances in medication therapy as well as continuing cost-containment pressure. These conflicting trends may result in changes in access to medications that will challenge the structure of pharmacy practice as it exists today. Pharmacy leaders must broaden their awareness of the factors influencing the development and diffusion of technology. Even more important, they will need to demonstrate the *value* of medication use, particularly of many of the new and expensive agents.

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Technology  
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