n recent times, employers, particularly larger firms, have become more sophisticated in their understanding of health care delivery and more active in addressing issues related to employee benefits. Some employers have initiated efforts to promote computerized physician order entry (CPOE) and to reduce medication errors in addition to the traditional aims of decreasing their costs of pharmaceutical coverage.

As is true in hospitals as well, competing quality and financial considerations cause decision-making at the point of patient-care delivery to become increasingly complicated and difficult for health care practitioners. This article presents some examples of the contemporary issues related to these concerns and various health benefit initiatives.

MCOs, HEALTH PLANS, AND RISING COSTS

Stafford and Radley¹ presented retrospective research from a medical group on the potential cost savings associated with the practice of pill-splitting by patients. Using this technique, patients obtain a higher-strength tablet or a similar dosage form (e.g., 100 mg) and then cut or split the tablet into two (50 mg each), thereby saving on the cost of the medication. Although pill-splitting has been of periodic interest to pharmacy benefit managers (PBMs) and physicians, serious questions remain about the true value of such a practice, which has been questioned by numerous professional groups. Furthermore, readers of such research need to fully understand the perspective and motivation behind some of these cost-savings initiatives as well as the significant limitations that are commonly associated with them. For example, physician group risk-sharing agreements can benefit from such shared drug cost savings with the health plan—or a hospital, similarly, might be able to lower its cost of drug components within a fixed reimbursement payment methodology, thereby improving its financial status.

Health plans, physician groups, and other managed care organizations (MCOs) are finding it increasingly difficult to control the rate of cost increases in health care. It is this ongoing trend of double-digit rate increases that has captured the attention (as well as the ire) of employers, who ultimately pay the cost of care through increases in health plan premiums. As a result, health plans and PBMs lack adequate responsibility for managing trends of rising costs. Furthermore, shifting the blame for cost-management deficiencies at the time of benefit reviews or renewals is common among health plans.

Recent financial pressures and the worsening economic conditions in the U.S. have again renewed many attempts to provide cost savings in budgets. Unfortunately, it is all too common to find a pennywise focus on pharmaceuticals without regard for the larger-budget categories and the impact on the cost-of-care “product” provided by health care organizations such as hospitals.

MARKETING ISSUES

During the past few years, the marketing of older drugs under new names and indications had been sporadic, but it has now become more common. Examples include Sarafem™ (fluoxetine, Eli Lilly), a medication used to treat body wasting; this is a drug whose original use was as a pediatric growth hormone for preadolescents of short stature.

Wellbutrin® (bupropion, GlaxoSmithKline) has been renamed, for use in smoking cessation, as Zyban® (bupropion, GlaxoSmithKline) and has also had line extensions (consisting of alterations in strength, bottle content size, or packaging) for its more traditional psychiatric indications related to depression.

The cardiovascular indications of Betapace AF™ (sotalol, Berlex) have been expanded to include atrial fibrillation; some experts might also consider this to be a line extension. In some cases, these approved drugs also have off-label uses, defined as those that are not in the Food and Drug Administration’s (FDA’s) product description.

All of these examples illustrate the goal of drug manufacturers to expand the use of accepted agents as they seek to maximize their return on investment (ROI) of key brands. This comes at a time when many pharmaceutical firms are facing a limited drug pipeline and must seek to bolster existing brands. Often the new indications are well known and published in the medical literature, and their use thus occurs without promotion by the company. The prohibitive cost of research required for filing with the FDA to receive additional indications has typically minimized the frequency of these types of marketing approaches that may significantly increase product utilization for previously off-label indications. Now, from the perspective of the pharmaceutical industry’s ROI, the incremental sales increases for flat-growth products are more attractive. For pharmaceutical firms, this results in incremental costs that might have been unplanned or unexpected in the budget beyond historical expectations.

Line extensions are also used to increase marketing efforts to maximize a brand’s ROI. Although line extensions are common for changes in dosage strengths or in traditional pill, capsule, or liquid dosage forms, the expanded range of possible dosage forms has fueled the proliferation of brands. For

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example, the introduction of Prozac® Weekly™ (fluoxetine, Eli Lilly, Distra) changed the paradigm of widespread chronic oral care for psychiatric disorders that had previously been possible only through injectable “depoo” formulations. A more traditional example of extended-release formulations in the popular and growing cholesterol-lowering category is Lescol® XL (fluvastatin sodium, Novartis, Reliant).

Other line extensions of dosage forms have included rapid-dissolve technology for oral migraine and antacid medications and skin-patch technology for the delivery of hormone products for contraception or menopause.

**DRUG CATEGORY REVIEW AND ACCESS TO MEDICATIONS**

A petition submitted to the FDA to approve the move of Claritin® (loratadine, Schering-Plough), a seasonal allergy medication, from prescription status to over-the-counter (OTC) status was accepted and implemented, effective on December 10, 2002, by the original manufacturer, Schering Laboratories. This change was the result of a unique request by Wellpoint Health Plan in Thousand Oaks, California, instead of a manufacturer-initiated change of status through the traditional route with the FDA.

The issues related to switching from prescription status to OTC status for medications and patent expirations are again in the forefront as a result of the number of blockbuster category drugs facing expiration of their patents. In the case of Claritin®, the patent for loratadine is expiring at the same time that the drug is moving to OTC status. This combination of events is setting up the arrival of several OTC competitors to loratadine in the marketplace, including consumer brands from Johnson & Johnson and Wyeth. As a result, the medications that health plans will continue to cover in the nonsedating class—and how consumers will react to changes in the status of drug benefit coverage within the drug class—remain unclear for now.

For the pharmaceutical firms, OTC products and competition can offer a mixed blessing in terms of product costs alone, but the overall cost of care will probably remain unchanged or might possibly increase. Costs can go up if patients seek alternative and more expensive medications that are covered under their drug benefit plans or if they do not treat themselves appropriately and thus need to seek emergency acute care.

Another petition to the FDA to approve Prilosec® (omeprazole, AstraZeneca) as an OTC drug has been recommended for acceptance, pending approval of consumer labeling by the FDA. Although still under patent protection, this ubiquitous proton pump inhibitor (PPI) may be a harbinger of changes to come in the classification status for this class of drugs. In any case, many of the same questions about loratadine remain, from a payer’s perspective relative to the cost of care as well as the share paid for care by payers.

The past experiences with ibuprofen (Motrin®, McNeil Consumer; Advil®, Wyeth Consumer); histamine (H 2) blockers such as Tagamet® (cimetidine, GlaxoSmithKline) and Zantac® (ranitidine, GlaxoSmithKline); and vaginal antifungals such as Monistat® (miconazole nitrate, McNeil) and Gyne-Lotrimin® Vaginal Cream ( clotrimazole, Schering-Plough) suggest that OTC status does not necessarily result in a net savings to patients or payers in the longer run. For example:

1. The doses of drugs that have moved to OTC status do not always stay the same in prescription strength. The dose of ibuprofen, for instance, was reduced from 400 mg and higher as a prescription drug to 200 mg as an OTC drug.
2. The quantity and packaging of the medications are usually limited to a course of treatment. Monistat® is to be taken for one to three days, and Claritin® is to be taken for seven days.
3. The retail costs of OTC drugs are not covered by insurance, whereas prescription co-payment fees can be less than the retail costs—or they might not exist at all—in certain drug benefit plans; this might serve as an incentive to some patients to utilize their benefits to obtain more expensive therapy.

**CONCLUSION**

Given the reality of change, PBM s today continue to be confronted with the challenge of difficult decision-making regarding the ease of access to medications in their organizations. The historical cost trend rate of pharmaceuticals is not going to significantly change over the next couple of years, and costs will probably grow faster later in this century. As a result, PBM s must move toward a dual strategy of managing the utilization of formulary drugs while establishing a cost-of-care model for benchmarking in organizations.

Department-level managers must serve not only the organizational mission but also the company’s financial plan for survival. Therefore, prudent review and implementation of drug utilization management, as well as enhanced outcomes from the use of effective medications in hospitals or ambulatory care settings, are important goals for pharmacists.

**REFERENCE**