

The Formulary Decision Process: What Are They Doing in There and Can Actuaries Help?

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Executive Summary

This paper provides an overview of the process used in making formulary decisions at a health plan and suggests how actuaries would add value. We believe that actuaries should understand the economic considerations involved, and that the presence of actuarial input in the process could improve it, especially by tying it to overall decision making for the health plan. A close partnership between actuaries and pharmacists can improve their organizations' ability to compete in today's marketplace.

We begin with a brief background on pharmacy benefit trends in recent years, illustrating why health plans are focused on keeping costs down in this area of the budget and getting the most for their pharmacy dollars. To do this, formularies are now commonplace, and economic research is expected in addition to traditional safety and efficacy data in order to evaluate a drug's proper place in treatment. This environment has led to the development of the Academy of Managed Care Pharmacy Format for Formulary Submissions, a guideline that specifies all the types of information, economic and otherwise, that formulary decision makers want from drug manufacturers. Since this has made economic evaluation of pharmaceuticals the focus of much more attention, a brief description of the typical methods used to do this is presented. These typically academic approaches to the analysis of pharmaceutical costs fall far short of what is needed for health plan decision makers, however.

After talking about some particulars of the formulary decision process, we conclude by suggesting that actuaries seem to be missing from this important process, and they should not be. While the plan actuaries analyze other elements of the health plan budget, pharmaceutical decisions are made separately. If pharmaceutical decisions were "brought into the fold" by using actuarial techniques, including total budget impact with specification of costs throughout the healthcare budget, dynamic population analysis and results focused on cost rates rather than ratios or other endpoints, an integrated approach to healthcare delivery and budgeting would be fostered rather than thwarted.

1. The Pharmacy Budget Crunch

Many prescription drugs are cost-effective treatment options.¹ Trouble is, there are so many prescription drugs available. Which ones should be covered, and encouraged, by health plans and which should not? It is the Food and Drug Administration's (FDA) job to ensure that only safe and effective pharmaceuticals are available in the United States. Given that this agency does its job well, why give the issue any further thought?

In the past, this line of thinking may have been acceptable. Health plans could allow their members access to whatever products were available and prescribed by their physicians. The difficulty has come with the explosion in cost in this area of healthcare. While total healthcare expenditure trends have ranged from 9 percent to 16 percent over the past five years, pharmaceutical benefit trends have increased at rates of 17 percent to 18 percent.² The explosive pharmaceutical cost trends have been attributed to increases in drug utilization (39 percent), increases in drug prices (37 percent) and shifts to higher priced drugs (24 percent).³ For example, in 1990 the average annual utilization was 4,141 scripts per 1,000 members with an average price per script of \$26.88 for a commercially insured population.⁴ The corresponding values for 2003 were 8,900 scripts per 1,000 members at an average cost per script of \$61.78.⁵ This is an increase of 215 percent in utilization rate and 230 percent in price per script in 13 years, for a total increase of 494 percent in per-member-per-month claim costs.

2. Pharmacy Benefit Management and the Use of Data

In order to manage this expense, health plans in recent years have had to consider carefully which pharmaceuticals to cover. Formularies have been designed for this purpose, relying upon differences in cost sharing to steer

¹ Neumann P.J., Sandberg E.A., Bell, C.M., Stone, P.W. and Chapman, R.H. "Are pharmaceuticals cost-effective?" A review of the evidence. *Health Aff (Millwood)*. 2000;19(2):92-109.

² Milliman USA. 2003 Intercompany rate survey.

³ The National Institute for Health Care Management Research and Educational Foundation. Prescription Drug Expenditures in 2001: Another Year of Escalating Costs. May 6, 2002.

⁴ Milliman & Robertson, Inc. Health Cost Guidelines, Standard Rating Structure, 1990.

⁵ Milliman Health Cost Guidelines, Commercial Rating Structures, 2003.

members and their physicians toward less costly or more cost-effective choices, thereby managing the total pharmacy budget. A critical role in this process is deciding which pharmaceuticals are to be covered, and at what level of cost sharing. Pharmacy and therapeutics (P&T) committees typically make these formulary decisions, and to do this effectively, they need good information.

Since the FDA requires extensive efficacy and safety data in order for a drug to gain its approval for sale in the United States, pharmaceutical companies have this type of information readily available for distribution. Published studies are readily accessible.

Efficacy research is designed to prove a drug's scientific value in an ideal setting. However, this setting will not be seen outside of a specifically designed and controlled experimental environment. The use of a drug in a typical healthcare environment, where compliance may be less than perfect and patients may have concurrent medical conditions, is more apropos. A drug's usefulness for treatment in the latter environment is called effectiveness. Effectiveness data are more useful for P&T committees, but less available. Effectiveness is assessed in more naturalistic studies than are used to demonstrate efficacy and safety, and therefore gives a better idea as to how pharmaceutical use will impact patients in the real world. Many such studies may also be found in the published literature, although they are not necessary to gain FDA approval for a drug. They are expensive to conduct and are therefore less common.

Less common yet, although still sometimes available, are studies of the pharmacoeconomic properties of pharmaceutical use. Such studies attempt to show the costs associated with using a drug. Costs are typically assessed in one of several ways, which will be discussed in more detail later. These types of studies are the least common of the three types mentioned.

To make the best drug coverage decisions, a P&T committee should study efficacy, safety, effectiveness and pharmacoeconomic data. This enables a health plan to make evidence-based decisions on how to spend its pharmacy dollars to obtain the best medical care.

3. Standard Pharmacoeconomic Analysis Methods

In some cases, making decisions as to what should be included on a formulary does not benefit from the presence of sophisticated

pharmacoeconomic analysis. In a case where only one drug is available to treat a very rare condition, for example, economic analysis would be superfluous. A very high cost drug with low effectiveness is unappealing for the formulary, and further cost analysis would be wasted. Conversely, a low cost drug with high effectiveness and good safety is automatically appealing for the formulary and further cost analysis is not necessary. More sophisticated cost analysis is appropriate when the cost and effectiveness of the drug are both low, when they are both high, or when the tradeoff between safety and effectiveness needs to be weighed. In these cases, a more in-depth look at the cost impacts of the drugs can help the P&T committee determine whether the drug provides good value for the money spent.

Pharmacoeconomics as a field is fairly young and has a very academic feel. Much of the research done on the cost impacts of pharmaceuticals uses techniques adapted from the field of economics, including cost-minimization analysis (CMA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA). These methods are described below.

CMA is the simplest, and probably least useful, of the methods listed. CMA identifies the least expensive option among several with equivalent effectiveness.⁶ For example, a CMA would conclude that the less expensive of two equally effective ace inhibitors is the preferred choice. CMAs are rarely done because few clinical trials result in the conclusion that a drug is equal to its comparator. Most aim to show its superiority.⁷ Two shortcomings of this approach are that: (a) it is rare to find a situation where comparators can be called equally effective; and (b) this method neglects other important variables such as the cost or unpleasantness of possible side effects.

CEA is done to determine the cost per unit of effectiveness, resulting in a cost-effectiveness ratio. This ratio can be stated as the cost per unit of outcome, or units of outcome per dollar spent.⁸ The outcomes are measured in terms of

⁶ Drummond, M.F., O'Brien, B., Stoddart, G.L. and Torrance, G.W. *Methods for the Economic Evaluation of Health Care Programmes*, 2nd Edition, Oxford University Press, 1997.

⁷ Newby, D. "Use of pharmacoeconomics in prescribing research. Part 2—Cost minimization analysis—When are two therapies equal?" *Journal of Clinical Pharmacy and Therapeutics*. 28:145-150.

⁸ Drummond, M.F., O'Brien, B., Stoddart, G.L. and Torrance, G.W. *Methods for the Economic Evaluation of Health Care Programmes*, 2nd Edition, Oxford University Press, 1997.

clinical events, such as heart attacks, hospital days avoided or life years saved. The lower cost-effectiveness ratio (cost per unit of outcome) is associated with the preferred treatment choice. The preferred choice is not necessarily the least expensive one, however, since the health gain of the options can vary as well. This type of analysis requires that the outcomes of the comparators can be measured in the same way. CEA can be a robust analysis, taking all associated costs and savings into account. However, there is considerable variation across CEA studies with respect to types of patients examined, measures of effectiveness and costs used and the way in which cost-effectiveness ratios are calculated and reported which can make their interpretation and comparison difficult.⁹

The most meaningful CEA analysis is calculation of the incremental cost-effectiveness ratio (ICER) between two alternative treatments. To do this requires data from head-to-head trials or at least from different trials that were fairly similar in study population and methodology. Since the manufacturer of one of the drug products studied sponsors most clinical trials, they rarely provide all the direct comparison data needed to answer the questions a health plan is asking. A rare exception is the recently published PROVE IT study, which compared two cholesterol-lowering drugs, Pravachol and Lipitor. Although the maker of Pravachol funded the study, it showed that Lipitor was better¹⁰. This outcome probably makes it less likely that other drug companies will want to fund head-to-head trials in the future.

CUA is done to assess the cost per outcome unit that is adjusted for patient value placed on those outcomes.¹¹ Rather than assessing simply life years saved, for example, the CUA would assess the cost per quality-adjusted life-years (QALYs) saved. For example, a patient whose work requires a lot of standing and walking might assign more utility to an orthotic device (a gait-correcting

⁹ Mullins, C.D., Blak, B.T. and Akhras, K.S. "Comparing cost-effectiveness analyses of anti-hypertensive drug therapy for decision making: Mission impossible?" *Value in Health*. 2002;5(4): 359-71.

¹⁰Cannon, C.P., Braunwald, E., McCabe, C.H., Rader, D.J., Rouleau, J.L., Belder, R., Joyal, S.V., Hill, K.A., Pfeffer, M.A. and Skene, A.M. "Comparison of intensive and moderate lipid lowering with statins after acute coronary syndromes." *New England Journal of Medicine*. 2004; 350. Pre-publication posting at www.nejm.org. (To be published in April 8, 2004 issue.)

¹¹Drummond, M.F., O'Brien, B., Stoddart, G.L. and Torrance, G.W. *Methods for the Economic Evaluation of Health Care Programmes*, 2nd Edition, Oxford University Press, 1997.

shoe insert) than a patient who does little standing or walking. In other words, the first patient would find that an orthotic device provides more improvement in quality of life than the second patient. These patient differences in values can be incorporated into the assessment of outcomes. Critics of CUA maintain that it is difficult to use and compare because there are numerous different ways to assign health status, no agreement upon what constitutes the gold standard and whose preferences are measured—patients, providers, or public—affects the results.¹²

CBA measures the cost per outcome where outcomes are translated into dollars.¹³ In the example above, the patient whose work requires a lot of standing and walking might be willing to pay more for an orthotic device than the patient who does little standing or walking. The cost to buy the device can be assessed against its value stated in dollars. The resultant measure can be either a ratio of dollars spent to dollars of value gained, or it can simply be a number. A positive number implies more benefit than cost, and a negative number implies more cost than benefit. This method has the drawback of having to obtain assessments of the monetary worth of health outcomes. In evaluating pharmaceuticals, CBA is often used to compare the cost of a more expensive drug with the expected savings from reduced need for other medical costs such as physician visits, hospitalization or emergency room care, thereby sidestepping this drawback.

Among the methods listed, CEA analysis is fairly common in the literature and can be conducted from a societal perspective or the perspective of a particular party. Studies conducted with a more academic goal in mind often reflect the societal perspective. The perspective of the economic analysis may make the results more or less useful to P&T committee decision makers, however. While they may consider several perspectives in their decision-making process, the perspectives of the health plan and its members will be of most importance to them. In some cases, the employer's perspective may be important, particularly if the condition being treated has major impacts on absenteeism or employee productivity. This is increasingly true as large employers become more sophisticated in their understanding of the value of healthcare. Analyses done from a societal perspective may not enable P&T committee members to

¹²Brinsmead, R. and Hill, S. "Use of pharmacoeconomics in prescribing research. Part 4: Is cost-utility analysis a useful tool?" *Journal of Clinical Pharmacy and Therapeutics*. 2003; 28(4): 339-346.

¹³Drummond, M.F., O'Brien, B., Stoddart, G.L. and Torrance, G.W. *Methods for the Economic Evaluation of Health Care Programmes*, 2nd Edition, Oxford University Press, 1997.

determine which costs and consequences are relevant to the health plan financial picture.

Whereas studies using the methods above may be available to P&T committee members, their results are not well suited to the needs of a health plan. Such results may help to determine which of the drugs compared in one study seems to be the better choice from a cost perspective, but they do little to help health plan decision makers quantify how and where pharmaceuticals will have an impact on the overall budget. Many of these studies compare a target drug to placebo, or one other drug, but they do not typically include a head-to-head comparison of important alternatives.

In addition, the pharmacoeconomic published literature has suffered from several important shortcomings. First, some researchers have relied upon sample sizes too small for credibly drawing the conclusions desired. Results from such studies are of little value. Second, many published studies are funded by the manufacturer of the target drug studied. While the results of such research may be sound, suspicion of bias nevertheless makes readers cautious about their use. Manufacturers have become quite adept in framing the research questions so that the answers will present their product favorably. While such studies may be technically well designed, they do not answer the questions the health plan is asking. In fact, reviews of economic studies have found that conclusions do seem to be biased in favor of the sponsor's product.^{14,15} Third, the published literature includes only studies that were submitted and accepted for publication. It is not a complete record of pharmacoeconomic research. Fourth, many published studies suffer from a lack of transparency. The reader may not be able to ascertain important details about the study, including how measurements were taken and what economic perspective was used to assess costs.

Pharmacoeconomic analyses often rely upon information from multiple sources, with potentially complicated study designs, making them complicated to perform and analyze. A study of submissions reviewed by the Australian

¹⁴Rochon, P.A., Gurwitz, J.H., Simms, R.W., Fortin, P.R., Felson, D.T., Minaker, K.L. and Chalmers, T.C. "A study of manufacturer-supported trials of non-steroidal anti-inflammatory drugs in the treatment of arthritis." *Archives of Internal Medicine*, 1994; 154; 157-163.

¹⁵Neumann, P.J., Sandberg, E.A., Bell, C.M., Stone, P.W. and Chapman, R.H. "Are pharmaceuticals cost-effective? A review of the evidence." *Health Aff (Millwood)*. 2000;19(2):92-109.

Pharmaceutical Advisory Committee found that 67 percent of 326 pharmaco-economic analyses had serious flaws.¹⁶ The resources available to make that assessment were considerable, possibly beyond the capacity of many individual health plans. While this may contribute to a health plan's reluctance to use such information, to avoid doing so misses a real opportunity to add value to the formulary decision process.

4. The Development of the AMCP Format for Formulary Submissions

In an effort to counter some of the problems with available research on pharmaceutical costs, the Academy of Managed Care Pharmacy (AMCP) developed and disseminated the first Format for Formulary Submissions in 2000. Version 2 of the Format, released in 2002, incorporates user feedback.^{17,18} The Format is a guideline that specifies what information health plans want to see from drug manufacturers in order to help them make informed, evidence-based, drug coverage decisions.

In developing the Format, the AMCP recognized that evaluating drug costs in a silo is not the best approach to understanding and controlling overall healthcare expenditures. As such, the AMCP developed the Format as a tool that incorporates efficacy, safety, effectiveness and economic evaluation into the formulary decision process. The Format puts responsibility on pharmaceutical manufacturers to provide all information available in a standardized format.

The Format urges health plans to request a standardized "dossier" from pharmaceutical manufacturers. The content of the dossier consists of five main sections: product information, supporting clinical and economic information, modeling report, product value and overall cost and supporting information.

¹⁶Hill, S.R., Mitchell, A.S. and Henry, D.A. "Problems with the interpretation of pharmaco-economic analyses." *Journal of the American Medical Association*. 2000; 283:16: 2116-2121.

¹⁷Academy of Managed Care Pharmacy. Format for Formulary Submissions Version 2.0. Academy of Managed Care Pharmacy, October 2002.

¹⁸Fry, R.N., Avey, S.G. and Sullivan, S.D. "The Academy of Managed Care Pharmacy Format for Formulary Submissions: an evolving standard—a Foundation for Managed Care Pharmacy Task Force report." *Value in Health*. 2003;6(5):505-521.

The product information section of the Format provides the basic information about the medication, such as the drug names, dosing, pricing and adverse reactions. This section also provides information about treatment indications and alternative therapy for the same condition. It contains all the information from the FDA-approved product labeling.

The supporting clinical and economic information section of the Format requests that manufacturers summarize all key studies, published and unpublished. It is recommended that this section include relevant clinical and economic research.

The Modeling Report section requests that manufacturers supply health plans with a model of the budget impact of a treatment. The suggested model should include clinical pathways, the patient population eligible for treatment, outcomes of therapy for each treatment option, compliance, costs and the time horizon for the expected costs and outcomes. The Format suggests that the analysis be presented in either a cost/consequence table or as cost-effectiveness ratios. Desirable elements of the model include transparency, population analysis and the ability of the plan to change inputs or incorporate its own data.

The product value and overall cost section is limited to two pages and allows the manufacturer the opportunity to present justification for the expected cost of the drug versus its anticipated impact on clinical and other economic outcomes.

The supporting information section is for copies of all references used in the supporting clinical and economic information and the modeling report sections of the documents. The Format also requests that the economic model be made available in this section containing all of the math and projections for checking. This is usually provided as an unlocked Excel spreadsheet, though in some cases another format may be submitted by mutual agreement. The spreadsheet should be designed to allow the health plan to adjust all significant input variables to correspond to its own assumptions as well as local medical costs and treatment practices.

Since the release of the latest guidelines, AMCP reports that adoption is spreading at a rapid pace.¹⁹ To date, no large studies exist on the impact of the Format on patient outcomes.²⁰

Proponents of formulary guidelines maintain that the Format makes great strides in leveling the playing field between manufacturers and health plans and improving the applicability and practicality of CEA.²¹ The Format creates a standard for constructing, presenting and critiquing models. The health plan can thus peer review the model. If it lacks expertise to do so, it can hire the services of a third-party expert to perform the review. Early experience suggested that manufacturers were not willing to comply with providing dossiers. However, recent information has suggested that most are now submitting dossiers, but they are frequently incomplete.²²

Although dossiers are being assembled and provided to health plans, their contents may still fall short of what is needed or wanted in order to aid decision making. Some dossiers provide no economic research, and others provide only budget impact models that do not typically detail the effects of adding a new drug to other areas of healthcare delivery and total costs. Manufacturers may not provide an interactive model at all, preferring to show cost impacts on paper or to send a representative to demonstrate modeling without leaving anything behind.

5. The P&T Committee

The literature on P&T committees is sparse. To get a better understanding of the process used by P&T committees in formulary development, one of the authors has done some informal observations of, and discussions about, P&T committees and their decision processes. Another of the authors is a formulary

¹⁹AMCP, The Year In Review, 2002-2003. Available at www.amcp.org. Accessed February 17, 2004.

²⁰Neumann, P. "Evidence-based and value-based formulary guidelines." *Health Affairs*. 2004;23(1): 125-134.

²¹Wang, Z., Salmon, W. and Walton, S. "Cost-effectiveness analysis and the formulary decision-making process." *Journal of Managed Care Pharmacy*. 2004; 10: 48-59.

²²Otompke, J. "A new format for making more cost-effective drug coverage decisions takes off." *Business and Health*. January 2002.

manager and leading member of a P&T committee. This section will discuss P&T committee features, relying to a large extent upon these observations.

There is a great deal of analysis and research that goes into the preparation for a P&T committee meeting where drug coverage decisions are made. As discussed above, information is gleaned from pharmaceutical manufacturer dossiers, published research, FDA analyses published on its Web site and possibly modeling and analysis done by the health plan itself. Pharmacy staff normally conducts a search for relevant primary literature using MEDLINE and possibly other databases. Secondary sources such as Cochrane reviews may also be consulted. Summaries of the information from these sources, and sometimes research articles themselves, are distributed to P&T committee member prior to a meeting. The homework for one of these meetings is substantial.

P&T committees we have seen are comprised of primarily physicians and pharmacists. One study reported a mix of 63 percent physicians, 32 percent pharmacists and the rest other.²³ We saw one committee with a majority of physicians (71 percent), and the rest had less than 50 percent. Pharmacists comprised most of the rest of the committee members. These committees ranged in size from 11 to 25 people. Other members included a psychologist, osteopaths, registered nurses and employer representatives. Two of the committees explicitly noted that only members not employed directly by the health plan were allowed to vote on formulary decisions. The pharmacy benefit manager (PBM) committee profiled allowed one vote per client, a representative of which sat on the P&T committee.

Several of the meetings began each discussion of a new drug with a question as to whether any committee member should be excused from that vote or discussion due to financial interest in the manufacturer of that drug. A pharmacist or team of pharmacists gave the presentation of information about the new drugs under consideration. These presentations were brief, the details having been supplied to the members prior to the meeting, including formulary recommendations, and were followed by discussion from the group in general. The discussions were very interactive, with many questions and dissenting points of view. In every meeting observed, at least one recommendation made by the presenting pharmacist(s) was not accepted.

²³Sanchez, L. "Pharmacoeconomics and formulary decision making." *Pharmacoeconomics*. 1996;9 Suppl 1:16-25.

Depending on the class of the drug or drugs under discussion, experts outside of the standard P&T committee were asked to give relevant opinions and observations. The pharmacists who prepare formulary reviews usually consult with one or more such experts prior to writing their recommendations.

Most of the discussion during the meeting revolved around the safety and effectiveness of the drugs in question. Information on these topics included both research findings and observations from clinical practice. Costs were not discussed as much, although the price of the drugs and patient copays were mentioned several times. Cost offsets and total budget impacts were never discussed during meetings. One group explicitly avoided the subject of costs, focusing instead on selecting the most effective and safe drugs from a class of drugs and narrowing that list down to the best few. Once that list was determined, the final formulary placement of those remaining was then determined by what deals could be negotiated with the manufacturers subsequently.

These committees meet four to six times per year, ranging in duration from one hour to all day.

While the subjects discussed revolved around those pertinent to the particular drugs under consideration, several interesting and fairly animated discussions occurred around the following topics.

While at least one biotech drug was discussed in all meetings observed, the impact of these new, and very expensive, drugs on the clinical outcomes and budgets was highlighted during one meeting. Examples of biotech drugs include Xolair for moderate to severe steroid-resistant asthma and Raptiva for plaque psoriasis. One committee was very focused on this subject, and special attention was given to the subject in general during its P&T committee meeting. This group routinely incorporates an educational component to its P&T committee meetings; in this case a presentation was given on special features of biotech drugs, their anticipated utilization and costs as a class and planned strategic initiatives to appropriately plan for their influence on treatment and the pharmacy budget.

In addition to their high cost, biotech drugs carry unknown risks. Their pharmacologic actions are new, and in most cases FDA approval is based on a relatively short longitudinal experience. Since most of these agents are

maintenance therapy to which a patient might be exposed for decades, the potential harm of such exposure can only be guessed. When the drug is immediately lifesaving, the risk may be acceptable, but when it offers only a modest enhancement to existing therapies, evidence-based medicine would urge caution. It is best to do no harm. Reluctance to add new drugs when there are established therapies for the same condition is also rational economic behavior. The potential risks and uncertain benefits may impose costs in the form of risk.²⁴

One group brought up a perceived connection between the FDA and the pharmaceutical industry and the resultant impact this was believed to have on that agency's ability to provide impartial expert opinions on products reviewed. This was relevant to a discussion of a new black box warning put out by the FDA on an older antidepressant Serzone. Although Health Canada recently removed it from the market in Canada and the manufacturer removed it from the market in Europe, the FDA did not remove this drug from the U.S. market.

Another discussion involved the desirability of covering drugs that provided no unique benefit to patients other than convenience. An example of such a drug is Seasonale, a new three-month course of oral contraceptive that allows the user to restrict menses to four times per year. The mix of hormones in Seasonale can be obtained from other available drugs, and simply taking the alternative drugs without using the placebo pills can mimic the three-month supply. This discussion pitted one person opposed to making formulary additions for this type of convenience against another who considered having Viagra on the formulary roughly the same and felt to refuse Seasonale would be inconsistent with that precedent.

Concern over the convenience and cost to patients when using the pharmacy benefit surfaced in several meetings. For example, in one meeting the copay advantages to members of a new combination diabetes drug, Avandamet, was mentioned. This new drug combines two drugs that are already separately available, but having them combined under a single copay would save members money at the pharmacy. In another, P&T committee members expressed concern that patients might be confused when required to obtain prior authorization for an injectable drug and then have to write a large check at the pharmacy when this was not required for other drugs. While this was done to their benefit design

²⁴de Lissovoy, G. "Weighing the evidence: trends in managed care formulary decision making." *Journal of Clinical Psychiatry*. 2003;64 Suppl 17:29-32.

to streamline administrative costs, this procedure might discourage members from filling their prescriptions.

Most meetings included some discussion of manufacturer strategic maneuverings. These included acknowledgement that drugs like Clarinex, which is slightly different from Claritin, or Nexium, which is slightly different from Prilosec, or new formulations such as Wellbutrin XL (once per day) are developed to capture market share from another product from the same manufacturer that is about to lose patent protection.

One meeting included a discussion on using clinical trial and other data to approve a drug for the formulary when much of the anticipated usage of that drug, epilepsy drug Trileptal, would be off-label psychiatric use. The off-label uses of the drug did not have data for review.

Among these groups, only one (a large PBM) specifically talked about rejecting pharmaceutical manufacturer models in favor of doing its own economic analysis. Other groups mentioned costs of the drugs or copays, or mentioned when economic research was not part of the dossier (evidently not uncommon), but did not talk about doing their own independent economic research or modeling.

With increasing public attention to pharmacy benefit management processes, health plans are encouraged to implement formulary decision-making processes whose goal is to improve clinical outcomes and reduce overall cost of care, rather than simply maximizing rebates and minimizing drug expenditures. These strategies may also help to align incentives for health plans, physicians, pharmacists and patients.²⁵ Cash-strapped state Medicaid programs are also experimenting with evidence-based formulary programs despite vigorous opposition from the drug industry.²⁶

²⁵Chung, R.S, Taira, D.A. and Noh, C. "Alternate financial incentives in multi-tiered formulary systems to improve accountability for outcomes." *Journal of Managed Care Pharmacy*. 2003;9(4):369-71.

²⁶Mello, M.M., Studdert, D.M. and Brennan, T.A. "The pharmaceutical industry versus Medicaid—Limits on state initiatives to control prescription-drug cost." *New England Journal of Medicine*. 2004; 350: 608-613.

6. Formulary Decision Making—What Do We Know About the Process?

According to available literature on P&T committees, health plans, PBMs and hospitals follow the same general process when evaluating a new drug for formulary submission.^{27,28,29} Guiding principles for clinical decision making have been defined as follows³⁰:

- Assess the findings of peer-reviewed medical outcomes research and pharmacoeconomic research,
- Employ published practice guidelines, developed by an acceptable evidence-based process,
- Compare the efficacy, effectiveness, value and therapeutic interchangeability,
- Compare drugs on patient compliance and
- Do a thorough evaluation of benefits, risks and adverse drug reactions (ADRs).

In practice, P&T committee decisions start with the examinations of safety and clinical efficacy first, followed by a determination of incremental value compared to existing alternative treatments. If a drug is considered to have superior clinical properties and has no equal counterparts, then it is added to the formulary. If a drug is inferior to a drug currently on the formulary, then it is not added. If the drug is equally effective to a drug currently on the formulary, then costs are considered in the adoption process. If there are unanswered questions about the product's safety, the decision is usually deferred until more data are available.

Most sources of information available to P&T committees—including manufacturer dossiers, published literature and FDA documents—focus on

²⁷White, J. "Making pharmacoeconomics in formulary development a reality." *Managed Care Magazine*. 2001; 10(2).

²⁸Grabowski, H. and Mullins, C.D. "Pharmacy benefit management, cost-effectiveness analysis and drug formulary decisions." *Social Science Medicine*. 1997; 45(4):535-44.

²⁹Saprong, D.F., "Application of pharmacoeconomics and outcomes research in formulary decision making." *Drug Benefit Trends*. 1999; 11(8):53-57.

³⁰Pharmacy Benefits Management Strategic Healthcare Group Department of Veterans Affairs, Principles of a Sound Drug Formulary System, available at <http://www.vapbm.org/PBM/formularyprinciples.pdf>, accessed March 1, 2004.

clinical and safety issues. Economic information is available, but sparser. Current evidence suggests that pharmacoeconomic information is not widely used by decision makers.^{31,32} Some reasons include the following.

- Health plan decision makers are skeptical of information provided by drug makers.
- Decision makers report being uncomfortable with the extensive use of assumptions in pharmacoeconomic analyses. They prefer observed data to estimates.
- Health plan decision makers have a general concern about the aggregation of health benefits into a single index such as QALYs saved. They prefer to examine independent components.
- Estimates of the total budget impact are often not provided. When they are, the cost of introducing a new drug is often summarized by its effect on the pharmacy budget alone. This misses the impact in other areas of healthcare expenditure.
- The information is usually not presented in language used by health plans. They want to know the effect on overall cost per member per month of their benefit, rather than the cost to prevent a hospitalization or cost per QALY gained.
- Pharmacoeconomic information presented by pharmaceutical companies often lacks the most relevant head-to-head comparisons with treatment alternatives.
- Health plan decision makers need to know how a particular drug is going to affect their own population. Concern about transferability of pharmacoeconomic models is a barrier to their use.

³¹Wang, Z., Salmon, W. and Walton, S. "Cost-effectiveness analysis and the formulary decision-making process." *Journal of Managed Care Pharmacy*. 2004; 210: 48-59.

³²Drummond, M., Brown, R., Fendrick, M., Fullerton, P., Neumann, P., Taylor, R. and Barbieri, M. "Use of pharmacoeconomics information—Report of the ISPOR Task Force on use of pharmacoeconomic/health economic information in health-care decision making." *Value in Health*. 2003; 6(4): 407-16.

7. How Actuaries Can Help

The media have recently devoted considerable attention to the high cost of drugs in the United States. One reason for this is that the FDA does not have a mandate to evaluate a drug's cost-effectiveness as a part of the New Drug Application (NDA) process. Although an NDA submission includes a literal truckload of data, the FDA review focuses entirely on safety and efficacy. As a result, an expensive drug with only marginal clinical benefit may be approved if the reviewers conclude that the reported efficacy outweighs the potential toxicity, regardless of cost. Therefore, P&T committees must do their own economic evaluation of new products if they are to weigh cost-effectiveness in their decision-making process.

Pharmacoeconomic research currently available to P&T committees, although much improved following the dissemination of the AMCP Format, is not fully meeting their needs as indicated above. This seems to be an area where actuarial methods can fill a need. While conducting economic research is not particularly actuarial, modeling is.

The primary area in which the pharmacoeconomic modeling falls short is in the inability to specify and quantify any medical cost offsets associated with the use of a drug. While the AMCP Format calls for quantification of budget impacts in the models requested, health plan decision makers have expressed dissatisfaction with this element of the dossiers received. An informal review of dossiers submitted to one health plan over the past three years showed that no more than 15 percent of them contained useful disease-based models. When a reasonably constructed model is submitted, the health plan may still need to adjust the manufacturer's assumptions to get a reasonable estimate. While this methodology is sub-optimal, it can sometimes yield useful results.

Furthermore, economic models provided by pharmaceutical manufacturers typically compare their own drug to a single comparator or to placebo. A more useful model would incorporate all the relevant treatment options for the medical condition of interest in a single head-to-head comparison.

Models could be made more useful by the use of dynamic population modeling typically used by actuaries. Pharmaceutical company models are often based on population studies in clinical trials or on populations that come from canned databases rather than (a) reflecting the population of the health plan of

interest, and (b) allowing the user to manipulate the population mix to test assumptions. The population considerations should include features unique to the type of payer populations, such as commercial, Medicare, Medicaid or TRICARE populations.

An ideal model would incorporate these capabilities, reflect the prescription coverage benefit design, medical condition incidence and prevalence, the rate at which the new drug will enter the system and replace or supplement other treatments, utilization and costs associated with the medical condition and side effects of the treatment options, expected compliance rates and the level healthcare delivery management expected in the system. Estimates of parameters in this model can be obtained from the medical literature, expert opinion about reasonable clinical pathways, study of prior claims data and expert judgment.

After talking about some particulars of formulary decision making, we conclude by suggesting that actuaries seem to be missing from this process. The people best qualified to create such a model are in the actuarial department. Such a model would not only be a valuable tool to aid in the formulary decision process, but would have much more broad usability within the organization. Economic outcomes expressed in per-member-per-month claim costs can be reviewed and used by actuaries when monitoring experience and preparing for pricing. Specification and quantification of medical cost offsets, or increases, that result from the use of drug treatments should be information that people in care management and utilization management roles should have in hand to aid the performance of their jobs. Ultimately, pharmaceuticals are an integral part of good medical care and their costs should be viewed as part of the total budget. As biotechnology drives up the average cost of new drugs, a strong partnership between actuaries and pharmacists is crucial to the success of a health plan.