BY ELISABETH PENA

Managing OUTCOMES

Limits on reimbursement for prescription drugs are expected to have a long-term impact on drug development.

TO ADDRESS PAYER CONCERNS, COMPANIES WILL NEED TO HAVE DATA ON COST VERSUS UTILITY, AND THOSE DATA COME FROM OUTCOMES STUDIES. BUT IF THEY ARE TO USE SUCH DATA EFFECTIVELY, PHARMACEUTICAL COMPANIES WILL HAVE TO START CONDUCTING SUCH EVALUATIONS EARLIER IN THE DRUG-DEVELOPMENT PROCESS.

OUTCOMES OBSERVERS

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Just because a drug receives marketing approval doesn't mean that it will automatically be reimbursed by payers. Increasingly, managed-care organizations, insurance companies, and government payers such as Medicare and Medicaid have been conducting outcome studies and using data that assess a products' value to patients against its cost.

ANDREA SPANNHEIMER

THE KEY ELEMENT FOR THE ACCEPTANCE OF OUTCOMES RESEARCH IS QUALITY. High-quality outcomes research studies are essential to speed acceptance of new therapies among the medical community.

Clinical-trial evidence provides regulators and physicians with proof that a drug is safe and efficacious for the indication it is intended for. This information is required for the approval process, but regulators, physicians, and payers need and want to look beyond this somewhat narrow view to understand the long-term effect.

Health outcomes data provide a full assessment of how a drug is performing when it is used in real-world situations.

Now pharma companies are beginning to conduct these assessments earlier in the development process to provide such data to payers when the product is approved. A common misconception about outcomes is that this is research that should be done only after a drug has been approved. Experts say 25% of clinical trials now collect outcomes data, with the majority of those evaluations being done during Phase III and Phase IV.

This is expected to change, however, as many companies are beginning to consider outcomes research earlier in development. Experts note that Phase II is becoming a more common starting point for the initiation of outcomes measurement. The contributing factors to this trend include increasing economic concerns regarding pricing and reimbursement, as well as increased consumer participation in their healthcare decisions.

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DR. SUSAN ROSS

THE CRUX OF THE ISSUE IS that there is not a consensus definition of outcomes research or management.

THE IMPACT OF OUTCOMES DATA

SPANNHEIMER. Practitioners, organization managers, and consumers want to know how a new treatment acts in the real world, not just in the sometimes artificial environment of a clinical trial. Furthermore, the quality-of-life aspect often included in outcomes research studies is of great importance to consumers since this is probably one of the key factors, besides effectiveness, that will influence their decisions. Also, because of the increasing cost pressures in the healthcare system, information on a new treatment's cost-effectiveness and economic impact in the real world is of great value for all decision makers and players in the healthcare system.

WILLS. There can be considerable value to practitioners or their organization managers in using health outcomes data. Outcomes data can effectively measure the quality improvement of a practice. Publicizing measurement and improvement to other organizations and to patients will make practitioners feel more comfortable using a company's services. This definitely impacts the bottom line, not to mention significantly improving patient care.

YOUNG. Currently pharmaceutical research produces two things: efficacy and safety information. Trials to determine that information are almost always placebo-controlled. There are not a lot of head-to-head trials in pharmaceutical research. Over time that information tends to sort out physician-use patterns. Outcomes studies of this type are useful if done in a format that addresses whether one drug produces a better result in the population than another. In other words, taking the information we get from trials and relating it to the mainstream of what is actually happening to the patient.

PASHOS. For pharmaceutical companies developing new treatments, outcomes data can help them to understand existing patterns of clinical care and the burden of illness in economic, quality-of-life, as well as clinical terms. That understanding of the cost of illness in different markets can be used to improve the design and implementation of clinical trials. Outcomes studies can be either piggybacked onto clinical trials or run parallel with them. Thus, outcomes data can give companies a solid basis for the real-world marketplace and their product's potential.

DICESARE. Health economics and outcomes research studies assess the total value of a drug — both the benefits and the costs. The cost of one drug may be more than another, but it may be more effective clinically and/or lead to savings in other healthcare uses that fully or partially offset the difference in drug cost. These data provide the evidence that decision makers need when deciding whether to use one drug or another. Health outcomes data provide a full assessment of how the drug is performing when used in real practice. In contrast, data from controlled, protocol-driven clinical trials frequently provide a rather artificial view of how drugs will actually perform.

WILLS. There are a number of cases in which outcomes measurement is making a substantial difference. The American Heart Association's "Get With The Guidelines" program is a key example of changing physician behavior and saving lives. This is the direction in which the payers, led by Medicare, are going and therefore, it's where providers need to be.

DR. THOMAS YOUNG

Practicing physicians find it difficult to see what the intervention or treatment does in the long term and how it really impacts the patient. **OUTCOMES DATA CAN IMPACT THAT AREA.**

DEFINING OUTCOMES

BURKE. The goal of outcomes management is to decrease inefficiencies and eliminate waste in the healthcare environment by reducing the unnecessary use of drugs where they are not optimal in getting the right treatment to the right patients at the right time. This approach will reduce safety problems and improve the effectiveness of treatment because medicines will be given to those patients who are going to respond. The optimal goal of outcomes management and outcomes research is to improve the quality of patients' lives.

DR. NANCY KLINE LEIDY

THE USE OF OUTCOMES RESEARCH IN THE PHARMACEUTICAL INDUSTRY IS CERTAINLY MATURING and is becoming a very important part of the product-development process, as companies understand how these data can enhance their product information portfolio.

LEIDY. In the pharmaceutical industry, as in the entire health field, outcomes research refers to the evaluation of the efficacy or effectiveness of an intervention and, in pharma's case, a pharmaceutical agent in a defined patient population. Often the outcomes are gathered from patients or caregivers, although not necessarily; they could be physiologic. The term patient-reported outcomes or PROs — a phrase coined several years ago by Laurie Burke of the FDA — is often used to refer specifically to outcomes provided by patients themselves.

PASHOS. Generally, outcomes can be categorized as clinical, economic, or quality of life. Clinical outcomes are closely associated with, and do in fact, tend to drive economic and quality-of-life outcomes. The three types of outcomes affect key healthcare stakeholders differently. Physicians and clinicians typically focus on clinical outcomes. U.S. managed-care organizations, European government pricing and reimbursement authorities, and insurers tend to focus on direct economic cost outcomes. Some large employers are beginning to focus on productivity economic outcomes, known as indirect economic costs. Patients tend to give more importance to quality-of-life and treatment-satisfaction outcomes. To manage outcomes, one first needs to assess or measure the data on the outcomes in question.

PATEL. Outcomes management is defined as managing the healthcare of a patient so that the patient ultimately receives the best chance of an optimal treatment result through the efficient use of the resources that are available. Outcomes management is all about understanding and identifying outcomes related to treatment or lack of treatment and then acting on those findings. Outcomes research is needed to uncover these findings and then proper education is needed to manage the outcomes appropriately.

WILLS. Outcomes management is a systematic approach or method to collect and measure outcomes data for the purpose of using the data to improve healthcare delivery systems. In a sense this is a data feedback loop. This may or may not include the perspective of the patient, such as patient-reported outcome studies.

PASHOS. Outcomes management programs are efforts to optimize the end results of care for a given population. Care broadly includes health-related interventions associated with prevention, diagnosis, and treatment. As pharmaceutical companies provide products that are significant aspects of healthcare, it is beneficial for companies to use part of their research and commercialization budgets to inform decision makers of the value of their products with respect to outcomes.

CANTER. The problem with the word outcomes is that it is too general. Just about anything can be classified as an outcome. A solution might be to define it as quality-of-life outcomes.

DHANDA. In this era of evidence-based medicines, outcomes management is the translation of research into practice — providing the best care for patients. We need to be able to define the value of the therapy.

SPANNHEIMER. The requirements and the methodology of a clinical trial and an outcomes research study differ. Outcomes research studies try to prevent any influencing of treatment behavior and encompass large patient samples often with incomplete data sets. A quality outcomes research study includes transparency in all aspects of the study, a sound and creative study design, and use of appropriate methodology.

DICESARE. There has been a significant change in the past 10 years as to how we conduct our outcomes research studies. In the past, we tended to do this research most often with academic researchers and consultants and then we would take the results to managed-care customers. Over the past few years, our customers have expressed interest in conducting research with us. They want to collaborate with us because they want to see the outcomes results in their patient populations. Now, the majority of our studies are done directly with customers or with a considerable amount of customer input into the studies to make sure the results are relevant to the decisions they need to make.

BURKE. Outcomes data empower the full range of treatment decision makers, which include the managed-care decision makers, clinical decision makers, other health professionals, and the patient or consumer. Outcomes data allow these stakeholders to provide the right treatment for

KAREN WILLS

HEALTH OUTCOMES DATA WILL BECOME INCREASINGLY IMPORTANT IN DIFFERENTIAL REIMBURSEMENT BY PAYERS. There will be more attention given to this in the next three years.

the right patient at the right time. This type of information should be the goal of product development.

ROSS. Many companies are paying lip service to outcomes data, yet I don't see a lot of companies figuring out how they are going to systematically collect outcomes data and use this information. The term has crept into pharma but people do not agree on what it means. The definition varies within a company as well as program to program. Part of the problem is that the state of the science is evolving.

ECONOMIC IMPACT

CANTER. In the rest of world, outcomes research has more legitimacy than in the United States. This is because other countries are more focused on a holistic approach to therapy because of their socialized medical systems. Those countries can only pay for so many drugs; therefore how a drug is reimbursed often is based on cost versus utility, which is derived from outcomes research. The United States is heading in this direction. The writing is on the wall. Drug companies have reached the limit on what they can charge for drugs. There will be constraints and limits on reimbursement and that is going to change the way that clinical development is done.

WILLS. Health outcomes data will become increasingly important in terms of differential reimbursement by payers, such as higher quality, higher payment, or referrals. There will be more attention to this in the next three years. Also it is not unusual today for providers and insurers to measure physicians in terms of reimbursement, referral, and other contracting decisions. Pay-for-performance programs are being used as a positive incentive and holdbacks for failing to show improvement have been introduced nationally.

CANTER. The economics of the healthcare industry are going to start to hit home. Until now, drug companies have been able to assume that if a drug is approved, it is going to receive reimbursement. In the United States, the ceiling, in terms of healthcare costs, has been reached. This already has happened in other countries, such as Australia, the United Kingdom, Canada, and others. In the United States, we have a closed budget, which we have never had before in our healthcare system. Medicare and insurance companies have a limited amount to spend on reimbursement, so there will start to be more limits placed on healthcare spending, including drugs. Those limits will be dictated based on cost verses utility, and the utility comes from outcomes studies. It is not going to be business as usual in the pharmaceutical industry and that is going to start to impact the way that pharma companies develop drugs. Companies are going to have to be cognizant of the fact that just because a drug gets approved, doesn't necessarily mean the drug will receive reimbursement.

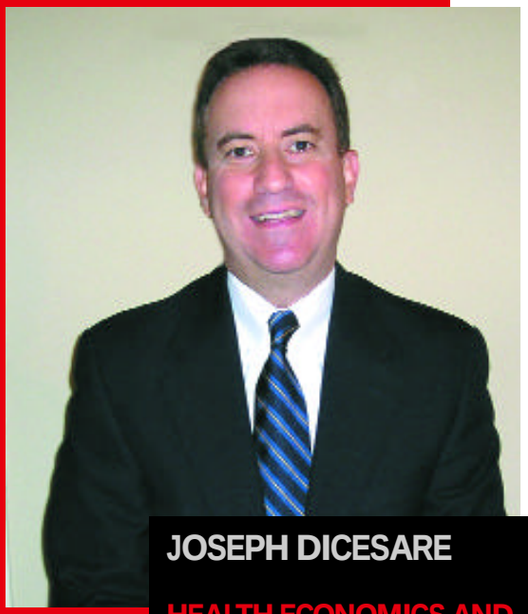
ROSS. Insurers are trying to decide which method of care should be covered for their populations. Anyone who is making a decision about choosing one drug over another needs to have outcomes information available. If these data have been collected and presented from a systematic, evidence-based point of view, the information will carry more weight.

DHANDA. Outcomes data evaluate the patient before treatment and after treatment to determine the impact of the treatment. Effectiveness of care is a holistic view. It answers the questions: does a product or therapy help to reduce the symptoms, does it improve patient function, does it add to patient satisfaction, and does it provide overall value? The value is defined as cost-effectiveness — the cost of the drug versus the effectiveness of the drug.

SPANNHEIMER. In the context of evidence-based medicine, outcomes data often have an impact on the design and content of treatment guidelines and disease-management programs. Additionally, in some countries, cost-effectiveness data for new treatments are important and are mandatory for pricing and reimbursement negotiations and formulary inclusion. For these reasons, the role of outcomes research in the healthcare-decision process will become even more important in the future.

THE NEED FOR EARLY ADOPTION

CANTER. Several companies are running Phase II trials that involve outcomes. But many pharma companies still have a misconception as to the utility of outcomes data and won't consider



JOSEPH DICESARE

HEALTH ECONOMICS AND OUTCOMES DATA help demonstrate the value of our products to decision makers.

DR. RAHUL DHANDA

In this era of evidence-based medicines, outcomes management is the translation of research into practice — **HOW TO PROVIDE THE BEST CARE FOR PATIENTS.**

incorporating outcomes into clinical trials until Phase III.

PATEL. A pharmaceutical company has to begin assessing outcomes as early as possible in the clinical-development process, although true real-world outcomes data may not be available until after product launch. Assessing outcomes data through structured outcome studies at the clinical-development stage will help a company form a strong clinical argument with payers and providers.

ROSS. The point at which companies begin collecting these data varies greatly. Recently, I have observed that pharmaceutical companies are thinking about outcomes much earlier than 10 years ago. Companies are starting to incorporate outcomes strategies earlier and earlier in the program, around Phase II and sometimes even earlier. Some companies are beginning to give a lot of thought about the outcomes that they hope to attain and that sometimes determines the patient populations that they will target for their clinical trials.

DICESARE. At Novartis, we typically start collecting health economics and other outcomes data when a product reaches Phase II. At this phase, we know what the potential indications might be and the potential benefits that the new product may have. We complete burden-of-illness analyses to understand what the treatment practice is and what the costs are of that particular disease. We look at the competition and what types of outcomes are associated with the use of those products. At this point we also are doing health economic evaluations with clinical trials, or designing Phase III or Phase II studies for health economics or health outcomes data. We then follow products from Phase II through their entire life cycle.

DHANDA. The company that I am employed with is a small-to-medium sized company, and our research is primarily geared toward trying to get drugs registered with the FDA. The registration process typically does not involve the inclusion of health outcomes data. This approach is not unusual for companies of this size. Thus, outcomes studies have to compete for resources with studies that are needed for registration, for example randomized trials demonstrating safety and efficacy, so outcomes research programs are limited. We don't have independent piggyback trials. If we do a Phase IIIb or Phase IV trial, we may throw in some patient-reported outcome measures. We do, however, conduct some retrospective studies to evaluate the effectiveness of our drug in the marketplace.

CANTER. Outcomes data should be viewed as a bridge. Many companies only think of outcomes as something to do once a drug is submitted. Some companies, however, are putting more efforts on outcomes during Phase III, and others are looking at outcomes in Phase II. Why should a company spend millions of dollars on a Phase III trial, if it could find out earlier that there is some limitation with its drug in terms of outcomes? Limitations should be determined during a less expensive trial, such as a Phase II trial. Many companies are essentially reactive and do only the minimum that is necessary. The industry needs to be proactive because the economic requirements for outcomes data are not going to be just a possibility; they are going to be a reality.

DICESARE. At Novartis, we demonstrate the value of our products with health economics and outcomes research studies in two ways. We communicate the results of larger studies we have done to customers via our scientific operations department. These studies may not have been done directly with the customer. The other way is to conduct the research directly with customers so they can look at their own data and evaluate their own patients and assess how our drug is performing.

COLLECTING THE DATA

PATEL. The challenge in reporting health outcomes primarily relates to gathering appropriate data from available sources. When we look to evaluate intermediate outcomes, such as blood pressure, symptom relief, or LDL cholesterol goals, right now the most comprehensive source for these data is the patient's medical record. Since electronic records are still slowly

developing, the process is very labor intensive. When looking at more long-term outcomes, such as ER visits, hospitalizations, and death, most information systems house these data, but the challenge lies in tying any specific therapeutic intervention to the outcome.

LEIDY. It is important that all members of the product-development team are involved, including staff members from clinical, health economic and outcomes, statistics, and marketing. There should be a coherent integrated system for outcomes planning, with each of these groups represented. Pharmaceutical companies that take a silo approach in the development of their products may be missing opportunities for efficiency, as well as effectiveness, in developing and securing their value message. Outcome planning also can occur across different products within a company, leading to a consistent, coherent company value message.

WILLS. Companies need to first take a look at the environment in which the system will be implemented and then break the system down into its component parts, which, simply put, are the inputs, processes, and outputs. From the input perspective, the data being collected must be sufficient for the study, but if over burdensome, long-term collection of data will fail. The environment in which the system must operate needs to be considered. Fitting into the workflow of that environment will increase the use of the system. Minimizing redundant data entry by importing information from existing systems and providing flexibility as to the method of data entry either via Web, IVRS, PDAs, or fax also is desirable. The processes followed also need to be flexible. Sites need to be able to define custom fields or expand forms based on selected information. Feedback is a critical component of any outcomes management system. It is important to incorporate a feedback mechanism so that the information collected can be acted upon in the best interest of the patient. In terms of the output, an important best practice is not only being able to see the data that are being collected but being able to compare the data against other sites or the entire program.

CANTER. If electronic data capture is used for patient-reported outcomes measurement, the electronic forms have to be large enough for a patient to read and in a format that a patient can easily work with. The Web is not a good format because it is not always available or convenient and many older patients have trouble manipulating a mouse and a computer. Palm Pilots are not a good vehicle because they are too small. There is a lot of content in many of the outcomes surveys and most surveys don't usually fit on a Palm Pilot screen. A good solution is to use a touch-screen device that has an eight-inch diagonal view and works offline and that is always available, battery operated, mobile, and convenient.

DHANDA. The best approach to collecting and managing patient-reported outcomes data is to use electronic data capture systems. Ideal systems would have the instrument of interest displayed on the screen, and patients via a touch-screen format can provide their answer. The data are better because the information is in real time and the data are cleaner.

PASHOS. Data collection has to be sufficiently comprehensive. The objective is to be able to link patient characteristics and clinical practice patterns to clinical outcomes and then to economic and quality-of-life outcomes. Having this chain of data enables us to uncover links between patient characteristics and outcomes that may be used offensively, to show a favorable relationship, or defensively, to show that a negative relationship does not exist. Also, inasmuch as the FDA and others are evaluating quality-of-life outcomes for labeling or promotional purposes, it is critical that these organizations be presented with the link between clinical outcomes improvement and any associated improvement in quality-of-life outcomes. Assuming the link exists, then approval of such a claim will be more likely to be forthcoming.

A REGULATORY PERSPECTIVE

BURKE. Drug companies need to do a better job evaluating what the FDA wants to know about a treatment at the beginning of drug development so the agency can plan the process to ensure that the information is available at the time of approval. But there is no way we are going to have everything we want to know at the time of approval. We have to balance the innovation costs and the time spent studying the drug against getting that drug on the market so patients can use it.

LEIDY. I believe the FDA appreciates the importance of the patient's perception of treatment and treatment effectiveness and will take

JAY CANTER

The real test of whether a drug is effective is what happens when it is on the market. **THERE IS A REAL DISCRIMINATING DIFFERENCE BETWEEN EFFICACY AND EFFECTIVENESS AND THAT IS WHAT OUTCOMES DATA MEASURE.**

these data under consideration and advisement during the review process. The agency also will consider patient-reported outcomes for labeling and promotional purposes if there is clear scientific evidence from two or more randomized controlled trials conducted according to sound scientific practices.

DICESARE. As a result of the Medicare Modernization Act, there likely will be an increased demand from decision makers for more real-world outcomes data, for example effectiveness data. More studies conducted with active comparators will be necessary as opposed to the usual placebo-controlled, efficacy studies that the FDA requires.

BURKE. The approval of a treatment is based on the risk/benefit assessment from the clinical studies. The FDA looks very carefully at where clinical benefits would justify the risks of treatment. A drug's approval is for a certain patient population studied under clinical conditions, therefore the outcomes of treatment can be optimal. Study conditions pre-approval are very controlled, and in many cases, the generality of those data are very limited. The FDA is trying to get a handle on how best to advise sponsors in collecting the most useful outcomes data that will provide the optimal information to be included in the product label at the time of approval. The FDA has several initiatives under way to make the label more user-friendly, both in terms of its format and content.

OUTCOMES MARKETING

DICESARE. Our outcomes data are primarily used by decision makers, including formulary decision makers for health plans, at PBMs, the government with Medicaid and Medicare, and more and more by employer benefit professionals who decide the plans for their employees. From a marketing standpoint, these data are used to demonstrate the value of our products to the decision makers who are deciding whether to use our drug or another drug or even to use any drug. This information rarely is used in a promotional piece; sometimes quality-of-life data are in a product's label and can be promoted, but more often the informa-

CASE STUDY: HEALTH OUTCOMES RESEARCH

AVENTIS PHARMA DEUTSCHLAND GMBH AND KENDLE INTERNATIONAL INC. TEAM UP

Decision makers in healthcare systems increasingly are requiring health economic data on the costs of various illnesses and the new drug therapies being developed to treat them. Kendle International Inc.'s Health Economics & Outcomes Research group recently collaborated with Aventis Pharma Deutschland GmbH on a study investigating the costs of community acquired pneumonia (CAP) and the influencing factors for hospitalizations in Germany, France, the United States, and Japan.

"We initiated this trial to receive detailed information about different approaches in treating patients with CAP, the impact of resource utilization, and the resulting costs to treat the illness," says Katrin Roscher, M.D., director of medical affairs, anti-infectives/asthma/allergy, medical department at Aventis Pharma Deutschland GmbH. "We wanted to have a clear view on the economic burden for patients who have to be hospitalized because of CAP."

The study was designed to provide background information on CAP, the usefulness of appropriate antibiotic treatments, resistance patterns, and the local behavior of antibiotic prescription. To identify these costs, Kendle performed interviews with 57 sites to gather information on more than 2,100 patients on the course of the disease and treatment during hospitalization, for example, procedures, investigations, medication, etc.

To meet tight timelines and achieve good data quality, Kendle developed an electronic case report form enabling direct data entry and plausibility checks during data collection on site. Kendle successfully completed the study, overcoming the challenges associated with a multicultural setting involving different healthcare systems and regulatory requirements.

Andrea Spannheimer, director of health economics and outcomes research at Kendle International, has observed that many companies are starting to investigate the market and treatment patterns through these types of studies to assess how a certain disease is being treated and the real-life conditions relative to the treatment that is to be developed.

Dr. Roscher believes studies gathering these types of data are becoming an important part of the clinical process.

"To meet the current requirements of the health authorities and the national health systems, gathering and analyzing corresponding data about health economics on an ongoing basis will become more important and necessary," she says.

DR. BARRY PATEL

WITHOUT OUTCOMES DATA THERE IS NO ROAD MAP AND NO INTERMEDIARY POINTS TO MAKE ADJUSTMENTS. Patients then fall through gaps. It is worth the effort for pharma to measure outcomes. They will identify new patients, the need for treatment, and so on.

DR. CHRIS PASHOS

OUTCOMES RESEARCH AND MARKET RESEARCH, IF DONE WELL, CAN BOLSTER AND SUPPORT EACH OTHER; they should be seen as complementary methods, not competitors for limited available funding.

tion is communicated through scientific discussions in response to customers' unsolicited requests for such information. These data also are included in the formulary dossiers we develop for all products according to the AMCP guidelines.

YOUNG. Outcomes data are critically important to marketing pharmaceuticals. As a physician, I received the slick and glossy promotional pieces from the marketing departments and clearly this is a successful tactic. But the question physicians always ask is: How is this product affecting the patient? The answer can be provided through outcomes data. As a company tracks outcomes information over time, it could provide that evidence back to physicians in a format that they could understand. In other words, track what actually happens to patients, what patients' responses were to the medication, and what was the reason people didn't take their medication.

DHANDA. Marketing teams can use health outcomes data to develop additional platforms on which to sell their products. From a marketing perspective, we need to differentiate our product from other products, and outcomes data are one way we can do that. As a result, we are able to develop effective messages that will allow us to gain a larger market share.

SPANNHEIMER. The current environment of increasing regulatory demands, reimbursement pressures, intense competition, and decreasing patent exclusivity means it is imperative to achieve rapid and sustained market uptake. To address these challenges, a strong late-stage development program with a focus on innovative and creative study design is an increasingly important factor. Outcomes data are being used more for marketing purposes because evidence-based medicine is increasing in importance. In this context, outcomes research delivers information on the effect and value of a new treatment or intervention in a real-word setting, a much broader setting than investigated in a clinical trial. This comprehensive information on the product value under everyday conditions is of immense value with regard to the marketing of an innovative treatment.

PASHOS. Upon approval by regulatory authorities, pharmaceutical executives are going to face skeptical customers who will wonder why they should change what they are doing and adopt a new drug. If a company can present customers with a full armamentarium of outcomes support, it will be better placed to overcome that skepticism.

WILLS. First and foremost, companies need to collect pertinent, accurate data. These data may then be used for several purposes. Collected data can prove the effectiveness of the treatment. This science-based commercialization is highly effective in changing behavior. Alternatively, creating value by obtaining differentiating characteristics of the drug, device, or therapy is another effective method. Companies should evaluate what is important to the target market and identify how the product does it faster, cheaper, or more effectively. And, of course, a company should then publicize the results.

ROSS. Companies have to use outcomes data in marketing to show that their product actually has value to convince formularies to list that product and to have the reimbursers fund it, but ultimately to offer information to patients. Information-savvy patients are demanding this type of evidence. Consumers don't care a whole lot about what worked in a clinical trial in a very narrow population. They are asking questions about what is going to work for them in the real world. Companies that are prepared to answer those questions with real evidence are going to be ahead of the game.

LEIDY. There are a number of different ways outcomes data are used for promotional or communication purposes. The clearest example is in DTC marketing in the United States. Patient-reported outcomes are a perfect way to communicate the value of a product directly to patients; the issues are important and the words are meaningful to them because they come from patients themselves. The second area is in communicating the patients' perspective of the value of a product to clinicians. The third area, which is becoming very important, is to communicate this value to payers.

PATEL. Outcomes research is an essential component of marketing. It is the centerpiece of physician marketing. Marketing has greater appeal to physicians if they can see data that show where treatment gaps are. ✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.