Meeting Highlights

Fourth Annual Conference of the Pharmacy & Therapeutics Society: Charting the Future

Marvin M. Goldenberg, PhD, RPh, MS

More than 100 health care professionals and parties interested in health care delivery attended the fourth annual conference of the Pharmacy and Therapeutics Society in Washington, DC, on April 22–23, 2004. Keynote speakers, panel discussions, and general sessions focused on improving patient safety and quality of care and reducing medication errors. A key feature included the Society’s response to the Institute of Medicine’s report on patient safety and medical errors.

PRESIDENT’S ADDRESS

The Value of Therapy: The Role of the P&T Society

Speaker: J. Lyle Bootman, PhD, President, P&T Society.

Drug-related morbidity and mortality represent a “silent disease in America.” The value of the quality of health care depends on the accessibility of medicine to patients and on the cost of medicine. The Institute of Medicine (IOM) is attempting to identify some of the reasons for the health care crisis in the U.S. and to challenge the health care community to eliminate the barriers to quality of care.

To Err Is Human: Building a Safer Health System, one of the landmark IOM reports, was released in 1999. This report articulated the economic and clinical consequences of medication errors and the misuse of medications. The report’s recommendation is to exert sufficient pressure to make errors costly to health care organizations and providers so that they will be compelled to improve safety. At the same time, there is a need to enhance their knowledge and provide the tools needed to improve safety and to break down legal and cultural barriers that impede improvements to safety. Given the current awareness about the magnitude of the problem, the IOM believes that it would be irresponsible to expect anything less than a 50% reduction in errors over five years.

In 2001, the IOM issued another report, Crossing the Quality Chasm: A New Health System for the 21st Century. This report stressed the need to improve quality, to develop strategies for fostering greater accountability for quality, and to identify areas of research to be pursued to facilitate improved quality. The report focused on the personal health care delivery system, specifically by providing preventive, acute, chronic, and end-of-life health care.

Safety flaws are unacceptably common, but the effective remedy is not to browbeat health care workers by asking them to try harder to give safe care. Members of the health care work force are already striving to do their jobs well. In fact, the courage and commitment of doctors, nurses, and others today are the only true means of stemming the flood of errors that are latent in the health care systems. Health care is faced with safety and quality problems because it relies on outmoded systems of work.

Crossing the quality chasm involves:

• providing services based on scientific knowledge to all who might benefit and refraining from offering services to those not likely to benefit.
• ensuring care that is respectful of, and responsive to, patient preferences and needs and guarantees that patient values guide all clinical decisions.
• reducing waiting times and harmful delays for those who receive and those who give care.
• avoiding waste (of equipment, supplies, ideas, energy).
• offering equitable care that does not vary because of patients’ sex, ethnicity, geographic location, or socioeconomic status.

Payers should examine their methods of payment to remove barriers to quality improvement. Their methods should provide incentives for adhering to best practices, improving patient outcomes, and encouraging the sharing of information. Academic medical centers should train their personnel to work more effectively and to create health care delivery organizations. These centers must also provide leadership and be prepared to make radical changes in medicine and pharmacy.

In 2003, Health Professions Education: A Bridge to Quality emphasized that education for health professionals was in need of a major overhaul. The problems were identified as follows:

• their lack of education for working in teams to treat chronic disease
• a lack of training in using and applying evidence-based data
• an inability to address diverse populations (e.g., because of language barriers)
• their inability to analyze primary causes of errors and problems relating to quality
• a lack of training in the adequate use of informatics in caring for patients

Planning for the future needs to take into account the drivers of health care, namely employers, business coalitions, consumer interest groups, and patients. Areas that will need particular attention are self-management and health literacy, screenings for cancer and major depression, hypertension, immunizations, pregnancy and childbirth, tobacco dependency, obesity, pain control, stroke, asthma, diabetes, ischemic
heart disease, and medication management—the key to success in all areas.

The misuse of antibiotics continues to be a problem, and more than 50% of such episodes are preventable. Programs on medication use and misuse have tremendous appeal and potential support, and leadership from the health professions is essential to rectify the problem.

The agenda of the P&T Society (PTS) for 2004–2005 should include a response to the IOM’s most recent report. Goals should be to track the IOM’s agenda, sponsor a P&T “best practices” compendium and P&T training programs, and provide guidance for medication therapy management services in response to changes resulting from the 2003 Medicare Modernization Act. The immediate goal of the PTS should be to maximize the value of drug therapy, with the ultimate aim of achieving enhanced quality of life.

KEYNOTE ADDRESS
The Institute of Medicine’s Agenda for Health Care Quality: Past, Present, and Future
Keynote Speaker: Harvey V. Fineberg, MD, PhD, President, Institute of Medicine.

The pathways to improving the quality of health care in the U.S. involve two strategies: developing better drug interventions and devising better ways to do things using existing technologies.

Dr. Fineberg cited the IOM reports mentioned by Dr. Bootman as the key elements in improving the quality of health care. Quality is considered a “systems” problem requiring a systems solution, and action is needed to solve problems at all levels.

Crossing the Quality Chasm outlined a blueprint for quality change. It established a common set of attributes and a definition of quality that virtually all health care professionals would adopt. It stressed the fundamental policy that the solution to problems of quality rests in making improvements in the system of care and nothing else. The report stated that one needed to act on several levels, for example, at an individual and a community level, where the interaction of physicians and patients is critical; at the organizational level; and in the environment of care. The quality chasm series, which emphasized leadership by example, examined all federal programs to introduce quality change in health care.

Health Professions Education: A Bridge to Quality (2003) stated that doctors, nurses, pharmacists, and other health care professionals are not being adequately prepared to provide the highest quality and safest medical care possible, and there is insufficient assessment of their ongoing proficiency. Educators and accreditation, licensing, and certification organizations should ensure that students and working professionals develop and maintain proficiency in five core areas:

- delivering patient-centered care
- working as part of interdisciplinary teams
- practicing evidence-based medicine
- focusing on quality improvement
- using information technology

Meaningful health care changes are difficult to produce; they require (1) motivation for change (a system of reward and punishment), (2) an understanding of patients’ cultures and values; (3) leaders who can make the changes, and (4) financial resources.

The IOM proposes 10 ideas to accomplish the changes required in our health care system:

- finding a middle ground politically and recognizing our social responsibility to provide universal coverage (with 43 million uninsured people, there is a need for means-based payments)
- paying for disease prevention or reimbursing for preventive services
- putting people first and ending unequal treatment of patients
- finding and deploying an information technology infrastructure
- using evidence-based guidelines as the presumptive clinical strategy with individualized decision-making
- rationing health care intelligently by defining the “basket of services” in the universal care package so that all citizens have access to such services
- insisting on transparency; supporting mandatory data reporting and public dissemination of data; refining adjustment standards over time
- experimenting with care models for chronic diseases (125 million people have at least one chronic disease) and using team-based care for patients
- strengthening partnerships between payers and providers
- providing education for, and building, quality of care

PANEL DISCUSSION
The P&T Society’s Response to the Institute of Medicine’s Reports
Moderator: Joseph Eichenholz, Managing Director, Tri-genesis Management Systems, Chatham, New Jersey.
(See Mr. Eichenholz’ overview on page 439.)

Speaker: Michael B. Nichol, PhD, Associate Professor and Chair, Department of Pharmaceutical Economics and Policy, University of Southern California School of Pharmacy, Los Angeles, California

Patient safety and medical and medication errors are national concerns, as expressed by the IOM in its recent reports. The PTS formed a Task Force consisting of institutional and outpatient working group members to identify problem areas in medication management. The approach of the Task Force was to describe the existing processes that have resulted in medication errors, the most frequent type of error in health care.

The PTS report describes the opportunity for improvement, the practice of excellence, and the PTS perspective of what can be done differently tomorrow. There must be a change in the behavior of P&T committees, health care providers, and management in order to make the cultural change stick. At the outset, the Task Force had to address the problem; place it in an organizational context; and assess the magnitude and impor-
tance of the problem.

The initial effort focused on specific diseases, assuming separate interests of inpatient versus outpatient settings. The Task Force then continued with concerns regarding P&T processes, with many inpatient and outpatient issues converging. Finally, it came full circle by examining the potential of process improvement, which is particularly relevant to selected chronic disease-management categories.

The Task Force realized that its concern was not all about hospitals and health plans. There were cross-setting sensitivities, with long-term care, particularly assisted-living settings that presented unique challenges. Correctional health care includes every management model—from privatized prisons with jails to directly managed systems—and includes every health care service financing and management model as well as every pharmacy management model.

P&T committees, which traditionally meet, make formulary decisions, and adjourn, need to collaborate with providers and organizations on a regular basis. These committees should maintain ongoing staff resources and seek opportunities for educational intervention and collaboration.

The Task Force report was distributed to all PTS meeting attendees, the IOM, the Leapfrog Group, and the U.S. Chamber of Commerce. The main area of concern in the report is a health literacy problem among patients, namely a difficulty in understanding what is needed for their care. Ninety million Americans face language barriers or have an inability to understand English.

The P&T Society Working Group Findings

Speaker: Burton Orland, RPh, Vice President of Pharmacy, Oxford Health Plans, Inc.

There is an opportunity for improving health care for patients with the following chronic diseases: asthma, diabetes, and dyslipidemia. In keeping with the PTS report, the “practice of excellence” in patient care would involve selecting the appropriate medication and developing and implementing programs aimed at ensuring the appropriate use of medications to improve quality of life.

The PTS response to the Working Group’s findings was positive. The PTS envisions an important and vital role for P&T committees in developing oversight programs for effective management of chronic diseases.

The risk of drug–drug interactions in patients receiving two or more drugs or herbal supplements is very significant, and there is a need to improve communication among the patients, the health care team, the family, and support groups, especially in the case of elderly patients. The practice of excellence would be to use the findings from P&T committee meetings as a resource for drug information and drug–drug interactions in products selected for the formulary.

P&T committees can provide the basis for assembling useful information about particular drugs. Together with medical and pharmacy leaders, they might plan to maintain and develop patient and family educational materials to facilitate communication between providers and patients. The PTS recommends a variety of measures to improve patient care, such as:

- providing education to patients.
- anticipating questions that patients might ask about their medications.
- developing a data-based system that collects, stores, and retrieves the medication history of each patient.

Patients sometimes receive the wrong medication or an incorrect dose when drug-dispensing protocols are not in place. One problem is that there is a lack of pharmacist interaction with the patient. The practice of excellence would be to avoid lapses in adhering to dispensing protocols. Efforts have focused on familiarizing staff members with the existing drug-distribution system, including its built-in safeguards, and educating patients about the benefits of following protocols.

The PTS suggests that standardized procedures be used to evaluate the effectiveness of dispensing protocols. It recognizes the importance of the development and use of technology-based information systems and urges further examination of these systems in both inpatient and outpatient settings. Additional training of staff members may be required.

Illegible writing occurs in both inpatient and outpatient settings and often leads to medication errors. The practice of excellence would be to implement a computerized physician order-entry (CPOE) program. The PTS believes that technology-based solutions have the potential to eliminate many medication errors that result from poor handwriting. Computer-based approaches would need to adhere to pharmacy data-management standards.

Patients sometimes receive the wrong drugs because of confusion surrounding drug product nomenclature or packaging that results in a look-alike/sound-alike mistake. The practice of excellence is to reschedule medications according to therapeutic class, grouping liquids and solids, and arranging the products alphabetically within their therapeutic class.

All dispensed drugs require a two-person read-back system. The PTS believes that this practice illustrates ways in which “low-tech,” cost-effective solutions can be used to address challenges faced by both outpatient and institutional health care providers. With nurses, pharmacy technicians, and others, this approach can also help to empower all members of the health care team in the goal of reducing errors.

The PTS Working Group believes that communication between pharmacists and physicians in critical-care settings represents an opportunity for improvement. The practice of excellence should include clinical pharmacists as participants on the health care team. There should be ongoing consultations with the clinical pharmacists, who would maintain communication with the nursing staff to assist in drug administration. When it is warranted and feasible, increased involvement of the clinical pharmacist in the critical-care setting would improve communication among members of health care teams in both inpatient and outpatient settings.

Managing medications in assisted-living facilities is problematic because:

- residents are free to select the pharmacy of their choice, so that a single assisted-living facility might have to keep track of any number of pharmacies.
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- medication packaging and dispensing systems may vary.
- patients like to maintain control of their medications.
- multiple health care providers are involved with the residents’ care.
- usually, only a limited skilled nursing staff is available.

The practice of excellence notes that Max Well Medical and other assisted-living facilities have developed a system designed to improve the quality and safety of medication management. The PTS believes that standards and systems should be developed at the highest level within health care chains and networks. It is necessary to establish guidelines and expectations for the development of corporate-level P&T committees, to issue guidance regarding medication processes used at each facility, and to implement chain- and facility-specific therapeutic product lists and related educational materials.

The PTS Working Group observed a lack of uniform standards for medication management and pharmaceutical care among practice settings. The practice of excellence expressed by the group identified a mock survey of a hospital to evaluate its compliance with the current Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines and the hospital has launched an institution-wide educational campaign to train its staff in practices that will reduce the potential for medical errors. The hospital’s P&T committee has also instituted changes in its procedures and practices. The PTS recognizes the value of the JCAHO guidelines as a means of standardizing care and encourages P&T committees to implement initiatives, similar to those discussed, to help institutions to move toward compliance with national safety and medical management standard goals.

Leveraging Dramatic Improvements in Safety, Quality, and Overall Value of Health Care

Speaker: Gregory Belden, MBA, Senior Program Associate, The Leapfrog Group.

The Leapfrog Group is a consortium of more than 150 large health care purchasers. One recommendation in the 2001 IOM report, Crossing the Quality Chasm, was that large health care purchasers, namely employers, take a leadership role in creating incentives that foster quality improvement. The Leapfrog Group has risen to the IOM’s challenge and, along with other Leapfrog employers and its various stakeholders, will follow the IOM’s recommendations.

The message of Leapfrog and the PTS is to improve patient safety and quality of care through standardization, transparency, education, and collaboration. Leapfrog supports the IOM’s improvement initiative in chronic disease management by rewarding results through “bridges to excellence.”

Leapfrog employs a strategy of using its market influence to affect dramatic improvements in the safety, quality, affordability, and overall value of health care by educating consumers to seek better performing providers and by motivating and rewarding providers for quality and efficiency-of-care improvements.

Leapfrog is a national movement that uses 22 targeted regions to develop “best practices,” creating early successes and learning from its stakeholders. It collects hospital-level data. For instance, 5% of the participating hospitals have fully implemented CPOE, and another 17% will have implemented it by 2005; 24% of responding hospitals have fully implemented intensive-care unit intensivist staffing.

The “leap” over the gridlock has begun with the rapid increase in purchasers signing on to Leapfrog’s approach, the rapid growth in the number of hospitals disclosing their status to their communities, active health plan support, massive education of consumers through purchasers, and market reinforcement through different channels.

GENERAL SESSIONS

The Impact of P&T Committee Decision Strategies: Prescription to Over-the-Counter Switches

Speaker: Celynda Tadlock, PharmD, MBA, Director of Corporate Clinical Business Operations, Wellpoint Pharmacy Management, West Hills, California.

Over-the-counter (OTC) drugs are an undervalued resource for several reasons:

- They are easily accessible to consumers.
- They are at least as effective as many prescribed drugs.
- The FDA’s standards for approving OTC drugs are the same as those for prescription drugs.
- Prescription strengths are relatively rare, so they are generally safe.
- Consumers like to use them, because doing so enables them to actively participate in their own care.

Consumers in the U.S. spend $32 billion on OTC medications per year; 58% of health problems are treated with one or more OTC products. Older adults buy 33% of all OTC drugs, which are less costly than prescribed drugs. For instance, the average cost of an OTC item is $7.00; the average cost of a brand-name drug is $74.90.

The requirements for OTC approval are as follows:

- acceptable safety margins
- a low potential for misuse or abuse
- the ability of an average consumer to self-diagnose and self-treat the condition
- adequate labeling that consumers can understand.

P&T committees should consider the following strategies when reviewing OTC drugs: (1) encourage the use of OTC drugs as first-line treatment, (2) exclude prescription drugs at OTC launches, (3) offer member coupons and prepare member announcements, and (4) provide point-of-service messaging.

The pros of switching to OTC products are as follows:

- increased accessibility of medications to health plan members
- encouragement of patient self-care when appropriate
- preservation of health care dollars to be allocated for more severe disease
- empowerment of plan members to participate in appropriate prescription treatment decisions.
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The disadvantages of OTC products include:

- the need for significant communication with brokers, group administrators, members, and providers about changing benefits and options
- the requirement of additional resources for customer service personnel and the need for prior authorization
- member dissatisfaction resulting from an attitude of entitlement (e.g., to prescription drugs).

When the prescription agent Claritin (loratadine, Schering) was transferred to OTC status, P&T committees in managed care organizations (MCOs) (1) removed Claritin from their formularies but still covered other nonsedating antihistamines, (2) removed all nonsedating antihistamines from their formularies, and (3) covered OTC generic products.

Many health plans discontinued coverage of the prescription version of Claritin, stopped covering the entire category, charged higher copayments for the prescribed version, and covered prescribed OTC products. There was a reduced ingredient cost of 32.6% per member per month and a decreased usage of 48.8% per member per year, and Claritin’s market share dropped dramatically in 2003. There was a shift to other prescription drugs, which increased the leukotriene market from 8% to 18%.

When Prilosec® (omeprazole, AstraZeneca) was switched to OTC status, the MCOs responded in several ways:

- they stopped covering prescribed drugs (provided coupons, did not cover OTC items, covered OTC drugs with prescriptions, or provided coupons).
- they moved prescription drugs to the highest tier (provided coupons or covered the cost of OTC drugs with a prescription).
- they continued to cover prescription drugs (some provided coupons, some did not; they did not cover OTC drugs).

Making the P&T Process Work in a Challenging Economic Environment: Past, Present, and Future

Speaker: Michael T. Brodeur, RPh, Head of the Formulary Development and Pharmacy Clinical Policies Unit, Aetna Pharmaceutical Management.

The traditional approach taken by MCOs and pharmacy benefit managers (PBMs) to drug coverage policy and formulary management is being challenged by dynamic changes within the pharmaceutical and benefit marketplace. Increasing pressure to provide affordable and consumer-directed benefits, coupled with issues surrounding patent expiration litigation, OTC switches, and drug safety, continues to affect the P&T process.

Aetna’s P&T committee formulary decision-making process includes therapeutic class reviews and takes into account prescription and OTC status and indications, current utilization, clinical reviews of the literature, appropriateness of treatment (precertification and “step therapy”), and cost.

The P&T review includes clinical quality evaluation of the literature, by physicians and pharmacists, in terms of the drug’s safety, effectiveness, and efficacy. Clinical policy bulletins and criteria developed to support precertification and step therapy programs, as well as nonformulary drugs, are also reviewed.

The national P&T committee clinical process categories I to III are also considered. These categories are used to rank the drug in question according to safety, efficacy, “breakthrough” potential, and efficacy in its class; its specific advantages; or its role as a niche product. The process consists of P&T reviews; category designation; and manufacturer contract area, which determines whether the drug adds quality for its members, whether it is cost-effective, the market share, and the drug’s additional value.

Patient safety is a key area of concern. Aetna partners with the Leapfrog Group, the Coalition for Affordable Quality Healthcare, Hospital Quality Review, and pharmacy initiatives. Aetna publishes alerts, disseminated to pharmacies, that are related to drug–drug interactions; drug–disease relationships; drug–age cautions; electronic prescribing alerts; and reports on controlled substances, drug recall programs, and polypharmacy. Pharmacy contraindications associated with patient safety are reported to physicians.

The future of quality-driven health care will necessitate greater consumer management and responsibility for health care through increased financial contributions from consumers along with improved information and decision support tools, which should increase literacy among patients. There will also be more “cash account” models, such as health reimbursement accounts and health savings accounts.

Evaluating Outcomes Evidence: Pharmaco-economics and Outcomes Study Interpretation

Speaker: Michael B. Nichol, PhD, University of Southern California, Los Angeles.

The focus of this talk was to help health plan staff and P&T committee members understand the key concepts in evaluating drugs for formulary consideration and disease-management interventions sponsored by MCOs.

Observational studies, in contrast to randomized, controlled studies, are important in outcomes comparisons. They allow comparisons among multiple treatments; however, blinding is not possible. In addition, longitudinal data are lacking, and definitions differ over time.

The problems of MCOs that affect data systems include capitation, shifting enrollment (e.g., Medicare + Choice), shifting participation by physician groups, changes in reporting, and data system alterations. There are also special problems associated with evaluating disease-management programs:

- Not all disease-management programs are created equal.
- Most personnel in managed care programs do not consider the literature in determining their intervention of choice.
- The nature of the intervention might be changed part way through the program because the MCOs don’t really know what they want to achieve.

To evaluate disease-management programs, one needs to
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know (1) the inclusion and exclusion criteria of patients and physicians, (2) the motivation for the program, (3) when to initiate interventions, and (4) the mechanism used to accomplish the program’s goals, such as mailings, referrals to management staff, or phone contacts.

Medication Safety Programs: Network Physicians and Integrated Health Systems
Speaker: Linda R. Young, PharmD, Drug Information Clinical Pharmacist, Lovelace Sandia Health Systems, Albuquerque, New Mexico.

The components of an integrated Lovelace Sandia health care delivery system were identified as part of Ardent Health Services. The Lovelace health plan covers four medical–surgical hospitals, a rehabilitation hospital, S.E.D. Medical Laboratories, and 15 outpatient clinics. The health care system follows the JCAHO standard MM.2.10 regulation, which states that medications available for dispensing or administration are selected, listed, and procured on the basis of several criteria:

- the indications for their use
- their effectiveness
- the risks, such as their propensity for medication errors, abuse potential, and sentinel events
- cost

This health care delivery system has several advantages: a good organizational structure; available resources; efficient communications via e-mail, voice mail, print articles, newsletters; and the ability to monitor and analyze effectiveness and compliance. The disadvantages include:

- the size and layers of bureaucracy.
- the system’s inability to accommodate individual practices.
- a greater number of people to notify.
- the absence of a guarantee that everyone will use all of the communications systems.
- the fact that variations might not be recognized as quickly in this type of system, compared with an independent practice.
- a prolonged improvement cycle because of the number of people involved.

KEYNOTE SESSION
Health Policy Update
Speaker: Rex Cowdry, MD, MPH, Associate Director, National Economic Council.

The market for health care poses a number of challenges for proponents of competitive markets, even though the markets have immensely desirable features in terms of incentives to enhance quality, control costs, and develop innovative approaches to treatment and to the organization and financing of care. The prospects for an effective market have never been brighter. For our current health care system to be transformed, the following crucial elements are needed: appropriate incentives, transparent quality and cost measures, and a robust health information technology system. The vital components of this vision must also include P&T committees, well-designed formulary incentives, and technology assessments.

Consumers will be asked to take a more active role in their health care; however, with imperfect information, it is difficult for consumers to make informed decisions. The markets are focused on consumers, and so they must bring value into the equation. There must be better, evidence-based health information (e.g., on chronic diseases) and practical information (e.g., on insurance) that is usable for patients and physicians. Incentives, such as financial rewards for preventing medication errors, must be developed.

The structure of health information must be improved; for instance, we need better information about how drugs actually work in practice and how they should be used. We also need a better system for documenting and recording adverse effects. Making these kinds of changes will undoubtedly improve the quality of care.

U.S. Department of Health and Human Services/Food and Drug Administration Update
Speaker: Mark Goldberger, MD, MPH, Acting Deputy Director, Center for Drug Evaluation and Research, Food and Drug Administration, Washington, DC.

The FDA is facing many challenges, such as (1) drug shortages, especially of intravenous (IV) steroids, anesthetic agents, and antibiotics; (2) safe and cost-effective drug importation; and (3) the short-term and long-term consequences of the Medicare Modernization Act (MMA) of 2003. Drug importation under the MMA assumes that the drug imported is the same product as the current product. There must be safeguards in place to ensure that customers are getting what they expect.

There is currently a decline in FDA approvals of new molecular entities. The cost to develop some new chemical entities is $1.7 billion apiece, from discovery to launch; the drug development process is long and arduous. Drug shortages are a growing problem. Such shortages arise from manufacturing problems and the fact that fewer companies are producing drugs in today’s medical and business environment. A naloxone shortage occurred because of extensive facility renovations and an inadequate inventory.

Shortages of methylprednisolone, a long-acting, injectable corticosteroid suspension administered epidurally to control chronic and severe low back pain, have also been reported. The FDA says that it will find another company to fill the void. These shortages were rectified several months after being reported.

The Current Political and Prescription Drug Benefit Environment
Speaker: Terry S. Latanich, JD, Consultant, Medco Health Solutions.

The MMA affects pharmaceutical manufacturers, pharmacies, PBMs, and health plans—and, by extension, their P&T committees.
People will decide which insurance plan to join depending on whether their prescription medication is listed on the formulary. Discount cards became available in June 2004 and will be continued until the end of 2005, when the new Medicare plan takes over. Under the plan, employers will receive a 28% subsidy from the government.

P&T committees are expected to come under increased scrutiny during this transition period. There is a growing belief that P&T committees sometimes rubber-stamp what the insurance companies demand and that they do not pay enough attention to the cost of medications. Some drug plans will respond by limiting the number of drugs covered in a therapeutic class in order to drive the costs down. P&T committees will probably attempt to choose the drugs in a plan based on scientific evidence and outcomes studies. However, drug manufacturers will look closely at P&T committees and will challenge those who do not include their drugs on the formulary. As a result, such pressure will make it difficult for some people to serve on P&T committees.

Drug importation and re-importation are under FDA scrutiny, and their impact is currently under federal watch. The next few years will be very important as Medicare prescription benefits begin to unroll.

**PANEL DISCUSSION**

Challenges in Formulary Management Across Patient Populations and Practice Settings

**Moderator:** Perry Cohen, PharmD, The Pharmacy Group, LLC, Glastonburg, Connecticut.

Representatives from diverse practice settings described their process for formulary management within their individual practice settings.

**Speaker:** Joseph B. Fox, MD, Vice President, The Healthcare Group

The Healthcare Group, a provider-owned regional health plan, develops and maintains direct relationships with employers. The group maintains and nurtures a close relationship with health care providers and sustains an adequate market share in Indiana and the surrounding region to preclude unacceptable influence by national carriers.

The pharmacy program is primarily for a health maintenance organization (HMO) product and is a partner with Prescription Solutions. The group has a connection to network hospitals for chronic disease care.

The P&T process consists of a subcommittee that meets monthly and makes recommendations to the full committee. The P&T committee’s first step in the evaluation process is the clinical component; this is followed by the contract strategy. The Healthcare Group and Prescription Solutions have successfully grown and have maintained market share through an ongoing complex marketplace.

**Speaker:** Mary Inguanti, RPh, MPH, Vice President for Operations, St. Francis Hospital, Hartford, Connecticut.

The Drug Therapy Management Committee of the hospital, formerly the P&T committee, is supported by seven clinical subcommittees (oncology, antibiotics, dialysis, anesthesia, psychiatry, medicine, and cardiology) and has been successful in attaining its clinical and fiscal goals. The configuration of the subcommittees (physicians, pharmacists, nurses), by clinical area of excellence and by choosing an effective physician chairman, has worked out well. The subcommittee functions consist of class reviews, disease management, specific formulary recommendations, reviews of trends in adverse drug reactions, computer screen changes, national issues, and treatment algorithms.

The subcommittee identifies disease-management strategies associated with high drug expenditures, evaluates the clinical literature and confirms best practices, reviews drug expense data, and considers opportunities for practice change.

A new drug admission process, a nonformulary drug process, and a process that reviews critical issues (e.g., IV to oral conversion and changes in antibiotic selection) are now in place.

The clear delineation of the subcommittee’s functions and responsibilities (including the fiscal impact)—along with multidisciplinary composition, strong pharmacy membership, and solid physician leadership—has effectively improved the formulary process at the hospital.

**Speaker:** Lynn L. Franzoi, Senior Vice President, Fox Entertainment Group, Inc.

Fox has implemented a disease-management program using drug treatment programs that will affect company costs, employee satisfaction, and worker productivity. Known as CareSupport, the program attempts to understand an employee’s medical condition, coordinate health care treatment, and manage his or her medication; this results in happier and healthier patients. Other goals are to decrease hospital stays, lower the costs of visits to specialty physicians, and monitor patients with chronic conditions and encourage their compliance with treatment plans.

The Fox program includes Drug Utilization Review (DUR), which identifies individuals who meet specific criteria for treatment and then recommends appropriate drug therapies. The DUR specifies the agents that are medically necessary, with the goals of lowering drug costs and reducing the incidence and expenses of medical services that result from drug–drug interactions, adverse drug effects, and patient noncompliance with prescribed therapies.

At Fox, the highest payout in 2003 was $561,864 to treat depression (6,697 claims by 1,131 members) with selective serotonin reuptake inhibitors (SSRIs), and $555,733 to treat high cholesterol levels (5,847 claims by 855 members). The preferred brands were Pfizer’s Zoloft® (sertraline) and Lipitor® (atorvastatin calcium).