Highlights of the Second Annual P&T Society Meeting
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P&T board members, society members, and other health professionals gathered in Philadelphia, Pennsylvania on May 15 to 16, 2002 at the Second Annual P&T Society Meeting and Exhibition to share ideas for improving their individual health care. P&T committees. Issues discussed included the future of the P&T committee, health care safety, the impact of pharmaceuticals, the importance of benchmarking, evidence-based medicine, and the influence of legislation.

Health Care Coat of Arms
Speaker: Jeffrey Lenow, MD, JD, Medical Director of JeffCARE, Thomas Jefferson University Hospital, Philadelphia, Pennsylvania.

Dr. Lenow, President of the P&T Society, opened the meeting by recounting some of his experiences in teaching medical school residents. These future doctors of America participated in an activity called the “Coat of Arms” exercise. In this exercise, participants outlined their vision of the most important parts of health care today and in the future. The main themes, which were illustrated in hand drawings of a coat of arms, were balance of cost and quality, the costs of pharmaceutical care, hope for unity inter-industry, the importance of new technology, the culture of safety/error management, social needs for improved access, a new era of accountability, and the new consumers.

Doctors today now know that they can’t afford to do anything they deem to be medically necessary, and they recognize that pharmaceuticals are a major factor in the cost-versus-quality issue. It is also important for them to realize that there are other people involved in health care besides physicians, and there are other industries involved too. Health care safety and medical errors are a subject of ongoing debate, as evidenced by the landmark Institute of Medicine (IOM) report, “To Err is Human.” Residents today recognize that with the high cost of medical school and the difficulties of earning money now compared to the days of earlier physicians, they have to want to be doctors for the right reasons. Consequently, they are more focused on the social mores and moral issues involved in health care delivery. In this new era of accountability, doctors’ futures will depend on how their performance is measured. People are now coming into their doctors’ offices with diagnoses and expectations; they want to be involved in their own care.

Dr. Lenow also outlined the responsibilities of the P&T Society: to be a multidisciplinary force committed to responsible P&T education and the creation of appropriate policies; and to be a forum in which various industries with stakeholder interest in these health care issues can partner, using an evidence-based approach to health care.

Key Issues Facing the P&T Committee
Speaker: David B. Nash, MD, MBA, The Raymond C. and Doris N. Grandon Professor of Health Policy and Medicine at Jefferson Medical College of Thomas Jefferson University, Philadelphia, Pennsylvania.

Dr. Nash, editor-in-chief of P&T and member of the board of directors of the P&T Society, discussed some of the important issues facing P&T committees in his welcome address. Dr. Nash focused on 12 key issues: direct-to-consumer (DTC) advertising, new pharmaceutical regulations dealing with physicians, reducing medical errors, state medicaid programs, tiered pharmacy benefits, discount programs, Agency for Health CERT programs (discussed below), pharmacogenomics, the Medicare drug benefit, the future of P&T committees, the role of managed-care formularies, and the future of pharmacoeconomics.

DTC advertising barely existed five years ago. The latest statistics for 2001 estimate that approximately $2.7 billion is spent on DTC advertising annually. The return on the investment is $3 to $4 for every dollar spent on this advertising, producing more of a profit than advertisements in medical journals.

Physicians are no longer being wooed with ringside seats and other lavish gifts from pharmaceutical companies. This might be an indirect benefit, because now they are forced to focus their energies on health care issues and pharmaceuticals, the core component of managed-care formularies, and the future of pharmacoeconomics.

Discount programs are another area of concern. These programs can come from the pharmaceutical industry, states, regional government, or private sector parties. Hardly anything has been published on these programs and their impact on health care.

The Center for Excellence in Research in Therapeutics (CERT) program functions under the auspices of the Agency for Health Care Research. The CERTs (which were discussed in the June 2001 editorial in P&T) are important to research on the effectiveness and cost of pharmaceutical agents.

With the advent of pharmacogenomics comes the prospect of precision prescriptions (also discussed in a P&T editorial, in the January 2001 issue). The future will involve a genetically focused armamentarium.

Trends in Managed Care Pharmacy
Speaker: Joseph Eichenholz, MA, Managing Director, Trigenesis Management Systems, Chatham, New Jersey.
Mr. Eichenholz outlined data in the Aventis Managed Care Digest Series to review managed care trends and their implications for the pharmacy. He noted that the major trends in health care were an increase in consumer power, a redefinition of the patient-physician relationship, an increasing sophistication of physician groups, a redefinition of relationships among stakeholders, changes in information and technology, a continued integration of “virtual” providers into organized delivery systems, and more aggressive employers and pharmacy benefit managers (PBMs).

The presentation reinforced Dr. Nash’s point that the underlying dynamics of health care were changing in part because of consumerism, and went on to say that the key to clinical and business success is benchmarking performance. The components of benchmarking will include demographics, the epidemiology of selected chronic diseases, clinical processes and outcomes, resource investment and results, and quality/satisfaction for consumers. Regarding consumerism, Mr. Eichenholz noted the effect of the “baby-boomer” population on the way in which health care is becoming more patient-centric. Mr. Eichenholz also discussed the history of HMOs and PPOs in terms of managing costs versus value, and how the future will probably require an integrated health care system.

How Does the P&T Committee Deal with the Rx to OTC Switch?

Speaker: Burton I. Orland, BS, RPh, Vice President of Pharmacy, Oxford Health Plans, Worcester, Massachusetts.

According to Mr. Orland, the main concerns of the P&T committee, in terms of prescription (Rx) drugs, are increased utilization/drug costs, mergers and acquisitions, combination therapies, legislative influence, DTC advertising, drug rider exclusions, and off-label uses. Mr. Orland noted that drug costs are increasing by 12% to 15% annually, or higher. Only 4% to 6% can be attributed to the pharmaceutical industry; other reasons are utilization and DTC advertising. The fewer companies that result from mergers, the less competitive the marketplace becomes. Combination therapies, which involve the use of three to four drugs in tandem (on average), are now being used to manage diseases such as HIV and diabetes. The influence of legislation on treatment problems like infertiltiy affects coverage. Patients are influenced by DTC advertising to request certain drugs from their physicians. Costs are kept down by excluding certain drugs (e.g., contraceptives, cosmetics, and other so-called “lifestyle drugs”). There are 400 to 500 drugs in development, with dosing costs of S3 to S5. One remedy to these Rx drug problems is to switch drugs to an over-the-counter (OTC) status, which shifts the burden from the insurer to the consumer.

The Durham-Humphrey Amendment (1951), which established the Rx and OTC classes, allows the FDA to switch prescription drugs to OTC drugs under three scenarios: the manufacturer requests a switch by submitting a supplemental application to its approved new drug approval (NDA), the drug manufacturer petitions the FDA, or the drug is switched through an OTC drug review process, which is the most popular method. There have been successful switches (e.g., Gynelotrimin, Zantac, Tagamet, Avid, Dimetapp, Sudafed, Tavist, Advil, Motrin, Duo Film, Lamisil, Lotrimin, Benadryl, and Niacin). Some current drugs up for OTC consideration are Claritin, Allegra, Zyrtec, the morning-after pill, as well as some proton pump inhibitors and statins. Smaller managed care organizations (MCOs), such as Fallon and Independent, are now covering OTC products within their formulary benefits. However, the larger HMOs (e.g., Cigna, Kaiser) are not. The criteria considered for covering OTC drugs include balancing the budget, reducing therapeutic category costs, minimizing out-of-pocket costs, balancing rebates versus the actual wholesale price (AWP) of OTCs, establishing co-pay differences, maximizing remaining rebates in the class, and avoiding higher cost drug choices.

Covering OTC drugs as a pharmacy benefit would lower drug costs, help track patient utilization, allow OTCs to be used as the first step in step therapy, and result in savings (compared to Rx drugs) for MCOs. For this to work, however, there needs to be physician buy-in. Incentives for physicians include reminding them that the costs are not out of pocket for them; providing them with prescription pads or stamps for convenience; demonstrating efficacy and safety profiles; and reimbursement. The ideal contract terms include “dollar one” rebates or market share, an NDC block on generic/competition, coverage for most sizes, customized “pull-through pieces” (drug information handouts), pharmaceutical company-educated MDs and network pharmacies, and product exclusivity (no generics). The PBM has to make sure that the generic will not be inadvertently dispensed; only the drug brand in the contract will. The various sizes (e.g., different pill amounts) should be covered. The customized pull-through pieces serve to ensure that the doctor is prescribing the drug correctly. The patient care and buy-in is facilitated by a lower co-pay, prepared patient information about the drug (making him/her better educated), and knowing that the physician is an advocate for the program, which represents the continuum of care. The member is motivated because there are fewer visits required, and patients can monitor themselves, so there is better compliance and reduced drug costs. There are some areas of concern, however, including inaccurate self-diagnosis, delays in treatment, suboptimal dosing, and inappropriate drug use. Suboptimal dosing results because OTCs are set at a lower dose than the Rx drugs. Working with the pharmaceutical industry to establish guidelines for patients, detailing physicians, being aware of over-utilizers of the drugs, and developing the aforementioned pull-through pieces can help avoid these problems. The PBMs have to be involved by messaging on-line to the network, adjudicating claims correctly, tracking utilization, dispensing brand drugs only, and working with the pharmaceutical companies to provide drug information to the doctors and pharmacists and letting them know that the drug in question is covered by the MCO.

Even with PBM involvement, drug utilization can still go wrong. The physician might not explain the benefit to the patient; the patient might forget to get the benefit; there is an off-the-shelf mentality among some physicians and pharmacists (just picking up any drug to give to the patient); the patient can have problems with an OTC drug; the PBM might not send the message that the drug is covered; or the network inadvertently dispenses a generic. To make a switch work, the physician, patient, MCO, drug company, and PBM all have to work together.

Integrating Clinical and Pharmacoeconomic Data in the Formulary Decision-Making Process

Speaker: Gary M. Owens, MD, Vice President, Patient Care Management, Independent Blue Cross, Philadelphia, Pennsylvania.
Dr. Owens discussed the drivers for pharmaceutical costs. While health care costs are still rising, managed care growth has flattened and employer-based coverage is declining. And the increase in pharmacy costs exceeds other health care costs. The primary driver of increased pharmacy costs is increased utilization. The growing research and development (R&D) budgets and faster FDA approval have led to more new products in the marketplace. The drivers for prescription drug spending include new drugs, biotechnology products, genomic/proteomic therapies, lifestyle drugs, and DTC advertising. The dilemma for health plans then becomes how to balance the desires of members and providers for the coverage of new pharmaceuticals versus the scientific evidence supporting their use. Health plans must be able to evaluate new pharmacy products as they come to market and understand the impact of new products in the marketplace and pharmacoeconomics (i.e., economic, clinical, and humanistic outcomes vs. cost). When using pharmacoeconomic steps and models, emphasis must be placed on real-world scenarios, value propositions, applicability to the plan, the ability to verify information, and understanding limitations. Limitations can include assumptions that are difficult to validate; a model creating multiple scenarios; the lack of a standardized format for pharmacoeconomic studies; and claim and pharmacy data that are not easy to merge. In addition, plan experts must review and understand the pharmacoeconomic studies; models will change and need refinement; and assumptions or the population might change for the plan.

**Strategies for Cost Containment: Designing Programs for Benefit Providers**

**Speaker:** Michael J. Sax, PharmD, Principal, The Pharmacy Group LLC, Glastonbury, Connecticut.

Dr. Sax discussed the value of pharmaceutical benefit to consumers, employers and unions, and health plan and individual providers. The role of drugs in health care has transitioned from cost plus reimbursement to science-based efficacy. The annual drug-cost trend will continue to rise and is projected to be in the 13% to 18% range every year over the next three years in an unmanaged program. New drugs that are expected to account for 75% of future trends are cardiovascular, hypertension, and cholesterol-lowering drugs; central nervous system, psychiatric, and neurological drugs; gastrointestinal drugs, anti-infective drugs; and endocrine and diabetes drugs.

HMOs were created to change physician and hospital behavior. Then PBMs were created to change pharmacists’ and pharmaceutical companies’ behavior. Pharmaceutical cost control is a mix of four basic approaches: benefit design, drug selection, utilization management, and drug purchasing. The traditional pharmacy benefit design operated with a silo mentality by controlling costs in a vacuum; pharmaceutical budgets were pitted against medical budgets. The focus was on short-term financial gains and there was no integration with medical management. The new thinking in pharmacy benefit design is to manage total health care costs and integrate with medical management. There is now an increased focus on appropriate drug use, documentation of positive health outcomes, and an attention to long-term gains. Pharmacy costs can be managed by increasing premiums to employers and increasing cost-sharing by members, as well as redesigning pharmacy benefits and improving cost-management strategies. Long-term pharmacy spending can be reduced with closed formularies, utilization management, negotiated discounts, and by increasing member co-pays. Costs can be shifted by differential and/or percentage co-pays, front-end deductibles, and benefit caps and/or exclusions. Patients can be sensitized to price variations if there are additional tiers, reference pricing, annual caps and deductibles, as well as increased costs for generics and a shift to percentage co-pays.

The challenge is to educate consumers to assume payment for non-covered drugs. By creating a triple-tier option where the co-pay at each tier is double that of the tier below, the short-term drug spending is slowed and consumers are steered toward less expensive drugs. Although this creates an incentive for the manufacturer to offer deeper discounts, it also raises questions about cost and the quality of pharmaceutical care for consumers. The current challenges are to balance the high-member demand for pharmaceutical benefits with the affordability of drugs, and to leverage opportunities to promote appropriate pharmaceutical drug use while controlling cost. The future challenges and opportunities lie in the advances of drug development, pharmaceutical marketing, prescription drug coverage, and in coping effectively with further increases in drug spending.

**Current Political and Prescription Benefits Environment**

**Speaker:** Terry S. Latanich, JD, Senior Vice President for Government Affairs, Merck-Medco, Franklin Lakes, New Jersey.

Mr. Latanich’s presentation covered the Medicare drug benefit, Medicare-endorsed prescription cards, re-importation of prescription drugs, the Patient’s Bill of Rights (PBOR), generics legislation, and issues affecting the composition of P&T committees.

The Medicare drug benefit passed in the House of Representatives in 2000, but it was never considered in the Senate and died when Congress adjourned. The House Ways and Means and Commerce Committees and the Senate Finance Committee have been working to create legislation, but nothing has been drafted yet. The House Republicans want a program that would encourage private insurers, PBMs, or others to offer private insurance coverage with the government contributing to the “stop-loss” feature included in the 2000 Medicare drug benefit. This feature served as a catastrophic cap on patient expenditures. Under the House Republican program, there would be more limited federal subsidies than in the original benefit.

The Senate Democrats favor a program that would use multiple PBMs in regions of the country that would compete for individual enrollment by beneficiaries, but the federal government, instead of private insurers, would carry all financial risk. Congress has agreed on a price tag of about $300 billion over a 10-year period, but the Bush administration has earmarked only $190 million. The AARP advocates $750 billion. The Medicare prescription drug benefit is not likely to take effect until 2005 at the earliest, even if it is enacted soon.

In the various proposals for the Medicare drug benefit, there are legislative proposals affecting the composition of and required procedures for the P&T committee. Most of the legislative proposals consider the use of some entity external to P&T committees that would create a standard therapeutic category definition. After the categories were cre-
ated, individual P&T committees and the plan sponsor would have to decide what goes into those categories.

President Bush proposed that private entities could create discount card programs for Medicare beneficiaries, if they met standards set forth by the Health and Human Services Department (HHS). This was intended to reduce the cost of prescription drugs. Those who offer the cards must cover one million lives in prescription drug programs regionally, and to offer the cards nationally, they must cover two million lives. The HHS has created a complex RFP to evaluate the programs. Most existing discount card programs would not qualify under this program. The enrollment had to be limited to Medicare beneficiaries in order to be endorsed by Medicare. Retail pharmacies filed a suit to block the proposal and the Centers for Medicare and Medicaid Services (CMS, formerly Health Care Financing Administration [HCFA]) was enjoined from implementing the program. The CMS has introduced a proposal through a Notice of Proposed Rulemaking (NPRM) that is similar to the enjoined program. NACDS and NCPA have sued in federal court to block NPRM, but there is no hearing date yet.

The last congress passed legislation to permit the re-importation of drugs, under defined circumstances, into the U.S. from a defined list of foreign countries. The goal was to make available the prices offered by drug manufacturers in foreign countries (many of which have price controls). The Secretary of HHS had to certify that such a re-importation would save money, but since she did not, the legislation was killed. In this congress, there is similar legislation regarding Canadian mail service pharmacies. Some U.S. physicians are having Canadian physicians rewrite their prescriptions, fill them out at Canadian pharmacies, and mail them to the U.S. The Canadian professional associations are reviewing the question of whether the rewriting of prescriptions is ethical.

Neither the House nor the Senate has been able to reconcile the legislation about the PBOR. House Republicans want to limit the use of state courts and punitive damages, while the Senate Democrats would permit suits in state courts, with less significant restrictions on the use of state courts and damage awards. In terms of pharmacy benefits, there are two issues for debate: the content of any formulary used must be made public and drugs that are off-formulary must be made available to patients if their physicians deem them necessary. For the latter, legislation has not defined whether the determination is based on physician preference or on a patient-specific determination of need.

There have been several bills and concepts introduced regarding the perceived abuses by pharmaceutical companies in blocking the entry of generic drugs into the market by filing lawsuits alleging patent violations. The main goal of the legislation is to allow generic drugs early entry into the market. There is widespread support in Congress, but passage of such a bill is uncertain.

These issues, especially the Medicare drug benefit, affect the role, power, and composition of the P&T committee of the future. Will there eventually be a “super P&T” committee, instead of thousands of individual committees? Probably not—but we might take some steps in that direction. Some would like P&T committees to be independent from the plan sponsor. P&T committee control over drugs existing on or entering the formulary will also be closely watched.