

## ISSUES IN BREAST CANCER POST-ASCO 2003

William Sikov, MD, Clinical Assistant Professor of Medicine at the Brown University School of Medicine and Chairman of the Breast Cancer Committee of the Brown University Oncology Group (BrUOG) discussed how data presented at the ASCO annual meeting in Chicago in May 2003 affects treatment decisions for patients with breast cancer.

After reviewing results presented from the NSABP B-28 study, which confirmed the benefit of the addition of adjuvant paclitaxel to the standard AC regimen in node-positive patients, he addressed a number of outstanding issues regarding the use of taxanes in the adjuvant setting, including which taxane (paclitaxel vs. docetaxel) and what treatment schedule (every 3 weeks vs. every 2 weeks vs. weekly) to choose and the role of hematopoietic growth factors. A lively discussion of these issues among the attending physicians made it clear that there is far from a consensus as to the answers to these questions. Dr. Sikov also addressed the controversial role of ovarian suppression or ablation in premenopausal patients with hormone receptor-positive cancers and reviewed results reported for novel chemotherapy regimens in the neoadjuvant setting.

Dr. Sikov discussed promising results with concurrent taxane, platinum and trastuzumab (Herceptin) regimens in Her2-positive patients with metastatic disease, in contrast to a number of studies that failed to demonstrate a clear benefit to concurrent as opposed to sequential use of chemotherapeutic agents in unselected patients. The roles of novel biologic (such as gefitinib -Iressa) and chemotherapeutic (such as the epothilones) agents, which demonstrate limited activity in heavily pretreated patients, in the treatment of breast cancer remain to be defined. Results of a long-awaited study comparing single agent q3week docetaxel to paclitaxel as 2nd-line therapy for metastatic breast cancer demonstrated prolonged time to progression and overall survival with docetaxel, but may be of limited value given evolution of the use of these agents towards weekly treatment over the past few years.

According to Dr. Sikov, data presented at ASCO confirm our impression that we are reducing the risk of recurrence in patients with early stage breast cancer and prolonging survival in patients with metastatic disease, but there remain many questions to address and challenges to face in managing this disease.



**Dr. William Sikov**

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## PERSPECTIVES ON BALANCING THE IMPLICATIONS OF INJECTABLE DRUG REIMBURSEMENT DECISIONS

Dr. F. Randy Vogenberg, Vice President & Group Practice Leader for AON Consulting, discussed pharmaceutical cost trends and challenges with implications for employers and insurer/managed health care organizations as well as government programs. Health Spending in 2000 in the U.S. was \$1.3 trillion or 13.2% of GDP with Health Expenditures per capita \$4,637. Source: CMS, Office of the Actuary, National Health Statistics Group.

Dr. Vogenberg discussed Pharmacy vs. Medical Trends, specifically Biotech Cost Trends. The identification of many more genes/proteins involved in the disease process has major implications for Managed Care Plans and their employer and provider constituents. Most drugs today are based on 500 known targets while Genomics is anticipated to discover 5,000 additional targets. Identification of new targets will facilitate drug discovery and result in disease-specific therapies, but cause a return to escalating health care costs. As a result, a balancing act among managed care plans, physician networks and employers must be achieved. That creates the emerging Value

Proposition of Biotechnology to include clinical outcomes, financial costs, and patient coverage values.

Finally, some key Government Issues were reviewed as it relates to employer sponsored health programs. The recent Congressional activity towards establishing a Medicare Pharmacy Benefit, known as Part D, will lead to further coverage chaos short term, while providing little change long term to current insurance coverage dilemmas in the marketplace.

Beyond privacy, The Health Insurance Portability and Administration Simplification Act (HIPAA) will also result in new billing claim form layouts that will be effective on October 16, 2003. A new billing CMS form 857 replaces the old HCFA physician claim form, and standardizes pharmaceutical product package information for billing using existing the NCPDP format, which is now used by all pharmacies, regardless of administration or dispensing site for a medication. Medical office software vendors are already working on the new programming and submission protocols.



**Dr. F. Randy Vogenberg**

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