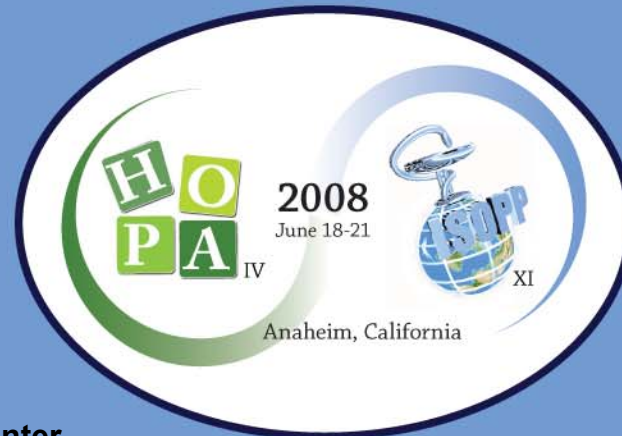


Unique Opportunities for Pharmacists: National Guideline Development, Clinical Research, and Legislative Change

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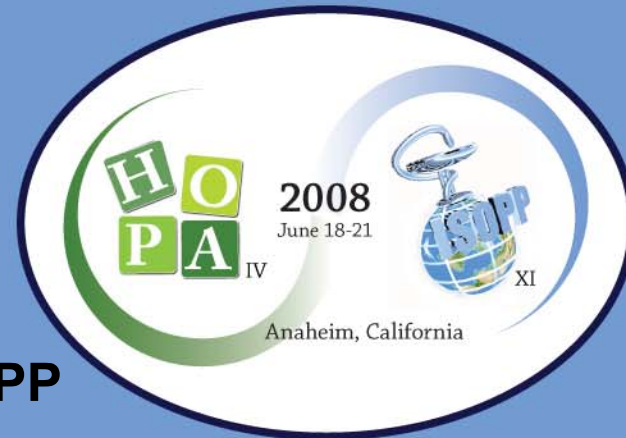
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Disclosure

- **Sally Y. Barbour, PharmD, BCOP, CPP has received fees for non-CE services from Amgen**
- **Cindy L. O'Bryant, PharmD, BCOP, has received consulting fees from Watson Pharmaceuticals, Inc., fees for non-CE services from Amgen, and research funds from Genentech**
- **Timothy Tyler, PharmD, FCSHP has received consulting fees from Carmel Pharma and fees for non-CE activities from Bristol Myers Squibb, Ortho Biotech, Amgen, and MGI PHARMA**

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Learning Objectives

- Describe roles of and opportunities for pharmacists in the development of national standard practice guideline development
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National Guidelines

- NCCN supportive care guidelines
 - Adult cancer pain
 - Antiemesis
 - Myeloid growth factors
 - Prevention and treatment of cancer-related infections
 - Venous thromboembolic disease
- ASCO
 - Antiemetics
 - Chemotherapy and radiotherapy protectants
- MASCC
 - Antiemetics

Why Guidelines?

- Improve patient outcomes through application of evidence-based guidelines
- Measure and improve quality of health care
- Continuous quality improvement

Clinical Practice Guidelines: Goals

- Optimize health care resources
- Improve health care outcomes
- Reduce inconsistencies in quality of care
- Enhance influence of scientific evidence in practice
- Provide timely and concise summaries of evidence

Clinical Practice Guidelines: Attributes

- Validity
- Reliability and reproducibility
- Clinical applicability and flexibility
- Clarity
- Multidisciplinary process
- Scheduled review
- Documentation

Pharmacists' Role in Guideline Development

- Pharmacotherapy key to many guidelines, so pharmacist crucial team member
- Improve patient outcomes, contribute to cost-effective patient care, promote multidisciplinary approaches to patient care and performance improvement

Factors Affecting Adoption of Guidelines

- Concise summary recommendations
- Synopsis of supporting evidence
- Quantify benefit to patient
- Grading the confidence of the recommendation
- Endorsement by major organization
- Endorsement by a respected colleague

NCCN Antiemesis Guidelines

- NCCN
 - “Dedicated to improving the quality and effectiveness of care provided to patients with cancer”
 - Primary goal of all NCCN initiatives is to improve the quality, effectiveness, and efficiency of oncology practice
- Multidisciplinary group
- Update process
 - Review new data and any data submitted to NCCN
 - Solicit input from practitioners at member institutions
 - Annual meeting
 - Updated annually or as new data emerges

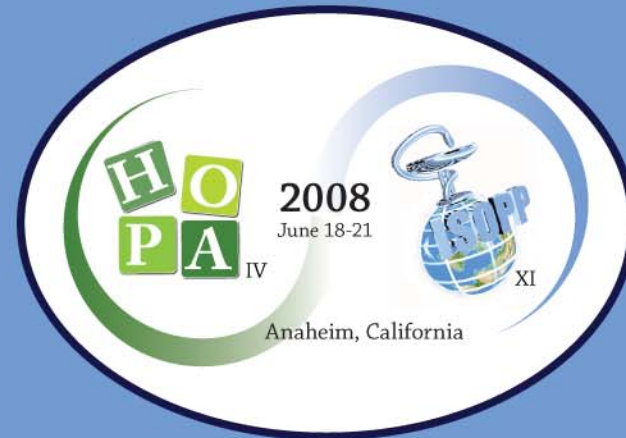
NCCN Standard Orders Panel

- Comprehensive order templates for all NCCN guideline regimens
 - Group of pharmacists with various areas of expertise
 - References, regimen, administration information, hydration, premedications, antiemetics, growth factors, monitoring parameters, dosage modifications, etc
- Initial release ASCO 2008

Summary

- Pharmacists participate in the development of numerous national and international clinical guidelines
- Pharmacists recognized as experts in pharmacotherapy
- Excellence in supportive care management lends itself to national guideline participation

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Practice Site



University of Colorado Cancer Center (UCCC)

Anschutz Cancer Pavilion

- **NCI designated cancer center**
- **200 patients/week**
- **Over 250 ongoing clinical trials**

Clinical Research

- **Types of research**
 - Pharmacy based
 - Medical oncology based
- **Developmental Therapeutics (DT) program**
 - Fancy name for Phase 1 studies
- **What do Phase 1 oncology clinical trials entail?**
 - The use of investigational new drugs or novel combinations of established drugs in humans
 - These studies are closely monitored and are conducted in patients who have failed standard of care or for whom there is no standard of care
 - Studies determine the
 - Safety and maximum tolerated dose
 - Pharmacokinetics and pharmacodynamics of the drug(s)
 - Studies may evaluate
 - Biological correlative studies and relationship to drug effect
 - Objective response rate

Goal of UCCC DT Program

- **The overall goal of the program is to reduce cancer burden through integration of the processes of discovery, development, and delivery of new anticancer agents**
- **Two components of the program**
 - **Preclinical**
 - **Clinical**

Go Team!

- **Multidisciplinary team**
 - **Physicians**
 - **Pharmacists**
 - **Nurse practitioners**
 - **Nurses**
 - **Clinical research coordinators**
 - **Clinical and basic science lab personnel**
 - **Social worker**

Not Just Your Same Old Investigational Drug Pharmacist

- **Roles within DT clinic**
 - **Patient Care Services**
 - Toxicity monitoring for patients on clinical trials
 - Drug information and education to patients
 - Supportive care management for patients
 - Drug counseling on chemotherapy and investigational agents
 - Chemotherapy order writing and review
 - Second check on all dose escalations and reductions per protocol guidelines

Not Just Your Same Old Investigational Drug Pharmacist

■ Roles within DT clinic

● Education

- Participate in education and training of physicians, nurses, and medical and pharmacy fellows and residents

● Research

- Principal and co-investigator of oncology pharmacy and medical oncology research
- Participation in clinical research protocol review process
- Participation in protocol development, abstract submission, and manuscript writing
- Participation in biological correlative lab research

Not Just Your Same Old Investigational Drug Pharmacist

- **Principal investigator role**
 - **DT program**
 - **A Phase I Clinical Trial of PDX101 and Bortezomib in Patients with Advanced Solid Tumors and Lymphoma**
 - **A Phase 1b Dose Escalation Study of the Safety and Pharmacokinetics of Apomab in Combination with Irinotecan/Cetuximab Chemotherapy in Subjects with Previously Treated Metastatic Colorectal Cancer**
 - **An Open-Label Study to Characterize the Pharmacokinetic Parameters of Erlotinib (Tarceva, OSI-774) in Cancer Patients with Advanced Solid Tumors, with Adequate and Moderately Impaired Hepatic Function**
 - **Phase I Dose Escalating and Pharmacokinetic Study of OSI-461 in Patients with Advanced Malignancies**
 - **Assessing Biological Correlates Associated with the Combination of a Molecular Targeted Agent and Bortezomib**
 - **Patient Attitudes Regarding Payment for Participation in a Phase I Cancer Clinical Trial**

From the Bedside to the Bench and Back

- **Initial clinical research experience**
- **Need to broaden my knowledge and skills**
- **Participation in developing and running lab-based translational projects**
- **Benefits:**
 - **Addition of laboratory research skills has enhanced my ability to carry out the clinical aspects of research and allowed me to independently bring translational research concepts to realization**

I'm Not in Kansas Anymore: How Did I Get Here?

■ Timing

- Being in the right place at the right time
 - Program startup

■ Collaboration

- Working with a group that respects my perspective and ability
 - Treated as a peer, not just the pharmacist

■ Initiative

- Going the extra mile
 - Taking time to learn and become involved
 - Attended the NCI/AACR sponsored “Methods in Clinical Cancer Research” course

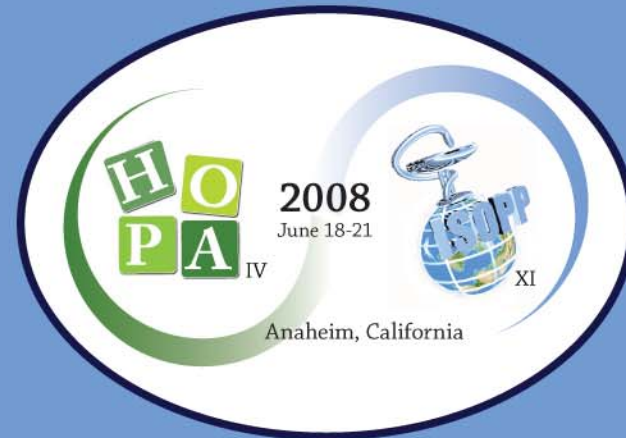
You Are Just as Good as They Are!

- **Unique contributions**
 - Pharmacy perspective
 - Patient care perspective
- **Stand up, you have been recognized ...**
 - **ASCO Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites**
 - Multidisciplinary involvement is desirable
 - Clinical pharmacists recognized as health care professionals who are able to contribute to cancer research

What Is the Payoff?

- **For me:**
 - **Inclusion on DT program study abstracts, presentations, and authorship on research articles**
 - **Ability to evolve as a practitioner**
- **For hematology/oncology pharmacy:**
 - **Demonstrating to the medical profession and those involved in drug development that oncology pharmacists are capable of doing high-quality oncology research as principal investigators**

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- To have some fun ...

Foster = to Nurture and Advance

fos·ter (fô st r, f s t r)

1. To bring up; nurture: bear and foster offspring. See Synonyms at [nurture](#).
2. To promote the growth and development of; cultivate: detect and foster artistic talent. See Synonyms at [advance](#).
3. To nurse; cherish: foster a secret hope.

No One Cares What You Know Until They Know That You Care

- Heme/Onc pharmacists are not currently a requirement in the private provider world
- Federal/state regulations are written by people like us – except we “know” how important we are to the safe and sane practice of oncology
- The perverse Golden Rule adage still applies
- Demonstrating value requires 2 things:
 - Documenting our contribution (continually)
 - Educating/promoting that contribution to those who make decisions > regulations > legislation

Some Legislative Areas That Affect Us

- USP 797 – Requirement for safe handling
- NIOSH Update – Hazardous drug guidance
- Specialty pharmacy requirements (none presently)
- Medicare reimbursement for pharmacy overhead
- CPT coding for pharmacist cognitive services
- National guidelines and standard of care
- Pharmacist advance practice regulations
- Specific drug usage mandates via FDA

The Desert Experience

- Liposomal doxorubicin denied by Medi-Cal (Medicaid in California) for metastatic breast CA
- USP compendia coverage for many years
- One patient was treated for a year and ultimately her claims were denied on every appeal
- Finally (frustrated) a letter was sent to the medical field officer about the coverage gap
- State policy was updated – now compendia

The Moffitt Experience

- Fiscal intermediaries are the for-profit insurance companies that bid for and then administer the Medicare funds to pay beneficiary claims
- They can be obstructionist in the way they process claims and provide feedback
- Moffitt not only made them see the center's point but now regularly meets proactively with them to inform, educate, and petition

Outpatient Prospective Payment System (aka OPPTS!)

- APC = Ambulatory Payment Classification
- Created by OBRA 1997 to begin in 2001
- Originally, no pharmacists were appointed to the 15-member advisory panel
- Emergency appointment after 1st year – demanded by PhRMA and BIO



OBRA = Omnibus Reconciliation Act.

PhRMA = Pharmaceutical Researchers and Manufacturers of America.

BIO = Biotechnology Industry Organization.

The Pharmacist and the APC

THE GOOD:

- Payment threshold
- 5HT₃ RA class exemption
- MedPAC reports
- Support of CPT codes
- The very concept of pharmacists in Amcare

THE BAD:

- Pharmacy overhead
- Bundling will never go away

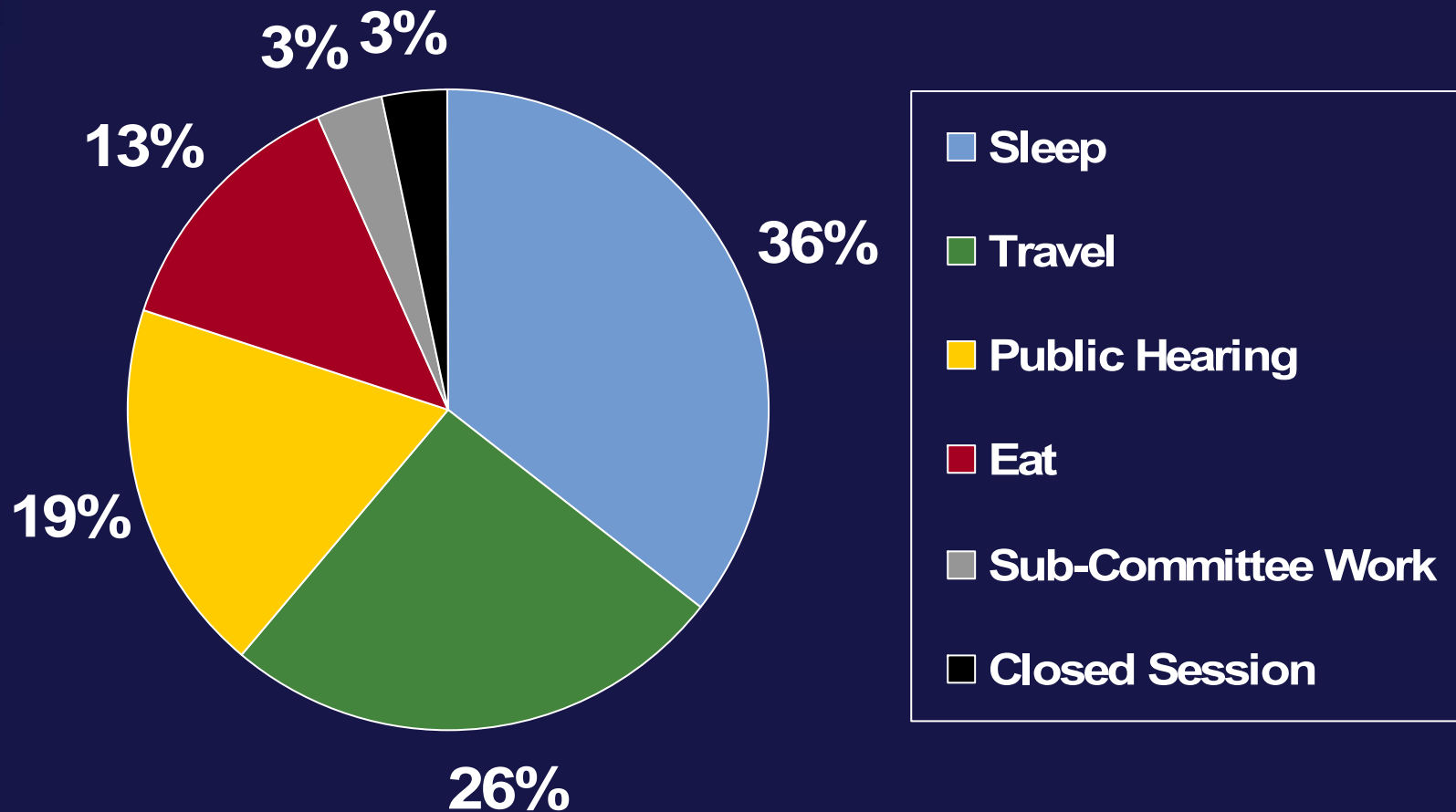
THE UGLY:

- ASP +6 ... 2005
- ASP +5 ... 2007
- ASP +3 ... 2009
- The future?

ASP = Average Sales Price.

MedPAC = Medicare Payment Advisory Commission.

Dr. Tyler Goes to Washington ...



Based upon a 96-hour experience – twice annually in March and August.

You Are the Only Pharmacist ...

- Ultimately – if you know what you are doing, then you are qualified to speak up
- Consider what would happen to your colleagues or your patients without you ...
- Start with your local administrators
- Work up to areas of local impact
- Consider what you could offer at an even larger scale