October 26, 2006

Council delegates present:

Deborah Nadzam, Chair
Carla McSpadden (ASCP), Vice Chair
Diane Cousins (USP), Secretary
Lee Rucker (AARP)
Joe Cranston (AMA)
Rita Munley Gallagher (ANA)
Anne Burns (APhA)
Carol Holquist (FDA)
Sal Peritore (GPhA)
Linda Hanold (Joint Commission) (by phone)
MaryAnn Alexander (NCSBN)
Ray Bullman (NCPIE)
Michael Murray (Chair, USP Safe Medication Use Expert Committee)

Alternates attending as representatives of their organizations:

Ron Nosek (DoD)
Michael Gaunt (ISMP)
Lynn Sanders (VA)

Alternates attending with their delegates:

Marcie Bough (APhA)
Mary Gross (FDA)
Kristin Hellquist (NCSBN)
Shawn Becker (USP)

Organizations/Members not represented:

AHCA
AHA
ASHP
ASHRM
HDMA
NPSF
PhRMA
David Kotzin

Observers:

Rebecca Snead (NASPA)
Tara Modisett (NASPA)
Arnold Mattis (VHA New England Medication Error Prevention Initiative)
Lenna Israbian-Jamgochian (APhA Student)
Jonalon Smith (ASCP Executive Resident)
Leanna DiBenedetto (ASCP Pharmacy Student Intern)
Mark Wiggins (PhRMA)

The Chair welcomed Council members, alternates, and guests and called the meeting to order at 1:38 p.m. Introductions were made for all observers. It was moved, seconded, and passed to accept the summary of the June meeting. Dr. Nadzam explained that subcommittees originally were topic-organized and not the standing subcommittees that exist today. Currently, there are four standing subcommittees – Promoting, Monitoring, and Evaluation; Practice Related Issues; Taxonomy; and Technology. Dr. Nadzam proposed a fifth standing subcommittee – Education – to promote the inclusion of medication safety content in basic curricula of professional medical, nursing, and pharmacy education programs. This subcommittee's activities could include assessing current curriculum requirements and content, identifying model curricula for each profession, and

establishing and disseminating recommendations to educational institutions. Dr. Nadzam asked members to become more involved in the work of the subcommittees.

Secretary's Report

1. Diane Cousins announced that AHA had selected John Brennan, MD, as its new delegate to the Council. Dr. Brennan is the Senior Vice President for Clinical & Emergency Services at Saint Barnabus Health Care System in New Jersey.
2. The following were requested and granted permission to utilize Council work products:
   - PMSLIC Insurance Company asked to include the Dangerous Abbreviations table as part of a continuing medical education home study course to be published in January 2007.
   - A graduate nursing student from Kuala Lumpur requested use of the Taxonomy to research medication errors by newly graduated nurses.

Membership

- It was moved, seconded, and unanimously passed to renew the memberships of ASCP, ISMP, and NCPIE for two-year terms.
- ISMP requested membership as a Steering Committee Member. After a brief discussion, this issue was tabled on condition that the Steering Committee hold a conference call in January to discuss membership issues and committee functions.
- The memberships for HDMA and David Kotzin expired with no requests for renewal. No vote was necessary. Notes will be sent thanking them for their contributions to the Council.
- It was moved, seconded, and approved to admit the National Alliance of State Pharmacy Associations (NASPA) and the Institute for Healthcare Improvement (IHI) as new members of the Council. NASPA was designated as a Member-At-Large and IHI was designated as a Risk Management/Quality Assurance membership category.

Action Item: The Secretary will send notes to HDMA and David Kotzin thanking them for their contributions to the Council.

Action Item: The Secretary will send letters to NASPA and IHI welcoming them as new members of the Council.

Subcommittee Reports:

- Taxonomy –*Rita Munley Gallagher and Ellen Quinn, Co-chairs*

Diane Cousins reported that the National Quality Forum's Patient Safety Taxonomy Maintenance Committee sent its first report to the NQF board several weeks ago. To address concerns raised by members, the taxonomy needs to be field-tested but may be used now for mapping. Data definitions need to be articulated and final criteria should be set by February, 2007. Four recommendations were approved: continued endorsement of the taxonomy, support of the Joint Commission in its efforts to develop the taxonomy, acting as a convener to lead to what could be a world health taxonomy, and reviewing progress and making recommendations in an annual report to NQF. Ms. Cousins also reported that AHRQ has drafted PSO regulations that may be public by January 2007.

- Technology – *Matthew Grissinger, Chair*

Michael Gaunt reported on the latest draft of the At-Risk Behaviors paper. It was agreed that the tone of the paper should not be punitive but should focus on behaviors. A question was raised as to

when at-risk behaviors become reckless behaviors and if thinking outside the box could be considered risky behavior. An organization's approach to discipline affects behavior and can be unproductive. What must be addressed are system issues that support risk taking behaviors.

Action Item: Michael Gaunt will rework paper for the February meeting, with assistance from Eleni Anagnostiadis and Anne Burns. Any additional comments should be forwarded to this group.

- Practice Related Issues – *Carla Saxton-McSpadden, Chair*

No report.

- Promoting, Monitoring & Evaluating — *Deborah Nadzam, Chair*

Members provided feedback on the latest version of the Council's Objectives and Strategies. Changes will be reviewed for a vote on Day 2. It was decided that separate sets of recommendations are needed for automatic dispensing devices and culture.

Action Item: Deborah Nadzam will formulate a first draft of a recommendation addressing the culture of safety.

The Chair announced that Day 2 would begin at 8:00 a.m.

The meeting was adjourned at 5:03 p.m.

October 27, 2006

Council Delegates Present:

Deborah Nadzam, Chair	Carol Holquist (FDA)
Carla McSpadden (ASCP), Vice Chair	Sal Peritore (GPhA)
Diane Cousins (USP), Secretary	Linda Hanold (Joint Commission) (by phone)
Joe Cranston (AMA)	Ray Bullman (NCPIE)
Mick Murray (Chair, USP Safe Medication Use Expert Committee)	

Alternates attending as representatives of their organizations:

Marcie Bough (APhA)
Ron Nosek (DoD)
Michael Gaunt (ISMP)
Kristin Hellquist (NCSBN)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Mary Gross (FDA)
Shawn Becker (USP)

Organizations/Members not represented:

AARP	HDMA
AHCA	NASPA
AHA	NPSF
ANA	VA
ASHP	David Kotzin

Observers:

Jonalan Smith (ASCP Executive Resident)
Leana DiBenedetto (ASCP Pharmacy Student Intern)
Tyler Martinson (NNMC Bethesda Pharmacy Resident)
Arnold Mattis (VHA New England Medication Error Prevention Initiative)
Mark Wiggins (PhRMA)

Ms. Nadzam reconvened the meeting at 8:17 a.m.

Drug Suffix Conference

The first version of the summary of the Drug Suffixes Conference was distributed to members. Suggestions for formatting or wordsmithing were postponed for later discussion. It was decided that the final summary would include a separate attendee roster and listing of sponsors. Ms. Hanold offered the services of one of her staff at the Joint Commission to copy edit a second version of the summary for Council review and approval. There was some confusion with several of the speaker sections so the Council agreed to send the speakers their specific sections of version 2 to edit for correctness. An attempt will be made to accomplish this by the end of the year. Ms. Hanold volunteered to draft a set of Council recommendations promoting the standardized use of suffixes in drug names. These would be forwarded to members for review by the end of the week and

comments should be returned to Ms. Hanold by November 10. Recommendations will be posted on the NCC MERP web site when they are finalized and approved by the Council. Work on the conference press release was put on hold until the recommendations are finalized.

Action Item: Linda Hanold will draft proposed recommendations regarding the non-standardized use of suffixes in drug names and forward to Council members for review and comment by the end of the week. Members are asked to review and comment by November 10.

Action Item: The Secretary will forward sections of the summary to individual speakers to edit for accuracy.

Suffix Survey

Michael Gaunt presented the latest draft of the survey on issues related to suffixes. Part A would be the only questions that all respondents would be asked to answer. The use of Survey Monkey would direct respondents to the appropriate portion of the survey for their professions. Dr. Cranston had concerns regarding the prescriber section and offered to send his questions to Dr. Gaunt for consideration. It would be the responsibility of each member organization to disseminate the survey to its constituents and to promote participation.

Action Item: Michael Gaunt will work with Matt Grissinger to revise the survey questions for Council review at the February meeting.

Action Item: Carol Holquist will ask a social scientist at the FDA to review the survey and provide feedback.

Presentations

1. *The Case for Requiring Hospitals to Conduct Medication Error Surveillance* – Arnold E. Mattis, RN, EdD, Project Director for VHA New England Medication Error Prevention Initiative

Dr. Mattis personally witnessed medication errors with his wife and saw how sub-optimum care could lead to injury and death. Inadequate information has been proven to be a major obstacle to improving patient safety. Since the IOM report in 1999, there has been no evidence that the frequency of medication errors in hospitals has declined. Most errors are unrecognized, undiscovered, and unreported. Dr. Mattis asked the Council to recommend to the Joint Commission that medication error surveillance be made a national patient safety goal or a standard. Joint Commission goals are processed more quickly than standards and could lead to earlier enforcement. Examples of surveillance methods include chart review using triggers, observation methodology, practitioner intervention, computer monitoring, bar coding data, smart pumps data, and override data. Active surveillance systems would make MEDMARX® more robust and more representative of the landscape. Dr. Mattis would like the Council to endorse a recommendation to the Joint Commission to require all accredited hospitals to begin using medication error surveillance methods to obtain more accurate information on the frequency and types of errors that threaten patient safety, and to use this information to monitor and reduce the rate of medication errors and near misses. Ms. Hanold stated that the endorsement of the Council would go a long way in getting the recommendation approved. Member response included the following questions and concerns:

- Many hospitals believe that they are already using surveillance. How would they view this as new?
- Some kinds of measures are needed to determine whether or not thresholds for action have been met.
- There is no way to detect potential errors.
- Accrued data must be used in a way that truly reflects change.
- How does the data lead to improvements?
- How does it affect liability?
- What is the cost benefit to hospitals?
- Most long term care is not Joint Commission accredited, rather it is state-based.
- Some active surveillance is being done.

Several major stakeholder members were not present at the meeting and the Council felt that it was inappropriate to vote on this issue without their input. It will be an agenda item at the February meeting with advance notice to members that a vote will be taken.

Action Item: Linda Hanold will inform the Sentinel Event Advisory Group that the Council is pursuing this topic. This will give the Council time to draft a formal statement.

2. *Salt Nomenclature Policy Update* – W. Larry Paul, PhD, Scientific Fellow, USP

In its efforts to standardize monograph titles and definitions and attain uniformity in expressing dosages, revisions to USP's Salt Nomenclature Policy (SNP) propose that the title of a monograph on a dosage form formulated with a salt of an acid or base shall be the same as that used in expressing the strength of the article and where the strength is expressed in terms of the salt, the salt name is used in the monograph. Where the acid or base is expressed in terms of the free acid or base, the same acid or base name should be used in the monograph title. Industry is concerned that current USP policy results in non-uniform and inconsistent nonproprietary names and monograph titles for drug products. Changing the name of a marketed nonproprietary drug product that has already been approved by the FDA due to the application of the USP Salt Nomenclature Policy could result in confusion for both patients and practitioners. Industry suggests that USP adopt a policy that expresses the product name using the drug's full salt name and strength in terms of the active moiety. This would provide consistency for both product name and product strength for drug products. It would allow the practitioner to know how much of a drug the patient is getting and indicate a clear differentiation among drug products containing different salt forms of the same active moiety. An alternative policy would be to express the product name and strength in terms of the active moiety. The USP Nomenclature Expert Committee will discuss revisions to the current SNP during its February 2007 meeting.

3. *USP Salt Nomenclature Policy: Industry Perspective/Call for Comments* – J. Mark Wiggins, RAS-Compendial Affairs, Merck & Co., Inc.

Industry believes that USP's goals of standardization and uniformity are not being met and result in non-uniform and inconsistent nonproprietary names. Because the current SNP is not applied by the FDA in all cases, many drug products would be required to change their FDA-approved nonproprietary names. Industry believes that new product development is the point at which the policy should begin and should not be applied retrospectively. Additionally, the SNP may cause public health concerns because of inappropriate drug substitution. PhRMA and NJPQCA recommend the implementation of a new nomenclature policy for drug products that uses the salt in the name and strength. They also ask that the comment deadline be

extended to allow for more stakeholder feedback and that impacted stakeholders have the opportunity to present at the Prescription Non-Prescription Stakeholder Forum in November.

Council Recommendations (Cont.)

1. Bar coding - There are differences between the Council's recommendations for bar coding and those of the FDA regarding over the counter and drug supplementary products. The Council was comfortable with its recommendations going beyond those of the FDA and noted that differences should be noted by use of an asterisk and an explanation. Any changes for specific wording for NDC codes should be sent to Dr. Cranston for incorporation into the recommendations. Carol Holquist will work with Dr. Cranston on a side by side comparison of recommendations.

2. Healthcare professionals – These recommendations were unanimously approved as amended but without a quorum present they will be sent to members for ballot.

3. Labeling and packaging for manufacturers – It was moved to accept these recommendations as revised but was tabled to Day 2. However, due to lack of a quorum present on Day 2 these recommendations will be sent to members for ballot.

4. Healthcare organizations – The first section of these recommendations will provide the basis for recommendations pertaining to a culture of safety. Dr. Cranston will rework the remaining sections for the February meeting.

5. Regulators and standards setters - As there was no quorum present, these recommendations will be sent to members for ballot.

Action Item: Joe Cranston will rework the recommendations for healthcare organizations for Council review at the February meeting.

Action Item: Deborah Nadzam will create a first draft of recommendations dealing with the culture of safety, incorporating the first section of recommendations pertaining to health care organizations.

Drug Samples – Diane Cousins

Report deferred until the February meeting.

Recycling of Medications in Nursing Homes – Carla Saxton

Carla Saxton-McSpadden reported that medication waste has an impact on the environment. The AMA recently adopted a resolution calling for the Environmental Protection Agency to study the disposal of pharmaceuticals in drinking water and collaborate with other stakeholders to develop guidelines for physicians and the public for safe disposal of pharmaceuticals and personal care products. AMA, ANA, ASHP, and NABP have similar policies regarding reuse of drugs in nursing homes including the keeping of adequate records for recalls, having policies and procedures on file,

including a billing mechanism in place for credit, and no controlled substances can be involved. Lyn Bentley stated that CMS policy is that facilities must properly credit the Medicaid program for the return of unused prescription medications upon discontinuance of the prescription or transfer, discharge, or death of a Medicaid beneficiary. In certain situations, unused drugs may be returned to nursing facilities and resold by them, provided all returns and sales are consistent with provisions of Federal and State law. Some states permit pharmacies to resell, reuse, or redistribute certain medications if the medication has been properly stored, returned unopened, and dispensed in the original packaging.
Washington State has 18 community pharmacies involved in a lockbox pilot program for consumers to return unused drugs. Consumers can use prepaid mailers for return of unused drugs to a Maine DEA burn site.

Action Item: Lyn Bentley and Rita Gallagher will determine how the Council should engage regarding this issue and report at the February meeting.

Action Item: Marcie Bough will keep the Council informed on what APhA is doing with Fish and Wildlife Services.

Roundtable Updates: The following member organizations submitted written reports for inclusion in the meeting summary:

AMA (Joe Cranston) – AMA continues to collaborate with the Institute for Healthcare Improvement (IHI) on its *100,000 Lives* campaign. AMA convened an expert panel that is writing a White Paper on the role of the physician in medication reconciliation. The AMA and the Centers for Disease Control and Prevention (CDC) continue to co-sponsor the annual Influenza Summit. AMA also is undertaking a strategic initiative to improve adult immunizations in the United States. Resolutions of interest that will be discussed at the AMA's Interim meeting in November include: 1) concerns about pharmacy compounding of "bioidentical" hormones; 2) support for FDA-approved "written" patient information to be dispensed with all prescription drugs; and 3) call for health plans not to pressure beneficiaries on chronic medications to switch formulary drugs or to raise their co-pays during the plan year.

NCPIE (Ray Bullman) – This October represents NCPIE's sponsorship of the 21st annual "Talk About Prescriptions" Month. Our theme this year is *"Preventing Medication Errors: What YOU Need to Know / What YOU Need to Do."* Materials supporting the observance can be found at www.talkaboutrx.org. Recognition is extended to the Institute of Medicine's (IOM) July 2006 report, "Preventing Medication Errors," as a stimulus to theme development for this year's observance. "Talk About Prescription" Month materials are "evergreen" and can be used year-round, not just during October. NCPIE is also starting work on a new program called the ***M***edication ***U***se ***S***afety ***T***raining Program for Seniors (*MUST for Seniors*). We will be developing hard-copy and web-based materials to enable interested persons to organize, promote, and conduct a *MUST* for Seniors program utilizing video "trigger tapes" to stimulate discussion and learning.

USP (Diane Cousins) – On October 11 USP held a Patient Safety Stakeholder Forum to discuss the concept of safe medication use practices. This forum was a high level exploration of the interface between patients and healthcare professionals and was an outgrowth of USP's 2005 Convention's adoption of Resolution Nine, which resolved that USP would work with appropriate constituencies to develop programs to promote safe medication use and disposal. The focus of the Forum was to

explore whether or not USP should proceed to produce a compendium of safe medication use practices.

The meeting was adjourned at 1:42 p.m.