June 24, 2008

Council members present:

Deborah Nadzam, Chair
Rita Munley Gallagher (ANA), Vice Chair
Diane Cousins (USP), Secretary
Evvie Munley (AAHSA)
Lee Rucker (AARP)
Beth Feldpush (AHA)
Ellen Quinn (ASHRM)
Paul Hoerner (DoD)
Carol Holquist (FDA)
Sal Peritore (GPhA)
Frank Federico, IHI)
Matt Grissinger (ISMP)
Linda Hanold (The JC)
Eleni Anagnostiadis (NABP)
Ray Bullman (NCPIE)
Diane Pinakiewicz (NPSF)
Marjorie Shaw Phillips, Vice Chair USP Safe Medication Use Expert Committee

Organizations not represented:
VA

Alternates attending as representatives of their organizations:
Barry Dickinson (AMA)
James Owen (APhA)
Tom Clark ASCP)
Karl Gumper (ASHP)
Tara Modisett (NASPA)
Kristin Hellquist (NCSBN)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:
Mary Gross (FDA)
Shawn Becker (USP)

Observers:
Kristin Binaso, APhA
Nancy Kupka, Presumptive JC Delegate
Crystal Lennartz, National Association of Chain Drug Stores
Jeanell Mansur, Joint Commission Resources
USP Attendees: Colleen Brennan, Manager, Safe Medication Use Expert Committee
Scott Kuzner, Web Content Manager
Rick Schnatz, Manager, Pharmacy Compounding Expert Committee
Marilyn Storch, Coordinator, Patient Safety Projects
Sue Thomson, Patient Safety Analyst
Diana Kwan, Summer Intern, HQI
Jeanne Sun, Summer Intern, HQI

The Chair welcomed Council members, alternates, and guests and called the meeting to order at 8:35 a.m.

Ms. Cook requested that the following edits to the Drug Samples Recommendations discussion be added to the February meeting summary (Changes are underlined.)

Ms. Cousins joined the discussion via phone. PhRMA's position was that

provisions of the Draft Recommendations that related to obligations on the part of manufacturers are more appropriately addressed by FDA through proposed rulemaking. Ms. Holquist responded that she did not think that the cited regulation applied to drug samples but she would check and report back to the Council. Ms. Cook maintained that PhRMA's concerns focused on provisions that were addressed to manufacturers, specifically Recommendations #5, #6, and #7. PhRMA requested the inclusion of a statement that PhRMA did not support these recommendations. The Council deemed that qualifying statements were neither necessary nor appropriate. It was moved, seconded, and passed with one dissension by PhRMA to approve the recommendations as amended. Ensuing discussion was ruled out of order.

It was moved, seconded, and unanimously approved to accept the summary of the February 2008 meeting as revised.

Action Item: Ms. Holquist will provide clarification at the October meeting regarding FDA's position on drug sample labeling.

It was moved, seconded, and unanimously approved to accept the agenda for the June meeting.

Secretary's Report

– Web Analytics – *Scott Kuzner*

Mr. Kuzner presented a traffic overview of the Council's website for the period January-March 2008. A noticeable spike in hits may be attributable to the posting of the set of Drug Suffixes Recommendation. 21 percent of those entering the web site did not enter through the home page. The phrase "patient safety" did not generate much response as a search term. It was questioned as to whether or not a search under "patient safety" should direct users to the Council's web site. What may be of future interest is the number of .gov, .org, etc. that are linking to the site. 80-90 percent of the traffic was generated from the United States. Mr. Federico asked if a survey of users had ever been done to ascertain the ease of using the web site. Mr. Kuzner responded that this had not been done but was an interesting suggestion that would be considered.

Action Item: All Council members should check that their web sites are linked to the Council's web site, as well as each others'.

Action Item: The Secretary will e-mail the Web Analytics presentation to Council members.

– Work Products

Five requests were made for the Council's work products (Index, Algorithm, Medication Error Rates Statement, and the Recommendations to Enhance Accuracy of Prescription Writing.) Two of these were from Canada and one from the Department of Defense.

Membership

As a means of reintroducing NCADS to the Council, Ms. Lennartz gave a brief presentation about the National Association of Chain Drug Store (NACDS), saying that 100 of its members are from foreign countries. She emphasized NACDS' promotion of the role of pharmacists in medication error prevention and its partnership with ISMP for quarterly webinars and funding of risk

assessment projects for community pharmacies. Its goals would be to collaborate with Council members regarding patient safety information and to disseminate that information to community pharmacies. It was moved, seconded, and unanimously passed to reinstate the membership of the National Association of Chain Drug Stores in the category of Trade and Manufacturers for a one-year term.

Action Item: The Secretary will send a letter to NACDS welcoming them as reinstated members of the Council.

Council Statement on the Use of Medication Error Rates

Discussion noted that the difference between medication error rates and medication error reporting rates should be strengthened. It was proposed that a second parallel statement be issued to assist hospitals understand this difference. It was moved, seconded, and passed with one opposition that the Council stands by the current statement but requested a current date to indicate that the issue had been revisited since its adoption.

Action Item: Mr. Federico will chair a subgroup to draft a statement expounding the differences between medication error rates and medication error reporting rates and internal measurement and the reporting of medication errors. Ms. Feldpush, Mr. Grissinger, Lt. Col Hoerner, Ms. Kupka, Ms. Quinn, and Ms. Phillips will serve on this subgroup.

Drug Suffixes Survey

Ms. Hanold provided the Council with an explanation of how Survey Monkey works. A work group will develop a draft paper but a statistician is needed to do that. Ms. Hanold volunteered to work with Mr. Grissinger on a qualitative review of the data collected and determine what the research questions should entail. She also volunteered the Joint Commission to provide guidance and counsel.

Action Item: All member organizations should provide the Chair with a list of resources that could assist in this project, as well as any thoughts and recommendations on how the Council should proceed.

Action Item: Mr. Grissinger will chair a workgroup to do a qualitative review and scan of the survey responses. Ms. Hanold, Ms. Holquist, Ms. Kupka, and Dr. Nadzam will serve as part of this workgroup.

Pediatric Medication Safety – *Jeanell Mansur, RPh, PharmD, FASHP, Practice Leader, Medication Safety, Joint Commission Resources*

Dr. Mansur referred to the Joint Commission's Sentinel Event Alert #39, Preventing pediatric medication errors, in providing an overview of the issue. Discussion focused on the strategies and recommendations in the Alert. Ms. Mansur stressed that monitoring errors are often overlooked and that standardized concentrations of medications could alleviate some of the errors that keep occurring. Developing recommendations for safeguards for high risk medications, such as smart pumps coded for microdrops, is one way that the Council could assist in this effort. The Council has three options in pursuing the development of recommendations for pediatric medication safety

(1) do nothing, (2) issue a set of recommendations and/or a white paper, and (3) host an invitational conference for stakeholders. However, before that decision can be made, the Council needs to review what other groups are already doing in this area – what overlaps and gaps exist – so that there is no duplication of efforts.

Action Item: A workgroup was established to do an environmental scan and review activities related to pediatric medication safety by other organizations. Dr. Nadzam will chair the workgroup. Members of the workgroup will inventory organizations in the following areas: Dr. Dickinson – medicine, Dr. Gallagher – nursing, Ms. Modisett – pharmacy, Mr. Peritore – manufacturing, Mr. Bullman and Ms. Rucker – patient areas, and Ms. Cousins and Ms. Holquist – federal and standards group.

Physician Office Risk Management Tool Kit - 2002

Ms. Quinn's presentation on ASHRM's tool kit provided the Council with an overview of risk management issues as they occur in physicians' offices. The most current version of the tool kit was released in 2002 for use in medical offices and by risk management and insurance companies. The tool kit needs revisions and ASHRM is interested in knowing if the survey questions in the toolkit could provide a basis for future Council recommendations relating to drug samples in physicians' offices.

Bar Coding

The development of a survey to determine why people are not using bar coding has been put on hold. There has been little evidence published supporting bar coding and it has been hard to quantify and survey something that is not happening. ASHP's bar coding statement and an article published in JAMA had been distributed prior to the meeting for the members' edification.

ACTION ITEM: The Secretary will setup a conference call where Dr. Nadzam and Ms. Cousins will join the bar coding subgroup to address the future role of the subgroup.

Technology – *Matt Grissinger*

Facilities have experienced problems with implementing technology that include limited fiscal resources, culture, etc. It has proven almost impossible to assess and determine the best technology for each organization when every organization has differing needs and resources. The issue was tabled and further consideration in technological implementation will be revisited at the February 2009 meeting.

Disposal of Drugs – *Kristen Binasco, RPh, CCP, FASCP, APhA*

There has been much debate about the science of drug disposal. Ms. Binasco, an APhA expert on drug disposal presented the SMARxT Disposal™ campaign, which is a public-private partnership between the US Fish and Wildlife Service, APhA, and PhRMA. The focus of the campaign is to elevate the issue into the public's consciousness and encourage consumers to follow environmentally friendly methods of disposal of drugs. Pharmacists can play a vital role in

educating consumers in the safest methods of disposal for their families, their pets, and the environment. The website www.smarxtdisposal.net has valuable information and answers many of the questions associated with this topic. A limited take-back programs and mail-back pilot programs have also been initiated. Ms. Binasco asked that the SMARxT Disposal web site be linked to the Council's website to further disseminate information about the program.

The meeting was adjourned at 1:55 p.m.