February 27, 2007

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)
Paul Hoerner (DoD)
Carol Holquist (FDA)
Sal Peritore (GPhA)
Matt Grissinger (ISMP)
Linda Hanold (The Joint Commission)
Eleni Anagnostiadis (NABP)
Ray Bullman (NCPIE)
Elizabeth Miller (Liaison to USP's SMU EC)

Council delegates/alternates participating by phone:

Ellen Quinn (ASHRM)
Michele Delisle (NPSF)
Rosemary Cook (PhRMA)

Alternates attending as representatives of their organizations:

Tara Modisett (NASPA)
Kristin Hellquist (NCSBN)

Alternates attending with their delegates:

James Owen (APhA)
Mary Gross (FDA)
Shawn Becker (USP)

Organizations/Members not represented:

AHA
ASHP
IHI
VA

The Chair welcomed Council members and alternates and called the meeting to order at 1:42 p.m. It was moved, seconded, and passed to accept the summary of the October 2006 meeting. Dr. Nadzam inquired about the Council's reactions to the monthly updates. The general response was that they are very helpful and should be continued.

Secretary's Report

1. Joint Commission Resources requested and was granted permission to reprint the Council's following work products in a publication titled *Tools for Medication Safety* to be published in February 2007:
   - Recommendations to Enhance the Accuracy of Dispensing Medications
   - Recommendations to Enhance the Accuracy of Administration of Medications
2. Results of balloting for recommendations up for revision:
   - In the recent balloting by mail The Recommendations for Health Care Professionals to Reduce Medication Errors Associated with the Labeling and Packaging of Pharmaceutical (Drug) Products and Related Devices and The Recommendations for Manufacturers to

Reduce Medication Errors Associated with the Labeling and Packaging of Pharmaceutical (Drug) Products and Related Devices received insufficient votes to carry.

- The Recommendations for Regulators and Standards Setters to Prevent Medication Errors Associated with the Labeling and Packaging of Pharmaceutical (Drug) Products and Related Devices contained errata.

It was recommended that the first paragraph of the Recommendations for Health Care Professionals be deleted, as well as the first two words of the second paragraph. It was moved, seconded, and unanimously voted to accept these recommendations as amended.

Discussion about the Recommendations for Manufacturers focused on proactive practices that would minimize errors. These practices would encompass the use of innovative lettering, which includes the use of color, fonts, character spacing and tall man lettering. The FDA has no current studies devoted to labeling and packaging. USP's Safe Medication Use Expert Committee believes that a lack of standards on tall man lettering has led to confusion and, therefore, is preparing an on-line survey on the issue. The Expert Committee requested the assistance of Council member organizations to distribute the survey. It was suggested to add other recommendations to discourage the overuse of tall man lettering and to encourage manufacturers to explore alternatives for parenterals that would replace the current embossing of drug names and strengths on ampuls and vials. FDA is adamantly opposed to anything but individual foil overwraps.

Action Item: Ms. Cook, Mr. Grissinger, Ms. Holquist, and Mr. Peritore will rework Recommendations 1 and 4 for Manufacturers and send them out to the Council for a vote.

The Council approved the addition of "Label" in the title of the Regulations for Regulators and Standards Setters. Recommendation 6 was changed to read "…to apply to the label, labeling, and packaging of…" Recommendation 8 was amended to read, "The Council encourages USP and FDA to take an active role on disseminating proposed FDA regulations (i.e., Federal Register) and USP standards (i.e., Pharmacopeial Forum) that relate to labeling and packaging of drug products to all affected health care practitioners." It was moved, seconded and unanimously voted to accept these recommendations as amended.

Action Item: Add "Label" to all labeling and packaging recommendations so that they read "Label, Labeling, and Packaging".

Action Item: Dr. Gallagher will draft a template for Council recommendations to standardize their format.

Council Structure Change

On January 29, 2007, the Steering Committee of the Council held a teleconference during which it voted to change the name of the Steering Committee to "Founding Members". An Executive Committee of the Council composed of the Chairperson, the Vice Chairperson, the Secretariat, and the Chairs of the Subcommittees was established to provide strategic direction for the Council. It was moved, seconded, and unanimously passed to accept these changes to the Council's structure.

Action Item: Changes in the rules regarding the structure of the Council will be posted on the website.

Membership

- It was moved, seconded, and unanimously passed to renew the membership of the National Patient Safety Foundation for a two-year term.
- The American Health Care Association (AHCA) notified the Council that it was dropping its membership due to changing resources and priorities.

Action Item: The Secretary will send a letter to AHCA acknowledging the request to drop membership on the Council, leaving open the possibility of reinstatement should resources and priorities change.

Council members were asked to forward to the Secretary names of organizations with similar constituencies as AHCA as potential replacements to AHCA on the Council.

Subcommittee Reports:

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

No report.

- Technology – *Matthew Grissinger, Chair*

Mr. Grissinger reviewed the latest draft of the At-Risk Behaviors paper. The Council decided that it preferred the term "At-Risk" rather than "Risk-Taking", as it has a more positive connotation. The paper will be a statement, rather than a set of recommendations. There was a question in Paragraph 1 as to the correct number of reports that were reviewed. The correct number will be inserted and the paper will be sent out to the Council for a vote. Any comments should be forwarded to Mr. Grissinger as soon as possible.

Action Item: Mr. Grissinger will insert the correct number of reports into Paragraph 1 and forward the paper to the Council for a vote of approval within one month.

Action Item: Dr. Nadzam is on the editorial board of the Patient Safety Newsletter and will check to determine whether that would be an appropriate venue to publish the At-Risk Behaviors paper.

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

No report.

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

No report.

Update of Council Recommendations

- Recommendations to Reduce Medication Errors in Non-Health Care Settings

It was moved, seconded, and unanimously passed to accept these recommendations as amended.

- Recommendations for Bar Code Labels on Pharmaceutical (Drug) Products to Reduce Medication Errors

The differences between FDA's recommendations and those of the Council should be noted. FDA refers to all drugs used within a hospital setting. The Council's recommendations refer to all drugs. Several recommendations should be combined to better aggregate the content. The pharmaceutical industry has made a significant investment in bar code technology and its use should be encouraged in health care delivery systems to support safe medication use. Recommendation was tabled until receipt of uptake data from ASHP. All comments and/or numbers should be forwarded to Joe Cranston.

- Recommendations for Health Care Organizations to Reduce Medication Errors Associated with the Labeling and Packaging of Pharmaceutical (Drug) Products and Related Devices.

There was a suggestion to change the title of these recommendations to labeling, packaging, and storage but not many storage issues are addressed.

Action Item: Ms. McSpadden will draft recommendations related to drug storage issues.

Action Item: Dr. Nadzam will use the former preamble to the Health Care Organization recommendations as the basis for a new set of recommendations on culture.

The meeting was adjourned at 5:04 p.m.

February 28, 2007

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)
Paul Hoerner (DoD)
Carol Holquist (FDA)
Sal Peritore (GPhA)
Matt Grissinger (ISMP)
Linda Hanold (Joint Commission)
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Ray Bullman (NCPIE)
Maryann Alexander (NCSBN)
Elizabeth Miller (Liaison to USP's SMU EC)

Alternates attending as representatives of their organizations:

James Owen (APhA)
Kasey Thompson (ASHP)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Mary Gross (FDA)
Kristin Hellquist (NCSBN)
Shawn Becker (USP)

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NPSF
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Dr. Nadzam reconvened the meeting at 8:45 a.m. and welcomed James Owen, APhA's new alternate. She then recapped the decisions and discussions from Day 1.

Dr. Gallagher reported on a Rand IT data study on bar coding. According to an AHA release in February 2007, 14% of hospitals have fully implemented bar coding systems and 19% have partially implemented systems. Incorporating these numbers into the Council's bar coding recommendations would add support to the recommendations but would also date the recommendations because the numbers would be always changing.

Action Item: Dr. Cranston will rework the bar coding recommendations, which will then be sent out to the Council for a vote.

Drug Suffix Conference

Discussion of the summary of the conference focused on substantive issues only. Editorial changes will be made by the Secretariat. Ms. Hanold requested that a thank you letter be sent to Kathy Domzalski, who wrote the initial summary. Dr. Cranston suggested incorporating sentences from

the issue statement into the introduction to define the issue. Mr. Grissinger has a statement to be inserted at the beginning of Mike Cohen's presentation.

Action Item: The Secretariat will send a letter to Kathy Domzalski to thank her for her efforts in writing the initial draft of the summary.

Action Item: Ms. Holquist and Mr. Grissinger will forward FDA's and ISMP's presentations to be posted on the website.

Action Item: Mr. Grissinger will check to verify whether or not "…from the pharmacist's perspective…" is part of the official transcript.

Action Item: Ms. Hanold and Ms. Holquist will identify examples to support the regulatory perspective.

Action Item: Ms. Hanold will draft a conclusion for the summary to be forwarded to the Council for review prior to the June meeting.

Rod Hicks, USP's manager of patient safety research, provided the Council with a report on tubing misconnections as discussed at the October 2006 meeting with USP, ISMP, and AHA. The focus was limited to one issue – enteral tubing connecting to parenteral tubing – with a first draft of a white paper due February 27 and possible publication in the Annals of Internal Medicine at a later date. The Council deferred the issue of tubing interconnectivity to other organizations.

Dr. Cranston stated that the drug suffix recommendations needed to be condensed to give clear directions for physicians. A condensed draft of the recommendations containing more examples will be circulated before the June meeting.

Action Item: Ms. Holquist and Ms. Gross will rework the drug suffix recommendations and forward them to the Council for review prior to the June meeting.

Ms. Hanold announced that the press release is approximately 80% completed.

Suffix Survey

To clarify the issue, it was suggested that the survey contain a definition of suffixes vs. modifiers. Dr. Cranston suggested using Steve Hartman's definition from his presentation at the conference and incorporating it into the introduction of the survey. All responding practitioners will be asked to select their primary practice setting, as well as their sub-specialty, using the NPI/NUCC specialty categories. Upon completion of the survey update, Mr. Grissinger will forward the survey to Ms. Hanold who will post it on Survey Monkey and send the link to the Secretary to be disseminated to members.

Recommendation to The Joint Commission

The request from Arnold Mattis to have the Council endorse a recommendation to The Joint Commission requiring "all accredited hospitals to begin using medication error surveillance methods to obtain more accurate information on the frequency and type of errors that threaten

patient safety" met with some very supportive discussion, but little consensus. The Council was reluctant to approve the recommendation at this time and suggested that Dr. Mattis submit the recommendation directly to The Joint Commission. The Council, at its discretion, could issue a statement supporting additional methodology at a later date. The subject was added to the list of potential future projects for the Council's consideration.

Action Item: The Secretary will send a letter to Dr. Mattis reflecting the Council's decision regarding his request for endorsement of his recommendation.

Pinnacle Awards

Dr. Gallagher proposed that the Council self-nominate for the Pinnacle Awards in Category 3. The deadline for nominations is March 26. Letters of support will be requested from users of the Council's workproducts.

Action Item: Dr. Gallagher will take the lead in organizing the support and collaboration for the Council's nomination for a Pinnacle Award.

Drug Samples – Diane Cousins

Ms. Cousins presented the results of her subcommittee's literature search on this topic. There is a general lack of available information but the questions that must be answered include the following: (1) what is in the current law; (2) what data is available; and (3) what recommendations would be effective in protecting patients? Several types of sampling programs exist, including programs for the indigent and the elderly, coupon/voucher programs, and immediate need/starter programs, such as in Emergency Departments when the pharmacy is closed. There are existing state and federal laws prohibiting the sale or purchase of drug samples and requirements for inventory control and record keeping. There are limits on the individuals who can obtain samples but nurse practitioners are denied access to samples for distribution. Drug samples are included in The Joint Commission's definition of "medications" but the FDA has issued no labeling requirements for them. Dr. Cranston stated that the AMA cannot support a voucher system or any system that does away with drug samples. The main issue is not drug samples, per se, but how the process works. A draft of 20 recommendations was discussed with the Council providing initial feedback. Additional and/or specific feedback should be forwarded to the subcommittee.

Action Item: Ms. Cousins, Ms. Anagnostiadis, and Ms. McSpadden will review all feedback and formulate Draft 2 for discussion at the June meeting.

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

AMA (Joe Cranston) – AMA is concerned about possible re-opening of (previously-passed) patient safety legislation that would reduce confidentiality protections of those who report medical errors. AMA also is carefully following drug safety legislation in the Congress. AMA is supportive of beefed up post-market surveillance and improved risk communication to physicians,

but is concerned about some risk management programs, like restricted distribution, that would give FDA statutory authority to regulate physician prescribing. AMA is implementing a number of strategic issues in 2007, including coverage of the uninsured, physician performance measures, education of physicians about patient safety, improving adult immunization, and improving healthy lifestyles.

USP (Diane Cousins) – On March 6, 2007, USP will release the MEDMARX® Annual Data Report, which focuses on medication error findings from the perioperative settings from 1998-2005. Analysis of data for this report was done in collaboration with AORN, ASPAN, and the United States Uniform Health Service (USUHS). Additionally, USP will hold a national invitational conference March 15-16 on medication error reporting systems, funded by a grant from AHRQ. This forum is a high level exploration and discussion of the methods, strategies, and tools that have been developed and/or employed to improve data collection and analysis. Participants will include MEDMARX users of more than five years, state reporting systems, FDA, and observers from AHRQ. USP's Center for the Advancement of Patient Safety resumed the monthly electronic publication of *CAPSLink* in January.

USP's Safe Medication Use Expert Committee (Elizabeth Miller for Mick Murray) – The Safe Medication Use Expert Committee has prepared an online survey to gauge awareness, perception, and effectiveness of the use of tall man lettering by manufacturers and vendors. Member organizations were asked to disseminate the survey to their individual members via e-mail or their electronic newsletters and on their websites.

Conclusion

The call for nominations for the positions of Chair and Vice Chair will be going out soon. It was suggested that the terms of service for these positions be extended to two years. As this involves a change from the current policy, the Secretary will send out a vote to Council members to change the Rules. This will be done prior to the call for nominations.

Action Item: The Secretary will put out a proposal for Council vote to extend the term of service for the Chair and Vice Chair from one to two years.

The Council reaffirmed the need for three meetings per year. It was noted that it is sometimes difficult to commit to two days for a meeting. The issue of changing the format of the meetings to a one day meeting with different start times was deferred until June.

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