Day One
September 23, 2004

Council delegates present:

Linda Hanold (JCAHO), Chair
Joseph Cranston (AMA), Vice Chair
Diane Cousins (USP), Secretary
Susan Raetzman (AARP)
Janet Myder (AHCA)
John Combes (AHA)
Rita Munley Gallagher (ANA)
Veronika Oven (AONE)
Ellen Quinn (ASHRM)
Carla Saxton (ASCP)
Ron Nosek (DoD)
Carol Holquist (FDA)
Sal Peritore (GPhA)
Eleni Anagnostiadis (NABP)
Jeff Ramirez (VA)
David Kotzin
Deborah Nadzam

Alternates attending as representatives of their organizations:

Anne Burns (APhA)
Susan Heffner (HDMA)
Kristin Hellquist (NCSBN)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Mary Gross (FDA)
Shawn Becker (USP)

Organizations/Members Not Represented:

ASHP
NACDS
NCPIE
NPSF
SEFH

Others attending representing their organization:

Matt Grissinger (ISMP)

Observers:

Seena Patal (FDA Office of Compliance)
Rachna Magoon (FDA)
Susan Camp (USP)
Rod Hicks (USP)

Linda Hanold (JCAHO), Chair, welcomed Council members, new alternates, and guests and called the meeting to order at 1:37 p.m. Ms. Hanold reviewed the procedural changes approved at the June meeting (the fishbowl concept, full Council voting on membership, etc.) and announced that actual voting for five Council membership renewals would be held the next day. The Council then reviewed the rules and procedures as they currently appear on the website and made several recommendations for changes. It was moved and carried to have an "Ex-officio" membership category and definition added to the listing of membership types.

***Subcommittee Reports**:*

- **Taxonomy**—— *Ellen Quinn (ASHRM) and Rita Munley Gallagher (ANA), Co-chairs*

The Subcommittee presented the Council with new versions of the Category Index and the Algorithm that included color changes and the introduction of "event" to replace "error". A motion to substitute "error" with "event" was made and later withdrawn. The Council members agreed that an error is part of an event; and, therefore, the terms are not interchangeable. Category B was subdivided into B1 (chance) and B2 (action). John Combes questioned whether there is really a difference between the two and stated that for the Council's purposes, B1 and B2 could be rolled up into "B".

ACTION ITEM: The Subcommittee will look at MEDMARX Category B errors to see if they can be subdivided into B1 and B2 groupings.

It was suggested that the Algorithm as presented may not flow as intended. This will be addressed by the subcommittee. Members were concerned that changing the color scheme, even to grayscale, might be too confusing for current users. A motion to change the colors was made and later withdrawn. It was agreed to leave the category index pie chart and algorithm as is. In response to a question about "near misses" the Chair deferred to NQF to take the lead in revising the definition if necessary.

Broad acceptance and use of the Taxonomy have been goals of the Council since the Taxonomy was developed and there have been frequent requests for permission to adapt the Taxonomy to individual circumstances. Initially, the Council vetoed allowing organizations and individuals to modify the Taxonomy but then opened the floor once again for discussion of this issue. It was agreed that some proposed adaptations may benefit everyone. John Combes stated the need for a set of basic principles to guide any altered use of the Taxonomy. The Council was firm in the belief that whatever changes are approved must not corrupt the underlying logic of the Taxonomy. It was also suggested that there should be some place in the taxonomy to indicate the correct course of prevention (what went right) when an error occurred.

ACTION ITEM: The Subcommittee will draft a set of principles to guide in the partial use of the Taxonomy for consideration at the next meeting.

The letter to the University HealthSystem Consortium (UHC) has not yet been completed Appropriate wording is needed to address their request. Jennifer Devine was contacted for a status on this wording.

ACTION TTEM: The Subcommittee will seek guidance from Jennifer Devine in finalizing the letter for UHC.

It was requested that meeting summaries be sent via e-mail instead of asking members to visit the website.

- **Practice Related Issues** - *Carla Saxton (ASCP), Chair*

The revised recommendations on the writing, dispensing, and administration of medicines were review by the Council. It was proposed that there be a separate bullet for

automated dispensing machines in the dispensing recommendation and that the writing recommendation contain a reference to companion recommendations regarding verbal orders. It was suggested that there be a statement in the preamble indicating to which healthcare provider each recommendation pertains and the level of oversight necessary for unlicensed personnel.

ACTION ITEM: Carla Saxton will incorporate the suggested changes, draft a general statement about the oversight of unlicensed personnel, and ballot members by e-mail for approval.

- **Technology** – *Matt Grissinger for Judy Smetzer (ISMP), Chair*

The Subcommittee has not met although data on tubing interchangeability has been received from MEDMARX, MER, and FDA. JCAHO has yet to forward its data.

ACTION ITEM: Linda Hanold will search the JCAHO sentinel event database for errors associated with tubing interchangeability and forward them to Judy Smetzer by November 15.

ACTION ITEM: Matt Grissinger will consult with Judy Smetzer to (1) develop a timeline for pushing forward the tubing interchangeability issue and (2) complete the risk behaviors analysis for presentation to the Council at the next meeting.

- **Promoting, Monitoring, and Evaluating -** *Deborah Nadzam, (Chair)*

The Subcommittee met via conference call and selected three issues on which to concentrate: (1) development of a fact sheet that would also be posted on the website, (2) development of a 10-year anniversary report of the Council's history and accomplishments, and (3) development of a commentary piece for submission to Health Affairs or other similar review journal. Using an outline provided by the Subcommittee, Council members volunteered to draft report sections where there was expert knowledge. It was noted that the number of professional literary citings would be an important addition to the section dealing with the Council's impact.

ACTION ITEM: The Subcommittee will collect draft sections from volunteers and will edit them into a cohesive document for presentation at the next meeting.

ACTION ITEM: Each member organization was asked to forward a paragraph to the Subcommittee by January 1, 2005, relating how their organization has utilized NCC MERP's products.

ACTION ITEM: The subcommittee will draft a letter to reserve space in a prominent journals July issue for publication of the commentary piece.

Medicare Modernization Act

The Council was presented with copies of the new CMS proposed regulations to implement the outpatient prescription drug benefit (PartD) of the Medicare Modernization Act and was asked to review them. The Council determined that a response letter should be sent to CMS regarding recognition of the Council's definition of medication error and

its views concerning medication error rates. The letter will also include a roster of Council membership and a disclaimer that the letter is not indicative of the views of individual Council member organizations. There is a need for a quick turnaround because all responses are due by 5:00 p.m. on Monday, October 4.

ACTION ITEM: Linda Hanold will develop a response to the Center for Medicare and Medicaid Services (CMS) on its proposed regulations for the Medicare Part D outpatient prescription drug benefit that incorporates the NCC MERP definition of medication error and references the Council's recommendations regarding medication error rates.

Evolving Role of the Council **–** *Linda Hanold,* Chair

The Chair requested that members review documents residing on the website to see if they accurately reflect current Council activities, mission, etc. She also inquired if the subcommittees felt they were living up to their charges. Answers to these questions will assist in the development of a strategic plan for the Council. It was noted that the mission statement of the Council is not posted on the website. Members indicated that the mission of the Council should be very broad – more of a grand vision rather than a concrete goal. It was understood that there will always be medication errors but the Council should work toward the prevention of harm. The Council is committed to the safe and effective use of medications and the idea was expressed that perhaps what is needed is a National Coordinating Council for Safe Medication Use. For homework members were asked to review the memo from the Chair and the materials provided and come up with two activities and projects that the Council should consider for future endeavors.

The meeting adjourned at 4:53 p.m.

Day Two
September 24, 2004

Council delegates present:

Linda Hanold (JCAHO), Chairperson	Ron Nosek (DoD)
Diane Cousins (USP), Secretary	Carol Holquist (FDA)
Susan Raetzman (AARP)	Sal Peritore (GPhA)
Janet Myder (AHCA)	Eleni Anagnostiadis (NABP)
John Combes (AHA)	Ray Bullman (NCPIE)
Joseph Cranston (AMA)	Jeff Ramirez (VA)
Rita Munley Gallagher (ANA)	David Kotzin
Ellen Quinn (ASHRM)	Deborah Nadzam
Carla Saxton (ASCP)	William Kelly (USP SMU EC)

Alternates attending as representatives of their organizations:

Anne Burns (APhA)
Susan Heffner (HDMA)
Ronna Biggs (NACDS)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Mary Gross (FDA)
Shawn Becker (USP)

Others attending representing their organizations:

Matt Grissinger (ISMP)

Organizations/Individual Members Not Represented:

AONE	NCSBN
ASHP	NPSF
HDMA	SEFH

Observers:

Scott Dallas (FDA)	Melissa Meekins (Student)
Rachna Magoon (FDA)	Susan Camp (USP)
Adesora Adetwon (FDA Student)	Will Brown (USP)

Linda Hanold, Chair, called the meeting to order at 8:40 a.m. and welcomed members and guests. Carol Holquist introduced Scott Dallas, a Safety Evaluator in FDA's Division of Medication Errors and Technical Support.

Presentation: Medication Errors Involving Suffixes – Scott Dallas, Ph.D., Safety Evaluator, FDA Division of Medication Errors and Technical Support, Office of Drug Safety at FDA

Suffixes – letters, numbers, or combination of letters and numbers that are attached to the end of proprietary drug names – differentiate a product line by identifying product characteristics such as dosing schedule, product strength, duration of therapy, number and strength of active ingredients, total drug contents, packaging configuration, and

indication for use. Unfortunately, there is no consistency in the meanings or usage of the extenders and numerous medication errors have resulted because of suffix confusion. Products of different companies have the same extenders and overlapping dosage amounts, leading to incompatible suffixes and strengths. According to Dr. Dallas, overlapping dosage formulations have been the main cause of errors involving suffixes. Additionally, there are differing suffixes between generic and brand name drugs. The implementation of a standardized system for suffixes would decrease confusion and medication errors with a new result of increasing patient safety and decreasing health costs.

***Presentation: Categories of Drug Release from Oral Dosage Form* – William Brown, B.S., USP Department of Standards Development**

Marketed drug products may have different release rates for the same drug. In the USP-NF compendium, oral dosage forms are either "immediate release" or "modified release" and modified release can be further divided into "extended release" or "delayed release". The following definitions explain the differences:

Immediate release – no deliberate effort has been made to modify the rate of release

Delayed release – release pattern has been deliberately modified to delay release of the active ingredient for a period of time after initial administration (e.g., enteric coatings)

Extended release – release pattern has been deliberately modified to slow down the rate of release; no specific release pattern.

Even though drugs may be bioequivalent, they may have different release mechanisms. Different manufacturers of "extended release" dosage forms may have separate release tests and these tests must be indicated in the labeling.

Council Discussion

According to Carol Holquist of FDA, the agency is required by law to follow USP definitions and would like USP to take the lead and create a standard regarding the drug labeling for these products. It was noted that eliminating trade names will not affect problems with sound-alike drugs. Release rates are not evident in generic names and have the potential to create errors and cause patient harm. The VA has limited its formulary to one generic drug per class of drug in an attempt to reduce these errors. The Council is interested in addressing this issue and to that end established an ad hoc committee to formulate a strategy and recommendations. Linda Hanold, Deborah Nadzam, Dave Kotzin, Ron Nosek, Sal Peritore, Carol Holquist, Eleni Anagnostiadis, Matt Grissinger, Rosemary Cook, Mary Gross, and Shawn Becker volunteered to be members of this ad hoc committee.

ACTION ITEM: Linda Hanold will convene an ad hoc sub committee via conference call to formulate a strategy for the Council to go forward exploring the issue of suffixes and will present its recommendations at the next meeting.

Presentation: Phonetic Orthographic Computer Analysis (POCA) System–Carol Holquist, R.Ph. Director, Division of Medication Errors and Technical Support FDA

The FDA Division of Medication Errors and Technical Support focuses on pre-marketing proprietary drug name review, post-marketing medication error surveillance, labeling and packaging review, and risk communication and management. The process includes expert panel review, literature and database searches, and handwritten and verbal analysis for simulated drug names. POCA comes into play when FDA is doing its database searches of handwritten and verbal analysis of drug names; however, it is not the sole tool used for evaluation of proposed proprietary names. The system incorporated USP's published sound-alike drugs list in its algorithm, and was able to identify at least 75% of the potentially confusing names identified by FDA evaluators. FDA is preparing a white paper on the strengths and weaknesses of POCA's algorithm and hopes to release it next year.

Evolving Role of the Council, Part 2

The Chair announced that beginning with the next meeting, the Vice Chair will track the meeting's Action Items and produce the highlights summary. Members were requested to review the summary of the June meeting and respond by October 1. The Chair has received a request from Michael Napoli in Guam for permission to use a simplified version of the Taxonomy for ADE reporting. Because the Taxonomy was not designed to address ADEs, a clarification on how exactly it would be altered is needed before permission can be granted. The Council resumed its discussion of the vision statement. It was agreed that the final vision statement would include the following components; (1) a statement that this is the vision of the Council, (2) concern with the safety of medication use, and (3) the prevention of harm. The purpose and objectives as posted on the website need to be updated and the mission statement added. Most of the web site data remains accurate. It was suggested that "to advocate" be added to the purpose. Business casual dress was adopted for future Council meetings.

ACTION ITEM: Linda Hanold will develop a response to Michael Napoli (Guam) relative to the taxonomy and electronic taxonomy support.

ACTION ITEM: The PME Subcommittee will develop a vision statement for the Council and send it out for review and approval by the full Council before the next meeting.

Presentation (by phone): Interrater Reliability of the NCC MERP Index for Categorizing Medication Errors by MEDMARX Users–Craig Pedersen, R.Ph., Ph.D., Ohio State University

Interrater reliability measures the validity of a rating scale and a high interrater reliability is a good predictor that different people will rate the same incident in the same way. USP developed an interactive tool for the Index and desired to test its validity in comparison to the Index category definitions and the algorithm. A letter was sent to all MEDMARX users inviting them to participate in this study. Although only 51 users were necessary, 119 users agreed to participate. A survey of 27 sample cases from the MEDMARX database were randomly ordered and complied. USP staff categorized the cases which became the gold standard. Participants were divided into three groups: one relied upon the category definitions, one used the algorithm, and the third used an interactive online version of the algorithm. Overall agreement was good. Agreement was best for Category I and worst for Category E. Of seven demographics that were modeled, only "years of experience" provided significant differences. The odds for correctly classifying a medication error were 36% higher for raters with five or more years of experience. Data was reanalyzed

combining Categories C and D and Categories E, F, and H. Collapsing the categories improved interrater agreement. Neither the paper-based nor the online algorithms resulted in more accurate ratings; however, they provided more consistent and accurate ratings for Categories E and H. Recommendations resulting from this study included building the computerized algorithm into MEDMARX, encouraging the development of a "power user" in each facility to improve consistency and accuracy, and developing a separate taxonomy to reflect cost factors. Findings from this study have been submitted as a poster to ASHP and will be published in a medical journal next year.

Membership

It was moved and unanimously carried to extend 2 year memberships to the following organizations: American Society of Consultant Pharmacists, Healthcare Distribution Management Association, Institute for Safe Medication Practices, National Council on Patient Information and Education, and to David Kotzin as an individual member. It was suggested that a letter be sent to the National Patient Safety Foundation, whose membership expired, suggesting that they rejoin the Council at a later time when they could attend meetings with regularity, as was done by ASCP. The Spanish Society of Hospital Pharmacy has had no contact or correspondence with the Secretariat and no attendance at Council meetings since its application for membership was approved. Therefore, it was moved and unanimously carried to revoke the Society's membership.

Roundtable Discussion – *The following organizations have submitted updates of their activities:*

AONE – AONE recently mailed its members a toolkit entitled "Strategies for Leadership: Nursing Leadership for Patient Safety." The toolkit was developed due to a grant from Eli Lily and includes patient safety literature, as well as a video and CD Rom on "Changing Attitudes and Approaches to Medication Errors at the Patient Bedsides." Rosemary Gibson, author of *Wall of Silence* will speak about the role of patients and families in patient safety at AONE's annual meeting in April, 2005. McKesson will be sponsoring a new award for the AONE Institute 2005 Award & Recognition Program titled "Keeping Patients Safe." The award is open to any AONE member who has worked on patient safety projects in his/her organization. More details can be found in the award application at www.aone.org.

ASCP – ASCP has appointed a new leadership council, the Patient Safety Task Force, which will launch in November. The Task Force will examine definitions of common terms associated with patient safety and available lists of dangerous abbreviations to determine if there are any missing that are pertinent to long term care. A recent article published in the AARP Bulletin profiled a pharmacist's ability to reduce medication errors, reduce ADRs, decrease inappropriate medication use, and increase the quality of life for seniors in the community and nursing homes. To date, this article has resulted in 2,400 phone calls, 150 e-mails, and 200 letters from AARP members to ASCP.

DoD – DoD continues an aggressive training program focused on Root Cause Analysis, FMEA, team training, and medication error reporting (MEDMARX). A total of six advanced patient safety manager courses were held this summer. Approximately 120 students were trained in RCA, FMEA, action planning and outcome measures, and MEDMARX. In

addition, MEDMARX and RCA training were held in Okinawa and Yokosuka, Japan; Fairbanks, AL; and Cherry Point, NC.

NABP – NABP is committed to making patient safety a priority for all initiatives undertaken by the Association. Electronic prescribing and the inclusion of indications on prescriptions are two initiatives that NABP's Executive Committee has identified as patient safety action items. On February 20, 2004, NABP released the updated Model Rules for the Licensure of Wholesale Distributors. These Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices. NABP has also been working closely with the FDA to educate and protect the public from counterfeit drugs.

NCSBN – NCSBN sent a letter to Tom Ridge, Secretary of the Department of Homeland Security, urging delay in implementation of the rules requiring certification of certain health care workers, primarily nurses, for an additional 18 months. It subsequently received word that Canadian and Mexican nurses who were licensed and employed in the US before September 23, 2003, must obtain the required visa certification by July 26, 2005. NCSBN estimates that up to 5,000 nurses may be impacted by this regulation but has no way to verify that number. The revised Model Nursing Practice Act and Model Administrative Rules for use by member boards of nursing have been completed. Polly Johnson has been elected as the new Vice President of NCSBN.

NCPIE – NCPIE's Consumer Medicine Information (CMI) Initiative to stimulate quality improvements and broader distribution of written prescription medicine information conveyed to consumers at community-based pharmacies, continues. This is an ongoing Initiative through 2006. Participating stakeholders include drug information publishers, pharmacy system vendors, pharmacist and pharmacy organizations, consumer and patient groups, and pharmaceutical manufacturers. NCPIE and participating stakeholders are awaiting release of a draft guidance document on CMI by the Food and Drug Administration. NCPIE is also sponsoring its 19th annual "Talk About Prescriptions" Month (October). To bolster educational outreach about the CMI Initiative, the 2004 "Talk About Prescriptions" Month theme is *Your Medicine Information is Important: Read It and Heed It*. The emphasis is on the role that written consumer medicine information (CMI) can play, in conjunction with medication counseling by healthcare providers, in promoting safe and appropriate medicine use. Materials for "Talk About Prescriptions" Month are posted on www.talkaboutrx.org.

USP – In March, USP released a book entitled *Advancing Patient Safety in U.S. Hospitals: Basis Strategies for Success,* a first-ever case study featuring the experiences of actual MEDMARX facilities, the hospital medication errors they encountered, and the steps taken to prevent similar mistakes. More than two dozen health care practitioners and administrators were interviewed to describe how they have changed their facilities' culture and reporting practices. Fear of litigation prevented some hospitals from participating. USP has introduced a 5-year program cycle and renamed the Quinquennial Meeting as simply the USP "Convention". The Convention will take place in March, 2005, during which a new Board of Trustees will be elected. A call for resolutions has been issued, allowing Council members, member organizations, and other interested parties to propose resolutions for the 2005-2010 term. USP has also issued a call for

candidates for Expert Committee chairs and members. Anyone interested is encouraged to submit an application. As indicated in Dr. Pedersen's presentation, the Safe Medication Use Expert Committee encouraged a validity and reliability study of the Category Index. The three groups of respondents compared the pie chart, the algorithm and a computer-generated algorithm with good correlation. More information will be forthcoming.

There being no new business, Ms. Hanold adjourned the meeting at 2:00 p.m.