June 11-12, 2002
Day One

Council delegates present:

Jerry Phillips (FDA), Chairperson
John Combes (AHA), Vice Chair
Diane Cousins (USP), Secretary
Andrew Smith (AARP)
Janet Myder (AHCA)
Joseph Cranston (AMA)
Rita Munley Gallagher (ANA)
Ellen Quinn (ASHRM)
Tom Clark (ASCP)
Kasey Thompson (ASHP)
Sal Peritore (GPhA)
Lisa Clowers (HMDA)
Linda Hanold (JCAHO)
Jon May (NABP)
Barbara Newman (NCSBN)
Rebecca DeVivo (NPSF)
Alan Goldhammer (PhRMA)
Jeff Ramirez (VA)
Deborah Nadzam (Cleveland Clinic)

Alternates present:

Dave Hardy (DoD)

Alternates attending with their delegate:

Mary Gross (FDA)
Shawn Becker (USP)

Delegates absent:

Karen Drenkard (AONE)
William Ellis (APhA)
Judy Smetzer (ISMP)

Observers:

Sharon Swan (ASCPT)
Ken Kobayashi (ASCPT)
Susan Camp (USP)
John Fowler (USP)
Rodney Hicks (USP)
Angie Long (USP)
Marilyn Storch (USP)
Serena McClam (USP Summer Intern)
Tim Alba (Premier Healthcare Infomatics) by teleconference

Jerry Phillips called the meeting to order and asked everyone present to introduce him/herself and identify the organization for which he/she works.

Diane Cousins (USP) announced the results of the recent elections: John Combes (AHA) was elected the new Chairperson and Linda Hanold (JCAHO) was elected the new Vice Chairperson.

Roundtable Update

- **AMA** (Joe Cranston) – The AMA has signed on as a partner with the NPSF, FDA, et. al. consumer brochure, "Think It Through". Ongoing projects include those dealing with risks in medicine, risk communication, and drug and vaccine shortages. At the annual meeting in July a number of resolutions will be presented - none, however, related to medication error.

- **ASHRM** (Ellen Quinn) – ASHRM has been conducting educational programs for risk managers across the country. Their annual seminar will focus on disclosure and the insurance crisis.
- **ASHP** (Kasey Thompson) – ASHP just concluded its summer meeting in Baltimore. The four-day meeting consisted of structured education in the areas of improvement strategies, research and education, funding for research grants, and using technology on web sites. ASHP has a national survey, whose key items include CPOE, bar coding, and unit dose packaging. They are working on a white paper on bar coding with subsequent educational materials for health system pharmacists on what will be involved. It was noted that unit dose packaging is disappearing from the market.
- **DoD** (David Hardy) – In its effort to integrate all points of service within its medical community, DoD has passed the first anniversary of the inauguration of its Pharmacy Transition Service (PTS). The system coordinates the information of 104 data bases and supplies information to doctors and pharmacists. It has processed 113 million transactions since its inception, which breaks down to approximately 355,000 per day, and has caught 39,000 Level 1 transactions. Recently DoD has begun working with the VA to coordinate reporting information.
- **AHCA** (Janet Myder) – Janet commented on a CMS proposal for drug cards and reported that AHCA agreed with CMS that it should be looked at it from a patient safety angle and that facilities should provide quality services. Copies of the proposal are available to members. AHCA is also working in conjunction with the CDC and CMS to achieve a 100% pneumocaucal and influenza vaccination rate for those who should be vaccinated.
- **ANA** (Rita Munley Gallagher) – The ANA's major concern continues to be staffing issues and how these concerns are being handled. There are still ten states that are taking a heavy-handed approach to impaired professionals. Mary Foley has been asked to serve on a NQF panel.
- **PhRMA** (Alan Goldhammer) – PhRMA was a partner with the NPSF & FDA on the "Think It Through" brochure. It also cosponsored a series of workshops on risk assessment with FDA and CERTs. PhRMA is undertaking the promotion of paperless drug product labels and are ready to begin a pilot program this summer with five pharmacies in the greater DC area. Also, PhRMA is working with two vendors on data bases but feels the FDA needs to establish a data base on all drug names that is available to all pharmacies within 24 hours. The long-term goal is to do away paper labels and product inserts completely.
- **VA** (Jeff Ramirez) – In May 2002 the second version of the VA's bar coding medication software was released. The Compare Patient Record System (CPRS) has an 82% compliance rate right now and the VA issued a directive to implement this software in all ICU's within six months. By 2004 the VA expects to have the funding to replace the computer system with new technologies and databases.
- **ASCP** (Tom Clark) – ASCP has cooperated with the FDA and HHS in a small hearing to develop an action plan for older adults. "Seniors at Risk" is the name of the paper related to medication errors to come out of this. An Assisted Living Work Group is working to provide guidelines and recommendations for medication management issues for those in assisted living and their families. Most of the work will be completed by the end of 2002 with a report to the Senate Committee on Aging due in the spring of 2003.
- **HDMA** (Lisa Clowers) – Lisa thanked Kasey and Jerry for their participation in a HDMA conference in May. HDMA has established a working group to look at the implications of FDA's plan to propose regulations on bar coding. Concerns will be presented to FDA prior to the public meeting this summer. HDMA Healthcare Foundation and Pharmacia have

joined to respond to the FDA's plan to propose bar coding on unit dose packages. HDMA is forming several taskforces to examine the issues of counterfeit drugs and drug availability. One taskforce will also explore the opportunity to develop voluntary guidelines. The bar coding workgroup is scheduled to hold a conference call with a week to get input from membership.

- **GPhA** (Sal Peritore) -- GPhA has been cooperating on the paperless label project.
- **NPSF** (Rebecca DeVivo) – The 4th annual conference was held in May. The next annual conference is scheduled for March 14-17, 2002. The NPSF has set up a Solutions Program contest that is calling for abstracts for improvements in patient safety in the specific area of elder care. The author of the winning paper will receive a $10,000 prize. A pharmaceutical safety steering committee has been established and is up and running. The new president of the NPSF is Bob Travis, formally of ASQ.
- **NABP** (Jon May) – Pharmacists are doing more extensive patient counseling, resulting in a larger responsibility of filling prescriptions being left to pharmacy technicians. The NABP is partnering with the Pharmacy Technicians Certification Board's (PTCB) Board of Governors to insure that pharmacy techs can prove they have a minimum level of competency. The object is to improve patient safety by raising the standards of technicians. At the annual meeting in Phoenix, the NABP passed nine resolutions on such topics as the reformulation of oxycontin, increasing enrolment at and expanding the roles of Colleges of Pharmacy, reducing medication and dispensing errors by more actively involving pharmacists, recognizing pharmacists as health care professionals, and standardizing clarification of DEA substances. Up until now pharmacy compounding has had no legal legitimacy and there is no section giving the FDA authority to enforce compliance policies. Nine new rules are now in effect that, if violated, allow the FDA to take action.
- **NSCBN** (Barbara Newman) – The annual meeting is scheduled for August 13-17 in Long Beach. The keynote speaker is Dennis Sherard, who will be addressing the crises in nursing. A current pilot program, the Citizens Advocacy Council, is looking at (1) elements that lead to practice breakdowns and how to avoid those risks, (2) alternatives to discipline, and (3) stressing education, not just regulation in avoiding risk situations.
- **AHA** (John Combes) – The AHA is sending a new tool kit to every American hospital that it hopes will assist with pro-active risk assessment and management. Although not an AHA initiative, the AHA is convening a meeting on June 25 at the Renaissance Hotel in DC for a new alliance that focuses on demands to standardize IT platforms. The initial panel is on bar coding. A completed set of site visits will determine the top hospital to have implemented a culture of safety and effected the best programs for patient safety. A $50,00 prize will be awarded at a health forum in July. John Combes represented the NCC MERP at a FDA meeting on the home use of medication devices. Issues still need to be defined to determine where regulation may be needed. John then thanked the Council for allowing the use of the Category Index to fulfill the new Pennsylvania law on medication safety.
- **USP** (Diane Cousins) – During its April 4-5, 2002, meeting the USP Safe Medication Use Expert Committee sent a letter to the FDA, encouraging it to adopt a standard method of concentration labeling. The Committee also set up a project team to access the feasibility of CPOE. David Bates will head this effort. On May 8 Roger Williams testified on Capitol Hill as part of USP's continued activity to seek protection for information reported to patient safety organizations. A copy of his testimony is available on the USP web site. The second annual report of summary information submitted to MedMARx was released on May 20. Council members should have received copies in the mail.

- **FDA** (Jerry Phillips) – FDA participated in several bar coding meetings in May – the 10th annual meeting of HCPC in Philadelphia and the annual meeting of HDMA also in Philadelphia. On May 22 FDA held a public hearing on risk management of medications. CDER will place medication errors and solutions on its Patient Safety News web site. Negotiations are concluded and for the first time post marketing errors will be recognized. Congratulations to the VA for receiving a Pinnacle Award. Seventy-three of its hospitals are now using bar coding.

Reports from Workgroups

Unlicensed Personnel in Non-Healthcare Settings– *Tom Clark (ACSP), reporting*

Settings for consideration included elementary schools, child day care centers, adult day care centers, group homes for the developmentally disabled, assisted living facilities, jails, and prisons. It is not always possible to have nurses or other health care professionals available to administer prescription or even over-the-counter drugs to residents of these kinds of facilities. As a result, medication errors (omission, wrong person, wrong dose, etc.) can go undetected due to lack or training and/or supervision. Although each type of facility is licensed by its resident state, each organization differs as to licensing requirements and training. The workgroup presented a set of draft recommendations as guidance to states to help ensure protection of those depending on assistance in these settings:

(1) Organizations that have medications stored and administered should have policies and procedures in place that address the acquisition of medications, the specification of which personnel have access to such medications and can administer them to residents, labeling and storage of medications, limitations on the types of medications are permissible for use or storage in that facility, storage and accountability of controlled drugs, and documentation of medication administration and medication errors.
(2) Training should be provided to ensure accurate administration and storage to any personnel with responsibilities related to medications,
(3) Safeguards should be in place to prevent and detect theft and diversion of controlled drugs,
(4) Medication information should be readily accessible.

Secondary recommendations dealt with licensure inspections, unit dosing, and what SOPs should be on file. The Council considered whether or not representatives from some of these facilities should be contacted to discuss these recommendations and get their feedback. Suggestions were made to devise a checklist, simple precaution reminders, promote minimum training, etc.

ACTION ITEM: The workgroup will rework suggestions and provide a second draft at the September meeting.

Jerry Phillips (FDA) announced that the FDA bar coding conference information was published in the Federal Register for July 26 at NIH. There will be speakers and interactive sessions. FDA is looking for input. Mary Gross is the contact person.

Medication Error Rates – *Shawn Becker (USP), reporting*

It was moved and passed to accept Draft 11 of the medication error rates statement.

ACTION ITEM: Shawn Becker will e-mail final statement concerning medication errors rates to the Council.

Consumer Education – *Lisa Clowers (HDMA), reporting*

The consensus of the workgroup was that there are many sources of consumer educational materials already available and the Council should not squander its resources duplicating the efforts of other organizations. The group's recommendations were (1) that the NCC MERP web site should have the ability to direct consumers to other appropriate web sites (NPSF, National Consumer League, AARP, FDA, etc.), (2) the Council should develop a liaison role with the National Council on Patient Information and Education (NCPIE) to utilize the strengths of both organizations, and (3) the workgroup should be disbanded to allow its members to participate on other issues within the Council.

ACTION ITEM: Lisa Clowers will draft a promotion for the NCC MERP web site that will direct consumers to other primary sites.

ACTION ITEM: The National Council on Patient Information and Education will be invited to the next Council meeting and asked to consider joining the Council.

Bar Coding – *Alan Goldhammer (PhRMA), reporting*

The manufacturing side of the bar-coding question has been actively working to promote an atmosphere conducive to wide-spread bar coding. Existing technology can scan down to the unit dose, but second data lines cannot be implemented right away. The technology is close to having something workable, but the end users have to weigh in with what is involved at that end with the huge data base costs. The Council agreed that drugs and biologics have to be a separate category from medical devices. The Health Leadership Council already has a set of draft recommendations pertaining to bar codes.

Taxonomy – *Jerry Phillips (FDA), reporting*

Premier Healthcare Systems requested permission to use the Taxonomy of Medication Errors as part of their web-based system for capturing and reporting incident report data by its member hospitals. Premier's goal is to increase reporting compliance with a standardized format and wants to use the whole Taxonomy with the exception of the "Causes" category as it now exists. Tim Alba, Senior Director of Premier Healthcare Infomatics, explained Premier's intent and concerns about liability of discovery and answered the Council's questions via a conference call. The Council's subsequent discussion centered on whether or not certain fields have to be used by everyone. The group found that some fields are not critical at all. However, the Council decided that for the time being permission to use the Taxonomy would require that the whole Taxonomy be used without alterations. Future investigation into why people do not want to use certain sections of the Taxonomy would be very informative for the Council.

The Council determined that a letter should be sent to Premier explaining that in regard to its request the Taxonomy had to be used in its entirety. If Premier wished to suggest changes in the Causes section of the Taxonomy, it should submit those changes to the Council, who will then approve them or not.

ACTION ITEM: A letter will be sent to Premier Healthcare explaining the position of the Council in regard to Premier's request for permission to use the Taxonomy.

The Taxonomy was originally designed to drive health care toward a standardized format for collection of medication error data. Although parts of the Taxonomy were deemed not critical, if the Council wants to encourage the use of the Taxonomy as a national standard then its use cannot be flexible. If the Taxonomy's role is just to provide guidance, then flexibility is a viable option. If flexibility were approved, then data would not be compatible and would have to be so designated. General use changes would make the Taxonomy unrecognizable within a short period of time. A suggestion of streamlining the Taxonomy raised the issue of how it would affect databases that are already in use. The following motions were considered by the Council: (1) If there is a request for permission to use the Taxonomy in building a database for analysis* of error, the Taxonomy must be used in its entirety. Any changes must be addressed by the Council and be applied to all users.{This would pertain to commercial usage only}; and (2) If there is a request for permission to use the Taxonomy in a collection and reporting** system, it can be used in part but must state that this is not its intended use. {Fields could be collapsed; however, data would not be comparable with that from facilities using the complete Taxonomy.} The Council's voted 9-7 with 1 abstention to pass the first motion and 16-0 with 1 abstention to pass the second motion. The question remained as to what to do with current commercial users who are using only part of the Taxonomy (ISMP-Canada).

ACTION ITEM: The Council will develop a definite policy for use of the Taxonomy.

The meeting adjourned at 4:52 p.m.

*Analysis is meant to have an external basis, such as mapping, benchmarking, trends, etc.
**Collection and reporting system refers to an internal collection of data for root cause analysis, etc.

Day Two
June 12, 2002

Council delegates present:

Jerry Phillips (FDA), Chairperson
Diane Cousins (USP), Secretary
John Combes (AHA)
Janet Myder (AHCA)
Joseph Cranston (AMA)
Rita Munley Gallagher (ANA)
Ellen Quinn (ASHRM)
Tom Clark (ASCP)
Kasey Thompson (ASHP)
Salvatore Peritore (GPhA)
Lisa Clowers (HDMA)
Linda Hanold (JCAHO)
Jon May (NABP)
Barbara Newman (NCSBN)
Rebecca DeVivo (NPSF)
Alan Goldhammer (PhRMA)
Jeff Ramirez (VA)
Deborah Nadzam (Cleveland Clinic)

Alternates present:

Dave Hardy (DoD)

Alternates that attended with their delegates:

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

Delegates absent:

Andrew Smith (AARP)
Karen Drenkard (AONE)
William Ellis (APhA)
Judy Smetzer (ISMP)

Observers present:

Ken Kobayashi (ASCPT)
Susan Camp (USP)
Jennifer Devine (USP)
Angie Long (USP)
John Fowler (USP)
Serena McClam (USP) (Intern)
Marilyn Storch (USP)
Roger Williams (USP)

Jerry Phillips, Chairperson, called the meeting to order at 8:47 a.m.

Strategic Planning – *John Combes (AHA), reporting*

The Council needs to recognize that it has tremendous strength in its credibility and in the diversity of expertise of its member organizations. It is most effective in developing and recommending courses of action that significantly impact patient safety. However, there are several weaknesses that should be addressed, among them lack of funding, attempts to tackle nebulous issues, the inability to work quickly, and a reluctance to capitalize on the clout implicit in the Council and do more to promote its own recommendations and interests. Some organizations who have original delegates or alternates sitting on the Council and could, perhaps, initiate a mentoring program for new delegates. Funding is an issue because the Council was not designed to deal with money, yet has developed programs that require funding. The question

arose whether the Council should become a dues-paying entity and if so, how would that change its mission. Roger Williams (USP CEO) emphasized that this is an important issue. USP has supported the Council since its inception and will continue to do so once the Council sorts out and determines how USP can do so. He also asked that the Council envision its imagined future and said that the future would be technology driven. The Council must address these technological changes that are taking place and determine what the Council's role should be. He suggested that the Council invite outside organizations (NQF, Leapfrog, etc.) to the next meeting to help focus the discussion on issues that would enhance the Council's work. The Chair stated that there is still plenty for the Council to do, such as develop a concise process for new recommendations, establish an on-going review of all recommendations, etc.

Practitioner Accountability Workshop

The Practitioner Accountability Workshop has been put on hold. It was suggested that the workshop be tied in with the top ten errors being reported in MedMARx. It was agreed that it would be a good idea to move ahead with a questionnaire that would be sent out with a one-page fact sheet about the Council to pharmacy and nursing boards, organizations who were providing speakers for the original workshop, and state patient safety officers.

ACTION ITEM: Make suggested modifications and send questionnaire to boards of pharmacy and nursing, state patient safety officers, and organizations who were providing speakers for the original workshop in 2001.

The next meeting of the Council is scheduled for September 12-13, 2002. The meeting was adjourned at 1:22 p.m.