March 18, 1999
Day one

Dr. Deborah Nadzam called the meeting to order at 1:40 P.M. Dr. Nadzam welcomed the newly elected members to the NCC MERP. Mr. David Keepnews of the American Nurses Association (ANA), Dr. Jon R. May of the National Association of Boards of Pharmacy (NABP), Mr. Jerry Phillips of the Food and Drug Administration (FDA) and Dr. Bert Spilker representing Pharmaceutical Research and Manufacturers of America (PhRMA). The guests and observers were also welcomed, and were asked to introduce themselves. The two invited guests, Mr. Cazemiro Martin, Chemist at FDA Division of OTC Products, and Mr. Jeff Ramirez, Chief Management and Clinical Information Systems, at the Veterans Administration were introduced.

The Chairperson opened the floor for any added agenda items. None were added.

Council delegates present:

Deborah Nadzam (Chairperson)
John R. Combes (AHA)
Andrew Smith (AARP)
David Keepnews (ANA)
Michael Cohen (ISMP)
Joseph Deffenbaugh (ASHP)
Bill Ellis (APhA)
Bert Spilker (PhRMA)
Diane Cousins, Secretary (USP)
Jerry Phillips (FDA)
Thomas R. Clark (ASCP)
Nancy Rapp Guilliom(ASHRM)
Joseph Cranston (AMA)
Jon R. May (NABP)
John Kessler (USP Advisory Panel on Medication Errors)

Alternates present:

Herbert Carlin (GPIA)

Other alternates that attended along with their delegates:

Mary Gross (FDA)
Shawn Becker (USP)

Delegates absent:

Linda Hanold (JCAHO)
Barbara Newman (NCSBN)
Alice Till (GPIA)
Janet A. Myder (AHCA)
LeRoy LeNarz (PhRMA)

Observers present:

Robert Shapiro (NACDS)
Larry Dwork (ISMP)
Jeff Ramirez (VA)
David Holmen (USP)
Judy McMeekin (USP)
Grace Deevo (PhRMA)
Sue Zmuda (USP)
Sara Foer (USP)
Grant Shetterly (CPMU)
Cazemiro Martin (FDA)
Fay Menacker (USP)
Elizabeth Cowley (USP)
Rita Calnan (USP)

Activities Update

⇒ **AMA** (Joseph Cranston) - Two big concerns for AMA in the drug area are Internet prescribing and direct to consumer advertising. With regard to drug safety or medication error prevention, the AMA and NPSF too are still going strong and are working with the VA on a list of best practices with Adverse Drug Events. Dr. Cranston distributed copies of an NPSF article that included a report entitled "A Tale of Two Stories: Contrasting Views of Public Safety" which can be found on their website (www.npsf.org).

⇒ **NABP** (Jon May) – Reported that NABP is concerned along with the State Boards of Pharmacy about the issue of adverse events associated with the filling of prescriptions. NABP is also concerned with the issue of Internet providers of pharmacy services and has recently developed, and will soon implement a system to provide verification of such services—the VIPPS system (Verified Internet Pharmacy Practice Sites). VIPPS will serve to inform consumers as to which Internet pharmacy service providers are registered with NABP as meeting State board requirements to practice pharmacy. In essence, consumers wishing to order their drugs in this manner will at least know if the provider is registered in the State and meeting licensing requirements, etc. NABP and FDA are working on a Memorandum of Understanding (MOU), that addressed the issue of shipping compounded prescriptions across state lines (i.e., the interstate transportation of compounded prescription drugs, an issue of great concern to the FDA). Some State boards of pharmacy have requested an extension of the time to respond and the agency has granted an additional 120 days. The MOU is causing concern for some State Boards of Pharmacy that are not in agreement with the principle that some level of control must be exerted on compounded prescriptions shipped in interstate commerce..

⇒ **ASHRM** (Nancy Rapp Gulliom) - The organization is utilizing ongoing efforts to educate and familiarize risk managers with conducting effective root cause analysis. Ms Gulliom thanked Tom Clark for the list of articles provided via the NCC MERP listserv. This list was distributed to the ASHRM members for assistance with their documentation of Root Cause Analysis.

⇒ **ASCP -** (Tom Clark) – ASCP is working on HCFA's proposed revision of the definition of a medication error that is used in nursing facilities, which is reviewed by state surveyors every year as part of the survey process. Comments on the HCFA draft were submitted. The final version is expected to be released in early May (copies of the draft were distributed for the delegate's review). ASCP created a laminated sheet with a revised list of medications that should not be crushed. Copies were distributed along with new additions of medication guides for long term care nurses.

⇒ **ISMP –** (Mike Cohen) - ISMP recently formed a new division called MEDERRS Medical Error Recognition and Revision Strategies to assist the pharmaceutical industry in testing products for safe names, labeling and packaging. A network has been setup with pharmacists, nurses, and physicians to implement projects with this organization to do failure analysis of products, and provide feedback to the companies involved. This will be implemented when ISMP is solicited by a company to do testing. ISMP has also started a new column on drug safety in the International Pharmaceutical Federation of Drug Associations, Journal for Physicians Assistants, and Nurse Practitioners. ISMP recently published preliminary data from their survey on hospital/pharmacy computer systems. Based on that information, ISMP would like to recommend looking into systems in more detail. Examples of the survey showed that only about 12% of American

hospitals even have the capability necessary for physician order entry. 60-70% will not pick up massive overdoses. This is very disturbing information.

⇒ **GPIA** – (Herb Carlin) - Nothing to report at this time.

⇒ **USP Advisory Panel on Medication Errors** – (John Kessler) - The Panel is revising the alerts from USP database based on reports received through the USP Medication Error Reporting Program. A draft copy of the Alert was distributed for comment by the members. This document once completed can be used by the member organizations. Five alerts are in development.

⇒ **FDA** – (Jerry Phillips) - FDA is busy with group activities and partnerships with NPSF and VA on best practices. They are also involved in the Presidents Advisory Commission on Consumer Protection and Quality in Healthcare. Healthy People 2010 is working on objectives to decrease medication errors and improve drug safety. FDA is paying close attention to reported medication errors with Cerebyx (Dear Dr. letter was sent out and product relabeled). Labeling changes are being made for Ketalar also. FDA is interested in a collaborative partnership to establish computer software to determine proprietary drug names. The project is called Cooperative Research and Development Agreement (CRDA) (CRADA) . CRDA CRADA is attempting to work with someone that allows for commercial development. Proposals will be requested via the Internet. It was suggested that this project have a practitioner component.

⇒ **AARP-** (Andrew Smith)- There are no existing estimates available regarding the level of cost associated with the elderly and medication errors. AARP is working on two projects at present. One is a study conducted by Dr. Lucian Leape, and Dr. Rothchild at the Harvard School of Public Health, and another project by Dr. Eric Thomas of the University of Texas Houston Medical Center, looking at medical errors and the cost implications with older patients. Dr. Eric Thomas is also working on looking specifically at older patients as follow-up to Harvard Medical Practice study conducted in Utah and Colorado. AARP is continuing its activities with NPSF.

⇒ **ASHP –** (Joe Deffenbaugh) - ASHP launched a major project, Medication Misadventures Resource Center that is now on ASHP's website. It features a link to the NCC MERP Taxonomy. ASHP is revising its guideline for preventing medication errors in hospitals, which is currently being reviewed by a number of experts in the medication error world. One of the more compelling comments from this review came from Bob Pearson, who is part of the Auburn group with Ken Barker and Betsey Flynn. He said that after 30 years of research we still have this crazy idea that medication errors are preventable. The ASHP guidelines and many recommendations that came out of NCC MERP, deal with structure and process, but the reality is that no matter how good the systems are made, from prescribing through administration, errors will happen. There must be systems in place that maintain their vigilance because of the fact that all errors cannot be prevented. Mr. Deffenbaugh gave an example of a sentinel event that occurred and after a root cause analysis, it was determined that everything was done right, except that the patient died. We need to look more at behavioral factors and cognitive psychological factors as well as environment in which medications are prepared. Comments ensued regarding the nature of the error described by Mr. Deffenbaugh and whether it could have been prevented. In lieu of additional information on the event, Mr. Deffenbaugh wanted the group to know that the point is that no matter how good the systems are we still have to be vigilant and follow up on all errors. Comments: There are things that can be done through the system to prevent errors. With major system changes, errors could virtually be eliminated. The bottom line is not to be complacent even when systems are improved.

⇒ **AHA** – (John Combes) – Addressed the Metropolitan Hospital section of AHA in Chicago, a governing committee which formulates policy related to large metropolitan area hospitals, addressing the issue of medical errors, and specifically medication errors. It is clear that medication errors will be the major topics at the upcoming AHA Board retreat in April. The Hospital and Healthsystem Association of Pennsylvania is working on a collaborative effort with Don Berwick of IHI on reducing ADEs. They are working on an eight-month collaboration with four area hospitals that should start in May. Continuing to work with ISMP in a collaborative effort for medical safety. A survey and assessment tool on systems of medication safety for hospitals, will be reviewed at their next meeting. The Pennsylvania group viewed the MedMARx program. Reaction to the demo will be compiled at the next meeting and the possibility of promoting the MedMARx program will also be discussed. Also looking to MedMARx at AHA level as well.

⇒ **ANA** – (David Keepnews) - Not currently on staff at ANA, but works as a consultant and volunteers for the organization on various issues. ANA is active on a number of fronts in terms of patient safety and quality issues. They are particularly interested in compiling and analyzing data on outcomes related to nursing care. A more thorough update will be provided at the next meeting.

⇒ **PhRMA** – (Bert Spilker) – Reported that due to resurgence in the media regarding drug safety, PhRMA is working on the industry side for safety (diagram distributed). On March 19, Dr. Spilker will be debating Sidney Wolfe of the Consumer Federation of America on the issue of drug safety. Janet Woodcock of FDA will also be present. PhRMA has created a conceptual framework that will be useful in differentiating the inherent safety and the safe use of drugs. PhRMA strongly urges that the message get out that safety is the balance between benefit and risk. On March 26, 1999, in Washington, DC, the American Enterprise Institute is having a session on basic principles and messages on safety. Mike Cohen and Lucian Leape among others will be speaking. Members were encouraged to attend.

⇒ **USP** (Diane Cousins) –As the Council Secretary, Ms. Cousins reported on the number of hits received on the NCC MERP website, which were numerous. There were a few dozen requests for Recommendations on Labeling and Packaging as well as for the Taxonomy. As the Secretary to the Council, Ms. Cousins was invited to participate in an effort by the NPSF partnership (materials were passed around) to review recommendations presented by the NPSF as best practices. Some of the recommendations had similarities to the recommendations put forth by the Council. Some of their recommendations were not as strong as those of the Council. The group is looking for more research to support issues addressed in the recommendations. Comment was made about the cases of machine-readable coding and that more data should be available to support the recommendations. The group also adopted the Council's definition of a medication error. Ms. Cousins reported that seven questionnaires were received in response to the published Taxonomy. All seven had a medication error reporting system, and five of those had databases in place. Five were in favor of using the Taxonomy. There was a comment that the Taxonomy was too complex to be adapted as a tool. However, all facilities agreed to be contacted at a later date. Dr. Ken Barker, of Auburn University, will attend the next meeting to present his research efforts on an observation method for reducing medication errors. As the USP representative, Ms. Cousins informed the group that USP presented at the ASHP mid-year clinical meeting in December on the MedMARx database and its potential public health impact and on MedMARx data collected through a 10-week beta testing period. Ms Cousins gave a synopsis of the data presented. The types of errors in both databases were discussed and some overlap was found. Both databases

showed improper dose or quantity and dose omissions as two of the most frequently reported errors. The three top causes of errors were similar in both databases. Ms. Cousins will be prepared to present results from the MedMARx database at the next meeting. Ms Cousins also addressed development of an RFP that will be presented for funding to the NPSF through a joint effort with ASHP and JCAHO, focusing on the study of system-based safeguards in hospital inpatient medication use process. Ms. Cousins said that essentially they would be looking to examine the process in inpatient facilities for the purpose of identifying the most and least vulnerable aspects of the process and the safeguards that exist within that process. Ms Cousin mentioned that a meeting is scheduled for March 29, 1999 to discuss adapting the MedMARx model to the ambulatory care and retail settings.

⇒ **Chairperson** - (Deborah Nadzam) - gave an overview of her responsibilities at the Quality Institute of the Cleveland Clinic Health System. Dr. Nadzam is charged with coordinating and standardizing the measurement of quality across the health systems, which comprises 10 hospitals. The Clinic is in the process of convening a medication use performance measurement team. Dr. Nadzam is hoping to bring 10 hospitals into MedMARx through that effort. Dr. Nadzam read an e-mail update received from Linda Hanold (JCAHO), on the Annenberg Conference. JCAHO is currently planning to present a Public Policy Forum in mid July 1999, to be held in Washington, DC. The forum will focus on five policy statements: 1) patient safety as an important measurable dimension of quality in health care 2) need to share information and create new knowledge about safety and health care to improve quality and prevent harm due to systems failure 3) every group in the health care system has a stake in improving safety performance 4) need to bring about a change or shift in attitude toward the application of non-punitive solutions to safety problems in health care systems and 5) patient safety as a significant public policy issue that should be at the top of every stakeholder's agenda. Key decision-makers, opinion leaders, business and public health professionals, etc., will be invited. JCAHO is also planning the Annenberg 3 conference for the Fall/2000.

Presentations

Mr. Cazemiro Martin, FDA Division of over-the-counter (OTC) Drug Products, was introduced by Jerry Phillips. Mr. Martin is the author of the newly announced regulation to simplify labels for OTC drug products. Mr. Martin thanked the members for the opportunity to present. He explained that on March 17, 1999, the agency published in the Federal Register a final Rule that established a standardized format, and standardized content requirements for the labels of OTC drug products. The citation can be found in volume 64 of the Federal Register, page 13253. Mr. Martin also informed the Council that joint efforts in authoring this document, included industry, consumer groups, and other well-known entities. The purpose is to standardize the process of OTC drugs, so that labels can be clear, simple, and easy to read. This includes products subject to OTC monographs and pre-market approval. Information to consumers should be readily accessible, readable, and easily understood. Small print size prevents consumers from using drug products safely and effectively. Five labeling changes are included in this document. Mr. Martin proceeded with his audiovisual presentation, and explained the standardized order in which this document will be used.

Headings, subheadings, format, and graphical features
Views of current samples and what they will look like after changes

List of interchangeable terms
General warnings

Other comments included:

- Labels will be similar to current nutritional labels of food, for easy consumer reading
- Need to request that monograph be amended
- Need public meeting to explain the new OTC labeling

FDA is planning in the near future to have public meetings to communicate the significance of this final rule. FDA is also considering another labeling comprehension study. Mr. Martin suggested contacting the press office at FDA for additional information on this project.

Jim Crandall, Director of USP Institutional Communications, reported on the progress made to date on the NCC MERP communications plan. The Taxonomy was published in the USP Standard, posted on several member organization websites and appeared in their newsletters/journals. Mr. Crandall distributed copies of an article featuring the Taxonomy published in Drug Topics. Copies of the latest news release on the Taxonomy, which is being mailed out to the healthcare trade press, were also distributed.

Mr. Crandall introduced Sara Foer, newly employed at USP, who is experienced in public and media relations, the healthcare arena, and also in journalism. Ms. Foer will be instrumental in providing the assistance needed to produce a higher level of service to the NCC MERP. One of Ms. Foer's objectives is to publicize the work of the Council and expand distribution of materials in conjunction with the NCC MERP.

A discussion of the use of the Taxonomy as it appears on the website ensued. Areas of discussion included:

Can it be altered
If it is a copyrighted document should it be used as is?
If changes are allowed, will it still be viewed as a NCC MERP document.
Verbiage on the NCC MERP website makes it seem as though text cannot be changed

ACTION ITEM: The Council needs to revise the Taxonomy statement to make clear their intentions with how the Taxonomy should be used.

Jerry Phillips, Associate Director, of the FDA Office of Post Marketing Drug Risk Assessment (OPDRA) presented the "Error Prevention Analysis" project. OPDRA is a new office that came out of the division of Pharmacovigilance of drug events, monitoring the safe use of drugs once approved. Mr. Phillips gave an overview of a new component for the center dealing with

medication errors and for increasing the safe use of drug products by minimizing user error related to drug labeling and packaging. The goals of OPDRA include:

- Post-market evaluation
- Risk communication (public and industry)
- Regulatory change
- Research
- Pre-marketing evaluation

Prior to the formation of OPDRA, this division consisted of the Pre-Marketing; Labeling and Nomenclature and the Post-Marketing; Medication Error Committee. Outcomes from these committees included:

- Reviewing 300 proprietary names of which 34% were rejected due to sound-alike, look-alike names
- 25% of post-marketing errors are due to tradename confusion
- 55 consults issued yearly to the center, of which 70% were returned with the committee's recommendations not followed
- Analysis of the 70% rejected recommendations, showed they resulted in errors

Plans for OPDRA activities include:

- simplifying the contents of package insert
- inactive ingredients moved to package insert as recommended by the USP Committee of Revision
- dosage and storage recommendations
- good labeling practices
- developing validated tools in predicting errors

OPDRA has had some success in working on Cerebyx, Ketalar and also Benzathine Penicillin. A review was done and six deaths were found as a result from Benzathine Penicillin and label changes were recommended.

Update on NCC MERP website Activity

Meredith Tcherniavsky (USP) reported that all is going well with the website at this time. The Taxonomy and Solid Oral Dosage were posted on the site. 1600 users downloaded the Taxonomy in February. May need to make modification to the member's page because the "Events" and "Products-Publications" are not generating much activity. The Council should advise on what to do and if something more useful should be posted instead. This issue will be discussed later.

Update on Guidance for Industry

Mike Cohen addressed the FDA Guidance for Industry report "Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling". Mr. Cohen expressed concern with

the FDA recommendations that allows companies to place therapeutic equivalence of their products on the labels. Adding additional text on the labels is in contrast to earlier information from Mr. Phillips on FDA's simplification of labels. There are products with two different dosage schedules that have occasionally been confused (i.e. procainamide/Procanbid). A second concern is that there is no information on whether the codes have been tested by practitioners for appropriate feedback. Mr. Cohen feels that this issue is important enough to place on the Council's agenda for discussion, and to alert others who may have the same concern.

Tom Clark inquired on the deadline status for comments on this document. Mr. Phillips thought the deadline was the end of March. Additional comments on this subject included:

- The coding was confusing
- With brand names on the label that are not equivalent, users may not understand the code
- Patients and nurses would be confused by these codes on the labels
- Labels are not changed frequently, new information may take a long time to replace
- Label cluttered with more than one name on the label
- Timeliness of the label as it relates to when equivalence may change

After some discussion, Mr. Phillips presented additional slides on the "Placement of Therapeutic Evaluation Codes." The driving force behind this document was the potential problem with product selection by pharmacists. The reason for the proposal to use AB Brand X was to link the name of the product equivalency for product selection. This history goes back to 1980, at which time section 301(I) of the Act prohibited therapeutic names on the labels. This was repealed in FDAMA, which opened the way for the current guidance under discussion. Examples were presented. Mr. Phillips requested comments from all concerned. This is voluntary labeling and not enforceable by FDA. Questions included:

- Where are the equivalency codes currently available, at the point of care, at the point of sale, or at the point of practice and has this been studied?
- Are there requirement limitations for size on the label?
- Are there restrictions to the size of the statement on the label?

Mike Cohen made a motion that "the Council formally communicate with FDA concerning the recommendations in the Guidance for Industry regarding the impact it may have on patient safety. John Combes seconded the motion.

The floor was opened for discussion. Discussion included:

- This document should be tested in a systematic way through practitioner review
- If the Council votes to write a letter to FDA, how will the member organizations feel about it? This could be a big issue if member organizations are perceived as "endorsing" the letter.
- Actual recommendation needs to be studied.
- AMA will have some concerns with this motion.
- Recommend organizations look at it and provide comments if they so desire

- Extension for comments should be requested from FDA (currently 60 days)

A vote on the motion was taken. There were eleven (11) votes in favor, two (2) opposed (NABP, AMA) and two (2) abstentions (FDA, GPIA). The motion carried.

Mr. Cohen made a second motion to formally request an extension of 60 days after March 31. The motion was seconded. A vote on the motion was taken fourteen (14) in favor, one (1) abstention (FDA). The motion carried.

Ms. Gulliom inquired about the codes available in the "orange book" as it would affect nursing practice. Is there any danger that the abbreviations or medical terminology of these recommendations might confuse the healthcare professionals? Jerry Phillips explained that there will be enough time to educate the healthcare profession in the use of these recommendations. Dr. Combes confessed that he had never seen some of these terms in his practice, and that there should be critical analysis of these abbreviations.

ACTION ITEMS –Draft letter to FDA requesting a study of the recommendations.(Diane Cousins and Mike Cohen). Draft a second letter requesting an extension of 60 days. (Diane Cousins). Letters will be posted on the member page for review and comments or through the listserve.

The Chairperson made a motion for adjournment, and it was seconded. The motion carried and the meeting was adjourned at 5:00 P.M.

March 19, 1999
Day two

The meeting reconvened on March 19, 1999, at 8:45 A.M.

Council delegates present:

Deborah Nadzam,(Chairperson)
John R. Combes (AHA)
Andrew Smith (AARP)
David Keepnews (ANA)
Michael Cohen (ISMP)
Joseph Deffenbaugh (ASHP)
Bill Ellis (APhA)
Diane Cousins, Secretary (USP)
Jerry Phillips (FDA)
Thomas R. Clark (ASCP)
Nancy Rapp Guilliom (ASHRM)
Joseph Cranston (AMA)
Jon R. May (NABP)
John Kessler (USP Advisory Panel on Medication Errors)

Alternates present:

Herbert Carlin (GPIA)

Other alternates that attended along with their delegates:

Mary Gross (FDA)
Shawn Becker (USP)

Delegates absent:

Linda Hanold (JCAHO)
Barbara Newman (NCSBN)
Alice Till (GPIA)
Janet A. Myder (AHCA)
LeRoy LeNarz (PhRMA)

Observers present:

Robert Shapiro (NACDS)
Grant Shetterly (CPMU)
David Holmen (USP)
Judy McMeekin (USP)
Grace Deevo (PhRMA)
Sue Zmuda (USP)
Sara Foer (USP)
Jeff Ramirez (VA)
Fay Menacker (USP)
Elizabeth Cowley (USP)
Rita Calnan (USP)
Linda Kohn (IOM)

Invited guests

Dr. Linda Kohn

The Chairperson began the meeting by welcoming Dr. Linda Kohn, Director of the Institute of Medicine (IOM), Quality Care Project of America, which focuses on medical errors. Dr. Kohn thanked the group for the invitation and proceeded with an overview of IOM and the connection with the National Academy of Science. IOM is a non-profit, non-governmental organization that conducts policy analysis by pulling together experts with diverse backgrounds, to conduct

policies and issue recommendations. Reports and books produced by the National Academy of Science are on the website (www.nas.edu). The Academy has no regulatory enforcement power.

The Quality Care of America is looking at errors in medicine and what needs to happen within healthcare organizations. A report is being produced on this subject (copies were circulated). The report will cover:

- Concepts in safety and errors
- Proposed model
- The role of government
- The role of professional societies
- The role of purchasers and consumers
- Actions within health care organizations
- Identification and evaluation of legal issues
- Areas of future research

The QCA's main goal is to reduce adverse events and enhance patient safety. The term Preventable Adverse Drug Event is used to define events that can be anticipated and that will cause or lead to inappropriate medication use or patient harm. The report is internally funded and targets a specific audience for recommendation assistance. The deadline for getting the report out is December 1999. Questions and comments included:

Will IOM setup a non-punitive system in order to create a reporting environment in institutions to look at reporting in a non-punitive fashion.
What is the difference between safety and quality
How will the report capture input from healthcare practitioners
IOM is not sure a reporting system will come out of this report
Studies completed are on inpatient settings, not enough knowledge on the ambulatory side

The IOM is meeting in mid June 1999. Committee meetings are opened to all. Dr. Kohn welcomed input from the NCC MERP organizations and suggested they contact her at 202-334-1929, or at lkohn@nas.edu. to discuss further input.

Jeff Ramirez

Mr. Ramirez, Chief Management and Clinical Information Systems, at the Veterans Administration (VA) gave an overview of the VA initiatives. The VA is transitioning from being an inpatient provider of care to an ambulatory provider interested in the reduction of medication errors. VA is working on a pilot of the MedMARx Program with USP. Dr. Kizer, VA Under Secretary, has approved this pilot for several of the VA VISN's. Mr. Ramirez also noted that VA operates seven complex automated mail systems in the US. Bar-coding is used to identify products. Accuracy rate on error tracking was 99.9%. VA is creating four patient safety centers for inquiry. VA has a number of different dissemination mechanisms to analyze errors for feedback to the public. One organization called Synopsis of Special Projects is using VA's Intranet to accomplish this goal and for incentive in reporting problems.

Update on Dispensing Recommendations

Bill Ellis took the lead on the recommendations for dispensing. He explained there is lack of definitive research that he would like to see in the recommendations. The current dispensing recommendations have basic and broad information, taking into consideration that there are variations in practice of ambulatory care, hospital care and nursing homes. A draft of the recommendations was distributed. Shawn Becker, Alternate Delegate for USP, was asked to provide an overview of the comments received on the recommendations from the last meeting. The recommendations were reviewed one by one, changes were made, and the recommendations were approved for distribution as revised.

Update on Administration Recommendations

Considerable discussion ensued regarding various aspects of the administration recommendations. Comments were made regarding the use of the five rights in one of the recommendations, and whether a sixth right was necessary as mentioned by Mike Cohen. Changes will be incorporated and sent out to members via listserv. The recommendations will be finaled and voted on prior to the next meeting.

Research Agenda

The Chairperson requested an update on the research agenda

Joe Deffenbaugh and Fay Menacker, provided information on conducting a literature search that will provide assistance in the development of the research agenda. The following databases were searched for appropriate medication error analysis:

International Pharmacy Association (IPA)
MEDLINE abstracts database
Healthstar Technology Administration and Research
Health Services Research Project in Progress (HSRPROJ)
National Patient Safety Foundations (NPSF Web Bibliography Jan. 1999)
Sigma Theta Tau International Registry of Nursing Research
The Clinical Index of Nursing and Allied Health Literature (CINAHL-is available by subscription. Some consideration is being given to the possibility of subscribing).

The group discussed the advantages and limitations of meta analysis with regard to exploring the medication error literature.

There are three specific actions the Council might take:

1. put together guidelines on how to report research in medication error area
2. conduct meta analysis
3. approach NPSF for funding to conduct the research

NPSF deadline for funding proposals is coming up (March 30 1999). A letter of intent from the Council asking for support should be sent. Bill Ellis volunteered to draft the letter. The Chairperson stated that if funding is received ($20-25,000.00), the Council may be able to fund a graduate student to do the research. Mr. Ellis said this process should be controlled by the Council, based on work already completed.

Other comments included:

- There has to be structure to a research agenda that identifies areas where research potential would yield results
- To put together a 3-year blue print or strategic agenda, the Council needs to know where it is today and where are the most fruitful areas to get to in three years
- Literature should include identification of methodologies and validation of methodologies and not a citation analysis that says where they got their papers
- Most research found on medication errors dealt with methods for detection and not how to fix them
- Need to bring to the table approach on how to go forward.
- Need to identify gaps and what has to be done to fill them - extremely important
- If funded the Council can instruct researchers based on work the Council has already considered, i.e. Taxonomy Classification etc.

ACTION ITEM: Bill Ellis will draft letter of intent for funding meta or gap analysis.

The Chairperson announced that the items not addressed at this meeting would be discussed at the next meeting scheduled for Monday-Tuesday, June 28-29, 1999

Possible agenda items for next meeting:

* Dr. Ken Barker will be invited to address his research
* Mike Cohen requested time on the agenda to discuss results on ISMP's survey on pharmacy automation
* Verbal orders
* The USP Advisory Panel on Medication Errors will prepare information for the verbal orders discussion
* Membership issues
* Update on funding for research agenda
* Measures for national comparisons (denominators need to be discussed)

ACTION ITEM: Send out tickler via listserv for members to consider who would be appropriate to discuss comparisons and denominators for medication errors.

Diane Cousins reminded the members that the call for nominations for Chairperson is due to begin in March. Candidates can be nominated from the pool of delegates or alternate delegates to the Council. Only one member from each organization may be nominated. The practice of

allowing non-delegates to be nominated as Chair was discussed. Due to time constraints, the Steering Committee Members will discuss these issues via a conference call.

Diane Cousins will explore the issue of the nomination of a non-delegate with the USP legal staff. Issue will be addressed and voted on by membership conference call.

A motion was made for adjournment and was seconded. The motion carried and the meeting adjourned at 3:20 P.M.