

NoDak

PHARMACY

Volume 24, No.1

January 2011

The White Coats Are Coming

JOIN US FEBRUARY 8TH
FOR THE 2011
LEGISLATIVE DAY/ICE
CREAM SOCIAL

- The White Coats are Coming
- Share concerns with your Senators and Representatives about YOUR future and the future of pharmacy in North Dakota
- Participate in Health Screenings to demonstrate your role as medication experts
- Personally invite your legislators
- Have an ice cream sundae with your fellow pharmacists and your legislators





Is a QA Program Missing From Your Checklist?

Pharmacy Quality Commitment™ (PQC™) is what you need!

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Pharmacy Quality™
COMMITMENT

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www.pqc.net for more information.**

PQC is brought to you by your state pharmacy association.

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COLLEGE OF PHARMACY,
NURSING, AND
ALLIED SCIENCES



URGENT

**THIS MAY BE
YOUR LAST
ISSUE OF
THE NODAK
PHARMACY.
FILL OUT
YOUR
MEMBERSHIP
RENEWAL
FORM PAGE 2**

Mark Your Calendar

FEBRUARY

February 8, 2011

The White Coats Are Coming
Pharmacy Legislative Day/Ice Cream Social

February 25, 2011

Legislative Crossover Date for Bills

MAY

May 13, 2011

NDSU Hooding Ceremony
Fargo, ND

JUNE

June 10-12, 2011

126th NDPhA Annual Convention
Grand Forks, ND

2011 National Meetings Calendar

- | | |
|-------|--|
| APhA | Annual Meeting March 25–28
Seattle, WA |
| NCPA | Legislative Conference May 9–11 Hyatt Regency on Capitol Hill
Washington, DC |
| | Annual Convention October 8–12 Gaylord Opryland Convention Center
Nashville, TN |
| AMCP | Annual Meeting April 27–30 Minneapolis Convention Center Minneapolis,
MN |
| | Educational Conference October 19–22 Atlanta Marriott Marquis
Atlanta, GA |
| ASCP | Midyear Meeting TBD |
| | Annual Meeting November 16–19 Phoenix Convention Center
Phoenix, AZ |
| ACCP | Annual Meeting October 16–19 David L. Lawrence Convention Center
Pittsburgh, PA |
| NCPDP | Annual Conference May 2–7 Arizona Biltmore Resort and Spa
Phoenix, AZ |

Taviah Lothspeich,

NDSU Pharmacist D. Student, Class of 2011

First and foremost I would like to start by saying thank you to Mike Schwab and Lorri Giddings for giving me such a great opportunity and enjoyable experience at the North Dakota Pharmacists Association. They were always willing to let me be an active participant in anything they were involved with and were great people to work with. I would also like to thank all of the pharmacists I met and interacted with while at the NDPhA. You all were very kind and great supporters of me and the involvement of any students who are interested in being active in the North Dakota Pharmacists Association.

As I prepared to write this article, I began by reflecting on the various things I participated in while completing my rotation at the North Dakota Pharmacists Association, and how far I had come in understanding what all the NDPhA is involved with. Going into this rotation I had only a vague idea of what all the Association does. I knew that they're involved with policy and advocacy and that they hold an annual convention, but anything beyond that was unclear to me. Now that I've completed my five week rotation here, I have seen that it is not possible to put the Association into just one category or role because they are actively involved with just about everything pertaining to pharmacy.

It became very apparent to me how active the NDPhA and Mike Schwab, EVP, are after only a few short days of being there. One of the major areas I participated in was attending meetings for various committees and organizations which included the North Dakota Rural Health Association, the Medicaid Medical Advisory Committee, Rotary Club, and the board meetings for both the North Dakota Pharmacists Association and the North Dakota Pharmacy Service Corporation. There were also many teleconferences and discussions that I participated in with topics including DME accreditation, AWP/Benchmark pricing, Medicare Part D Dual Eligible Plans, the Drug Take Back program, and Health Care Reform. I was also able to collaborate with Howard Anderson, the Executive Director of the North Dakota Board of Pharmacy to develop a guide to assist pharmacies in meeting various OSHA requirements. As a result of participating in these meetings and discussions I was able to meet pharmacists and other professionals from around the state and it gave me a great appreciation for the many "behind the scenes" activities they are involved with on a daily basis.

Another area I was involved with was the About the Patient Program. I participated in discussions about the disease state management programs taking place in many pharmacies in the state, researched resources for programs currently being developed, and updated information for the Brand Name Drug Rebate page. Seeing this aspect of the NDPhA gave me great insight into what pharmacists throughout North Dakota are doing to provide exceptional patient care.

Other major activities I participated in were related to the advocacy and education side of the NDPhA. One aspect of this was participating in the Government Affairs Committee and discussing pharmacy-related legislation that will be brought up during the legislative session, as well as researching and revising the legislation of the Committee. Another aspect of advocacy and education I participated in was meeting with legislators to discuss legislation being brought forward in 2011 that may affect pharmacy. In this meeting I got to see how pharmacists and legislators interact and saw the importance of answering any questions the legislators had. I also attended an open forum with the Insurance Commissioner and various stakeholders to learn about the Affordable Health Care Act and how it will affect our state. All of these activities were an amazing opportunity to become educated about the entire legislative process and to understand the importance of being involved with the public policymaking process. An especially important lesson that I learned was showing policy-makers that pharmacists in North Dakota have a voice, and they want that voice to be heard. This really resonated with me and reminded me of the saying "If you won't stand up for pharmacy, who will?" Pharmacists in North Dakota are willing to get involved and stand up for pharmacy which plays an active role in shaping how pharmacists practice pharmacy in this state.

Even though I have completed my rotation with the NDPhA, I know that my participation has only just begun. I look forward to seeing the end result of things I was involved with while there, but I most look forward to being an active member of the North Dakota Pharmacists Association. Thank you again to everybody who made this rotation so great and for having such a positive influence on my interest in this organization and what it does on a daily basis for pharmacy in ND.

Invoice for NDPhA Membership

January 1—December 31, 2011

ND License # _____

Full Name: _____

Home Address: _____

City, St, Zip: _____

Home Ph: _____

Business Name: _____

Business Address: _____

Business City, State Zip: _____

Business Ph: _____

Fax: _____

City, St, Zip: _____

Prefer Mail Go To: ☐ Business ☐ Home

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☐ Yes ☐ No

Legislative District _____

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| <input type="checkbox"/> Hospital | <input type="checkbox"/> Other |
| <input type="checkbox"/> Independent | |
| <input type="checkbox"/> Owner | |
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☐ Health-system Practice Academy (HPA)

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☐ Nuclear
☐ Compounding
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☐ Corporate Member (Having a business interest in Pharmacy) \$750

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*These must be a separate check or credit card charge
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PAC—Donate Tab or PhAC—Donate Tab*

- ☐ Contribution to NDPhA Political Action Committee (PAC)
(**Cannot be Corporate Checks AND must be a Separate Check**)
Amount _____
- ☐ Contribution to the Pharmacy Advancement Corporation (PhAC) NDSU Scholarship Fund (These funds are used entirely to provide scholarships to NDSU College of Pharmacy Students. Personal or Corporate Checks are accepted.)
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PHARMACY RALLY '11



**LEGISLATIVE HALL – STATE CAPITOL
TUESDAY, FEBRUARY 8, 2011**

11 A.M.-1 P.M.

RALLY IN THE LEGISLATIVE HALL



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AS MEDICATION EXPERTS**



ICE CREAM SOCIAL FOR PHARMACISTS & LEGISLATORS

Pharmacy _____ City/Zip Code _____

Contact Phone Number _____ FAX _____

Names those attending:

**PLEASE WEAR
YOUR PHARMACY
NAME BADGE**

- 1) _____
- 2) _____
- 3) _____

Duplicate this form as needed.

Return by Friday, February 4, 2011 to NDPhA.

Email: ndpha@nodakpharmacy.net or FAX to (701) 258-9312

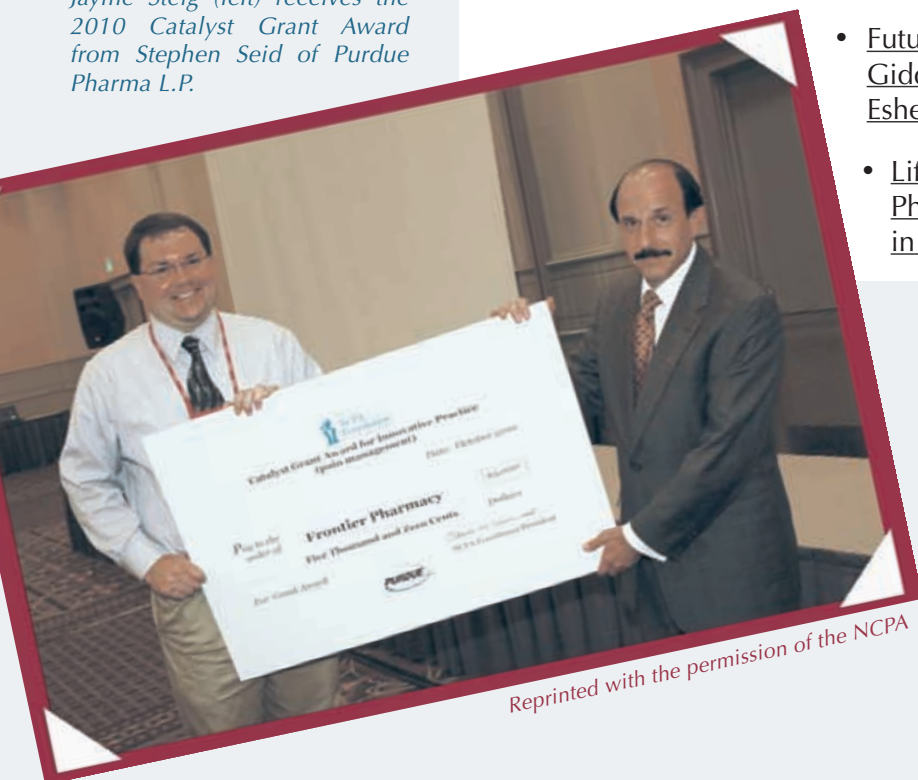
A big congratulations goes out to Mark Aurit of Gateway Pharmacy located in Bismarck. Mark was honored during NCPA's annual convention and received the Entrepreneur of the Year Award, NCPA's programs top honor. Way to go Mark! An article from Businesswire a Berkshire Hathaway company talking about the award winners can be found at <http://www.businesswire.com/news/home/20101026006868/en/Next-Generation-Pharmacist-Winners-Announced>. Mark Aurit was also featured on the cover of Pharmacy Times Journal, a first for the journal in its 113 year history.

The 2010 Next-Generation Pharmacist Awards also honored winners in 10 categories:

- Entrepreneur of the Year: Mark Aurit, RPh, owner of Gateway Health Mart Pharmacy in Bismarck, N.D.
- Green Pharmacist of the Year: Whit Moose Jr., BSPHarm, with Moose Pharmacy in Mount Pleasant, N.C.
- Civic Leader of the Year: Terry Spears, RPh, owner of Family Health Mart Pharmacy in Vernon, Texas.
- Technology Innovator of the Year: Dr. Tim Davis, PharmD, owner of Beaver Health Mart Pharmacy in Beaver, Pa.
- Patient Advocate of the Year: Dr. Lisa Strucko, PharmD, RPh, with Leesburg Pharmacy in Leesburg, Va.
- Industry Advocate of the Year: Harry Lattanzio Jr., RPh, president of PRS Pharmacy Services in Latrobe, Pa.
- Technician of the Year: Deborah Boland, pharmacy lead technician with Kmart Pharmacy in Smyrna, Tenn.
- Rising Star of the Year: Dr. Chris Williams, PharmD, pharmacy advocate, for the Manatee Your Choice Health Plan in Bradenton, Fla.
- Future Pharmacist (student pharmacist): Adrienne Giddens, student of University of North Carolina's Eshelman School of Pharmacy.
- Lifetime Achievement: Dr. Randy McDonough, PharmD, CGP, BCPS, owner of Towncrest Pharmacy in Iowa City, Iowa.

Caption:

Jayme Steig (left) receives the 2010 Catalyst Grant Award from Stephen Seid of Purdue Pharma L.P.



Reprinted with the permission of the NCPA

Steig Receives 2010 Catalyst Grant Award

Jayme Steig, PharmD, president of Frontier Pharmacy in West Fargo, N.D., received the 2010 Catalyst Grant Award for Innovative Practice award. The award is sponsored by Purdue Pharma L.P. Conducted over several years, this program will generate a significant body of knowledge and evidence to highlight the effectiveness of pharmacy-provided services and the efficacy of pharmaceuticals when properly used. The selected best practices will be widely communicated to healthcare providers, policy makers, and patient and disease advocacy groups. The NCPA Foundation will team with NCPA's Management Institute staff to administer this program.



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Jayne Steig, PharmD RPh

NEW PROGRAM ANNOUNCEMENT

What a whirlwind start to the New Year! Blizzards, holidays, many health care plan changes on Jan 1, and the start of a new ND legislative session. All that on top of the demanding schedules we all already have. I would like to take this chance to update you on a new patient care opportunity from the About the Patient program.

NEW PAIN MANAGEMENT PROGRAM

We have some exciting news regarding the About the Patient program. The NDPSC has entered into a contract with ND Workforce Safety and Insurance (workers comp) to offer a pilot pain management program to injured workers in Burleigh, Morton, Stark, and Walsh counties. Tara Schmitz has been working very hard on getting a pain management certificate program set up. We are going to be using a set of modules from the AMA. Instructions on the certificate program will come out VERY shortly. We will also have a live session at Mid Winter, held Jan 29 in Fargo, that we hope to broadcast via webinar as well as a part of the certificate program. We look to launch the program in March. The goal of the program is to help injured workers better manage their pain from their injuries and properly manage their medication. While the pilot program will comprise of injured workers from 4 counties, the ND Board of Pharmacy has provided a grant to offer the certificate program to all pharmacists in the state. We encourage anyone interested to complete the certificate program. It contains valuable information that is of benefit to any practice setting. If the pilot is successful, we hope WSI will offer the program statewide and that we will already have a statewide network set up.

DIABETES PROGRAM UPDATE

The NDPERS diabetes management program continues. It is currently authorized through June 30, 2011. In the next few months, the NDPERS board will decide upon renewing the program. An economic outcome analysis was done by NDPERS using a group from UND to do the analysis. The analysis showed positive, statistically significant clinical outcomes. It also showed mean cost savings trends of \$2.34 saved per \$1 spent on the program (\$853.68 per program participant annually). However, this economic result was not statistically significant do to our relatively small sample size and wide standard deviation in medical costs. This happens to most studies similar to this for the same reasons (including Asheville). The PERS board will take into account the UND analysis as well as input from the NDPSC to make its final decision on the program. Regardless of what happens, the program accomplished its primary goal of improving our patients health. Our program results, both clinical, humanistic, and economic, closely resemble that of Asheville. We should be proud of that.



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NAPT

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Please enter the name of the candidate and place of employment under the title of the award. The nominator must prepare a letter of recommendation listing the outstanding achievements of the nominee and send the letter to the Selection Committee, attention Chairperson of such committee. Such letter must arrive within the determined due dates as posted yearly by the Selection Committee. The criterion for each award is listed below.

DISTINGUISHED YOUNG PHARMACY TECHNICIAN

Minimum Selection Criteria/ Nominations will be accepted from any member of NAPT, NDPhA or NDSHP

1. Practicing as a Pharmacy Technician for less than 10 years.
2. Registered as a Pharmacy Technician in North Dakota.
3. Practice sites shall include but are not limited to; Institutional, Managed Care, Retail, or consulting pharmacy in the year selected.
4. Nominee should demonstrate an outstanding work experience in the Profession of Pharmacy. Participation in national technician association, professional programs, state association activities, and or community services is not required but would be good examples of dedication to the profession.

Nominee: _____

Submitted by: _____

DIAMOND AWARD

Minimum Selection Criteria/ Nominations will be accepted from any member of NAPT, NDPhA or NDSHP

1. Current or past registration as a N.D. pharmacy technician is required.
2. The nominee must be living, awards are not posthumously.
3. The nominee is not a past recipient of this award.
4. The nominee is not currently serving as an officer of the NAPT Association.
5. The recipient has demonstrated and outstanding record of community service such as; involved in church, community (scouts, school, PTA, Jaycees or other organizations). The recipient also demonstrates an outstanding service to the Profession of Pharmacy.

Nominee: _____

Submitted by: _____

FRIEND OF NAPT

Minimum Selection Criteria/ Nominations will be accepted from any ND Registered Pharmacy Technicians

1. The nominee has not been a previous recipient of this award.
2. The nominee has been an advocate of NAPT and the Profession of Pharmacy Technicians.

The nominee may include but are not limited to; Registered Pharmacy Technician, Registered Pharmacist, or any related Pharmacy Business. The recipient is not limited to a specific person; a company can also be noted as a recipient.

Nominee: _____

Submitted by: _____

NAPT PHARMACY TECHNICIAN OF THE YEAR AWARD

Minimum Selection Criteria/ Nominations will be accepted from any member of NAPT, NDPhA or NDSHP

1. The nominee shall be a Registered Pharmacy Technician in North Dakota.
2. No nominee shall be a member of the Selection Committee or past recipient of the award.
3. Each nominee shall be actively practicing as a Pharmacy Technician in North Dakota. However, need not be actively involved with NAPT.

Nominee: _____

Submitted by: _____

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2010 (Fourth Quarter)

1985—Twenty-five years ago:

- Prescription revenue in community pharmacies accounted for 62% of total sales.
- First Pharmacy in the 21st Century held in Millwood, VA. Attendees represented 8 pharmacy associations and 9 manufacturers. While no consensus developed, 3 later P=21 Conferences helped support the move to pharmaceutical care and the acceptance of the PharmD degree.
- Invitational Conference of Directions for Clinical Practice in Pharmacy (The Hilton Head Conference) focused on the role of clinical pharmacy primarily in the institutional setting.
- There were 72 accredited colleges of pharmacy in the US (including Puerto Rico)

1960—Fifty Years Ago:

- 109 companies introduced 45 new chemical entities and 98 new dosage forms.
- In the first large scale use of Sabin oral polio vaccine in the US 180,000 school children were vaccinated.
- 50% of US hospitals lack the services of registered pharmacists.
- There were 75 accredited colleges of pharmacy in the US (including Puerto Rico).

1935—Seventy-five Years Ago:

- Over 18% of community pharmacies were operating at a loss compared to 1932 when 34% were in the red.

1910—One hundred Years Ago:

- There was an average of 1500 pharmacy graduates annually. However, not all states required graduation as a prerequisite for licensure.
- There were 26 colleges of pharmacy represented at the annual meeting of the American Conference of Pharmaceutical Faculties (now the American Association of Colleges of Pharmacy).

By: Dennis B. Worthen Lloyd Scholar, Lloyd Library and Museum, Cincinnati, OH

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: www.aihp.org

2011 (First Quarter)

1986—Twenty-five years ago:

- 38.5% of pharmacy graduates chose to work in chain community pharmacies for their first job while 18.9% choose independent pharmacies.
- U.S. space shuttle Challenger exploded on launch, killing 7 astronauts.

1961—Fifty Years Ago:

- The American Association of Colleges of Pharmacy (AACP) opened its Washington office with Charles Bliven named first full-time executive secretary/treasurer.
- University of Michigan offers the first optional post-baccalaureate PharmD outside of California.

1936—Seventy-five Years Ago:

- Subsection on Hospital Pharmacy formed within the APhA Section on Practical Pharmacy and dispensing with Iowa Dean Louis Zopf the first chair.

1911—One hundred Years Ago:

- The School of Pharmacy of the University of Colorado at Boulder was established as a department of the School of Medicine opened.

1886—One hundred twenty-five years ago:

- South Dakota Pharmacists Association then known as the Dakota Pharmaceutical Association Southern District founded in Mitchell, SD

By: Dennis B. Worthen Lloyd Scholar, Lloyd Library and Museum, Cincinnati, OH

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: www.aihp.org

2011



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This Article replaces #0047-9999-10-002-H01-P
printed in error in Nodak Pharmacy Volume 23, No. 3 • October 2, 2010.



USP's Role in Patient Safety

ACPE # 0047-9999-11-001-H05-P

1.5 CE Hours (0.15 CEU), Expires 01/01/2014

This continuing education monograph is adapted from the United States Pharmacopeial Convention (USP) series of white papers prepared by the Council of the Convention (CoC) titled "Focus On: Future Directions for USP." The learning objectives and assessment questions were developed by National Alliance of State Pharmacy Association's (NASPA) Continuing Education Advisory Panel. No financial support was received for this activity. This activity may appear in other state pharmacy association journals.

Council of the Convention Section on the Quality of Patient Care

Rita Munley Gallagher, Ph.D., R.N., Section Chair (American Nurses Association)

Thomas R. Clark, R.Ph., M.H.S. (American Society of Consultant Pharmacists)

Charles W. Maas, M.D., M.P.H. (California Medical Association)

Stephen P. Spielberg, M.D. (Association of American Medical Colleges)

Goals:

The goals of this lesson are to review and be aware the current methods used by various organizations to increase patient safety and those future potential opportunities for USP to be involved in patient safety.

Objectives:

At the conclusion of this lesson, successful participants should be able to:

1. Describe current methods to increase patient safety
2. Describe future patient safety opportunities for USP

INTRODUCTION

For the last four decades, the United States Pharmacopeial Convention (USP) has relied on spontaneous reporting information to support creation of safe medication use and quality of care standards in the *United States Pharmacopeia* (USP) and allied reports. For the most part, these are standards and supporting information that speak to how practitioners within healthcare systems should adjust their processes and practices to promote safe medication use. At times, USP product standards call for the adjustment of labels and labeling to reduce the likelihood of error.¹

As a volunteer-driven, practitioner-based, standards-setting organization, USP provides an important and unique pathway for practitioners to set standards they use in daily life. USP is not itself a regulatory body and does not enforce its standards; however, conformity assessment bodies may recognize USP standards in ways that enhance their value, impact, and at times make them mandatory. Irrespective of their voluntary or mandatory character, standards provide a safe harbor for practitioners and support optimum health care outcomes.

While beyond the scope of this white paper, USP acknowledges—and has always supported—the remarkable work of academia, the Institute of Medicine (IOM), highly involved standards- and conformity-assessment organizations (many of whom are Convention members), and many others who have worked tirelessly to develop information and provide evidence-based approaches to promote patient safety, safe medication use, and optimal quality care. Much of this effort culminated in the seminal reports of the IOM beginning in 1999 and follow-on activities in the IOM and elsewhere.

The Council of the Convention Section on the Quality of Patient Care presents this white paper as a means of reviewing USP's prior efforts in this area and to encourage the Convention to consider future patient safety opportunities for USP.

¹ For the most part, USP does not provide clinical practice standards, which are the responsibility of practitioner associations, state practice boards, and other certifying bodies.

In the United States, under the Federal Food, Drug, and Cosmetic Act (FDCA), the *United States Pharmacopeia* (USP) and *National Formulary* (NF) are recognized as official compendia. A drug with a name recognized in USP-NF must comply with compendial identity standards or risk being deemed adulterated, misbranded, or both. Drugs must also comply with compendial standards for strength, quality, and purity, unless they are labeled to show all respects in which the drug differs. These Federal requirements arise under the adulterated drugs provision of the FDCA at §501(b) as well as the misbranding provisions at §502. The role of nomenclature is particularly important, since the link to drugs “recognized in an official compendium” at §501(b) arises in the statutory provision that addresses the designation of drugs by “established names” at §502(e).

As explained in 21 CFR §299.4, the Food and Drug Administration (FDA) has statutory authority to designate “official” or “established names,” yet it rarely does so. Instead, while continuing to review *proprietary* (brand) names as part of the drug approval process, FDA defers to USP’s Nomenclature Expert Committee in the Council of Experts and to the U.S. Adopted Names (USAN) Council, in which USP plays a key role, to provide *established/nonproprietary* drug product and drug substance names. Accordingly, the term “established name” means an article recognized in USP-NF (see FDCA §502(e)(3)), and drugs with such names must meet USP-NF standards for identity as well as (unless labeled otherwise) strength, quality, and purity.

The FDA has extensive authority regarding the labeling of drugs, ranging from the package insert, dispensing, and containers, to advertising and promotional materials. The FDCA provides that a drug with a name recognized in an official compendium—including USP or NF—will be considered misbranded unless it is packaged and labeled as prescribed therein (FDCA §502(g)). Monograph requirements for packaging and labeling are noted in the USP-NF General Notices at 4.10 and are reflected in various monographs and General Chapters.

CURRENT ACTIVITIES

1. THE USP NOMENCLATURE EXPERT COMMITTEE

USP’s Nomenclature Expert Committee establishes nonproprietary names for drug substances, drug products, excipients, biologics, dietary supplements, and medical devices for humans and animals. It also promotes uniformity and consistency among the official titles in the USP and NF. The Committee is concerned with nomenclature for dosage form monographs and other aspects of the language used in the prescription, dispensing, sale, or manufacture of drugs. The Committee works in a collaborative fashion with the USAN Council, and USP has committed to using the USAN as the title of a drug monograph for that substance. The Committee’s authority to develop official nonproprietary names is identified in section 502(e) of the FDCA. The section indicates that a drug is misbranded if its label does not include the “established name” of the drug and each ingredient. It further specifies that the established name of a drug or ingredient is the official title used for the drug or ingredient in an official compendium such as USP or NF, as long as the FDA has not designated an official name in accordance with section 508 of the FDCA. In early 2006, a federal appeals court decision confirmed that the nonproprietary names assigned by the USP Nomenclature Expert Committee take precedence over the names informally approved by the FDA during regulatory review. Taken together, the public-private partnerships created through Congressional authority have provided U.S. practitioners with coherent non-proprietary drug substance and product names, and these good naming conventions promote safe medication use and quality of care.

2. SAFE MEDICATION USE EXPERT COMMITTEE

The Safe Medication Use Expert Committee (SMU EC) began its work in the 2000-2005 cycle and continued in the 2005-2010 cycle. The nineteen members of the 2005-2010 SMU EC were drawn from the professions of medicine, nursing, and pharmacy, and include representatives from academia, research, government, and consumer interest. In this cycle, the SMU EC has reviewed and analyzed medication error reports submitted to USP, and from those, the Committee established recommendations for revision and development of standards in USP-NF and made recommendations to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) discussed later in this white paper. It also developed guidelines, recommendations, a General Chapter, and publications related to safe medication practices and patient safety. The SMU EC’s members provided support to USP’s two reporting programs—MEDMARX® and the Medication Error Reporting (MER) Program. The SMU EC’s focus has been on policy-level priorities for the safe use of medications and patient safety initiatives. Examples of initiatives appear below:

- Total Dose per Total Volume — The SMU EC developed crosscutting support for a requirement to change labeling to indicate total dose per total volume for parenteral packages of 100mL or less. The recommendation was based on errors in which health professionals mistakenly administered the entire vial content in error—published in *Pharmaceutical Forum (PF)* 31(4) [July-Aug 2005]: Strength and Total Volume for Single –and Multiple-Dose Injectable Drug Products.
- Neuromuscular Blocking Agents — An article, “Improving the safety of neuromuscular blocking agents: A statement from the USP Safe Medication Use Expert Committee” was published in the *American Journal of Health-System Pharmacists*, Vol 63, Jan 15, 2006. The work stimulated a new policy statement from the American Society of Health-System Pharmacists (ASHP) on the use of neuromuscular blocking agents. The publication of this article followed the standard instituted by USP that required the warning, “Warning – Paralyzing Agent,” on the closures of neuromuscular blocking agents.
- Patient Safety Stakeholder Forum — A cross-disciplinary Patient Safety Stakeholder Forum was convened on October 11, 2006 to discern the need for the creation of a new USP publication: “Safe Medication Practices Compendium.” This forum was followed by a USP white paper, “Exploring a Strategic Proposal for the Concept of a Compendium of Safe Medication Practices.” It was eventually concluded that additional exploration was needed to develop such a compendium.
- “Error Avoidance Recommendations for Tubing Misconnections When Using a Luer-Tip Connector: A Statement by the USP Safe Medication Use Expert Committee” was published in the *Joint Commission Journal on Quality and Patient Safety*. May 2008. Volume 34, Number 5: pp. 293-296.
- Physical Environments that Promote Safe Medication Use — General Chapter <1066> *Physical Environments that Promote Safe Medication Use* was created to provide safe medication use standards for all health care settings.
- Guidelines or Standards for Computerized Prescription Order Entry and Other Technologies — The SMU EC is working with Dr. Andrew C. Seger and Dr. Gordon Schiff from Brigham and Women’s Hospital on an analysis of computerized prescription order entry (CPOE) errors from the MEDMARX® database to develop guidelines/standards.
- “High Alert Drugs by Location” is being drafted by the Medication Error Data Analysis Advisory Panel of the SMU EC.
- Health Literacy and Prescription Container Labeling— The Health Literacy and Prescription Container Labeling Advisory Panel of the SMU EC is working on recommendations for the development of standards regarding simplifying language; using explicit text to describe dosage/intervals, including purpose for use; organizing the label in a patient centered manner; improving readability; and including supplemental information.
- Standardized Intravenous Concentrations — The SMU EC completed analysis of a Standard Intravenous (IV) Concentrations survey of health system pharmacy directors in order to determine the standard drip and flush concentrations being used in their respective facilities for the treatment of neonates, pediatrics, and adults. The goal is to standardize product concentrations to help decrease medication errors. The SMU EC will recommend standard concentrations for ten High Alert Drugs as a follow-up to an IV SMU survey (and an IV Summit held at USP) and publish an article identifying standard IV concentrations for ten High Alert Drugs by patient type.
- Tall-Man Lettering — The SMU EC will publish an article based, in part, on a research survey titled “Tall Man”/ Enhanced Lettering for Medication Name Differentiation. The survey on Tall Man Lettering was conducted in an effort to better understand the current landscape regarding use of and experience with enhanced lettering as a safety tool. Based on the survey results, the USP Nomenclature Expert Committee will consider the advisability of developing standards. A significant number of responses (1,788) were received from pharmacists (60%), nurses (16%), and physicians (16%), with the remainder coming from pharmacy technicians, nurse practitioners, and other healthcare providers. Cooperation in disseminating the survey was obtained primarily from the American Society of Consultant Pharmacists, the ASHP, the Institute for Safe Medication Practices (ISMP), the Joint Commission, and the National Alliance of State Pharmacy Associations.
- Harmonization with WHO Label Standards for Vincristine and Other Vinca Alkaloids — Three component changes were recommended to reduce the chance of vincristine (and other vinca alkaloids) being administered by the intrathecal route (which is universally fatal). Through a reworded cautionary statement, the recommendation would change to overwrap alert labeling and add a cautionary statement on the cap and ferrule of the vial. (This proposal is currently under consideration by the Nomenclature Expert Committee.)

3. THE NATIONAL COORDINATING COUNCIL FOR MEDICATION ERROR REPORTING AND PREVENTION

USP serves as the Secretariat for the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP/The Council), an independent body comprised of numerous national organizations. The Council was formed in 1995 through the efforts of its member associations and agencies to focus on ways to enhance patient safety through a coordinated approach and a systems-based perspective.

An interdisciplinary group of 15 organizations and agencies held its first meeting in July 1995. In the past 14 years, the Council has grown to 26 member organizations and two individual members. The five goals that continue to direct the Council's activities are:

- Stimulate the development and use of reporting and evaluation systems by individual health care organizations;
- Stimulate reporting to a national system for review, analysis, and development of recommendations to reduce and ultimately prevent medication errors;
- Examine and evaluate the causes of medication errors;
- Increase awareness of medication errors and methods of prevention throughout the health care system; and
- Recommend strategies for system modifications, practice standards and guidelines, and changes in packaging and labeling.

Council Accomplishments—1995 to Present:

- Defined a “medication error” and encouraged all stakeholders to use this definition to provide a uniform basis for medication error reporting and analysis.
- Developed a medication error taxonomy, index and algorithm for categorizing medication errors
- Issued a statement on calculating medication error rates
- Promulgated recommendations for:
 - o Prescribing
 - o Labeling and packaging
 - o Dispensing
 - o Administration
 - o Verbal medication orders
 - o Standard bar codes on medication packages and containers
 - o Reducing medication errors in non-health care settings
 - o Reducing at-risk behaviors
 - o Bar coding labels to reduce medication errors
 - o Promoting safe use of drug suffixes
 - o Avoiding medication errors with drug samples

The Council has had national and international impact through its multidisciplinary conferences on bar coding, drug nomenclature, and suffix use. Continuing activities and other accomplishments include:

- 1) Developing and disseminating standardized definitions for terms such as *adverse drug event*, *adverse drug reaction*, *harm*, *preventable event*;
- 2) Establishing a dedicated Web site for organizations, government, and practitioners to reference The Council's recommendations and other information;
- 3) Developing a solid oral dosage forms article for broad dissemination;
- 4) Endorsing the ISMP *Safety Self-Assessment for Community/Ambulatory Pharmacy*;
- 5) Establishing consumer information links to The Council's Web site;
- 6) Developing and disseminating a white paper on the use of bar codes;

- 7) Signing on to a set of *General Principles* supporting legislation to uphold, as privileged, information submitted to error reporting programs (These *General Principles* were incorporated into the Patient Safety and Quality Improvement Act of 2005 that was signed into law on July 29, 2005.);
- 8) Recognition with the 2007 American Pharmacists Association Foundation Pinnacle Award; and
- 9) Receipt of the 2008 Eisenberg Award.

In the coming years, The Council will continue to focus on key issues impacting the safe use of medications. With the help of new and enthusiastic member associations and agencies, The Council will address medication reconciliation as well as geriatric and long-term care issues. The members of The Council are recognized at www.nccmerp.org.

PRIOR ACTIVITIES: USP'S REPORTING PROGRAMS TO SUPPORT STANDARDS

1. DRUG PRODUCT PROBLEM REPORTING PROGRAM

Because of concern with the quality of drug products on the market, in 1971, the USP and the FDA co-founded the Drug Product Problem Reporting Program (DPPR). This was a national program in which health professionals voluntarily reported problems and defects experienced with drug products marketed in the United States. Often, product problems or defects had to do with inadequate packaging or labeling that could lead to errors or confusion on the part of health professionals. Other problems such as inclusion of foreign matter, suspected contamination, questionable potency, and "bioinequivalence" based on observed therapeutic response were also reported among the more than 100,000 observations gathered in DPPR. USP terminated the DPPR contract with the FDA in 1987, but continued a USP Drug Reporting Program until August 2000.

2. MEDICAL DEVICE AND LABORATORY PRODUCT PROBLEM REPORTING PROGRAM

Together with the DPPR Program, USP operated the Medical Device and Laboratory Product Problem Reporting Program (PRP) under contract with the FDA Center for Devices and Radiological Health (CDRH). In this program, USP collected reports on defective medical devices and shared that information with both CDRH and the manufacturers involved in incidents. This program had a major impact on the use of breast implants, dental implants, and marijuana testing kits. It was the precursor to the FDA's MedWatch program. This contract with the FDA was terminated in September 1995.

3. VETERINARY REPORTING PROGRAM

In 1994, USP established a Veterinary Reporting Program (VRP) to assist the FDA's Center for Veterinary Medicine (CVM), the Environmental Protection Agency, and the Department of Agriculture in obtaining information about adverse events with veterinary products. Reports were shared with the appropriate government agency and with the manufacturers of the products involved in the reports. The program was terminated in April 2003.

4. MEDICATION ERROR REPORTING PROGRAM

In 1991, USP established its first Medication Error Reporting Program (MER) in conjunction with the ISMP. MER was designed to obtain spontaneous reports both for the medicine itself and the system in which the medicine was prescribed, dispensed, administered, and used. Between 1991 and 2008, MER received more than 6,000 voluntary reports of actual and potential medication errors. MER identified errors in various health care delivery environments, including hospitals, nursing homes, physicians' offices, pharmacies, emergency response vehicles, and home care. The reports documented that errors are multi-disciplinary and multifactorial and that they may be made by experienced as well as inexperienced health professionals, support personnel, interns, students, and even patients and their caregivers. Medication errors can and regularly do occur anywhere along the continuum from prescribing to transcribing to dispensing and administration. The causes of errors may be attributed to human error, to product names or designs, and to the medication handling and delivery systems in which the products are used and in which individuals operate and interact. USP submitted MER reports to the FDA as a MedWatch partner, including adverse drug reactions that came to MER but were not evaluated. MER reports were also shared with the relevant manufacturers.

Examples of important changes USP made to its standards as a result of MER reports appear below:

- Potassium Chloride—Reported deaths due to the accidental misadministration of concentrated Potassium Chloride Injection led to: 1) changing the official USP name to Potassium Chloride

for Injection Concentrate to give more prominence to the need to dilute the product prior to use; 2) requiring that labels bear a boxed warning with the words “Concentrate: Must be Diluted Before Use;” 3) requiring that the cap must be black in color (the use of black caps is restricted to this drug product only); and 4) requiring that the cap must be imprinted in a contrasting color with the words “Must be Diluted.”

- Vincristine Sulfate — Reported deaths due to confusion and the resultant injection of the anticancer drug, Vincristine Sulfate for Injection, directly into the spine instead of the vein resulted in changes in the requirements for packaging by pharmacies and manufacturers preparing ready-to-use doses. Each dose, whether prepared by the manufacturer or the pharmacist, must now be wrapped in a covering labeled “FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES” and that covering may not be removed until the moment of injection.
- Amrinone/Amiodarone — Reported deaths due to the confusion of similar names Amrinone and Amiodarone led USP and the USAN Council to change the nonproprietary name and official title of Amrinone to Inamrinone.
- Neuromuscular Blocking Agents — Reported deaths due to the inadvertent mix-up of neuromuscular blocking agents (which paralyze the respiratory system) with other drugs led to recommended changes in standards for labeling and packaging of the therapeutic class of neuromuscular blocking agent products.

5. MEDMARX®

MEDMARX® was developed by USP in 1998 as an Internet-accessible, anonymous reporting program that enables hospitals to voluntarily report, track, and trend data, incorporating nationally standardized data elements (i.e., definitions and taxonomy). These standardized elements were drawn from the work of the MER Program, the FDA, NCC MERP, and the ASHP. MEDMARX® is structured to support an interdisciplinary, systems-approach to medication error reduction and fosters a non-punitive environment for reporting. USP created MEDMARX® with the intent to broaden the model to include other health care settings, e.g. long-term and ambulatory care settings, and to include other types of reporting such as medical error and adverse drug reactions.

Hospitals are encouraged to use MEDMARX® as part of their internal quality improvement processes, thereby extending their “peer-review” to other hospitals in the program. Hospitals can review errors entered by other institutions in “real time” and also see any reported action taken by another institution in response to an error in an effort to avoid similar errors in the future.

This feature affords institutions the opportunity to examine errors in a proactive manner. For example, the institution can review the error profile of a drug or class of drugs to determine if certain risk prevention measures or training programs should be established within the institution before a product is added to the institution’s formulary. If the error profile is significantly serious, a determination may be made not to stock the drug. MEDMARX® supports the performance improvement standards of the Joint Commission, which requires institutions to look outward at the experiences of others in order to reduce risk.

USP transferred its reporting programs, MEDMARX® and MER, to Quantros and ISMP, respectively, in 2008. USP will continue to use data from these and other programs to enhance its standards-setting activities to promote patient safety and safe medication use. In the interest of public health and to assist practitioners and patients, USP has posted eight annual reports on its Web site free of charge, ensuring full access to this clinically important information.

FUTURE OPPORTUNITIES

1. NOMENCLATURE, SAFETY, AND LABELING EXPERT COMMITTEE FOR THE 2010-2015 CYCLE

In the next cycle, a new expert committee—Nomenclature, Safety, and Labeling Expert Committee—will combine the work of the Nomenclature and Safe Medication Use Expert Committees from the 2005-2010 cycle. This new Expert Committee will build on the work of its predecessors by continuing to develop guidelines, recommendations, General Chapters, and publications related to safe medication practices and patient safety, as well as by linking these efforts to drug naming and the labeling of medications. Via Expert Panels, specific standards-setting activities can be addressed on a broad range of safe medication use and quality of care standards.

2. INSTITUTE OF MEDICINE

In 2007, the IOM published *Preventing Medication Errors*, a report by its Committee on Identifying and Preventing Medication Errors. The report called on USP to work with the FDA and others in several areas related to drug naming, labeling, and packaging. The IOM posited that there are many ways that basic information about a specific drug is communicated to providers and patients and identified some of the more obvious problems:

- Brand names and generic names that look or sound alike
- Different formulations of the same brand or generic drug
- Multiple abbreviations to represent the same concept
- Confusing word derivatives, abbreviations, and symbols
- Unclear dose concentration/strength designations
- Cluttered labeling—small fonts, poor typefaces, no background contrast, overemphasis on company logos
- Inadequate prominence of warnings and reminders
- Lack of standardized terminology

The proposed IOM action plan focused on two overarching principles: 1) product naming, labeling, and packaging should be designed for the end user—the provider in the clinical environment and/or the consumer; and 2) safety should always take precedence over commercial interests. In addition, Recommendation #4 of the IOM report included USP in a list of organizations that should work together to address labeling, packaging, and the distribution of free samples.

CONCLUSION

Based on its nomenclature and labeling recognition in the FDCA and exhortations from the community, the need for USP's involvement in standards to promote safe medication use and quality care is as strong as ever—and may increase in an era of health care crisis and reform. One of USP's greatest strengths lies in its ability to convene a broad and diverse group of stakeholders around issues common to all, and USP can leverage this role by helping to advance standards related to medication safety that are beyond the scope of a single health profession or professional organization. For many years, USP has devoted substantial resources and energy to its safe medication use and quality of care standards-setting activities, but has struggled to find a sustainable financial and public health model for these activities. Convention Delegates must now ask: What is the appropriate role for USP in setting standards related to medication/patient safety, and how will this role be financially supported? The Council of the Convention Section on the Quality of Patient Care calls on the Convention membership to articulate ways in which a standards-setting body such as USP can continue its work based on USP's historical contributions, unique capabilities, and current and possible future positions in law.

ABOUT USP and NASPA

The United States Pharmacopeia (USP) is an official public standards-setting authority for all prescription and over-the-counter medicines and other health care products manufactured or sold in the United States. USP also sets widely recognized standards for food ingredients and dietary supplements. USP sets standards for the quality, purity, strength, and consistency of these products—critical to the public health. USP's standards are recognized and used in more than 130 countries around the globe. These standards have helped to ensure public health throughout the world for close to 200 years. More information can be found at www.USP.org

The National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among state pharmacy associations and pharmacy leaders nationwide, and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives (NCSPA). More information can be found at www.naspa.us

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Continuing Education Quiz:

- An article with an “established name” must meet USP-NF standards for which of the following**
a. Identity b. Strength c. Quality d. All of the above
- Which of the following works in collaboration with the USAN Council?**
a. USP Nomenclature Expert Committee
b. Safe Medication Use Expert Committee
c. National Coordinating Council for Medication Error Reporting and Prevention
d. None of the above
- Which of the following does USP serve as the Secretariat for?**
a. USP Nomenclature Expert Committee
b. Safe Medication Use Expert Committee
c. National Coordinating Council for Medication Error Reporting and Prevention
d. None of the above
- Which of the following developed guidelines, recommendations, a General Chapter, and publications related to safe medication practices and patient safety?**
a. USP Nomenclature Expert Committee
b. Safe Medication Use Expert Committee
c. National Coordinating Council for Medication Error Reporting and Prevention
d. None of the above
- How many members does the 2005-2010 Safe Medication Use Expert Committee have?**
a. 16 b. 17 c. 18 d. 19
- Studies on which of the following were conducted in an effort to better understand the current landscape regarding use of an experience with enhanced lettering as a safety tool?**
a. Tall Man Lettering
b. Harmonization
c. Health Literacy and Prescription Container Labeling
d. Standardized Intravenous Concentrations
- Changes were recommended to reduce the chance of vincristine and other vinca alkaloids from being administered incorrectly. The correct route of administration is:**
a. intravenous b. intrathecal
c. intramuscular d. intracranial
- Which of the following is true regarding the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP/The Council)?**
a. They defined a “medication error” and encouraged all stakeholders to use the definition
b. The first group had 26 member organizations and 2 individual members
c. The council examines medication errors but does not evaluate causes of those errors
d. All of the above are true

USP's Role in Patient Safety

ACPE # 0047-9999-11-001-H05-P

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PASSING SCORE IS 70% OR ABOVE

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|--------------------|---------------------|
| 1. A B C D | 7. A B C D |
| 2. A B C D | 8. A B C D |
| 3. A B C D | 9. A B C D |
| 4. A B C D | 10. A B C D |
| 5. A B C D | 11. A B C D |
| 6. A B C D | 12. A B C D |

Program Evaluation – Must be completed for credit

Today's Date _____

Program Expiration Date: 01/01/2014

Please rate the following items on a scale from 1 (poor) to 4 (excellent).

- Overall quality of the article**
1 2 3 4
- Relevance to pharmacy practice**
1 2 3 4
- Value of the content**
1 2 3 4

Please answer each question, marking whether you agree or disagree

4. The program met the stated learning objectives:

Agree Disagree
☐ ☐

Continued on next page

Continued on next page

Impact of the Activity**5. The information presented (check all that apply):**

- ☐ Reinforced my current practice/treatment habits
☐ Will improve my practice/patient outcomes
☐ Provided new ideas or information I expect to use
☐ Adds to my knowledge

6. Will the information presented cause you to make any changes in how you do your job?

- ☐ Yes ☐ No

7. How committed are you to making these changes?

(Not committed) 1 2 3 4 (Very committed)

8. Do you feel future activities on this subject matter are necessary and/or important?

- ☐ Yes ☐ No

Follow-Up

As part of our ongoing quality-improvement effort, we would like to be able to contact you in the event we conduct a follow-up survey to assess the impact of our educational interventions on professional practice. Are you willing to participate in such a survey? ☐ Yes ☐ No

This lesson is a knowledge-based CE activity and is targeted to pharmacists. This program has been approved for **1.5** contact hours of continuing education credit (**0.15 CEU**). To receive continuing education credit, please provide the following information: [insert your information]

A statement of credit will be mailed to those participating within 4-6 weeks of the program. Satisfactory completion will be assessed by completion of a program evaluation and an evaluation of learning.

9. Which program was operated under contract with the FDA Center for Devices and Radiological Health (CDRH)

- a. Drug Product Problem Reporting Program
b. Medical Device and Laboratory Product Problem Reporting Program
c. Veterinary Reporting Program
d. Medication Error Reporting Program

10. Between 1991 and 2008, Medication Error Reporting Program (MER) received how many voluntary reports of actual and potential medication errors?

- a. Over 3,000 b. Over 4,000
c. Over 5,000 d. Over 6,000

11. Which is NOT true regarding MEDMARX?

- a. It was developed by USP in 1998 as an Internet-accessible reporting program
b. Standardized elements were drawn from the MER program, FDA, NCC MERP, and ASHP
c. It enables community pharmacies to voluntarily report, track, and trend data incorporating nationally standardized data elements
d. USP transferred its reporting programs, MEDMARX and MER, to Quantros and ISMP, respectively in 2008.

12. The proposed IOM action plan focused on which of the follow principles?

- a. Product Naming b. Product Labeling
c. Safety d. All of the above

Continued from page 19

Continued from page 19

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- Golf Tournament Fundraiser

Friday, Saturday, and Sunday

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- Exhibiter's Theatre
- Ice Cream Social
- Phun Run/Walk
- Awards Ceremonies
- President Elect's Banquet
- President's Banquet & Scholarship Auction

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Please contact:
Lynn Swedberg
701.371.3849
lynn.swedberg@dmckesson.com

MISC0162-03-07

Nominations should be submitted **along with biographical information**. The following awards will be presented:

Awards Nominations Criteria

AL DOERR SERVICE AWARD

The recipient must: be a pharmacist licensed to practice in North Dakota, The recipient must be a member of the North Dakota Pharmacists Association, be living (not presented posthumously); not have been a previous recipient of the award; has compiled an outstanding record for community and pharmacy service.

Nominee: _____ Submitted by: _____

NASPA Innovative Pharmacy Practice

- ❖ The recipient should be a practicing pharmacist within North Dakota and a member of NDPhA who has demonstrated Innovative Pharmacy Practice resulting in improved patient care.

Nominee: _____ Submitted by: _____

Pharmacists Mutual Distinguished Young Pharmacist

- ❖ The goal of this award is to encourage the newer pharmacists to participate in association and community activities. The award is presented annually to recognize one such person for involvement and dedication to the practice of pharmacy. The recipient must: have received his/her entry degree in pharmacy less than nine years ago; be a pharmacist licensed to practice in North Dakota; a member of NDPhA; have practiced community, institutional, managed care or consulting pharmacy and who has actively participated in national pharmacy associations, professional programs, state association activities and/or community service.

Nominee: _____ Submitted by: _____

NASPA Bowl of Hygeia

- ❖ The recipient must: be a pharmacist licensed to practice in North Dakota; a member of NDPhA :be living (not presented posthumously); not have been a previous recipient of the award; is not currently serving, nor has he/she served within the immediate past two years as an officer of the association in other than an ex-officio capacity or its awards committee; have compiled outstanding record of community service, which apart from his/her specific identification as a pharmacist, reflects well on the profession.

Nominee: _____ Submitted by: _____



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NDPhA *Legislation To Watch*

Bill

Description

House Bills

HB 1052 (Failed)	Info and analysis of managed care under Workers Comp managed care program
HB 1053 (Failed)	Worker's Comp benefits for generic drugs
HB 1054 (Passed)	Worker's Comp compensation coverage of prescriptive drugs as part of pain therapy
HB 1126	Creation of state health insurance exchange
HB 1152	Critical access hospital grant program for ND
HB 1386	Freedom of Choice of Pharmacy Service being replaced with health care services
HB 1422	Related to Pfizer's electronic prescription transmission act
HB 1418	PBM Audit legislation
HB 1434	Pharmacy Ownership Legislation

Senate Bills

SB 2035	Related to pharmacist administered immunizations and vaccinations
SB 2037	Related to confidentiality of health info under the state health information exchange
SB 2080	Related to practice of pharmacy and dispensing veterinary prescription drugs
SB 2088	Related to dispensing of veterinary prescription drugs
SB 2119	Related to the scheduling of controlled substances
SB 2122	Related to electronic prescriptions
SB 2151	Relating to access to the prescription drug monitoring program by addiction counselors
SB 2241	Grading of theft offenses for theft of a prescription drug and providing a penalty – C felony
SB 2259	Relating to records of sale of methamphetamine precursors
SB 2276	Related to reporting of immunization data and vaccine group purchasing board