NoDak Pharmacy

Volume 23, No.2

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A Voice for *Pharmacy* Since 1885

ND Bowl of Hygeia Recipients

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NDSU College of Pharmacy/
ASP Representative

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Support Our Advertisers

Mark Your Calendar

JULY

July 10-14, 2010
AACP Annual Meeting
Seattle, WA

July 17-18, 2010
Dakota Drug Trade Show
Fargo Civic Center, Fargo, ND

AUGUST

August 28-31, 2010
NACDS Pharmacy & Technology Conference
San Diego, CA

OCTOBER

October 2, 2010
NDSU Homecoming–Goooo Bison!

October 13-16, 2010
AMCP Education Conference
St. Louis, MO

October 17-20, 2010
ACCP Annual Meeting
Austin, TX

October 23-24, 2010
NASPA Fall Meeting
Philadelphia, PA

October 23-27, 2010
NCPA Annual Convention
Philadelphia, PA

NOVEMBER

November 10-13, 2010
ASCP Annual
Orlando, FL

Michael Schwab, Executive Vice President

Hello members,

First, I want to thank NDPhA District II in Minot (and Lorri in our office) for planning an excellent convention. A big thank you to all of you who attended. We had a great turnout and a lot of fun!

Convention Recap:

We had well over 200 individuals attend. We had a great CE program totaling about 19 CE hours. We had a number of pharmacy technicians, pharmacy students and pharmacists from all practice settings attend. The set-up and details of the convention were top notch. Governor John Hoeven joined our group for lunch on Friday and also spoke to our group. Congressman Pomeroy spoke to our group during breakfast on Saturday morning and Rep. Rick Berg joined us for lunch and spoke during NDPhA's luncheon.

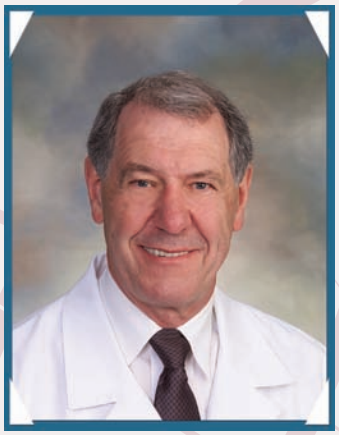
We had the Attorney General present for the public hearing and our Drug Take Back Program kick-off on Saturday. Thanks to all the pharmacists that signed up for the Drug Take Back Program. For those of you who don't sign up or were not able to attend, NDPhA will be sending out an additional email with all the details. A special thanks to Dakota Drug for helping get all the Drug Take Back program supplies to the convention and thanks to the ND State Board of Pharmacy for seeking funding for this program for the first year so it could be offered to pharmacies free of charge. Rep. Jim Kasper was also in attendance for Saturday nights banquet and was honored with the ND Pharmacy Service Corporation's Friend of Pharmacy award.

Thanks to all of our vendors for their support as well. The students auction on Saturday night was also a big success...thanks to everyone for supporting NDSU and the students! If you would like more information about the convention or have any questions, please feel free to give me a call. Please talk to your colleagues and encourage them to become members of NDPhA so we can continue to grow our proud history. Feel free to share with others. Thanks again!

Mike Schwab

Tony Welder,

R.Ph retires from Pace Alliance Board of Directors after 25 years of servcie...



Tony Welder, R.Ph. of Bismarck, North Dakota has retired from serving on the Board of Directors for Pace Alliance. Tony was installed as Director in 1985, the year Pace was started. He was elected to the Executive Committee in 1987, the first year of the Executive Committee, and has served as Treasurer for the last 8 years. His 25 years of service to Pace Alliance is marked with commitment, dedication, and success.

Tony is a graduate of North Dakota State University College of Pharmacy. He has had ownership in a number of pharmacies in North Dakota and has served in a key leadership role for pharmacy in North Dakota and nationwide. Tony is a Past President of the North Dakota Pharmacists Association, served as President of the North Dakota Pharmacy Services Corporation for 14 years, is a Past President of the National Community Pharmacists Association (NCPA), and has served on the National Home Infusion Association and Community Care Rx Advisory Boards.

Tony has received numerous professional awards including the Bowl of Hygeia Award, the North Dakota State University Kappa Psi Fraternity Man of the Year Award, and the Al Doerr Service Award in North Dakota. He also received the Small Business Person of the Year in North Dakota.

During his tenure on the Board of Directors, Pace Alliance grew with the idea that if Independent pharmacies could form one entity, that effort would benefit independent pharmacies by providing cost savings and services to the entire group that would otherwise not be available to the individual pharmacies. To date, Pace Alliance has benefited thousands of pharmacies nationwide and has provided substantial financial support to State Pharmacy Organizations for the promotion of Pharmacy.

Tony also understood that Pharmacy is best served when Pharmacy Associations, both at the National and State levels, work together as a united front. He joined his Pace Alliance colleagues in promoting and developing policy that ensures Pace Alliance financially supports State and National Pharmacy Organizations. A pharmacy that supports and is supported by its national, state, and local organizations is best prepared to fulfill its mission of providing the best healthcare to its patients.

Tony has two daughters, Sara and Renae, and one granddaughter, Caroline.

Pace Alliance is a better organization because of Tony Welder. He will be immensely missed and never forgotten.

Pace Alliance was founded in 1985 and is owned by 19 State Pharmacy Organizations with a dual goal of helping community pharmacies compete in the marketplace and to generate funding for the State Pharmacy Organizations.

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March 17, 2010

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For more information contact Laurie Harms at (515) 295-2461, ext. 7247 or laurie.harms@phmic.com.

PRESIDENT'S TRIP

The 2008-2009 President's Trip incentive was a two-year incentive contest for Pharmacists Mutual and Pro Advantage Services®, Inc. sales representatives. The incentive was based on several areas of criteria: property and casualty insurance production, life and benefits insurance production, territory profitability, customer service and timeliness measurements. Points were awarded to each of these criteria levels. Qualifiers must have achieved points within each of the criteria to qualify for the incentive. Qualifiers attaining all levels of the contest earned a trip to Hawaii with Pharmacists Mutual President Ed Berg. Trip qualifiers include: Joe Baker, Arkansas Field Representative; Bruce Charon, Pennsylvania Field Representative; Curt Davis, Tennessee Field Representative; Bruce Lafferre, Kentucky Field Representative; Ryan Ludwig, Missouri Field Representative; Karla Krogman, Iowa Field Representative; and Sheila Welle, North Dakota and Northern Minnesota Field Representative.

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March 15, 2010

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For more information contact Laurie Harms at (515) 295-2461, ext. 7247 or laurie.harms@phmic.com.

TPL SALES LEADER IS SHEILA WELLE

The 2009 Pharmacists Life Insurance Company Sales Leader award was awarded to **Sheila Welle**. Sheila earned this award by having the highest Pharmacists Life production and selling 24 life insurance policies last year. She also qualified for the President's Trip to Hawaii in March. Sheila was recognized at the 2010 Annual Sales and Marketing Meeting in Omaha, NE.

Sheila Welle, CIC, LUTCF, LTCP is a Field Representative for North Dakota and Northern Minnesota. Before joining Pharmacists Mutual in 1996, Sheila was employed at Pioneer Mutual in Fargo, ND. Sheila is originally from Emerado, ND, attended Larimore High, and graduated from Wahpeton College. Sheila and her husband, Steve, currently reside in Hawley, MN. Sheila has one son, Casey and two stepsons, Ray and Chris.

Sheila Welle - Second from the Right

NDPhA Awards Photos

Tony Welder presents the North Dakota Pharmacy Service Corporation Friend of Pharmacy Award to Representative Jim Kasper

Due to the cancellation of the 2009 convention we are recognizing the 2009 & 2010 Award Recipients

Tony Welder recognition for his dedicated service to the profession of pharmacy

2010 Innovative Pharmacy Practice Award recipient Wendy Brown

Not Shown: 2009 Innovative Pharmacy Practice Award Recipient Jayme Steig

2010 Diamond Award Diane Halvorson

Not Shown: 2009 Diamond Award Katherine Kochevar

2009 Distinguished Young Pharmacist Mark Hardy and Sheila Welle, Pharmacists Mutual

Robert Treitline with 2009 Al Doerr Service Award recipient Fred Baillie

2010 Distinguished Young Pharmacist Thomas Uhde and Sheila Welle Pharmacists Mutual

NDPhA Awards Photos

2010 NDPhA Lifetime Recipients Delbert Nelson and Roberta Southam and 2009 Lifetime Recipient Richard McElmury

Lifetime Recipients not Shown: Patricia Churchill (2009), Loretta Aipperspach (2009), Kenneth Ryan (2009), Charles Frisch (2010) and Raymond Vellenga (2010)

Ted Scherr accepts the NAPT Friend of Pharmacy Award on behalf of Dakota Drug

Not Shown: 2009 Friend of NAPT Al Schwindt

Bob Treitline with 2010 Al Doerr Service Award Recipient Mark Aurit

Susan and Earl Abrahamson

2010 Distinguished Young Pharmacy Technician Kristen Bonness; Sheila Welle, Pharmacists Mutual; 2009 Distinguished Young Pharmacy Technician Kerri Ring

2010 Pharmcy Technician of the Year Kristen Striha

Not Shown 2009 Pharmacy Technician of the Year Lana Bernhardt

USP's Role in Setting Enforceable Quality Standards for Medicines

ACPE # 0047-000-10-001-H04-P
Expires 2/01/2013
1.5 CE Hours (0.15 CEU)

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 Manufactured Medicines
Gordon R. Johnston, R.Ph., Section Chair (Generic Pharmaceutical Association)
Barbara J. Ferguson (New Jersey Pharmaceutical Quality Control Association)
N. Lee Rucker, M.S.P.H (AARP)
Joseph G. Valentino, J.D. (Honorary Member)

Goals:
The goals of this lesson are to provide an overview and update on the current status of USP and address some of the challenges they are facing in acquiring and maintaining sound public standards.

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

1. Discuss the current status of USP standards and the deficiencies that exist in the *USP* and *NF*
2. Explain the challenges USP is facing in acquiring and maintaining sound public standards and some approaches taken to address these challenges
3. Describe how USP is moving towards more harmonized standards

INTRODUCTION

For nearly two hundred years, the United States Pharmacopeial Convention (Convention or USP) has worked to set quality standards for drugs (medicines and their ingredients). Much has changed during that period, including the globalization of the pharmaceutical industry, ongoing availability of better drugs to promote health and treat disease, demands for access to good quality medicines, systems that deliver interchangeable multi-source products after periods of patent and market protection, advances in measurement and manufacturing science, and calls for regulatory and compendial harmonization. In these contexts, USP's public standards continue to play an important role in assuring both practitioners and patients that the medicines they use are of good quality relative to their safety and efficacy. If anything, recent events such as the rise in counterfeit and substandard medicines and adulteration crises (diethylene glycol, melamine, heparin) have heightened concerns about the quality of drugs, and reinforced the importance of USP's public standards as part of the safety net that protects practitioners and patients in the U.S. and elsewhere.

USP's standard-setting activities have a long and distinguished history. At the first meeting of the Convention in 1820, the convening practitioners established recipes for the first Pharmacopeia of the United States of America (*United States Pharmacopeia* or *USP*). These recipes were used in the preparation of medicines to assure their consistency— process standards for articles of medicinal commerce. In the latter part of the 19th century, Charles Rice, Chair of the Committee of Revision (predecessor of the Council of Experts), transformed the *United States Pharmacopeia* from a book of recipes to a book of tests with procedures and acceptance criteria for medicines and their ingredients—product standards for articles of medicinal commerce. The *National Formulary* (*NF*), originally a repository for preparations deleted from the *USP* when such preparations were deemed less effective, later became a compendium of excipient product standards. *NF* was acquired by the Convention in the 1970s, and *USP-NF* is published now as a combined text of documentary standards. In the early part of the 20th century, the Convention began offering reference materials to assist analysts in the conduct of monograph procedures. Today the procedures for all monographs in *USP-NF* are likely to (or should) have an allied reference material.

USP's drug standards are given special force by their long-standing recognition in U.S. law. In the 1906 Pure Food and Drug Act, Congress created a role for the Federal government to enforce (assess conformity to) Convention standards by naming *USP* as an official compendium of the United States. Congress strengthened

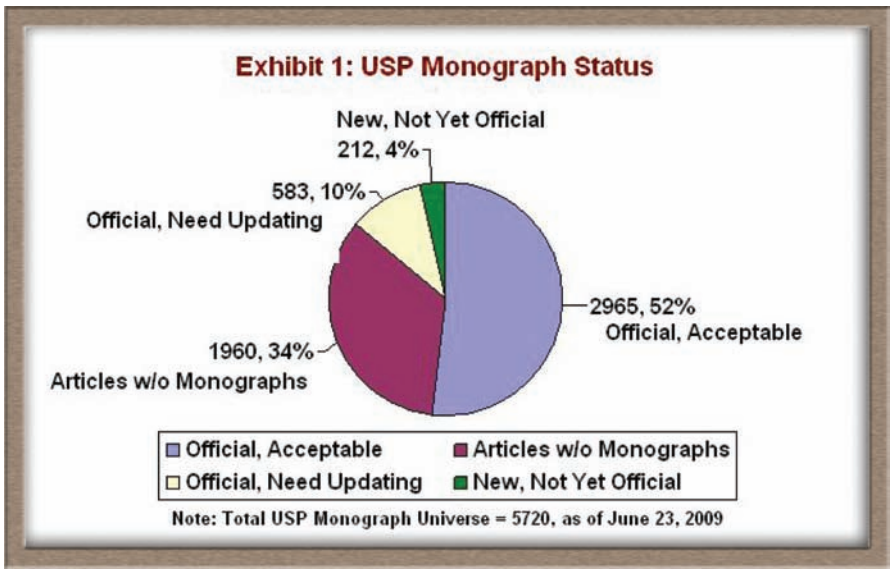
this role in the 1938 Federal Food, Drug, and Cosmetic Act (FDCA) and made USP's standards enforceable by the newly-created Food and Drug Administration (FDA) under the adulteration and misbranding provisions of the FDCA. *NF* was subsequently added as well as an official compendium of the United States. Today, the FDCA continues to mandate compliance with *USP-NF* standards, giving them broad impact across both the innovator and generic pharmaceutical industry. This legal status and the public-private partnership between the United States Federal government and USP created through these laws reflects a societal agreement recognizing the importance of public standards for both manufactured and compounded medicines. Many state laws also recognize USP's standards, reaffirming this societal agreement.

With this history in mind and looking towards the future, the Council of the Convention Section on Quality of Manufactured Medicines describes in this white paper ways that USP might be further transformed to better fulfill its historic and legal role of establishing quality standards for drugs and helping to address current challenges in assuring a safe global drug supply. A general thesis of this white paper is that the original societal agreement reflected in Federal and state laws tying the Convention and FDA together in the early part of the 20th century must evolve in today's environment to allow continued availability of public standards to help assure the quality of drugs. At the same time, modern measurement science allows opportunity for change that can transform USP and pave the way both for global harmonization and rapid detection of adulterated medicines.

The *Overview* section below discusses the current status of USP standards, and the deficiencies that exist today in the *USP* and *NF*. The next section explains the challenges USP faces in acquiring and maintaining sound public standards. It also describes the innovative approaches USP has taken to address these challenges, and how USP is working to facilitate movement towards more harmonized standards while advancing the measurement science behind its standards. The last two sections explore the current societal problems of adulteration and contamination and ways that USP identity standards can play a role.

OVERVIEW AND CURRENT STATUS OF USP STANDARDS

Although the complexity of the discovery, development, registration, and utilization processes for a medicine can be staggering, the concepts behind these processes are straightforward. A medicine and its ingredients must have specified quality and be produced under good manufacturing practices. Based on consistency in quality attributes over time (sometimes termed "equivalence") relative to clinical study materials, practitioners and patients can expect predictable safety and efficacy outcomes when a medicine is administered. For new drugs, quality attributes are developed and maintained privately as part of the new drug application process and eventually, if a manufacturer is willing to provide this information to USP, can become public standards in *USP*. The private and public standards contain tests, procedures, and acceptance criteria that form the specification for the article, for both the medicine itself and its ingredients. Those in Congress and at USP framing the societal agreement embodied in the legislation of 1906 and 1938 may have expected a public standard for all medicines legally marketed in the U.S. While that expectation is currently expressed in USP's Board of Trustees strategic plan for the 2005-2010 cycle, it has not been realized. The table below indicates the current status of *USP* in terms of monographs in four stages: 1) approved drug articles where no monograph exists, 2) articles with newly acquired monographs that are not official, 3) articles with official monographs that need updating, and 4) articles with official monographs reflecting the state of the industry.



The numbers indicate that about 44% of *USP* is deficient—either because of articles for which there are no monographs (34%) or because of monographs that need updating (10%).

1. CHALLENGES TO DEVELOPING AND MAINTAINING PUBLIC STANDARDS

A key reason for the lack of up-to-date monographs in *USP* lies in the fact that USP has no way to compile information and receipt of candidate materials to support a public monograph. Via the FDA Freedom of Information Act exemptions at 21 CFR Part 20, FDA is prohibited from giving USP the private regulatory specification—a prohibition generally termed trade secret or data protection. Manufacturers may resist voluntary donation of needed information and materials because of: 1) the need for some time after market access for controls in the private specifications to finalize, 2) the involved resource burden, and 3) a desire to protect trade secret information. Moreover, despite the fact that the societal agreement reflected in federal law does not distinguish between single-source and multi-source drugs, the innovator industry sometimes questions the need and rationale for a public monograph prior to generic entry.

USP has been slow to develop a monograph in the absence of donated information and material because of the difficulty in developing suitable analytical procedures and certain science and technical constraints. For example, without knowledge of synthetic and degradation routes for a drug substance (active pharmaceutical ingredient or API), USP has little understanding of which impurities exist within a drug product or its ingredients. Similarly, understanding of degradant impurities requires special studies that are, for the most part, beyond USP's capability to conduct. Patent barriers may limit access to and availability of certain reference materials.

2. USP EFFORTS TO ADDRESS CHALLENGES

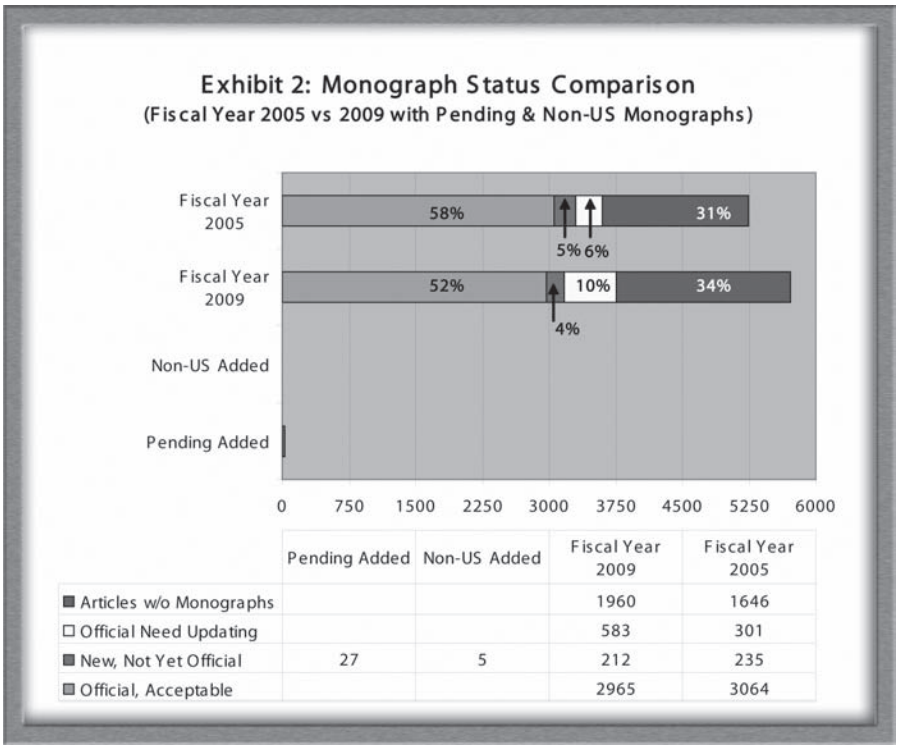
a. Alternative Monograph Development Paths

One way in which USP has attempted to respond to its monograph acquisition challenges is to develop alternative pathways for monograph development. These allow greater flexibility for manufacturers and may enhance the usefulness of monographs to manufacturers, regulators, and—ultimately—practitioners and patients/consumers.

- The *flexible monograph* moves away from a "one size fits all" approach for the monograph's specification to an approach that allows differences in the tests, procedures and acceptance criteria of the monograph depending on routes of synthesis, differences in formulation, or other factors. This approach facilitates voluntary donation of information from multi-source manufacturers of pharmaceutical ingredients and products and reduces the likelihood of "lock-out" specifications from any single manufacturer.
- The *pending monograph* encourages voluntary submission of information and material to support a Web-based public monograph in advance of a regulatory decision, coupled with rapid advance to official status in *USP* at the time of regulatory approval. This approach is particularly applicable to multi-source manufacturers.
- A *non-U.S. monograph* allows USP to develop Web-based monographs for medicines and their ingredients that are marketed outside the United States. This approach is an effort to provide standards for manufacturers and the public interested in having a sound public monograph irrespective of (and at times in the absence of) strong regulatory systems. Thus, these monographs may be of special value to manufacturers, purchasers and regulatory authorities in developing countries who are seeking assurance of quality. The program is limited now to medicines and their ingredients intended to treat neglected infectious disease, and thus has a very targeted public health focus.
- The *performance based monograph* (PBM) is a new idea to USP, although the approach has been widely used by other industries. Conceptually, the model is straightforward. A PBM might consist of tests and acceptance criteria, as presented now, but the procedures of the monograph would not be specified. Instead criteria for an acceptable procedure would be provided, and over time a list of acceptable procedures would be made available. The approach is based on the availability of a qualified reference material, and this reference material preferably would be certified. The reference material would be the drug substance itself or an "equivalent" material, or one or more impurities. Taken together, the general approach has many positive advantages,as well as features that merit special consideration. From a global standpoint, the approach might allow rapid advance towards compendial harmonization. Only the tests and acceptance criteria would need to be harmonized— the procedures themselves would be the responsibility of manufacturers and their corresponding regulatory agencies. Any acceptable procedure would be allowed for determining if a medicine or its ingredients were suitable for use. And these procedures could be public or private, depending on the interests of involved parties. The relationship between these repositories can

be clearly understood based on modern metrological principles and careful collaborative studies. The PBM approach is still in the exploratory stage and there are many important questions to be answered, including those related to FDA's need for a default or referee procedure in a monograph to readily determine non-compliance with *USP* standards.

While all of these opportunities are of interest and have some value, those implemented to date have not had a substantial impact on the acquisition of new monographs or the updating of existing monographs. Comparisons of monograph backlogs at the beginning and close of the 2005-2010 cycle indicate a rise in the backlog (i.e. the number of articles for which there is no up-to-date monograph).



	Pending Added	Non-US Added	Fiscal Year 2009	Fiscal Year 2005
Articles w/o Monographs			1960	1646
Official Need Updating			583	301
New, Not Yet Official	27	5	212	235
Official, Acceptable			2965	3064

b. Sponsor Outreach and Prioritization Efforts

USP has increased its efforts in recent years to educate manufacturers as to USP's role and the value of public standards. In order to lessen the resources required from manufacturers to provide needed information, USP has assisted with monograph development—including providing easy-to-use templates for monograph submission and furnishing USP staff on-site at a manufacturer's facilities to work on monographs. Although these efforts seem to have been well-received, as the table above indicates they have not had an appreciable effect in increasing the development of USP standards.

Understanding that the effort needed to correct all of the deficiencies in *USP* is an immense challenge, USP has made efforts to prioritize its monograph acquisition and modernization activities so that it can conduct more targeted outreach to manufacturers. This includes working with industry to identify those monographs that are of greatest importance in terms of public health impact. Such prioritization activities help USP to more effectively utilize its acquisition resources, and make it easier for manufacturers to understand and allocate the resources requested of them for development of high-priority monographs. USP has also worked to expand the recognition it gives to sponsors of monographs and reference standards, so that it can more publicly acknowledge the contribution that monograph sponsors make to the public health. It is too early to tell whether these efforts will prove fruitful in increasing the quantity of monograph submissions.

3. INTERNATIONAL COMPENDIA AND COMPENDIAL HARMONIZATION

In today's global pharmaceutical market, the desire and need of industry for harmonized standards and requirements have become more pressing, and USP has recognized this. Harmonization of regulatory requirements has occurred in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for countries and regions with advanced drug regulatory systems, and at the World Health Organization (WHO) for all countries. The primary mechanism for compendial harmonization has been the Pharmacopoeial Discussion Group (PDG), begun through Convention impetus in 1989, which continues to this date and operates in connection with ICH.

PDG includes representation from organizations that elaborate the major compendia of the world—the *European Pharmacopoeia* (European Department for the Quality of Medicine and Health Care or EDQM), the *Japanese Pharmacopoeia* (Ministry of Health, Labor, and Welfare or MHLW), and USP, with WHO as an observer. WHO itself continues to elaborate *The International Pharmacopoeia*, which focuses on essential medicines. PDG does not work to harmonize monographs for medicines or their active ingredients; rather, PDG has concentrated on excipient monographs and allied general chapters (with 40 monographs and 26 general chapters concluded to date) and other non-excipient general chapters. PDG-harmonized documents may undergo a further evaluation in ICH to become guidances to assist in developing the private regulatory specification for the ICH regulatory agencies (FDA, Japan's MHLW, and the authorities of the European Union, including the European Medicines Agency). Recently, PDG participants agreed to continue and expand their work. However, the PDG process, which requires the pharmacopoeias to retroactively revise varying and conflicting standards to achieve harmonization, remains slow and laborious. Moreover, although a 2005 Convention resolution encouraged USP to broaden harmonization efforts outside of PDG, for the most part this has not occurred as a PDG activity, although all major pharmacopoeias hope for and at times realize opportunities to work together. USP has been particularly vigorous in these activities in this cycle, reflecting the intent of prior Convention resolutions.

Another harmonization opportunity has arisen through a pilot currently being conducted by USP and EDQM, known as "prospective harmonization," in which a manufacturer works with USP and EDQM simultaneously on the development of a monograph and accompanying reference standard. The advantage of this approach is that a monograph would at least be harmonized between the *European Pharmacopoeia* and *USP* from the outset, avoiding the difficult process of attempting to harmonize such standards after the fact. In addition, because manufacturers benefit from obtaining a harmonized monograph through a single process, they may be willing to provide the necessary information and materials for such monograph and reference standards at an earlier stage in the life of the product. Although, again, it is far too soon to tell whether this new approach will be successful in significantly accelerating the development of harmonized monographs. Early phases of the pilot have proceeded well.

Harmonization with less-developed pharmacopoeias may also be advanced through USP's "adopt/adapt" approach. Under this activity (started in the 1990s with plans to reinvigorate the general approach), USP permits pharmacopoeias in regions with limited resources to incorporate *USP* monographs and general chapters in their own pharmacopoeias as they see fit. While the primary purpose of this initiative is to help these countries develop better standards for use with their domestic manufacturers and raise the standard of quality in these regions, it may also result in de facto harmonization between *USP* and other pharmacopoeias.

4. MODERN MEASUREMENT SCIENCE

In recent years, USP's standard development activities have been aided by its growing understanding and application of measurement science—termed "metrology." Metrology is the science of measurement and embraces both legal and fundamental aspects. The societal agreement created by Congress between FDA and USP relies on metrology, which in this context helps assure that a material is fit for its intended use; i.e., that a medicine may be used suitably by practitioners and patients to maintain health and treat disease. Today, modern measurement science undergirds the tests, procedures, and acceptance criteria in USP's standards.

Metrology originally was driven by needs of commerce, and commerce still is the major motivation for legal aspects of metrology. Fundamental metrology is of more academic interest and involves the establishment and realization of measurement units (such as the International System of Units or SI), research into new measurement methods, the development of measurement standards, and the transfer of metrological traceability throughout a measurement system. A country's national metrology institute—in the United States, the National Institute of Standards and Technology—typically has statutory responsibility for a nation's measurement system, including the advancement and maintenance of the nation's primary standards. The interface of legal metrology and fundamental metrology is often called "applied metrology," which concerns the application of measurement science to manufacturing, ensuring the suitability of measurement instruments, their calibration, and quality control of measurements. The Convention's official compendia, *USP* and *NF*, represent the application of applied metrology, which includes both legal and fundamental metrology.

Through staff and Council of Experts' activities, the Convention has worked to enhance metrological science in USP. In part, the way has been made easier by a general movement of national drug control laboratories (official medicines control laboratories) towards International Organization for Standardization (ISO) 17025 and other standards. These standards encourage traceability of results to enhance consistency and reliability of measurements. A specific example of the Convention's use of applied metrology is

release of a certified reference material as an official USP Reference Standard by the Council of Experts Reference Standard Committee. Such certified reference materials may result in a better understanding of repositories of reference materials at the global (global primary), regional (regional primary), national (national primary), and manufacturer (secondary, house, or working standards) levels and their respective uses to assess the quality of drugs in global commerce. They also allow manufacturers, regulators, and others to compare results across different procedures—a critical task now with supplier-purchaser relationships in question—and also assess contributions of manufacturing and analytical variability to avoid "out of specification" results.

DETERMINING "QUALITY" MEDICINES: CONCEPTS OF ADULTERATION AND IDENTITY

In some respects, issues of adulterated or substandard medicine —and the challenges USP faces in trying to address these through compendial standards—are far from new. Even in the earliest edition of the *USP*, the presence of a recipe to assure consistency in the quality of what we would now term a "compounded medicine" could not protect against the possibility of a medicine that might be deemed unacceptable or adulterated. Efforts to protect patients gained great force in Congressional decisions of the early 20th century as the Federal government sought ways to remove medicines from the market that were unsafe, ineffective, and/or of substandard quality. Congress relied on the terms "adulteration" and "misbranding" in the FDCA, and it is in these provisions that *USP* and *NF* are specifically recognized as official compendia of the United States as a means of assessing adulterated or misbranded products. In modern terms, USP's standards speak to the identity of a medicine, as well as its strength, quality, and purity—terms now comprised, through harmonization, under the overarching term "quality." Our understanding of identity insofar as it relates to a medicine, its ingredients, and its packaging is rapidly evolving based on the science of spectroscopy. The use of both identity testing and spectroscopy to help combat today's problems of substandard and intentionally adulterated drugs is addressed below.

1. ADULTERATION

Over the years, many countries around the world, including the United States have been challenged by economically motivated adulteration. Examples include melamine in pet food and infant formula, oversulfated chondroitin sulfate in heparin, and diethylene glycol in glycerin. Such instances involve the deliberate substitution of a less costly substance for a more expensive one, resulting in patient harm and even death.

USP's role in helping to address these challenges stems from its legal recognition and the requirement under the FDCA that medicines meet the identity, strength, quality, and purity standards in *USP* relative to an established name, as discussed more fully below. Even a well manufactured medicine may at times fail these standards and must be removed from the marketplace or risk a claim of adulteration. The approach is used daily by manufacturers (first parties), and information about it is often publicly available at http://www.fda.gov/Safety/Recalls/default.htm. The public-private partnership established by Congressional and Convention forebears a century ago thus works still today—quietly and without notice—when a manufacturer tests a batch to assure it meets requirements in *USP* or withdraws a drug from the marketplace when it does not.

The matter becomes more challenging when manufacturers themselves may unknowingly or, worse, intentionally adulterate a medicine or its ingredients. Work at FDA and in the Convention is advancing approaches that rely on identity standards to reduce the likelihood of economically motivated adulteration. Placement of limits on known adulterants in the Identification test of a *USP* monograph requires manufacturers of a medicine to test to assure absence of the adulterant prior to use of a material in manufacturing. The approach relies on knowledge of the adulterant and thus is limited to known examples. Unfortunately, there are many other materials that might be used to adulterate a medicine, either for economic or other motivations, which at this time remain unknown.

2. IDENTITY PROVISIONS IN THE FDCA

Identity standards (and related tests and reference standards) play an important role in defining or characterizing what is meant by a "drug" as defined in USP. The identity component of a compendial standard is distinct from the array of specifications related to strength, quality, and purity. Identity may not legally vary from the USP specifications, although strength, quality, and purity can, if a medicine is appropriately labeled. The 1906 Pure Food and Drug Act first officially recognized the role of USP standards for strength, quality, or purity in terms of defining when a drug would be deemed to be adulterated. The 1938 FDCA built on the 1906 Act with Section 501(b), which contains the more extensive, two-part, modern, *USP*-related provisions related to adulteration:

501(b) - "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, *and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium*. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, ..." FDCA 501(b).

The first section (underlined) creates an implicit compendial role in establishing standards for identity (i.e., is it, or is it not, the drug addressed in the compendium?). The second section (italicized) includes the explicit compendial role for standards related to strength, quality and purity (i.e., whether the drug measures up in terms of various quality parameters). FDA regulations subsequently established an important and unambiguous role for compendial standards of identity, and reflect the interconnection between the naming and identity authority in FDCA [at 502(e)] and the compendial adulteration standards [at 501(b)].

Part 299 of the Code of Federal FDA regulations concerns official and established names. One subsection in particular addresses the role of compendial naming and identity requirements, as well as other compendial standards; it has remained unchanged in FDA regulations since Part 299 was first promulgated in 1975 (40 Fed. Reg. 14041, March 27, 1975). Under FDCA and in Part 299, a drug with a name recognized in *USP must comply with compendial identity standards or be deemed adulterated, misbranded, or both. Such drugs may vary in terms of strength, quality, or purity, if truthfully labeled [per FDCA 501(b)], but they may not vary from the compendial identity specified for such a drug.*

As noted above, USP has worked with FDA to leverage this distinctive role of identity standards to address recent cases of intentional adulteration. These recent efforts reaffirm the value of the public-private partnership created in law and reinforce the ongoing importance of public standards in today's environment.

3. THE ROLE OF SPECTROSCOPY

Identity frequently relies on use of portions of the electromagnetic spectrum to "see" an article —just as humans recognize each other (relative to their established names) by sight —which relies on the visible portion of the electromagnetic spectrum. For well-manufactured medicines, USP has long allowed the use of infrared (IR) spectra as a means of establishing identity in the *USP* Identification test (General Chapter <197> *Spectrophotometric Identification Tests*). And spectral images (photographs) have long been used by practitioners to identify medicines, e.g., *Physician Desk Reference (PDR)* photographs. Modern analytical instrumentation offers the opportunity to use far larger portions of the electromagnetic spectrum and with modern informatics and hand-held devices can now bring identity tests to any site on the globe for screening purposes. Using near-IR instrumentation, China's government has led the way in the use of mobile vans and personnel to utilize this technology to check for counterfeit and substandard medicines.

USP has considered using Raman spectroscopy to assess identity in the field, and pharmaceutical manufacturers have built non-public spectral libraries to allow rapid identification of incoming materials. Results typically require confirmation via more in-depth laboratory studies—as with the eye, instrumentation recognizes what it has seen before. Consequently, identification of materials used to adulterate for economic or other purposes require additional study. But even here, understanding of likely adulterants would pave the way for spectral libraries using repositories of likely and potentially dangerous adulterants. For episodes of intentional adulteration, such as the production of fake medicines (counterfeits), rapid reporting systems might allow the detection of outbreaks of poor quality manufacturing, just as we now identify outbreaks of infectious disease. Thus, scientific advances in instrumentation and informatics, linked with repositories of spectral images of legally marketed medicines (and their ingredients and packaging), coupled with spectral images of undesirable materials and medicines, allow understanding of identity in ways that would have amazed Convention forbears 100 years ago. At the same time, the use of "sight" to establish the identity of a medicine and its ingredients would have been entirely comprehensible to them. USP intends to continue the exploration of spectral libraries as a potentially important weapon in the ongoing global battle against adulterated and substandard medications.

CONCLUSION

This white paper suggests several avenues that might be pursued to help resolve current deficiencies in the availability of public monographs and reference materials, promote compendial harmonization, advance the availability of good quality medicines, and detect and deter adulterated (counterfeit/substandard) medicines. The basic approach remains the concept of a public monograph containing product standards for all legally marketed medicines and their ingredients, allied with publicly available reference materials. The procedures of the monograph would be clearly linked to and supported by global, regional, national, and manufacturer reference materials for both the medicine (drug product) and its ingredients and their packaging. Availability of this material would allow comparisons across procedures and yield results, where feasible, traceable to SI units. Public reference materials would be a public repository of chemicals and mixtures of chemicals reflective of legally marketed medicines and their ingredients. The repository would also include likely adulterants. The materials of the repository would be associated with spectral images drawn from the electromagnetic spectrum to allow screening to assure identity and to detect and deter adulterants.

Many aspects of the approach are transformational. Yet none are beyond current scientific capability, nor would the general approach require major changes in policy, with possibly the exception of adjustment in barriers to the availability of reference materials. While full expression of the concept might await stronger global institutions, the approach could be implemented now nationally or regionally. The USP Convention might be a major advocate for advancing the general approach, working on the assumption that the Convention itself supports public standards for medicines and their ingredients—in the 21st century as it did in the 19th and 20th centuries—and recognizes the value of such standards in assuring patients and practitioners of good quality medicines.

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 (NCSPAE). More information can be found at www.naspa.us

Continuing Education Quiz:

1. What percentage correctly represents the USP Monograph status for articles with newly acquired monographs that are not official?

a. 4% b. 10% c. 34% d. 52%

2. Which type of alternative monograph development pathway moves away from the "one size fits all" approach?

a. Performance based monograph

b. Pending monograph

c. Flexible monograph

d. Non-U.S. monograph

3. The pending monograph approach is *particularly* applicable to which of the following?

a. Single source manufacturers

b. Multi source manufacturers

c. Regulatory authorities

d. Purchasers

4. Which of the following would need to be harmonized under compendial harmonization?

a. Tests b. Acceptance criteria

c. Procedures d. A+B

5. Who has been the primary mechanism for compendial harmonization?

a. European Department for the Quality of Medicine and Health Care (EDQM)

b. World Health Organization (WHO)

c. Pharmacopoeial Discussion Group (PDG)

d. Food and Drug Administration (FDA)

6. Which year did the Pharmacopoeial Discussion group begin?

a. 1980 b. 1989 c. 2000 d. 2009

7. In "prospective harmonization" USP works simultaneously with which of the following?

a. European Department for the Quality of Medicine and Health Care (EDQM)

b. World Health Organization (WHO)

c. Pharmacopoeial Discussion Group (PDG)

d. Food and Drug Administration (FDA)

8. Which of the following is true regarding "metrology?"

a. It is not considered a science, but a measurement

b. It was originally driven by the needs of commerce

c. It embraces only legal aspects

d. It embraces only fundamental aspects

9. An example of adulteration is:

a. Melamine in pet food

b. Oversulfated chondroitin sulfate in heparin

c. Diethylene glycol in glycerin

d. All of the above

Continued on next page

USP's Role in Setting Enforceable Quality Standards for Medicines

ACPE # 0047-000-10-001-H04-P

The College of Pharmacy, Nursing and Allied Science, North Dakota State University, is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. To receive 1.5 hours (0.15 CEUS) of continuing education credit, complete the following and mail with $10.00 to:

Continuing Pharmacy Education Office
NDSU Dept 2660 - P.O. Box 6050
Fargo ND 58108-6050

Name _____

Social Security Number (SSN) XXX-XX- ___ ___ ___ ___

Address _____

City _____

State _____ Zip _____

Your SSN will be used to maintain a permanent record of the courses you have taken. Your SSN will be kept confidential and will be used ONLY to identify you at NDSU.

CE Assessment Answers

PASSING SCORE IS 70% OR ABOVE

Please circle your answers (one answer per question)

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: 02/01/2013

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

1. Overall quality of the article
1 2 3 4

2. Relevance to pharmacy practice
1 2 3 4

3. 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

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**).

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.

Continued from page 13

10. Which of the following can NOT legally vary from the USP specifications?

a. Strength
b. Identity
c. Quality
d. Purity

11. Part 299 of the Code of Federal FDA regulations concerns which of the following?

a. Purity
b. Truthful labeling
c. Strength
d. Official and established names

12. Which type of spectroscopy has USP considered using to assess identity in the field?

a. Raman spectroscopy
b. Laser spectroscopy
c. Mass spectroscopy
d. Electron spectroscopy

Continued from page 13

Northland Association of Pharmacy Technicians

President's Report 2009–2010

NAPT President, Angela Buchanan

Executive Board Meetings

The NAPT Executive Board met four times and had four teleconferences throughout the 2009-2010 term to discuss various topics. The following is a brief summary of the topics the Board focused on in the scheduled meetings and throughout the year.

Pharmacy Technician Registration verses Certification

A survey was conducted of ND Registered Pharmacy Technicians to understand the logistics of Registered Pharmacy Technicians and the current status of Certification. A total of 596 surveys were mailed out and 322 surveys were completed and returned; a 54% return rate. When directly asked the number of participants that were certified, 312 responded with 28% not certified and 78% certified. The topic of certification nationally focuses on the education and validation of competency of Pharmacy Technicians. In many states, certification is becoming a standard requirement of Pharmacy Technicians to work in that state.

NAPT Fall Conference

The 2009 Fall Conference was held in Devils Lake, North Dakota on September 11th & 12th with a total of 45 participants in attendance. The conference offered 9 CEUs. Continuing education topics presented at the conference included a Prescription Drug Monitoring Program; Fraud, Waste and Abuse; Drug Diversion with Prescription Medication presented by the Devils Lake Police Department; Health and Fitness in the Workplace; Medicare 3rd Party Enrollment, Billing and PA; Pharmacy Ownership Succession; Pharm-assist Program; and Technician Certification. The General Business meeting also included the presentation of our awards: Diamond Award – Katherine Kochevar, Friend of NAPT – Al Schwindt, Pharmacy Technician of the Year – Lana Bernhardt, and Distinguished Young Pharmacy Technician – Kerri Ring. I would like to once again extend a great big "Thank You" to the Fall Conference Planning Committee for their hard work with creating an excellent conference! The 2010 Fall Conference will be held in Minot, North Dakota with the tentative dates of September 24th & 25th. We are looking forward to another successful and motivating conference!

In summary, it was an honor and pleasure to serve as the NAPT President. I would like to thank my fellow Board members for their participation and dedication to the Pharmacy profession and for their assistance to me throughout the year. Josie Olson, Vice President/ President-Elect, Kristen Striha, Secretary, Becky Prodzinski, Treasurer, Jodi Hart, Outgoing President, Barb Lacher, Parliamentarian, Melissa Heley and Kerri Ring, Members-at-Large, and again Barb Lacher, NDSCS Representative and North Dakota Technician CE Provider. There is great strength in numbers and diversity and I wish NAPT continued success in all of their accomplishments.

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GRAND INTERNATIONAL INN – MINOT, ND
April 23rd-25th, 2010

Thank you, on behalf of the North Dakota State Board of Pharmacy for the opportunity to serve you, to have a small part and sometimes a large part in setting the direction of our profession and in helping you care for your patients.

With the activities in healthcare reform, Medicare Accreditation and the potential for initiated measures, things sometimes seem to be happening faster than we can keep up with them.

Some of this is our own fault, and well it should be. When you, the pharmacists and technicians of North Dakota, set the stage for high quality care and efficient use of resources, you get asked to help everyone in the country.

Our Telepharmacy Model continues to be the example for the country and sometimes for the world. The first question from those interested in getting into telepharmacy is often directed to Dean Peterson, Ann Rathke, or one of you already in the telepharmacy business.

We learned from others and are consequently running one of the most efficient and accepted models for a Prescription Drug Monitoring Program, in the country. Kathy Zahn and Pat Churchill have been taking the operational vision of a Prescription Drug Monitoring Program to others around the country.

We also learned from others in designing and operating one of the most efficient Prescription Drug Repository / Donation programs in the country. We believe that successful implementation of other programs will model ours.

At this convention, we will kick off a prescription drug return program, which will allow consumers to get their unused prescription drugs destroyed, either at sites set up by law enforcement through the Attorney General's office or at your pharmacies, through the take-back and subsequent incineration program.

We are very likely to have the opportunity to vote on the Pharmacy Ownership Law in the fall elections in North Dakota. This will be a test of my statement in last years report, that *"if the patient can't tell the difference, what difference does it make."* We trust that if you have been taking care of your patients in the manner which they expect, they will vote to keep or to change the Pharmacy Ownership Law as they perceive it is in their own best interest. I look forward to the vote. I trust that if the change fails, you will all work doubly hard to earn the trust that your patients have placed in you. If the vote succeeds and the law changes, I trust that each of those who support the change in our Pharmacy Ownership Law will work doubly hard to be sure that they take advantage of all of the opportunities that they perceived the law change might provide them. Regardless of the outcome, we all have the responsibility to care for the people of North Dakota in the manner dictated by the Oath we took when we obtained our pharmacy degree.

Remember the words of Ken Baker, legal counsel for Pharmacists Mutual Insurance Company, "Your employer cannot have a pharmacy without you." The Pharmacist along with their technician assistants are the necessary link in the pharmacy model to care for the people who come into your pharmacy.

Howard C. Anderson Jr., RPh

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CURRENT STATISTICAL DATA

2009		**2010**
817	Active Pharmacists	854
51	In-State In-Active Pharmacists	40
1216	Out-of-State Pharmacists	1102
103	Lifetime	111
2,187		2,107
114	Delinquent / yet to renew	118
584	Registered Pharmacy Technicians	624
46	Delinquent / yet to renew	44
194	Technicians-In-Training	244
365	Licensed Interns – NDSU PharmD Students	381
90	$10 Pre-Pharmacy Interns	99
236	In-State Pharmacies	241
425	Out-of-State Pharmacies	438
745	Wholesales	774

NDSCS Pharmacy Technician Report to the 125th Annual Convention of the NDPA

Minot, North Dakota

April 23, 2010

Greetings to everyone from the NDSCS Pharmacy Technician Program. We are very pleased to report to the Convention that we have a fine group of quality students on campus in Wahpeton, our PATSIM program continues to be strong and popular, and our on-line degree program is successfully operational.

Once again we have 100% of our on-campus students passing the PTCB national certification exam. Additionally, the preceptor reports regarding the summertime internships have been quite positive, and 100% of applicable graduates have obtained employment.

We currently have **twenty-five** students enrolled on campus, of which **fifteen** are expected to graduate this summer. **Thirty** PATSIM students completed the program in 2009, **ten** so far in 2010, and we have **one hundred and fourteen** enrolled at this time. Four on-line students received their degrees in 2009, and **we currently have thirty-nine enrolled of which six are graduating Spring 2010. Twelve are students currently serving in the Army, and are enrolled utilizing our SOCAD agreement. These have completed their technician training at Fort Sam Houston which offers an ASHP accredited training program.** All for a total of **one hundred and seventy-two** students in our programs at this time.

We just completed a formal comparative analysis of industry needs and our curriculum. This project entailed two days of meetings with a group of technicians and a group of pharmacists facilitated by NDSU's School of Education. The goal of this project is to critically analyze our curriculum from the viewpoint of our industry's needs, both now and in the future. We received a summary report and analysis last week and we now face the task of integrating applicable facets into our programs. We are very interested in this project and excited at the potential it presents. It represents the involvement and commitment we have enjoyed from you, our state's practicing professionals. Our programs can only get stronger from this project.

The Department has participated in a number of additional activities during the past year. NDSCS Allied Health Departments held its 9th Annual Health Career Fair in October. In addition to having over 20 prospective employers visit with our students we concurrently hold an event for high school students in each department. We also participated in the Career Exploration day at the FargoDome, a Career Exploration day in Morris MN and we visited several high school Health Occupations classes. Next year in addition to these we will be traveling to the Jamestown Civic Center for their Career Exploration day. In April NDSCS hosts a day for Junior High Students, this year Jodi Bakken will be supervising 7th graders in a hands-on compounding experience. In June the college hosts a Career Awareness Seminar for high school counselors, principals and faculty. The Allied Health Careers will be participating in this 4 day event for the first time this year. The focus of this event is to showcase our careers, particularly with some hands on experience. Jodi will be on hand again to lead a hands-on compounding experience for these folks. This is the 4th year of this event, but the first for the Allied Health professionals.

However, we continue to need your support in encouraging people to pursue a career as a Pharmacy Technician. We have educational options to fit almost anyone's personal situation, from as short as two semesters on campus for a Certificate, four semesters for an Associate Degree, and off-campus programs of the paper-based PATSIM as well as the Associate Degree via the internet with only a few Saturdays spent on campus. We have found that the vast majority of students stay in or return to their home areas, so your proactive efforts to promote Technician education can have a great impact in your community. If your local school district has health occupation courses or sponsors career fairs, please ask them to invite us! We are eager to present our programs, but the rules are we must be invited to attend, so contact your local high school administration about this and help us promote Pharmacy Technician education opportunities. Please do not hesitate to contact our office for more information.

We want to thank everyone who has contributed to the success of our programs, especially the Pharmacists and Technicians who participated in the comparative analysis focus groups last month, our Advisory Committee, the State Board members, Dr. Peterson and the College of Pharmacy, our loyal faculty and those of you who serve as Externship preceptors for our experiential sessions. Without the support of all of you, our College and these students and graduates would not enjoy the successes we have achieved. Thank you very, very much.

Ken Strandberg, MBA, RPh, Program Director

Barb Lacher, BS, RPhT, CPhT, Assistant Program Director

The 61st ND legislative session was a busy one for the NDPhA with some very contentious issues being examined by the legislature. Below is a listing of the major bills the NDPhA was following during the 61st ND legislative session. Thank you to the Government Affairs Committee members for their time and commitment and taking an active role in their profession.

The Committee is very diverse in that it contains members from different practice settings. Members come from hospital practice, community practice, rural community practice, research setting, and pharmacy sales. The committee met twice by teleconference before the 2008-2009 legislative session. Moving forward we will began to meet to discuss the ownership law ballot initiative along with the 62nd legislative session beginning later this year.

A big THANK YOU goes out to Mike Schwab. He did a tremendous job during the legislature and the profession of pharmacy in ND is lucky to have your leadership. THANK YOU to Lorri, Courtney, Kirby, and Micah for all their time and efforts during the session.

I urge all members of the NDPhA to continue to take the time to educate all elected officials about the challenges you face in your practice. The pharmacy profession is continuously changing and we have to make sure our voice is heard!!

House Bill 1091 - continuing pharmaceutical education process

Each pharmacist shall complete at least fifteen hours of approved continuing pharmaceutical education every year as a condition of renewal of a certificate of licensure as a pharmacist in the state. This changed the old requirement of 30 hours for a 2 year time frame. PASSED unanimously.

House Bill 1105 - relating to controlled substances and the listing of such

This bill was heard by the Judiciary Committee and was PASSED unanimously by both the House and the Senate.

House Bill 1385 – Prior Authorization Program

This bill dealt with the Drug Utilization and Review Board and changes "carve outs" which are not initiated by the DUR board. It allowed certain medications to be exempt from the prior authorization process through ND Medicaid. This bill has been PASSED.

House Bill 1440 - related to the repeal of the 51% pharmacy ownership law

This bill would have completely repealed the current statute. This legislation would have allowed anyone to own a pharmacy and would have removed the current 51% ownership requirement. An amendment to this bill which would subsidize new rural pharmacies and create a loan forgiveness program failed in committee. The original bill FAILED 35-57 in the House.

House Bill 1523 – creating an exemption for hospitals under the 51% ownership law

This bill would have allowed any hospital or integrated health system to fully own and operate a retail pharmacy within any of their locations. This bill FAILED 21-71 in the House.

Senate Bill 2039 - related to NDPhA membership and the size and makeup of the Board of Pharmacy

This bill was originated from an interim legislative study. This legislation has removed the integrated membership of the NDPhA and changed it to an opt-in system. It also will add a consumer and pharmacy technician to the State Board of Pharmacy, thus changing the size of the Board from 5 to 7 members. The bill PASSED 89-3 in the House and was PASSED unanimously in the Senate.

Senate Bill 2164 - related to Optometrist dispensing certain pharmaceutical agents

This piece of legislation was introduced to allow an Optometrist to dispense contacts with medication delivery systems included in them. The NDPhA did not oppose the effort but did follow it closely for amendments. This bill PASSED unanimously in the House and Senate.

Senate Bill 2218 - further regulation of Internet pharmacy operations in ND

The intention of this bill (Justin's Law) is to provide a penalty for uncertain drugs and unlawful distribution of dispensing of controlled substances and counterfeit controlled substances by means of the Internet. The ND Attorney General's office was behind the effort, as well as the Medical Association, Board of Nursing, ND State Board of Pharmacy, and NDPhA. The purpose of implementing this law is to protect the public and to provide a penalty. This bill PASSED unanimously in the House and Senate.

Senate Bill 2332 - creates a Health, Information, and Technology Department within the ND Department of Health and calls for an appropriation.

This created a department and provided funding for implementation and the shift to electronic health records and e-prescribing. Passing of this bill will provide a means to make sure ND is on board and ready to go once electronic health records and e-prescribing becomes mandatory. It PASSED in both the House and Senate.

Moving forward in 2010, it looks to be a busy year for the profession of pharmacy in North Dakota with the ballot initiative challenge to the ownership law. Now is not the time to sit back!

Respectfully submitted,

Mark Hardy

Dean's Report

Charles D. Peterson, Dean and Professor

125th NDPhA Annual Convention, April 23-25, 2010
Minot, North Dakota

Executive Summary

The College has had another very busy and productive year. On September 18th, the College held its eighth Annual Career Fair at the Fargodome with 51 tables/exhibits representing the professions of pharmacy, nursing, and allied sciences including various healthcare facilities from the state, region, and nation. Both pre-professional and professional students as well as area high school juniors and seniors attended the event exploring careers in pharmacy, employment opportunities, and internships. It was a tremendous success and the day was capped by our Annual Scholarship Recognition program which the College disbursed $240,919 in scholarships to deserving students. The College awarded 201 scholarships, from 92 total donors (56 private individual donors and 36 corporate donors), with the average scholarship award being approximately $1,200 (range $250 - $13,600). I would like to thank all the alumni and corporate friends of our College who have given so generously to help us support our students. Thanks to you, our scholarship program is alive and well. Next fall, the 10th Annual Career Fair and Scholarship Recognition Program will be held on Thursday, September 16, 2010 at the Fargodome. So mark your calendars and plan to attend. Like last year, North Dakota Opportunities Night will be held the evening before the Career Fair on Wednesday, September 15th. Come join us for these awesome events ! To register for any of these events or for more information, contact Sara Wald, Director of Advancement, at (701) 231-6461 or email at Sara.Wald@ndsu.edu.

On October 14, 2009, Dr. Joseph A. Chapman submitted his letter of resignation to Chancellor William Goetz, effectively stepping down as President of NDSU. In an email to the entire campus, President Chapman gave the following reasons for resigning, "Controversies in recent days have created distractions that have made it impossible for me to provide the leadership this institution deserves. Students have always been paramount, and I fear these distractions have impaired my ability to serve their interests." Dr. Chapman joined NDSU as its 13th President in June 1999, and brought bold leadership to the University which focused on five themes, "It's About People, Students are Paramount, Programs, Leveraging Support, and Stature". His unprecedented achievements over the past 11 years include, record student enrollment growth for 10 consecutive years (from 9,600 to 14,189), graduate doctoral programs increased from 18 to 44, and annual research expenditures increased from $44 million to $115.5 million. The campus itself also experienced unprecedented growth during President Chapman's tenure including, the Research and Technology Park, NDSU Downtown Campus, Renaissance Hall, Richard H. Barry Hall, Klai Hall, Bentson Bunker Fieldhouse, Memorial Union, Sudro Hall, the Equine Science Center, Bison Sports Arena, to name just a few. The effective date of President Chapman's resignation was January 2, 2010, however, his last day at NDSU was November 30th. On October 23, 2009, Dr. Richard A. Hanson was named the Interim President of NDSU by the North Dakota State Board of Higher Education. Dr. Hanson's previous experiences include: President of Waldorf College in Forest City, Iowa, from June 2005 through November 2009; Vice President for Academic Affairs and

Dean at Augustana College, from 1995 to 2005; Interim Vice President for Academic Affairs at NDSU, 1995; Associate Vice President for Academic Affairs, at NDSU, from 1992 to 1995; and Department Chair, Home Economics at California State University in Chico. Dr. Hanson is a native of Hillsboro, ND and earned his bachelor's degree in sociology and a master's degree in child development and family relations from NDSU. He earned a doctorate in applied behavioral science from the University of California, Davis. He played football for NDSU, and for the New York Giants in 1971 and 1972. Dr. Hanson began his duties as Interim President at NDSU on December 1, 2009. On December 16, 2009, a 20 member Presidential Search Committee (Steve Swiontek, Chair) met with Chancellor Goetz to begin the search process for recruiting a new president for NDSU. The North Dakota State Board of Higher Education (SBHE) hired a search firm (Academic Search, Inc, Washington DC) to conduct the search. The search timeline was identified as follows: February 1st (advertisement), March 1st (application deadline), April (conduct interviews), May 13th (have three finalists selected), May 21st (SBHE interviews), May 24th (SBHE selects next NDSU President), July 1st (new President begins).

This is a big change for us and for NDSU. However, we need to remember that President Chapman is a great leader who also happened to lead a great University. This same great University is still here, including all the great people who implemented all the transforming changes that have occurred on campus over the past 11 years. As Dean of the College, I want you to know that we are fully committed to marching forward with the same energy and momentum that has brought us to this point in time. So, it is business as usual for us, including striving for even greater heights not previously seen before. We will continue to march on and march forward, something we all would expect from a thundering herd. Go Bison !

In January 2010, the College began a formal self-study process for the pharmacy program in preparation for its next accreditation visit by the Accreditation Council for Pharmacy Education (ACPE) which is currently anticipated to be in April of 2012. The ACPE self-study process takes approximately 18-24 months to complete and requires involvement of all faculty and key stake holders of the College (ie. students, staff, practitioners, alumni, Board of Pharmacy, State Association, Advisory Board). We have organized a Self-Study Steering Committee (chaired by Dr. Cynthia Naughton, Associate Dean for Academic Affairs and Assessment) which will lead our accreditation self-study process and will be preparing a self-study report that addresses how well we are meeting ACPE's current accreditation standards. Six self-study subcommittees have been created to work on each of the major sections of the ACPE standards including: Mission, Planning, and Evaluation (chaired by Dr. David Scott); Organization and Administration (chaired by Dr. Robert Sylvester); Curriculum (chaired by Dr. Amy Werremeyer); Students (chaired by Dr. Daniel Friesner); Faculty & Staff (chaired by Dr. Sanku Mallik); Facilities & Resources (chaired by Dr. Stephen O'Rourke). The Self-Study process and report will take a critical look at our entire program and identify our strengths, our weaknesses, and areas needing improvement. This process is not only important for our continued accreditation with ACPE, but it will also be used to help lay the ground work and foundation for directing our future goals, priorities, and plans as a College. We invite the profession to participate in this very important accreditation process.

As a result of its strategic planning efforts, the College has identified new growth opportunities for the future. Recommendations from our Pharmacy National Advisory Board, and new ACPE accreditation standards for the pharmacy professional program, have helped the College identify the area of public health as a future priority and growth opportunity. The pharmacy accreditation standards as well as the profession of pharmacy desire (and see the importance of) pharmacists in their practices to play a more active role in advancing public health within the community. As a result, the Department of Pharmacy Practice has forwarded a request to the Graduate Council and University Senate, for the development of a new Master of Public Health (M.P.H.) degree program. This program will be uniquely different than other M.P.H. programs, in that, it will train health professionals (pharmacist, nurses, physicians, other disciplines) with the necessary knowledge and skills to deliver meaningful public health (ie. health promotion, disease prevention, intervention, and education) to patients at the point of care. This discipline-specific (applied) M.P.H. training program will allow pharmacy, nursing, medicine, and other disciplines to create their own discipline-specific curriculums (tracks) to help integrate public health into the various health professions practice environments. North Dakota does not currently have a public health school or a North Dakota developed M.P.H. program. The College has been working this past year with Dr. Terry Dwelle, State Health Officer, to design an innovative curriculum, developed by North Dakota, for North Dakota. Once approved, the College plans to offer public health training programs to students and practicing pharmacists which will have a convenient on-line distance education mode of delivery, and offer various flexible options, including credits toward pharmacists continuing education, credits toward a formal public health certificate program, and even allow pharmacists to pursue their public health training all the way to a full Master of Public Health (M.P.H.) graduate degree. The College sees this future public health degree (and training program) as a wonderful opportunity for the profession of pharmacy (and practicing pharmacists) to work with the State Health Officer to identify and help resolve numerous public health concerns currently facing North Dakota citizens, with the ultimate goal of improving their overall health and wellness. Through this program, pharmacists in the future will have opportunities for participating in public health programs, services, education, and research activities, all of which, it is anticipated, will provide opportunities for reimbursement. Clinical practices and clinical training sites (and preceptors)

will need to be developed within the State to support the program, including opportunities for residencies in public health. On November 9, 2009, the University Senate at NDSU approved the College's proposal for a Master of Public Health (M.P.H. degree). The College submitted a comprehensive Stage 2 proposal to the Provost Office on March 23, 2010, which will hopefully be placed on the agenda for the State Board of Higher Education meeting in April. If all goes well, the College anticipates the program could begin either in the Fall of 2011 or Fall of 2012 depending on available funding to support the program. In addition, the College has authored two recent publications on rural public health including an article entitled, "Rural public health education as a pharmacist-led team endeavor recently published in *J Am Pharm Assoc*. 2010;50:207-213 and a 30-page book chapter entitled, Rural health and telepharmacy: public health challenges and opportunities published in a soon to be released (May 2010) textbook *The Pharmacist in Public Health* published by the American Pharmacists Association.

The State of North Dakota recently established a Center of Excellence Program (COE) to promote and encourage linkages between academia and the private business sector to enhance economic development within the state through adding new businesses, new jobs, and new commercialization. The 2005 Legislature set aside $23 million to invest in the COE program managed by the Department of Commerce. As a result of its strategic planning efforts, the College of Pharmacy, Nursing, and Allied Sciences in July 2008 submitted an application to the State to develop a Center of Excellence within the Department of Pharmaceutical Sciences at NDSU called the Center for Biopharmaceutical Research & Production (CBRP). After going through the formal COE due diligence process, on September 26th, the College was notified by the North Dakota Department of Commerce that its Center of Excellence application had been approved for funding for $2.0 million. The following are the goals, objectives, and plans for the College's new state-supported Center of Excellence in biopharmaceuticals including vaccines: The CBRP COE will develop a comprehensive vaccine cluster that is capable of performing all aspects of vaccine research & development right here in North Dakota (basic science research and discovery, animal testing, screening and manufacturing, and even human trials). NDSU has been involved with vaccine research and development for more than a decade and we would like to build this area further. The CBRP COE will utilize or capitalize on the strengths that already exist in North Dakota in the life sciences, biomedical fields, pharmaceutical research, biotechnology, robotics, and nanoscience, combining the strengths of academia with private sector partners such as Aldevron, Pracs Institute, ParaClin, MeritCare, Clinical Supplies Management, etc. all working together toward a common goal. These are well established private sector partners that have excelled in their respective fields that have a track record of excellence in the health care industry. Specifically, the CBRP COE will create a basic science research laboratory at NDSU including hiring a high profile "star" vaccinologist which will build the basic science foundation for vaccine R & D for the participating private sector partners with the goal of developing new vaccines, and other biopharmaceuticals which will: (a.) enhance the life sciences business sector in North Dakota; (b.) attract new biotechnology companies to North Dakota; (c.) expand and retain existing companies (like Aldevron) in North Dakota: (d.) create new jobs (estimate initially 40 high paying jobs); (e.) train and generate a highly skilled biotechnology workforce for private sector partners/businesses in North Dakota (workforce development); (f.) enhance economic development and sizable revenue to North Dakota through grants, contracts, commercialization, IP, patents, private investment (vaccine market current $22B/year will grow to $36B in next 5 years); (g.) provide us the opportunity to work on some of the most challenging health problems in North Dakota and the world (global connections) including H1N1, Bioterrorism, Bird Flu, West Nile, Malaria, HIV, Cancer, TB, others. Solving global health issues will bring recognition and revenue to North Dakota and solving State health issues like West Nile Virus will directly benefit North Dakotans; (h.) allow North Dakota to become a market leader through use of innovation in the ways and means by which target vaccines are discovered through use of high throughput processes, robotics, biotechnology, nanotechnology (already strengths at NDSU). Through these innovative approaches to vaccine development, North Dakota will have an opportunity to set a new industry standard for the marketplace for how vaccines are developed. The College has successfully recruited a high profile vaccinologist researcher who has strong ties to the vaccine industry to be Director of the CBRP-COE. This individual will begin his duties at NDSU on May 3, 2010. The CBRP-COE will initially be located in Sudro Hall. Designs are currently being developed to occupy approximately 4,000 sq. ft. of space in the Appareo building in the RTP to support the CBRP. The CBRP ultimately desires to attract private sector partners with hopes of eventually building a new vaccine research facility (up to 75,000 sq. ft) in the NDSU Research and Technology Park to support the College's new CBRP COE.

The College is currently making plans for a summer travel schedule (June 14-17th) to visit with practitioners and alumni at several locations across the state. I, along with several members of my administrative leadership team, including our Associate

Dean for Academic Affairs and Assessment (Dr. Cynthia Naughton), our Interim Associate Dean of Student Affairs (Dr. Daniel Friesner), our Department Chair of Pharmacy Practice (Dr. Donald Miller), our Director of Experiential Programs (Prof. Wanda Roden), and our Coordinator of Introductory Pharmacy Practice Experiences (Dr. Rebecca Focken). Individual visits, group luncheons, and preceptor training will be a part of the College's agenda for this trip across the state. Dates, times, and locations of meetings will be forthcoming. I hope to see many of you during our upcoming trip across the state this summer.

During the 2008 Spring Semester, the College was given permission from NDSU to hire an architect to develop preliminary plans to define its future space needs. T. L. Stroh Architects & Interiors, Ltd was hired by the College. The architects met with the College's Administrative Council who based on the College and Department's recent strategic planning efforts, developed a list of future space needs to support future growth. Space priorities included faculty/staff offices, classrooms, research laboratories, and additional conference rooms. The architects completed preliminary designs and drawings of the College's future space needs. The space plans included a multistory 62,410 sq. ft. building addition to Sudro Hall including 25 offices; 13 semi-private workstations for part-time faculty/staff; 3 large classrooms with seating capacity of 180, 200, 240, respectively; five new research laboratories; six new conference rooms; a new student lounge with 18 computer workstations; and a new Dean's Office. In addition, an additional floor (shell space) is available for future expansion if needed. The space plans were presented to the faculty and staff of the College on September 29, 2008 and to the Pharmacy National Advisory Board on October 3, 2008 during Homecoming. The space plans include space for nursing and allied sciences departments. These space plans will now be reviewed by University Central Administration and Facilities Management to determine how these plans fit with the greater University's Master Space Plan recently created by an outside consultant firm. The University will determine a priority list of capital projects from the University Master Space Plan which will allow certain projects to go forward. If the University approves the pharmacy program space plan, it would then require approval from the North Dakota State Board of Higher Education and the State Legislature. As of April 1, 2010, the new Sudro Hall addition has been placed on the University space list and is currently being targeted for the 2015-2017 biennium.

The American Association of Colleges of Pharmacy released the 2009 national rankings for National Institutes of Health (NIH) funding for pharmacy schools. Out of 116 schools of pharmacy, NDSU's pharmacy program was ranked 9th in the United States for the percent of doctoral faculty with National Institutes of Health funding. NDSU has 45.5 percent of full-time equivalent pharmaceutical sciences faculty receiving funding from the National Institutes of Health. NDSU's percentage of pharmaceutical sciences faculty with competitive NIH funding exceeded many other prestigious research universities including the Purdue University, University of Illinois at Chicago, University of North Carolina at Chapel Hill, The Ohio State University, University of Minnesota, University of Maryland, and the University of Florida. NDSU ranked 45th nationally for total NIH grant dollars awarded per full-time equivalent faculty, just behind the University of Oklahoma and Texas Tech University. National Institutes of Health research grants are the most difficult, most competitive, and most prestigious research grants awarded in the United States. In 2008, NDSU ranked 13th in the nation for NIH funding.

On September 1, 2008, the North Dakota Telepharmacy Project received additional federal funding of $805,399.00 from HRSA/OHIT/OAT for developing a telepharmacy program that will provide 24-hour pharmacist staffing and pharmacy services to small rural hospitals in North Dakota. Many rural hospitals have limited pharmacist coverage or pharmacy services which greatly impacts their ability to deliver even the most basic pharmacy services. There is a critical need to provide access to pharmacists and pharmacy services especially after hours (evenings, weekends, holidays, vacations, sick days, professional meetings) for remote rural hospitals including critical access hospitals in North Dakota. Telepharmacy services can provide these hospitals with 24/7 access to a pharmacist to deliver high quality pharmacy services. It is our hope that the new OHIT/OAT federal funds will help North Dakota establish a national model for delivering telepharmacy services to small rural hospitals that will make North Dakota a national leader in delivery of pharmacy services to rural hospitals and rural areas. With the new grant funds, Catholic Health Initiatives (CHI) is currently establishing a central order entry facility in Fargo to deliver 24/7 pharmacist staffing and pharmacy services to rural hospitals in need. Over the next two years, the goal of the project is to establish the central order entry site, and develop services to at least nine remote rural hospitals in North Dakota. Remote rural hospitals in North Dakota currently receiving telepharmacy services from the CHI Central Site in Fargo include: Mercy Medical Center in Williston, Carrington Health Center in Carrington, Mercy Hospital in Devils Lake, Towner County Medical Center in Cando, St. Joseph Hospital and Health Center in Dickinson, Lisbon Area Health Services in Lisbon, Jamestown Hospital in Jamestown, Oakes Community Hospital in Oakes, and Nelson County Health System in McVille. Additional sites

in Minnesota are also being developed by the CHI-COE including: Little Falls, Park Rapids, Baudette, Breckenridge, Detroit Lakes, Roseau, and Albany. An article describing this new hospital telepharmacy model was recently submitted and accepted for publication (and will soon be published) in the *J Pharm Technol* entitled, "Establishing a Central Order Entry System for Delivering Telepharmacy Services to Remote Rural Hospitals". In addition, the College is currently working on submitting a federal ARRA grant from the Agency for Healthcare Research and Quality (AHRQ) for the category of Comparative Effectiveness Delivery System Demonstration Grants for the purposes of delivering telepharmacy services and medication therapy management to the eight Human Service Centers located in North Dakota. With the assistance of Senator Byron Dorgan, the NDTP thus far has received more than $3.3 million to support its efforts. As of September 1, 2009, the North Dakota Telepharmacy Project now has developed (or in the process of developing) a total of 72 telepharmacy sites in North Dakota, 51 retail sites, and 21 hospital sites. Ann Rathke serves as our Telepharmacy Coordinator, and Dr. David Scott serves as Co-PI for Assessment for the project. Principal investigator for the telepharmacy AHRQ Health Service Centers grant will be Dr. Daniel Friesner. For more information contact Ann Rathke at Ann.Rathke@ndsu.edu or visit our telepharmacy website at http://www.ndsu.edu/telepharmacy.

In the Summer of 2007, the College hired an outside consultant (Bernard Consulting, Group, Inc.(BCG), Kansas City, Missouri) to assist the College in the development of a new 2008-2013 strategic plan. The new plan was approve by the faculty on August 21, 2008. This document will pave the way for the future success of our College over the next 5 years. As we begin further developing and implementing our strategic plan including all the exciting new ideas that we want to be pursuing to keep NDSU students on the cutting edge nationally for pharmacy education, financial resources will be of critical importance to help us realize our goals and priorities for the future. The College recently launched a new annual giving program called "Sudro Society". This new annual giving program replaces the previous Dakota 100 Club. Sudro Society recognizes individuals who make annual, unrestricted contributions to the NDSU pharmacy program of $1,000 or more. The annual investment helps provide a critical base of funding which allows the College to respond to new initiatives, urgent program needs, and special projects that would not otherwise be funded through the College's annual budget. Funding from annual alumni giving supports many areas of the college including: College Student Ambassadors Program; travel expenses for students to attend regional and national pharmacy conventions; support and upgrades for the Concept Pharmacy; instructional technology; classroom innovations and renovations; faculty and staff development opportunities; recruitment of new faculty and staff; alumni relations activities including events and our alumni newsletter; annual career fair and scholarship program; computer and software upgrades; visiting scientist research lecture series; and many other areas. The financial support received from Sudro Society will help us sustain our tradition of excellence and it will also allow us to pursue new areas in need of funding. We would greatly appreciate it if you would consider partnering with us by becoming a full Sudro Society member. Your support will have a great impact on our pharmacy students and will help us fulfill our dreams for the future. For more information about Sudro Society, including becoming a member, contact Sara Wald, via email at Sara.Wald@ndsu.edu or call Sara at (701) 231-6461.

The pharmacy program is currently in the process of evaluating applications for admission to the pharmacy professional program for the 2010 Fall Semester. There currently are 178 applications (up from 126 in 2009) in this year's applicant pool and 85 students are expected to be admitted for this coming 2010 Fall Semester. Of the 132 students recently invited for formal interviews, 131 applicants were actually interviewed, the average selected GPA was approximately 3.69; and the average PCAT score was approximately 65.35 for those interviewed. Preference is given to students with demonstrated leadership skills; work or volunteer experience in a health-related area; and residency in North Dakota. An ethics exam is now also part of the admission's assessment. Although, admissions to pharmacy schools remains fiercely competitive, students applying to NDSU currently have a much greater chance of being admitted to the pharmacy professional program than other schools in our region. Over the past two years, NDSU has admitted 67% percent of the total applicant pool, compared to an average of 20-25% for other pharmacy schools regionally and nationally. The pharmacy program has admitted more than 80% of North Dakota residents applying to the program. Student tuition and fees for students enrolled in the pharmacy professional program at NDSU for the current 2009-10 academic year are approximately $11,858.00/year. So NDSU continues to be one of best quality and best value programs for a pharmacy education nationally. The 2009 North Dakota Legislature infused an additional $8.2 million into the North Dakota University System this session which has helped contain student tuition increases over the current biennium. As a result, tuition increases have been capped at 4% per year for North Dakota's four year schools for the past two years.

The College had four students graduate from the pharmacy professional program on December 19, 2009. We will have 88 pharmacy students graduating during Spring Commencement

on May 15, 2009 at the Fargodome. The NDSU Pharmacy Program Graduation Hooding Ceremony will be held at Festival Concert Hall on NDSU campus at 10:00 am Friday, May 14th, with a reception to follow. The keynote speaker for this year's hooding ceremony will be Paul Iverson ('82 BS in pharmacy and owner of Iverson Corner Drug in Bemidji, MN). This year again, the University will have two commencement exercises, a graduate commencement for graduate degrees (and doctoral professional degrees), and an undergraduate commencement for undergraduate degrees. The NDSU Graduate Commencement exercises will be held on Friday, May 14th at 4:00 pm at the Fargodome, which will include students graduating with graduate degrees from the Graduate School, and also those with professional doctoral degrees, including the College's doctor of pharmacy graduates. The NDSU Undergraduate Commencement exercises will be held on Saturday, May 15th at 10:00 am at the Fargodome, which will include students graduating with undergraduate degrees. We invite everyone to come join us for these celebrations to honor this year's graduating class.

Noteworthy pharmacy awards from this past year include: College Awards – Dr. Sanku Mallik, Professor of Pharmaceutical Sciences, received the 2009 Dean's Award for Excellence in Research; Wanda Roden, Director of Experiential Programs, received the 2009 Dean's Award for Exemplary Service; Polly Olson, Program Director for Allied Sciences, received the 2009 Dean's Award for Outstanding Advising; and Pharmacy Program Awards – Dr. Robert Sylvester, Associate Professor of Pharmacy Practice, received the 2009 Teacher of the Year Award; Dr. Mark Dewey, Assistant Professor of Pharmacy Practice, received the 2009 Faculty Preceptor of the Year Award; and Mr. Jeff Sawyer, Pharmacist, Melrose, MN, received the 2009 Adjunct Preceptor of the Year Award. National Awards - In addition, the Family HealthCare Pharmacy, NDSU, received four prestigious national awards this past year from the Health Resources and Services Administration (HRSA) Patient Safety and Clinical Pharmacy Services Collaborative. This HRSA program is a national effort to improve the quality of care delivered in the United States through the integration of health care providers and increased provision of clinical pharmacy services. The four awards received by the Family HealthCare Pharmacy (and its staff) include the Clinical Pharmacy Services Improvement Award, the Health Outcome Management Award, the Life Saving Patient Safety Award, and the Patient Safety and Clinical Pharmacy Services Collaborative Performance Award for overall excellence. Also, Ramona Danks, fourth year professional pharmacy student, received the United States Public Health Service (USPHS) Excellence in Public Health Pharmacy Practice Award. The award was presented in class at NDSU by retired Rear Admiral and Chair of the Pharmacy National Advisory Board, Fred Paavola who had more than 30 years of service in the USPHS. NDSU Awards - In addition, during the 2009 NDSU Homecoming Celebration, three pharmacy alumni were honored by the University at the 2009 Alumni Honors Dinner and Awards Presentation. Dr. Darryle D. Schoepp ('78 BS in pharmacy and currently senior vice president and franchise head for neuroscience at Merck and Company) received the NDSU Alumni Achievement Award; Dr. Bradley J. Undem ('79 BS in pharmacy and currently full professor of medicine at Johns Hopkins University School of Medicine) received the NDSU Henry L. Bolley Academic Achievement Award; and Dr. William J. Grosz ('51 BS in pharmacy, retired, and former Executive Director of the North Dakota Board of Pharmacy, and former member of the Pharmacy National Advisory Board) received the NDSU Heritage Award. Congratulations, to all these outstanding award recipients !

The ACPE Board of Directors at their January 20-24, 2010 meeting approved simulation experiences to satisfy for introductory pharmacy practice experiences (IPPE). This is good news for our College because it will finally allow us to use the Thrifty White Concept Pharmacy instructional laboratory at NDSU for satisfying some IPPE requirements for students which previously was not allowed. The College still has a great need for additional experiential training sites and preceptors especially for satisfying IPPEs, rural rotations, and hospital experiences. If you are interested in training pharmacy students in these and/or other areas of practice, please contact Wanda Roden at (701) 231-5178 or email at Wanda.Roden@ndsu.edu, or Rebecca Focken at (701) 231-7477 or email at Rebecca.Focken@ndsu.edu.

After almost six years of serving our College as Associate Dean for Student Affairs, Dr. Kimberly Vess Halbur announced recently that she has accepted a new position as the Associate Dean for Diversity at the School of Medicine at the Medical College of Georgia in Augusta. Dr. Halbur's last day is April 16th. Dr. Daniel Friesner has been appointed as the Interim Associate Dean for Student Affairs until a national search can be completed to find a replacement.

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Copy for June 2010 Hub on Health Care Reform

The new law: Divide and analyze

Implementation of the Affordable Care Act (ACA) is now in full swing at the Health and Human Services Secretary's office, CMS, FDA, and other federal agencies responsible for various aspects of this complex law. APhA has a yeoman's task before it in keeping up with proposed regulations, identifying provisions that affect pharmacy and pharmacists, calling for input from members, formulating a response, and then working to make sure the profession's voice is heard before the rules are finalized.

Beginning this month and in future installments of the Hub, both in ***Pharmacy Today*** and also on the Health Care Reform Hub page in the Government Affairs section of pharmacist.com, the many facets of ACA will be evaluated, explored, and explained. Specifically, plans are to cover one major aspect of the new law in each remaining 2010 issue, starting with accountable care organizations this month.

Most of the analyses will cover sections of ACA that are directly relevant to the profession of pharmacy and therefore are being regularly monitored by APhA. Other parts of the bill will be covered briefly—including aspects with the potential to affect APhA members as pharmacy owners or employees.

ACOs coming, and pharmacy can help

The Affordable Care Act (ACA) has been labeled the reform of the American health insurance, not care, system. That is true to some degree, but many elements of the new law will affect the daily practice of pharmacy and medicine. These were mostly ignored during public and congressional debate over HCR.

Leaders of APhA's three Academies were briefed in detail on April 17 about one of the most important practice-related provisions of ACA: accountable-care organizations (ACOs). ACOs feature a new type of payment model that seeks to address some of the problems inherent in the two dominant models in use—fee for service and capitation.

Under the new law, many ACOs will likely emerge from existing patient-centered medical homes. The two terms are not synonymous. A medical home is more a care model in which primary care practitioners take responsibility for coordinating services provided to a group of patients. Medical homes use tools such as electronic medical records and multidisciplinary care. Certified patient-centered medical homes can receive additional compensation for care coordination.

ACOs are more a payment or financing model. These organizations assume some of the risk involved in patient care, as described below. Certified patient-centered medical homes can morph into ACOs, but ACOs do not have to be medical homes.

"Patient-centered medical homes or care models will be important, and how pharmacy fits into those will be important," Thomas E. Menighan, BPharm, MBA, ScD, Executive Vice President and CEO of APhA, told the leaders. "I've seen this model described as a house with information technology and systems on the first floor, primary care on the second floor, specialists on the third floor, and so on. But there's still room for growth and improvement in the design. And we're in a position now to design how pharmacy will fit into this model."

What are ACOs?

Essentially, an ACO shares risk between payer and provider, and providers can be reimbursed at higher levels for attaining quality goals. The cost of care is attributed to providers in the ACO, said S. Lawrence Kocot, MPA, JD, LLM, Deputy Director of the Engelberg Center for Health Care Reform at the Brookings Institution in Washington, DC, and Senior Counsel at Sonnenschein, Nath and Rosenthal, a firm that worked with APhA throughout the health care reform debate.

Take rehospitalizations, for example; under a fee-for-service model, these generate additional payments. Under capitation, each admission generates a payment based on the diagnosis, even if the hospitalization is the result of poor care during a previous stay.

Under such models, providers quickly learn how to manipulate the system, Kocot said, recalling his experiences at CMS with physician fees and imaging. When payments for fees were restricted, service intensity and billings went up.

ACOs add cost and quality components. "ACOs allow physicians to group together, if they have a minimum of 5,000 covered lives," Kocot said. "Physicians bill fee for service, just as they do today. But at the end of a year, 2 years, or 3 years, their goal is to look at the spending growth target, and if they beat the target, they may share in the savings. But in addition to the cost target, they must meet certain quality standards. The quality standards are there to be sure the physicians don't skimp on the costs. This system starts to realign the incentives so that the physician does the right thing for the patient."

Thus, in the case of rehospitalization, all of the costs are attributed to the ACO. With too many rehospitalizations, an ACO may miss its cost target, its quality standards, or both.

ACO pilots are already under way at the Carilion Clinic in Roanoke, VA, Norton Healthcare in Louisville, KY, and Arizona's Tucson Medical Center.

Where does pharmacy fit in ACOs?

Pharmacy will play an important role in ACOs, but whether the profession does so from within the organization (and therefore accepts risk with the other providers) or as a contracted, external entity remains to be seen. But one thing seems clear, especially when it comes to cost and quality: The ACO will have difficulty meeting its goals without partnerships with pharmacists.

"The ACO will bring to physicians the recognition that there are other providers in the community who can do a lot more for them, be cost-effective, and improve their bottom line," Kocot said. "As physicians start looking at this a little more methodically, they're going to realize the pharmacist is their savior, not their enemy."

Increased use of nurse practitioners and other nonphysician providers, improved care coordination, reduced waste, better management of chronic diseases, and point-of-care reminders are just some of the ways in which ACOs can control costs, Kocot said.

"Pharmacists very well could be part of an ACO," Kocot added. "But I don't know if that's really that important … because any doctor in the community is going to realize that pharmacists are key to the practice.… The issue is what pharmacists can do. Literature supports that pharmacists play a key role in improving patient adherence to recommended care, care coordination across providers, and avoidable complications. Pharmacists have a big role in being the bricks, or the cement, for the primary care physicians, if the pharmacists position themselves right."

The other point to remember is that ACOs are "not some big monolithic system that you have to penetrate," Kocot said. "These are your local providers. Some ACOs are very small. There is no choice but to rely on the pharmacist. Pharmacists need to get with these community groups as they start planning. Pharmacists need to be at these meetings to emphasize their roles from the very beginning."

What happens next?

The next two steps spelled out in ACA are coming up fast, making it important that pharmacists engage others in their communities now. Being established in CMS is a Center for Medicare and Medicaid Innovation. It has $10 billion in authorized funds (for use over 9 years) to begin testing payment and delivery models by January 1, 2011, Kocot said. A year later, a Medicare shared-savings program based on ACOs will begin.

"The time is now to change the system," Kocot said. "Pharmacists can and should be a part of this."

—L. Michael Posey, BPharm
Editor, Pharmacy Today
American Pharmacists Association
Washington, DC

HCR/regulatory scorecard: What is happening NOW!

Proposed regulations receiving public comments

- ❑ FDA: June 24–25 public workshop on reduction of medication errors through improved naming, labeling, and packaging practices (comments close July 23).
- ❑ FDA regs on direct-to-consumer advertising (comments close June 28).
- ❑ FDA collecting information on experimental study of patient information prototypes (comments close July 1).

Regulations whose comment periods have closed

- ❑ DEA request for comment on interim final rule on electronic prescribing of controlled substances.

Regulations recently finalized

- ❑ **Medicare Coverage Gap Discount Program:** When Medicare Part D beneficiaries hit the doughnut hole next year, the pharmacist will once again be a key messenger about what the 50% discount on applicable medications will mean to them. But, as APhA told CMS in comments filed on May 14, patients will need to realize that the pharmacist is only conveying information calculated by Part D plans through the claims adjudication process. APhA recommended that CMS work with APhA and other pharmacy stakeholders in developing and disseminating educational tools, point-of-service messaging, and patient-education materials. Within a week of receiving comments, CMS finalized its guidance and in that, acknowledged the need for education and awareness activities. It held a public hearing on June 1 to get feedback on an agreement manufacturers must sign to participate in the discount program, which launches on January 1. Beneficiaries who hit the gap this year will receive a one-time federal payment of $250.

Etc.

- ❑ **What is the name of the health care reform law?** HCR took an unusual path in Congress as Democrats chose to avoid a second vote in the Senate, which had approved the bill on Christmas Eve. Thus, the HCR bill signed by President Obama on March 23 was the Patient Protection and Affordable Care Act (Pub. L. 111-148). It was then amended by section 1101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), signed a week later. Because neither bill title alone is accurate, the Obama administration is using "Affordable Care Act," or ACA, to refer to these bills collectively, and ***Pharmacy Today*** will adopt that phrase in its reporting.
- ❑ Be sure to **thank your Members of Congress** for considering pharmacy's position during the HCR debate. APhA members can use the Legislative Action Center in the Government Affairs section of pharmacist.com to access preformatted letters, one for Members who supported HCR and another for those who opposed the bills.
- ❑ For a list of all the issues and regulations being monitored and acted on by APhA, access the **Government Affairs** section of pharmacist.com. Also, readers of the print version of the Hub should know that hyperlinks to pharmacist.com, *Federal Register* notices, and other useful websites can be accessed in the online version of the Hub, located at www.pharmacytoday.org.

HUB ON HEALTH CARE REFORM provides readers with practical information on health care reform issues, what APhA is doing to keep pharmacists' important role front and center with decision makers, and simple ways for pharmacists to participate in the processes that will determine the structure, function, and processes of a reformed American health care system. Send an e-mail message to APhA at gvtaff@aphanet.org to offer suggestions for future content, ask questions, make comments, or request permission to use or copy this issue.

2009 Recipients of the "Bowl of Hygeia" Award

Pfizer Pharmaceuticals takes great pride in continuing the "Bowl of Hygeia" Award Program developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community which richly deserves both congratulations and our thanks for their high example.

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

NDSU
COLLEGE OF PHARMACY, NURSING, AND ALLIED SCIENCES

1641 Capitol Way
Bismarck, ND 58501-2195

Change Service Requested

Job Title: Director of Pharmacy Services
Department: Pharmacy
Reports To: COO

JOB REQUIREMENTS

Education: Graduate from an accredited school of pharmacy with a Bachelor of Science in Pharmacy (BSPH) PharmD preferred.Must be licensed to practice in the North Dakota. Can meet requirements based on reciprocity of the state he/she resides or by taking and passing the required examinations by the State Board of Pharmacy.

Experience: A minimum of five years experience is required in Acute Care Hospital Pharmacy

Physical: Normal hospital environment. Close eye work. Hearing within normal range. Uses office machines including data processor. Frequent sitting and walking.

JOB SUMMARY

Plans, organizes and directs all aspects of TRINITY HEALTH Pharmacy.
This includes adherence to all state and federal laws governing pharmacy. It also includes following all policies and procedures in accordance with established TRINITY HEALTH policy subject to administrative approval. This person must be familiar with professional and commercial phases of pharmacy. They should have a working knowledge of pharmaceutical purchasing, compounding, dispensing and control procedures. He/She should understand the role of the pharmacy department in the hospital, its interrelationships with other departments, and the functions of a department head.

ADDITIONAL INFORMATION

Position Responsibilities:

- Develop and implement job descriptions / performance reviews/ policies and procedures within the department.
- Responsible for all administrative duties such as hiring and terminating employees, payroll, budget, and record keeping functions.
- Maintain adequate staffing of the department
- Maintain cost-effective purchasing, inventory management and appropriate storage of Pharmaceutical supplies
- Oversee in-service education within the department. Primary emphasis
- Should be direction at age-specific training for all personnel.
- Maintain good working relationship with other departments within the Medical Center.
- Be responsible for the dissemination of drug information to the medical staff and nursing personnel.
- Maintain membership in appropriate state and/or national professional organizations.
- Maintain a record of CE as required by State Board of Pharmacy. In addition, participation in age-and disease-specific CE is also required.
- Perform all duties in accordance with all departmental and Trinity Health-wide policies and procedures.
- Participate / Direct Performance Improvement Activities
- Support all Clinical Areas with Medication Reconcilation, Narcotic / Diversion monitoring, Appropriate antibiotic usage, Core Measure Compliance, Pain Management
- Develop specific action plans to increase Patient Satisfaction Scores as related to Medication Management
- Maintain competencies of all staff
- Meet all JC standards; meet all State and Federal Regulatory standards
- Serve as a member of the Pharmacy and Therapeutics Committee
- Other duties as directed by management.

For more information, please contact:

Daniel Logan, COO
The PACE Group
dlogan@thepacegroup.com

Or visit the following websites:
The PACE Group: www.thepacegroup.com, **Trinity Healthcare**: www.trinityhealth.org