NoDak Pharmacy

Volume 19, No. 3, May 2006

Bob Treitline, recipient of the 2006 Bowl of Hygeia Award

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June 3
NDPSC Board Meeting in Bismarck

June 25 - 28
ASHP Meeting in Orlando

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To be announced

Dennis Johnson, RPh

> *"There are many ways of going forward, but only one way of standing still."*
>
> *Franklin D. Roosevelt*

Clearly, we have had enough experiences in the past couple years to acknowledge that the profession of pharmacy is living in an endless sea of change. Whether we perceive any of this as good or bad, pharmacists are being forced to make personal and professional choices in response to these changes. Some people resist change, which is human nature but not always in our best interest. Others tend to embrace change and look for ways to improve their pharmacy practice. Either is a legitimate response because it is your choice.

Part of the frustration with today's change is the fact that we gave away an important part of our practice many years ago, as did other healthcare providers – our information and our patient information. The entities that now control all the information now control us. We have little or nothing to say about decisions they make that affect us and our patients.

It doesn't matter if you are a hospital pharmacist, or in a long-term care facility or community pharmacy… we are in the same boat. A famous John F Kennedy phrase says it best, "a rising tide lifts all boats." We need to support one another for the betterment of all.

I believe we have a responsibility to improve our profession, to enhance our expertise and increase services directed at improving patient care. Just as important, we must fight in the political arena to gain back, or re-establish, the critical nature of our role as healthcare providers. Recognition of pharmacists as vital member of the healthcare team will lead to fair and equitable reimbursement for the care and services we provide in all practice settings.

At a recent meeting I attended, the CEO of a national pharmacy organization said that pharmacists have not done enough politically or professionally. Politically we have failed when major public policy decisions are made without having pharmacy involved. Professionally we have failed when we spend $1.70 to correct errors for every dollar spent to purchase medication. There is plenty of room for improvement, and we are the only ones who can change this.

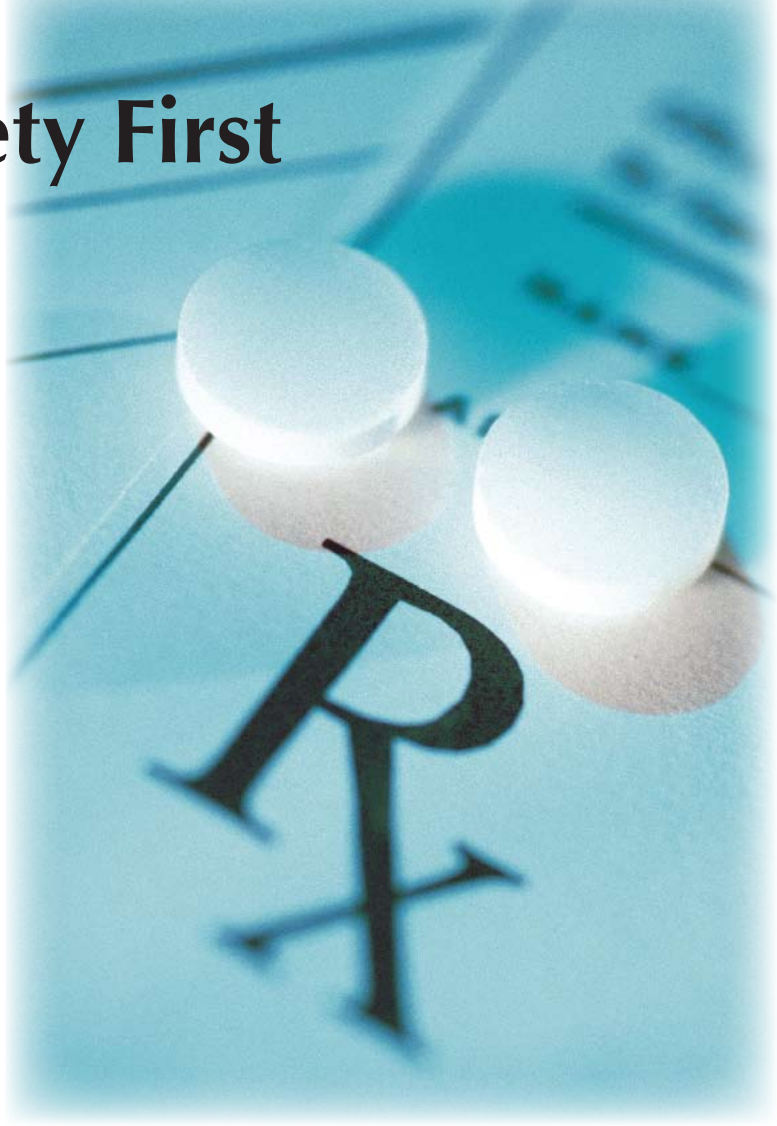
I look forward to coming year with a focus on improvements, and I believe NDPhA can help us make great strides.

Reports from the 2006 State Convention are available online at

www.nodakpharmacy.net

Putting Patient Safety First

Pharmacy Quality Commitment® Comes to North Dakota



Original copy written by:
Kate Puetz, Pharm.D., Director, Professional Programs
Iowa Pharmacy Association
Adapted by:
Lori Petoske and Stacey Christ

The following article has been adapted from articles shared with state pharmacy organizations by the Iowa Pharmacy Association via a grant from the National Council of State Pharmacy Association Executives (NCSPAE) and the winter, 2006 edition of the Washington Pharmacy Journal. This article follows the article entitled "Quality – The First Duty of Every Pharmacist," written by Kenneth Baker in the July/August 2005issue of JPSW.

Reports from the Institute of Medicine highlight the suboptimal level of quality in the American healthcare system.[1,2] Each year 44,000 to 98,000 people are killed as a result of preventable adverse medical events. Medication errors alone are estimated to cause 7,000 deaths annually in the United States. Because pharmacists are human, and humans do make mistakes, errors are a reality.

But the healthcare marketplace and new federal guidelines are looking to reduce those errors. In fact, language in Medicare Part D directs Prescription Drug Plan (PDP) sponsors to have in place "quality assurance measure and systems to reduce medication errors and adverse drug interactions and improve medication use."

The Patient Safety and Quality Improvement Act of 2005

In addition to the new state legislation, a federal law important to CQI was passed in July 2005. The Patient Safety and Quality Improvement Act of 2005 protects any information gathered by a certified patient safety organization for the purpose of improving patient safety from being admissible in criminal, civil, or administrative proceedings. In the past, pharmacists may have been hesitant to document quality related events occurring in their practice, afraid that they could be used against them for litigious or disciplinary purposes.

Pharmacy Quality Commitment®

Pharmacy Quality Commitment® (PQC) is a quality improvement program designed specifically for community pharmacies. PQC consists of: the Sentinel™ System and the Quality Manager™ System. The Sentinel System outlines a standard workflow with recommended processes and risk management techniques to be employed at each of the workflow stations. Peer Review Audit Forms are used to track every Quality Related Event (QRE), or any deviation from quality. A QRE can be either an error which reaches the patient or a near-miss which is discovered before reaching the patient. A near-miss is considered a 'success' and an opportunity for pharmacies to learn and make improvements. A few examples of QREs include: wrong drug, wrong strength, wrong directions, incorrect or omitted refills, use of easy-open caps without patient release, and confidentiality failures such as bag mix-ups with more than one patient's prescriptions.

The Sentinel System

The recommended workflow stations in the Sentinel System are: receiving the prescription, data entry, assembly of the prescription, professional prescription review and final check, and delivery with patient counseling. One final station is 'special care prescriptions' where prescriptions that require additional time are pulled out of the normal workflow. These prescriptions may require the

pharmacist or trained staff member to contact a prescriber or insurance company, special order an item, or compound a medication. Within the standard workflow, a pharmacy must have 'Best Practice' techniques in place. Each workflow station has a recommended list of at least ten 'Best Practice,' or risk-management techniques. Examples of the Sentinel System's Best Practice techniques include 'echo and verify' and the '2 second rule.' 'Echo and verify' is a risk-management technique for receiving a telephone prescription. The person taking the phoned-in prescription, after reducing it to writing on a prescription blank, reads back (echoes) each part of the prescription. When the caller 'verifies' what was read back is correct, the pharmacy staff member initials, dates, and places a 'V' (for verified) on the new prescription. The '2 second rule' is a risk-management technique for assembling the prescription. No prescription vial which contains medication should be unlabeled for more than 2 seconds. One can see how these techniques, when incorporated into a standard workflow, reduce the likelihood of errors. The workflow and risk-management techniques are an important part of the Sentinel System, but are not concrete. They can be modified to fit each practice environment.

The Quality Manager™

One of the tools provided with the Quality Manager™ is the Peer Review Audit form. This is a daily log on which every QRE is recorded. The information on this form includes: where the QRE was caught (e.g. pharmacist final check, patient discovery), QRE type (e.g. wrong drug, wrong directions), where the mistake was made, and medication(s) involved. Other information recorded is the date and time of each QRE, the pharmacist recording the QRE (in case a question arises later), and the total number of new and refill prescriptions for that date of service. The name(s) of who was involved in the QRE is NOT recorded. This creates a non-punitive environment, so that there is no blame associated with recording QREs.

Data collection onto the Peer Review Audit form takes roughly 30 seconds per QRE. At day's end, this information is entered online through PQC's website, which should take 1-2 minutes per 100 prescriptions filled. Once the

The Pharmacist's PERSPECTIVE

Several pharmacies across the state of North Dakota have had the opportunity to try the Pharmacy Quality Commitment program over the past year. Three pharmacists have offered their opinions concerning the program.

Jane Gere, RPh, Dakota Pharmacy, Bismarck

Jane Gere of Dakota Pharmacy found the PQC program to be very beneficial. Since she found the instructional manual rather repetitive, she was pleased with the training cards that came with the program. "With the time restraints that we now have in pharmacy it was somewhat frustrating to read a manual that was so repetitive, but the training cards were the whole program. They made the training process go much faster," she said.

Gere found the inputting process to be simple, and it was the part of the program that helped her find the most errors and near misses at Dakota Pharmacy. "We don't utilize the analysis tools as much as we could, but just from inputting the information I can see where our mistakes are happening and how we can fix them."

Megan Krueger, PharmD, Velva Drug, Velva

Megan Krueger at Velva Drug chose to modify the PQC program to better fit their pharmacy's needs. She added elements to help the program correlate with the way they were already doing things. "The PQC program helped us fine tune our workflow from data entry to counseling the patient; our process now flows smoother than before," she said.

Krueger gave the responsibility of inputting information to one of her pharmacy technicians. "We don't input information on a daily basis, but more so on a monthly basis, and it still only takes our technician about a half-an-hour to do it."

Teri Lutz, White Drug #61-T, Fargo

Teri Lutz has the responsibility of monitoring four telepharmacy sites – three in North Dakota and one in Minnesota. She uses the PQC program for each of the North Dakota telepharmacy sites. She found the online tools most beneficial because she was able to visually see the errors or near misses occurring at each site even though she couldn't physically be there to monitor them. "The website was able to show me which errors and near misses were most consistent, allowing us to zero in on where we can improve," she said.

Even though Lutz in inputting information for three sites, she finds it sufficient to input the information weekly. This process takes her approximately 20-30 minutes each time. "I definitely find the program to be helpful and would recommend it to other pharmacies."

Although Gere, Krueger and Lutz use the PQC program differently and for various reasons, they all find it useful in catching near misses and errors. They suggest implementing a continuous quality improvement program into the pharmacy workplace and would recommend the Pharmacy Quality Commitment program.

data is entered, the website offers Quality Management Tools to assist in analyzing each pharmacy's quality. These tools help pharmacists and pharmacy staff members evaluate the workflow, risk-management techniques, and trends which are occurring at their site. By performing quarterly analyses, pharmacists are able to learn from past failures of quality and improve quality in the future, ultimately increasing patient safety.

When implementing a CQI program, pharmacies must create an environment which makes quality the top priority. In this environment, staff must be willing and feel open to discussing all failures of quality. Reporting errors cannot lead to blame or be punitive, but instead must be seen as an opportunity to learn and improve for the future. When an error occurs and QREs are evaluated, no one asks, "Who is at fault?" but the question becomes, "What in our system allowed this error to occur?"

As a profession, pharmacy is continually looking for ways to improve patient safety and reduce medication errors. A quality improvement program is a valuable tool for all pharmacies, and the North Dakota Pharmacists Association (NDPhA) is working to make this program available to community pharmacies throughout North Dakota.

To request more information on the Pharmacy Quality Commitment® program, see ad on page ##; to purchase the Pharmacy Quality Commitment® program, contact the NDPhA at (701) 258-4922 or visit www.pqc.net

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1. Kohn LT, Corrigan JM, Donaldson MS, et al. To err is human: Building a safer health system. Institute of Medicine Committee on Quality of Healthcare in America. Washington, DC: National Academy Press; 2000.
2. Kohn LT, Corrigan JM, Donaldson MS, et al. Crossing the quality chasm: A new health system for the 21st century. Institute of Medicine Committee on Quality of Healthcare in America. Washington, DC: National Academy Press; 2001.

Pharmacy Students Tackle PQC

Ten NDSU pharmacy students attended the 121st Annual NDPhA Convention with the purpose of promoting the Pharmacy Quality Commitment program. "We were there to assist NDPhA in getting information out to pharmacists about the program and to assist with signing up," said Nicole Cariveau, P2 of Grand Forks, ND. Each student was thoroughly trained in the PQC program and Cariveau assumed a leadership role as the "expert" among the group.

What is your overall opinion of the PQC program?

"I think it's good; it is a well thought-out, easy to use system to improve the quality of pharmacy."

- Nicole Peters, P2, Dickinson, ND

"The nice thing about the system is that it is web based and there is nothing to install, which allows the information to be entered from anywhere."

- Justin Heiser, P3, Dickinson, ND

"This program is a systematic, team-oriented application of the professional responsibility that pharmacists, students and technicians strive for daily."

- Heidi Fritz, P2, Fargo, ND

"I think this is a simple to use system which provides the data necessary to improve patient safety. It is also an affordable option for pharmacies looking to comply with the new Medicare Part D requirements."

- Jeff Shorten, P3, Fargo, ND

"I think the program would be a great addition to any pharmacy. It seems easy to use and has numerous benefits that will help to improve quality in pharmacies."

- Katey Briski, P2, Hibbing, MN

How do you feel you may benefit as a student learning the PQC program?

"I think it will help me be a better pharmacist as far as not making as many mistakes and learning how to fix error problems when they do occur."

- Sara Kay Hermans, P1, Milbank, SD

"Exposure to this type of program helps me realize that proper steps can be taken to minimize pharmacy errors."

- Amanda Meyer, P2, Pierz, MN

"Learning about this program prior to graduation is a good opportunity to realize that there are vital approaches to catching mistakes that lie outside of the human process."

- Coralyn Lennberg, P2, Walker, MN

"Learning about this program as a student gives us ideas of what we can do when we're out in practice to optimize the quality of pharmacies and to maximize patient care."

- Nicole A. Cariveau, P2, Grand Forks, ND

"As a student it's great to get exposure to this type of program and learn what is being done to improve pharmacy practice."

- Lance LeClair, P1, Fargo, ND

A Penny For Your Thoughts...
What Is The Value Of Pharmacy Services?

Recently members of Congress received pill bottles containing only a penny and affixed with a cranky note from pharmacists. The label read: "Thanks to you, this penny is about all my pharmacy is worth now."

This grassroots advocacy effort was not a prank. It was a coordinated protest organized by a little-known organization called the Association of Community Pharmacists Congressional Network (ACPCN) - an offshoot of the North Carolina pharmacy association. The pill-bottle campaign is part of the organization's effort to help each member of Congress hear from his constituents.

Messages on pill bottles were sent earlier to President Bush following his Feb.8 statement in defense of Medicaid cuts "...it's not immoral to make sure that prescription-drug pharmacists don't overcharge the (Medicaid) system." That remarked sparked comments on pill bottles such as, "Mr. President, I hope you buy your drugs from Canada, because you don't deserve service from any pharmacist in the United States. You stabbed us right through the back, and straight through the heart. I can't believe that you would knowingly put me out of business. I am ashamed of having voted for you." And, "Your legacy will be the downfall of my profession, and your country's health."

Pharmacists say the Medicare drug benefit shortchanges them and has forced them to bear the brunt of the problems it endured during its rocky first months. If that wasn't enough, community pharmacists are now expected to weather drastic reductions in their payments from Medicaid, beginning January 2007.

Pharmacists are hopping mad.

ACPCN says that its members lose money on the prescriptions they fill for Medicare drug-benefit enrollees. Pharmacists are offended that they are treated simply as retailers and are not compensated for their services as healthcare providers.

Pharmacists also feel unfairly targeted for federal spending reductions. The cost of the product is what's going up... the cost to dispense medications is not the problem.

Rural pharmacies are the most vulnerable and are sometimes the only places within reach of local patients. But lawmakers do not like being credited with increasing patient risk by limiting access, which is what the pharmacists contend will happen.

The deficit reduction bill will cost pharmacy about $6 billion in Medicaid payments over the next five years, yet President Bush wants more. This debate rages in Washington, and Republicans are concerned about alienating blocks of influential voters in an election year... millions of Medicare beneficiaries.

(Excerpts from "Druggists Prepare Bad Medicine for Lawmakers" March 30, 2006, by Jeffrey Young)

Update on More Medicaid Cuts

Not long after US Health & Human Services Secretary Mike Leavitt praised our nation's pharmacists for their "heroic" efforts in shouldering the burden of implementing the new Medicare Part D program, Medicaid reimbursement rates to these same community pharmacies went on the chopping block. North Dakota community pharmacies, still reeling from the aftershock of Part D coupled with drastic cuts from BCBS of ND are uncertain of their future, and are concerned for their patients.

It's not rocket science! If pharmacies are reimbursed less than their cost they will be forced to close. The current trend to attack the amount paid to pharmacies in the name of reducing cost to consumers is NOT the answer. The price paid to drug manufacturers is the root problem, and is NOT addressed in any attempts to lower costs.

The Deficit Reduction Act (DRA) of 2005 eliminates the traditional formula to determine payment to pharmacies for generic drugs (using MAC) and replaces it with Average Manufacturers Price (AMP) plus a dispensing fee. AMP is currently defined as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade. However, the new law does not clarify that manufacturers should also deduct sales to mail order and nursing homes in the calculation of AMP. If manufacturers continue to include these sales in the calculation of AMP it will push the base price lower than what retail community pharmacies can actually purchase the product for.

Over the next nine months, the definition for this new pricing formula will be finalized by the Centers for Medicare and Medicaid (CMS). The results will affect how each state deals with pharmacy reimbursements for their Medicaid patients. And those reimbursements will, ultimately, determine patient access to care.

A press release received April 3 from CMS announced a new CMS strategy called the "Roadmap to Medicaid Reform", which Secretary Leavitt sent to the nation's Governors. The "Roadmap" outlines ways states can use the new tools provided by the Deficit Reduction Act (DRA) in combination with options under titles XIX and XXI and other programs, as a strategy to align the Medicaid Program with today's health care environment to:

- Expand access to affordable mainstream coverage
- Promote personal responsibility for health and accessing health care
- Improve quality and coordination of care

In Larry Kocot's weekly update for Part D (4-3-06), he draws attention to one section of the new strategy saying "pharmacists should pay particularly close attention to the last section of this paper on improving quality and coordination of care.

Kocot references the following text:

States retain the overall authority for pharmacy reimbursement and may target reimbursement to providers, for example, through higher dispensing fees for independent pharmacies, pharmacies serving a large share of low-income beneficiaries, or pharmacies in rural areas to assure access. States can also adjust payments to provide more financial support to pharmacists that improve quality and reduce costs of drug coverage and chronic disease management...

Herein lies our greatest opportunity!

Our greatest opportunity is to partner with our state's Human Services Department and develop a plan that will provide patient access to pharmacy services, improve patient outcomes, and lower overall healthcare costs.

In the middle of all the frustration from Part D and threats from Medicaid cuts, there is an opportunity for us to partner with our state's Human Services Department and proactively pursue reasonable reimbursement. Our responsibility clearly demands persistence and fairness as we advocate on behalf of a public policy that ensures patient access to quality pharmacy services all across North Dakota, improved patient outcomes, and lower overall healthcare costs.

New "Pharmacist Activist" Free Monthly Publication

by Daniel A. Hussar, Editor

The profession of pharmacy is facing many threatening issues. We need many more activists to address these issues and it is this recognition that has motivated me to develop this publication. Each monthly issue will include an editorial on a topic of importance to our profession. The opinions provided are intended to be thought-provoking and a stimulus for action. Some will disagree with certain opinions expressed, and that is fine.

The second regular feature in each issue will be a New Drug Review. This information is intended to enable pharmacists to recognize the relative importance of the drug and effectively use the information in their interactions with patients and other healthcare professionals. A primary focus is to compare the new drug, when possible, with older drugs that are used for the same indications for which the new one is approved.

This publication is provided to pharmacists for free. Support is expected from sources with an interest in providing objective and unbiased information on new drugs and important issues facing the pharmacy profession. Financial support will not be accepted from anyone perceived as wishing to influence the content of the publication. My services as editor is a part-time responsibility, and I continue in my full-time faculty position at the Philadelphia College of Pharmacy at the University of the Sciences in Philadelphia.

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The inaugural issue of the "Pharmacist Activist" includes a stimulating editorial on the critical importance of advocacy by pharmacists to address current and future legislation that will be enabling or restrictive to the profession. Hussar refers to the profession as the "Sleeping Giant" because most pharmacists and pharmacies have done little or nothing to try to influence the outcomes of federal and state laws, even though they could negatively impact both pharmacies and patients. He sites the "Giant" as the latent potential to persuade patients, communities, legislatures and Congress through grassroots efforts.

AWAKE THE SLEEPING GIANT!

Go to www.pharmacistactivist.com for your free subscription

Joel Aukes, RPh
President, NDSHP

Over the next year the face of North Dakota's pharmacy organizations may undergo significant change, including the opportunity to unite all pharmacy organizations under one "umbrella". The other exciting change is the increase of our NDSHP membership to 384, which will hopefully provide NDSHP with extensive professional leadership.

The duty of evaluating and developing a plan for the consolidation of all of North Dakota's pharmacy organizations was given to the NDPhA Advisory Council, which was formed last spring. The council is comprised of executive committee members from the Boards of NDSHP, NDPhA, NDPSC, NAPT as well as representatives from the State Board, the NDSU College of Pharmacy and the Pharmacy Tech Program at NDSCS. The new structure will allow us to have a more unified voice when addressing issues at both a state and national level. Members of such an organization will have the option of joining academies or sub-groups representing their particular interests within pharmacy. There are still some details to be fully defined such as funding of essential functions and final configuration of the NDPhA Board to provide representations for all groups including technicians. I feel confident that we can successfully resolve these issues and take advantage of the possibilities. To achieve this goal we must avoid getting distracted and stay focused on advancement of the profession and the benefits of producing a unified voice. My hope is that through communication and mutual respect we can formulate "win-win" solutions, which will move the pharmacy profession forward in North Dakota.

As President of NDSHP I need to hear the ideas and concerns of all of our 384 members in order to best represent NDSHP as an organization. In the up coming months NDSHP Board will be mailing a survey to all members to solicit input on current and upcoming issues. I urge you to take a couple of minutes to complete the survey so I have a true indication of the desires of our members. I would also ask our membership to become involved at the district or state level -- we are always looking for new faces to serve as leaders for the profession. Involvement allows you to influence the changes you most want to see for our profession.

Swearing in ceremony of 2006 officers for NDSHP: (l to r) Wendy Baisch, Joel Aukes, Melanie Cairns.

2006 The Battle Continues

By Josh Dozak, NDSU Pharm. D. student
NDPhA Intern

As I have spent the past five weeks interning at the NDPhA office in Bismarck, I have had the opportunity to speak with numerous pharmacists, legislators, and consumers about the issues facing pharmacies and pharmacists today. Going into the year, each and every one of us involved in the profession knew that we would be facing a battle like none that we have ever faced before, simply due to the fact that never in history have so many people joined into an insurance plan at one time as what happened with the implementation of Medicare Part D. What we weren't expecting were the prolonged problems that we have been faced with. Continually we are told that things are getting better, but they sure have a long way to go before all will be well.

One of the biggest issues that I have heard about while talking to both pharmacists and consumers alike is the overabundance of prior authorizations required. The need to fill out and request prior authorizations is overburdening both pharmacy staff and physicians, and is preventing some patients from receiving the medications that they so desperately need. In one rural community, the physician and his staff have been so overwhelmed with the constant need to fill out PA's that they have decided that they will no longer take the time to do them. It is truly sad that we have reached the point that insurance company demands are actually preventing us from doing the job that we are trained to do, treating patients. It is very tough to help patients and look out for their best interest when you are elbow deep in paperwork with no end in sight.

The next major hurdle that we are now faced with is the first round of formulary changes. Many pharmacists that I have talked to have said that the chaos has already begun. Medications that were covered when the patient signed up for the plan are no longer on the formulary, and the pharmacist is stuck trying to find a solution to this problem, whether it be contacting the physician to change the medication or to begin the paperwork necessary for an override. The startling fact of the matter is that what works today, may not in a couple months when the formulary changes yet again.

May 15th is just around the corner and many seniors have yet to sign up for a Part D plan. To avoid another onslaught like we saw in January, we should be reminding eligible seniors of this upcoming deadline so that at least some of them can get signed up earlier as to avoid the madness that could possibly occur when the next wave of patients sign up.

As if Medicare Part D wasn't enough to make life interesting for pharmacists, the current reimbursement rates offered by Prime Therapeutics are making keeping the pharmacy doors open very difficult. One of the major complaints heard from by pharmacists by consumers is that 90 day supplies are no longer available under the new Prime Therapeutics plans. The truth behind the matter is that many pharmacies were not even given the option to sign up for a 90 day contract, and those that were offered the contract found that the reimbursement offered was less than their actual acquisition cost of the medications. Filling prescriptions under those contracts would drive many pharmacies right out of business.

2006 surely has been a challenge thus far. The battle is certainly not over, though some progress has been made. Medicare Part D payments are finally being received by pharmacies and help desk service has been improving. As professionals we must keep ourselves informed on the issues at hand and voice our concerns to those individuals in office that can help us fight this battle.

Continuing Education for Pharmacists

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Advances in Cancer Chemotherapy 2006: Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma: Nelarabine

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Goals. The goals of this lesson are to provide background information on acute lymphoblastic leukemia and lymphoblastic lymphoma, and discuss their treatment with a newly-approved chemotherapeutic regimen.

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

1. describe the etiology and incidence of T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma;

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2. identify the pharmacologic classification and therapeutic considerations for nelarabine; and
3. select from a list, the indications, mechanisms of action, adverse effects and toxicities, drug interactions, and benefits and limitations of nelarabine.

FDA has approved a new-molecular entity drug for use in treatment of two rare, but very aggressive malignancies: T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma. Before its approval, there was no standard of treatment for these patients and their prognosis was poor. Nelarabine (Arranon®), thus, became the first drug approved to treat this limited population of patients.

Arranon was cleared under FDA's accelerated approval program, which permits the agency to approve products for cancer based on early evidence of effectiveness. Evidence consisted of complete disappearance of cancer cells in some patients. Arranon also received Orphan Drug designation, which is granted to products that treat rare diseases (i.e., those that affect fewer than 200,000 people in the United States). The Orphan Drug Act provides the sponsor with seven years of exclusive U.S. marketing.

Progress in Cancer Control

Prevention and treatment of cancer are among the nation's most urgent health concerns. Cancer remains the primary cause of death in the United States, and the disease that many people fear most. More than 1.3 million new cancer cases will be diagnosed in the United States this year, and more than a half million people will die from the direct or indirect effects of cancer or its complications. At the same time, there is good news. Nearly 10 million people in the United States today are living with a cancer history. Of this group, 1.5 million were diagnosed more than 20 years ago. This means that cancer victims are living longer today than ever before. Their quality of life is also better than at any other time in history. More than two-thirds of people with cancer can now expect to live five or more years; for children with cancer, the five-year survival now exceeds 75 percent. Cancer chemotherapy and auxiliary drug treatments are definitely improving mortality, morbidity, and overall quality of life.

Leukemia

Normal formation and development of blood cells (hematopoiesis) is a closely regulated symphony of biological events that lead to proliferation and differentiation of hematopoietic stem cells that develop into mature peripheral blood cells. Acute leukemia results when a malignant event (or events) occurs during an early stage in the hematopoietic process. Instead of proliferating and differentiating normally, the af-

fected cells continue to proliferate but in an uncontrolled fashion. As a result, immature lymphoid cells (in acute lymphoid leukemia) or myeloid cells (in acute myeloid leukemia) called *blasts*, that normally compose <5 percent of cells manufactured by the bone marrow, accumulate rapidly, and progressively replace the normal cells within bone marrow. The outcome is diminished production of normal erythrocytes (red blood cells), leukocytes (white blood cells), and thrombocytes (platelets). This, in turn, leads to the familiar clinical complications of leukemia: anemia, infection, and hemorrhage. With time, the leukemic blasts enter the bloodstream and eventually invade normal organs; they concentrate in the lymph nodes, spleen, liver, and other vital tissues. Left untreated, acute leukemia is rapidly fatal with most patients dying within several months to a year of diagnosis.

Leukemia's impact is magnified greatly because of the young age of some of its patients. To illustrate, acute lymphoblastic leukemia (ALL) affects children, accounting for approximately one-fourth of cancer diagnoses among people younger than 15 years of age, and is the second leading cause of death in children in this age group. Caucasian children are affected more frequently than African-American children. There is little difference in incidence rates by gender among children. In older age groups, ALL occurs more commonly in males. Its occurrence peaks between ages two and 10 years. It then undergoes a second, more gradual increase in frequency later in life. An estimated 2400 children and 1200 adults are diagnosed with ALL in the United States each year. Approximately 700 of these victims have T-cell-ALL (T-ALL), explained subsequently.

Classification. The leukemias are classified as acute or chronic. Cancerous cells reproduce rapidly and accumulate in both forms, crowding out normal white blood cells. The primary difference between the two forms is that, with *acute* leukemia, bone marrow cells do not reach maturity and immature cells accumulate. In *chronic* leukemia, the bone marrow cells appear mature but are abnormal in function, and live longer than normal white cells.

ALL can be divided into several forms based on cell surface antigen expression. The five most common forms are early pre-B-cell, pre-B-cell, B-cell, T-cell, and null-cell ALL. T-ALL is less common with increasing patient age, being truly rare in patients exceeding 60 years of age.

Non-Hodgkin's Lymphoma

Non-Hodgkin's lymphomas are cancers that affect the lymphatic system, particularly lymphocytes. Lymphoblastic lymphoma (LBL) is an especially aggressive type of non-Hodgkin's lymphoma that occurs more often in children than adults. Patients with predominantly nodal disease, who have minimal or no involvement of the bone marrow, are frequently classified as having *lymphoblastic lymphoma*, whereas persons with more than 25 percent of neoplastic cells in the marrow are described as having *lymphoblastic leukemia*. These distinctions are arbitrary and, as a rule, reflect the stage of disease rather than different diagnoses. The pathological basis for this is not understood. Of an estimated 50,000 patients diagnosed with non-Hodgkin's lymphoma each year, approximately 900 have T-cell LBL (T-LBL).

There is significant biological and clinical overlap between cancers diagnosed as acute lymphoblastic leukemia and lymphoblastic lymphoma. Some patients have predominantly lymphomatous involvement (e.g., presence of a mediastinal [area between the two lungs] mass or other solid lesion). Most, however, have or later develop marrow involvement. In a similar fashion, patients who present with leukemia may have or develop extramedullary tumors. Both lymphoblastic leukemia and lymphoblastic lymphoma can, therefore, be considered the same disease with different clinical characteristics.

Clinical Manifestations

Acute Lymphoblastic Leukemia. At the time of diagnosis, most patients with ALL have symptoms of anemia, expressed by fatigue, pallor (paleness), and headache. Predisposed patients may experience angina or heart failure. Thrombocytopenia (decreased platelets) is often present, with approximately one-third of patients experiencing clinically evident bleeding, usually in the form of petechiae (small, pinpoint, nonraised blood spots on the skin's surface), ecchymoses (extravasation of blood under the skin), or bleeding from the gums or nose. Granulocytopenia (deficiency of granulocytes) will usually be noted and, as a result, patients with ALL will have significant, perhaps life-threatening, infections that are usually bacterial in origin.

Leukemic cells that invade normal organs can cause enlargement of lymph nodes, liver, and spleen. Bone pain probably results from leukemic cell infiltration of the periosteum (thick, fibrous membrane covering bone) or expansion of the medullary cavity (narrow cavity in the shaft of long bones), and is a common symptom, especially in children with ALL. Leukemic cells that infiltrate the skin can result in a nonpruritic rash, called *leukemia cutis*. Leukemic cells that invade the brain's pia-arachnoid meninges (leptomeninges) can cause *leukemic meningitis* leading to headache and nausea. With disease progression, seizures may occur. Fewer than 5 percent of patients experience CNS involvement at the time of diagnosis; however, the CNS is a common site of relapse. Testicular involvement is also seen in males, and the testicles are a frequent site of relapse.

Lymphoblastic Lymphoma. Lymphadenopathy (disease of the lymph glands) is the most common symptom at the time of diagnosis.

Patients may notice swelling and tenderness in the groin, neck and underarm area. Lymph nodes containing lymphomatous cells generally are firm and nontender, and not associated with infection. In some patients, lymphadenopathy in sites such as the mediastinum or retroperitoneum (area behind the peritoneum) provokes symptoms such as pain in the chest, abdomen or back, and cough that cause them to seek a physician's advice. Spinal cord compression, and symptoms of renal insufficiency associated with ureteral compression are characteristic.

Non-Hodgkin's lymphomas may cause nonspecific systemic symptoms. The most common ones include fever, night sweats, and unexplained weight loss. Other less characteristic symptoms are fatigue and itching.

Any organ system can be affected in non-Hodgkin's lymphoma, and symptoms resulting from malfunction of that system may lead to the diagnosis. For example, skin lesions occur with cutaneous lymphomas, neurologic symptoms with primary brain lymphoma, shortness of breath with pulmonary lymphoma, epigastric pain and vomiting with gastric lymphoma, and bowel obstruction with small bowel lymphoma. Lymphoma that involves the bone marrow can cause extensive marrow failure that results in infection, bleeding, and anemia, as noted with leukemia. Non-Hodgkin's lymphomas can also result in a variety of immunologic abnormalities; for example, symptoms of autoimmune hemolytic anemia and/or immune thrombocytopenia may be the patient's noticeable manifestation.

Arranon (nelarabine)

Nelarabine is a T-cell-selective cytotoxic deoxyguanosine prodrug that is demethylated by adenosine deaminase into ara-G, then monophosphorylated by deoxyguanosine kinase and deoxycytidine kinase, and subsequently converted to the active 5'-triphosphate, ara-GTP. Ara-GTP accumulates in leukemic blasts as a fraudulent nucleoside triphosphate where it competes with the native substrate for incorporation into DNA by DNA polymerase. This disrupts DNA synthesis, thus inducing cellular apoptosis (programmed cell death). Additional cytotoxic actions, including inhibition of RNA synthesis and ribonucleotide reductase, may contribute to the drug's overall activity, but these actions are not fully understood.

Clinical Trials. Arranon approval was recommended following completion of two clinical trials designed to investigate the drug in pediatric and adult patients. Both trials were multicenter, phase II, single-arm (i.e., test drug only; no placebo or comparator drug controls) by design. Every patient had relapsed or refractory T-ALL or T-LBL. Most patients in both groups had T-ALL and most were white males. At the time of writing this lesson, Phase III studies were underway to evaluate long-term efficacy and safety.

One trial enrolled 84 pediatric patients, aged 21 years and younger at the time of initial diagnosis. Thirty-one subjects had received one prior chemotherapy regimen, and 39 had received two or more. The drug was administered at the recommended dose of 650 mg/m^2 via one-hour infusion for five consecutive days in 21-day treatment cycles. Thirteen percent of subjects achieved complete disease response (bone marrow blast counts $\leq$5 percent) and full recovery of peripheral blood counts. Another 10 percent achieved complete disease response without full hematological recovery. Response to treatment persisted 3.3 to 9.3 weeks. The median overall survival was 13.1 weeks.

In another study, 39 adult patients aged 16-65 years (mean 34 years) were enrolled. Twenty-eight patients in this group had received at least two courses of chemotherapy. Arranon achieved a complete response and hematological recovery in 18 percent of this cohort. The duration of complete response was four to $\geq$195 weeks, with a median overall survival of 20.6 weeks. Response duration assessment was complicated by the fact that patients in Arranon-induced complete remission may have received additional therapy, including stem-cell transplantation, prior to disease progression or recovery of normal peripheral blood cell counts.

Adverse Effects and Warnings. Arranon was evaluated for safety in phase I and phase II clinical trials. The safety profile is based on data from 103 adults and 84 children.

The most common adverse events in children included hematologic disorders (anemia, leukopenia, neutropenia, and thrombocytopenia). The most frequent non-hematologic adverse events reported were headache, vomiting, increased transaminase and bilirubin levels, and decreased potassium and albumin levels.

The most common adverse events in adults were fatigue; gastrointestinal disorders (nausea, diarrhea, vomiting, and constipation); hematologic disorders (anemia, neutropenia, and thrombocytopenia); respiratory disorders (cough and dyspnea); nervous system disorders (somnolence and dizziness); and fever. Blurred vision was reported in 4 percent of adult patients.

Arranon is a potent chemotherapeutic drug that has potentially significant toxic side effects. The product's label contains a "boxed warning" of its potential to cause neurotoxicity, and neurotoxicity is the dose-limiting outcome. Common signs and symptoms of neurotoxicity include ataxia (loss of muscle coordination), confusion, convulsions, drowsiness, and tingling and/or numbness in the fingers and toes. Full recovery following severe neurologic toxicity may not occur with cessation of therapy. Patients treated previously or concurrently

Table 1
Patient Information for Arranon

- The manufacturer supplies a patient information brochure for Arranon. Be sure to request one and ask your doctor or pharmacist if you have questions.
- Tell your doctor about all health conditions you (or your child) have, including nervous system or kidney problems, before receiving Arranon therapy.
- Tell your doctor about all prescription or nonprescription medicines you (or your child) take, including vitamin/mineral supplements and herbal remedies.
- Tell your doctor right away if you (or your child) develop fever or signs of infection while receiving Arranon. Also tell your doctor right away if you (or your child) are more tired than usual, pale, or have trouble breathing.
- Tell your doctor right away if you (or your child) bruise easily or have any unusual bleeding.
- This drug may cause serious side effects including extreme sleepiness; seizures; coma; numbness and tingling in the hands, fingers, feet, or toes; and weakness and paralysis. Call your doctor at once if you (or your child) have these symptoms, are unsteady or experience increased tripping while walking, feel weak when getting out of a chair or walking up stairs, or have problems with fine motor skills such as buttoning clothes.
- Do not operate dangerous machines or drive while receiving Arranon.
- You or your child should not receive vaccines made with live germs while receiving Arranon.
- Women: Tell your doctor if you become pregnant or are expecting to become pregnant, or are breastfeeding.

with intrathecal chemotherapy or previously with craniospinal irradiation may be at increased risk for neurologic damage.

Drug Interactions. Arranon and ara-G have been shown to not significantly inhibit the activities of the human hepatic cytochrome P450 isoenzymes 1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6, or 3A4. Fludarabine (Fludara®) administered by infusion does not affect the pharmacokinetics of Arranon, ara-G, or ara-GTP.

Indications and Uses. Arranon is indicated for treatment of patients with T-ALL and T-LBL whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. This use is based on the induction of complete responses. The term *complete response* (i.e., *complete remission*) is defined as the disappearance of all signs of cancer in response to treatment. Studies to confirm increased survival or other benefit from drug treatment have not been conducted.

Dosage, Administration, and Availability. The recommended pediatric dose is 650 mg/m^2 administered intravenously over one hour daily for five consecutive days, repeated every 21 days. The adult dose is 1,500 mg/m^2 administered intravenously over two hours on days 1, 3, and 5, and repeated every 21 days. Patient information for Arranon is summarized in Table 1.

The appropriate dose of Arranon should be transferred into polyvinylchloride (PVC) infusion bags or glass containers and administered undiluted. The drug is stable in PVC bags and glass containers for up to eight hours at 30° C. The recommended duration of treatment has not been established. During clinical trials, treatment was generally continued until there was evidence of disease progression or unacceptable toxicity, the patient became a candidate for bone marrow transplantation, or the patient no longer derived benefit from treatment. Appropriate measures (e.g., hydration, urine alkalinization, and prophylaxis with allopurinol) must be instituted to prevent hyperuricemia or tumor lysis syndrome.

Patients with severe renal impairment (CL_{CR} <30 mg/dL) or severe hepatic impairment (bilirubin >3.0 mg/dL) should be monitored closely for toxicity when treated with Arranon.

Immunocompromised patients should not receive vaccines containing live microbials. Because Arranon is a cytotoxic agent, proper aseptic technique should be used during handling and preparation. Wearing rubber gloves and other protective clothing to prevent skin contact is recommended.

Arranon is supplied by GlaxoSmithKline as a clear, colorless, sterile solution designed for intravenous infusion. The solution contains 5 mg of nelarabine per mL.

Summary and Conclusions

T-ALL and T-LBL are aggressive malignancies that have high mortality rates in patients who do not receive adequate treatment. Nelarabine is a prodrug of ara-G that, intracellularly, is converted to active ara-GTP, which has activity in the treatment of T-cell hematologic neoplasms. Although treatment outcome is modest at best, nelarabine remains the only proven option at present to treat T-ALL and T-LBL.

Continuing Education Quiz

Advances in Cancer Chemotherapy 2006: Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma: Nelarabine

1. All of the following statements about Arranon are true EXCEPT:
   a. it is approved for use in the treatment of T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma.
   b. it was cleared under FDA's accelerated approval program.
   c. it received Orphan Drug designation.
   d. its sponsor has 14 years of exclusive U.S. marketing.
2. The correct term defining the formation and development of blood cells is:
   a. hematocephalus. c. hematopoiesis.
   b. hematomyelitis. d. hemostasis.
3. The correct term defining immature lymphoid cells in acute lymphoid leukemia is:
   a. blasts. c. clasts.
   b. chromocytes. d. basophils.
4. The primary differentiation between acute and chronic forms of leukemia is that with the chronic form, bone marrow cells:
   a. do not reach maturity and immature cells accumulate.
   b. appear mature, but are abnormal in function.
5. The correct term defining clinically evident bleeding, in the form of small, pinpoint, nonraised blood spots on the skin's surface is:
   a. angioedema. c. hematomas.
   b. ecchymoses. d. petechiae.
6. Lymph nodes containing lymphomatous cells generally are characterized by all of the following EXCEPT:
   a. they are firm.
   b. they are infected.
   c. they are nontender.
7. Nelarabine is a T-cell-selective cytotoxic prodrug of:
   a. deoxyadenine. c. deoxyguanosine.
   b. deoxycytosine. d. deoxythymidine.
8. Which of the following is NOT included in the most common hematologic adverse events seen in children receiving Arranon?
   a. Eosinopenia c. Neutropenia
   b. Leukopenia d. Thrombocytopenia
9. Patients receiving Arranon should be advised to tell their doctor right away if any of the following occur EXCEPT:
   a. altered taste.
   b. being more tired than usual.
   c. trouble breathing.
10. All of the following statements about Arranon are true in pediatric dosing EXCEPT:
    a. the recommended dose is 650 mg/m2.
    b. it is to be administered daily for five days.
    c. the dosage regimen is to be repeated every 21 days.
    d. it must be further diluted before it isadministered.

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College of Pharmacy
North Dakota State University
Sudro Hall, Room 123
Fargo, ND 58105

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Name _____

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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.

COURSE EVALUATION

Evaluation Must Be Completed To Obtain Credit

How much time did this lesson require? _____

Today's Date_____

EXPIRATION DATE: 2-15-09

Learning objectives on first page were addressed.

	1 Disagree - 5 Agree
Objective 1	1 2 3 4 5
Objective 2	1 2 3 4 5
Objective 3	1 2 3 4 5
Material was well organized and clear.	1 2 3 4 5
Content sufficiently covered the topic.	1 2 3 4 5
Material was non-commercial in nature.	1 2 3 4 5

Answer Sheet:

1. a b c d	6. a b c d
2. a b c d	7. a b c d
3. a b c d	8. a b c d
4. a b c d	9. a b c d
5. a b c d	10. a b c d

CMS' McClellan Announces Pharmacy Quality Alliance New Pharmacy Payment Models Possible Based on Patient Outcomes

Mark B. McClellan, MD, PhD, administrator of the Centers for Medicare & Medicaid Services (CMS), has announced the formation of the Pharmacy Quality Alliance (PQA), an unprecedented collaborative effort among the pharmacy community, health plans, government, employers, physicians, and consumer groups aimed at improving health care quality. The announcement came during a press conference on April 19, attended by PQA founding members including the National Community Pharmacists Association (NCPA), the National Association of Chain Drug Stores, America's Health Insurance Plans, and CMS.

McClellan said that pharmacists already had demonstrated the great value they provide in the implementation of the new Medicare Part D prescription drug benefit that went into effect on Jan. 1.

"[Pharmacists] have also shown they can add much more-helping people find lower cost drugs like generics, helping people with multiple illnesses understand how to use their medications, improving compliance," McClellan said. "All of these things can improve quality of care and reduce overall health care costs. This helps us get to a health care system that provides the right care for every person every time."

While the primary goal of PQA will be to develop strategies to define and measure pharmacy performance, McClellan also said CMS expects the efforts of PQA could lead to new pharmacy payment models for optimizing patient health outcomes. He said CMS is very interested in supporting the testing and development of such models.

McClellan said pharmacists have more to offer to improve quality and reduce costs in our overall health care system, but that may require changes in the way pharmacy care is financed and delivered. This Alliance could represent a paradigm shift in pharmacy - the prospect of bringing together the forces of these diverse groups to improve pharmacy care and patient outcomes is staggering.

North Dakota community pharmacies can get involved in this quality movement by using the Pharmacy Quality Commitment Program in their daily practice. See details on PQC in the feature article of this issue of the Nodak Journal, and get more information in the advertisement below.

Contracting Alert

by David M. Heckman, R.Ph.
PAAS National®, Inc.

A new third-party contract arrives in the mail. You take a quick look at the AWP discount and dispensing fees to decide whether to accept it or not. But there is much more to evaluating a contract than just looking at the reimbursement rate. What follows are some important points to remember before you sign a contract with any PBM or third party.

- **Draw your "line in the sand."** You need to know your cost of dispensing and what additional transaction and administrative fees you will be charged so you can accurately predict whether or not you will make a profit.
- **Be wary of contracts that are not pharmacy specific.** Some third parties will offer you the same "general" contract they offer to non-pharmacy providers. These contracts may contain language that is inappropriate for a pharmacy provider agreement.
- **Be alert for contract wording that allows the third party to retroactively determine payment.** Medical necessity, appropriateness of service, or whether an alternative service would have been less expensive are things that should be determined at the time a claim is adjudicated. Some plans will say they have the sole discretion to deduct for services they decide were paid incorrectly.
- **Watch for wording that sets a higher standard than that required by state or federal law.** If a third party wants you to conform to a higher standard, they should compensate you for doing so.
- **Avoid contracts that require you perform extra duties without compensation.** Some third parties expect you to expend time and effort performing medical management and marketing activities without paying you for your time.
- **Be wary of contracts that require you to monitor multiple sources to keep up to date regarding policies and procedures.** The pharmacy manual, printed newsletters, and web based information centers may have to be regularly referred to in order for you to comply with plan requirements.

PAAS National® assists our members in understanding and developing negotiating strategies for third-party contracts. For information on joining PAAS please call 1-888-870-7227.

North Dakota State Science & Engineering Fair

The North Dakota State Science and Engineering Fair was held Friday, April 7, 2006 at the North Dakota State University Bison Sports Arena, sponsored by North Dakota State University. There were 234 students from all over the state of North Dakota in attendance. NDPhA was one of the many organizations that took part in the sponsorship of awards for these very deserving students. The next step for the senior division participants will be the 57th International Science and Engineering Fair in Indianapolis, Indiana, May 7 - 13. Eighteen North Dakota students will present their research projects along with 1400 other high school students from all 50 states and 18 foreign countries.

Outstanding Projects In The Junior Division Related Pharmacology: **Angel Kordovsky, Hankinson Junior High School**

Outstanding Projects In The Senior Division Related Pharmacology: **Kali Shephard, Valley High School, Hoople, ND**

And The Law

By Dena Kroska and
Karen E. Peterson, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

Collaborative Practice: Risks And Rewards

Increasingly, pharmacists are becoming more involved as decision-makers in patient care through collaborative practice agreements with physicians and other practitioners with prescriptive authority. A collaborative practice agreement is defined as a voluntary agreement between a prescriber and pharmacist establishing cooperative practice procedures under defined conditions. The term "collaborative practice" is often used interchangeably with the term "collaborative drug therapy management", which refers to the practice where prescribers authorize pharmacists to engage in specific activities, such as the initiation, adjustment or evaluation of drug therapy.

These collaborative arrangements between prescribers and pharmacists offer many benefits for patients, such as increased access to healthcare through a pharmacist, a reduction in the number drug-related complications due to optimal management of drug therapy, and a decrease in costs. In addition, benefits to prescribers include reduced costs of care, as well as fewer chronic care patient visits, which allows more time to care for acute care patients. Finally, these arrangements allow pharmacists to focus on the patient instead of the product, so they are able to apply their specialized knowledge of drug therapy to improve patient outcomes.

As with any practice opportunity, it is necessary to evaluate the risks, as well as the benefits, before deciding to become involved. However, one factor that makes the risk of engaging in a collaborative practice arrangement difficult to evaluate is that it is difficult to tell what, if any, authority is granted to a pharmacist by a state board of pharmacy to enter into these arrangements. An informal survey of state boards of pharmacy revealed wide variances from state to state, as well as scope of practice rules that are not always easy to interpret. Pharmacists practicing in states where collaborative practice arrangements are neither explicitly allowed, nor explicitly prohibited may consider seeking further clarification from the state board before entering in to such arrangements.

Pharmacists practicing in states where collaborative arrangements are explicitly allowed must be cautious to strictly adhere to the rules and regulations governing the arrangements. Regulations may determine minimum qualifications of parties to collaborative agreements, set limitations on activities or classes of drugs that are the subject of agreements, or set forth the necessary structure or components of the agreement.

By assuming responsibility of the initiation of drug therapy according to a collaborative arrangement with a prescriber, a pharmacist may assume a greater risk of liability if there is an adverse event. When considering an opportunity to enter in to a collaborative arrangement with a prescriber, it is crucial that both parties thoroughly review the proposed agreement. The agreement will set forth the rights and responsibilities of both parties. It is particularly important that the parties understand how responsibility for adverse outcomes is apportioned. It is wise for both parties to confirm that their activities under such an arrangement are covered by their respective professional liability insurance carriers and for each party to obtain proof of the other's coverage.

Collaborative practice arrangements present some very exciting opportunities for pharmacists to tangibly impact patient care in a positive manner. They may also allow a pharmacist to grow his or her business in a new direction.

The opportunities are abundant, but so are the risks. A thorough understanding of both will allow a pharmacist to make wise decisions about his or her role in this evolving area.

References:

http://www.go2ec.org/CollabPracticeAgreements.htm

http://www.aphanet.org

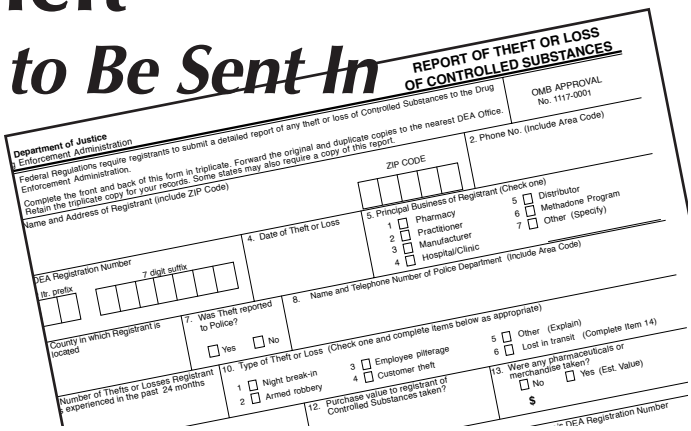
http://www.ashp.org/gad/monthlyupdates/state/June_2005.pdf

 Dena Kroska is a Pharm. D Candidate at Drake University in Des Moines, Iowa.. Karen E. Peterson, R.Ph., J.D. is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

DEA Must IMMEDIATELY Be Notified of Significant Loss or Theft

DEA Form 106 May Have to Be Sent In


REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Department of Justice
Drug Enforcement Administration

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Forward the original and duplicate copies to the nearest DEA Office.
Complete the front and back of this form in triplicate. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL No. 1117-0001

Name and Address of Registrant (include ZIP Code)

ZIP CODE

2. Phone No. (Include Area Code)

DEA Registration Number

tr. prefix

7 digit suffix

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)
1 Pharmacy
2 Practitioner
3 Manufacturer
4 Hospital/Clinic
5 Distributor
6 Methadone Program
7 Other (Specify)

County in which Registrant is located

7. Was Theft reported to Police?
Yes
No

8. Name and Telephone Number of Police Department (Include Area Code)

Number of Thefts or Losses Registrant experienced in the past 24 months

10. Type of Theft or Loss (Check one and complete items below as appropriate)
1 Night break-in
2 Armed robbery
3 Employee pilferage
4 Customer theft
5 Other (Explain)
6 Lost in transit (Complete Item 14)

12. Purchase value to registrant of Controlled Substances taken?

13. Were any pharmaceuticals or merchandise taken?
No
Yes (Est. Value)
$

DEA Registration Number

Prepared by: Eric Sonsalla, NDSU PharmD student

There have been a couple of changes to the wording in 21 CFR Section 1301.74. The Drug Enforcement Administration (DEA) has now included the word "immediately" before the phrase "upon discovery" in the following passage:

Section 1301.74(c) "Other security controls for non-practicioners; narcotic treatment programs and compounders for narcotic treatment programs." states that "the registrant shall notify the Field Division office of the Administration in his area of any theft or significant loss of any controlled substances immediately upon discovery of such theft or loss.

In addition, 'significant loss' has been further defined by the DEA to include a list of factors that they felt were relevant in deciding whether a loss was significant. This list is as follows:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances lost;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. Whether the specific controlled substances are likely candidates for diversion;
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

When a theft or significant loss occurs one should immediately notify the DEA by telephone, as well as sending in a short fax stating the situation (please see end of article for contact information). After notifying the DEA the provider should determine whether the circumstances of the theft are immediately known.

If the specific losses are immediately known a DEA Form 106 should be used to detail the circumstances of that theft or significant loss. If the specific losses are not yet known at the time of discovery the DEA suggests faxing an initial notice including a short statement advising the DEA of the theft or significant. If investigation determines there was not a significant loss or theft the DEA should also be notified of that; in this case, there will be no DEA Form 106 sent in.

Other actions that are not required by the DEA, but are recommended, include the notification of local law enforcement and the North Dakota Board of Pharmacy. Prompt notification of law enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion.

To report a theft or significant loss, please contact the director of the DEA, Jack Henderson at (612) 344-4130, or fax the information to (612) 344-4130.

A copy of the DEA Form 106 can be found at the following web address: www.pharmalogistics.com/forms/dea106.pdf, or by contacting the North Dakota Board of Pharmacy by phone (701)-328-9535) or e-mail: ndboph@btinet.net.

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NAPT Updates

By Danika Braaten - NAPT Presidnet

At the Fall conference in Fargo, ND in 2004 I volunteered to host the 2005 Fall Conference in Grand Forks. I'm not sure what came over me, but I had a sense that I wanted to have some input on the topics chosen for CE. I wanted to let everyone know what I thought would be interesting to learn more about. After I volunteered I asked myself what am I doing; I have not been an active member in NAPT or been involved in what was going on. I suddenly became overwhelmed and was sure that I had gotten myself in a pickle. I quickly called a member of the board and found out how easy it was to ask for help, and to get it. I couldn't believe how everyone on the board was willing to take time out of their day to talk to me and help me out in anyway possible. It turned out that planning this wasn't going to be so bad. I was amazed at the support I got from my fellow technicians. Something happened during this whole process that made me want to get involved in NAPT. Even though I was not a strong presence in the past, I was ready to be heard in the future and wanted to be the voice for all of the technicians. I thought to myself what better way to get involved then to just dive right in. What was I waiting for; this was time to help somebody else out. So here I am today, excited about being the incoming President for NAPT. I hope to serve all you well. I will do my best to make sure that technicians are heard loud and clear. Issues that we have will get resolution, and we will stride in professionalism along the way.

A little about me...I am Danika Braaten, and since 2001 have been the College Lab Assistant at Northland Community Technical College in East Grand Forks. I also work at Altru Healthsystem in Grand Forks as a Pharmacy Technician and have been there for 9 years. I have a wonderful husband and 2 beautiful sons.

Some issues I hope to accomplish this year:

- Continue in improvement of communication between organizations
- Travel meetings
- Technician involvement

Marisa Dolebeare (recipient of Pharmacy Tech of the "Year) and Jeanette Bleecker

This past year while I served as Vice President has been a wonderful learning experience and I hope to continue to learn and grow in the future. Thank you to all, on the board that have helped me through this process.

There are some familiar and some fresh faces that are coming on the board this year.

Vice President- Brittany Muchow
Secretary-Barb Kalloch
Treasurer- Melissa Heley
Past President- Jeanette Bleecker
Parliamentarian- Diane Halvorson
Member at Large-Colleen Brown
Member at Large- Eileen Darkow

NDPhA 121st Annual Convention

Krispy Zueger (receiving Convention Dedicant plaque in honor of her husband, Emil) and Bob Trietline

Tim Carlson and tony Godfried (recipient of Innovative Pharmacist Award)

Curt McGarvey and Joan Johnson (recipient Bristol Meyers Leadership Award)

Bob Treitline (recipient of the Bowl of Hygeia) and Mike Fedorchak of Wyeth

LeeAnn and Tim Carlson (recipient Bristol Meyers Leadership Award)

Dennis Johnson (recipient of NCPA Leadership Award) and Tony Lee of NCPA

Pat Churchill (recipient of Al Doerr Award) and Tim Carlson

Marisa Dolebeare (recipient of Pharmacy Tech of the Year) and Jeanette Bleecker

Lorri Giddings receiving 15 year service recognition

Pat Churchill

Dr. Hill and Brianne Kent (receiving Medicare Outreach Award on behalf of NDSU students)

Carolyn and Steve Irsfeld (convention chairman)

Rollie Schell, Pfizer and Joan Johnson (recipient of Helath-System Pharmacist of the Year)

Lifetime Award recipients Jerry Dufault and Odell Krohn, with president Tim Carlson

Sheila Welle, Pharmacist Mutual and Amy Noeske (recipient of distinguished Young Pharmacist Award)

Charles Peterson, Dean
NDSU College of Pharmacy

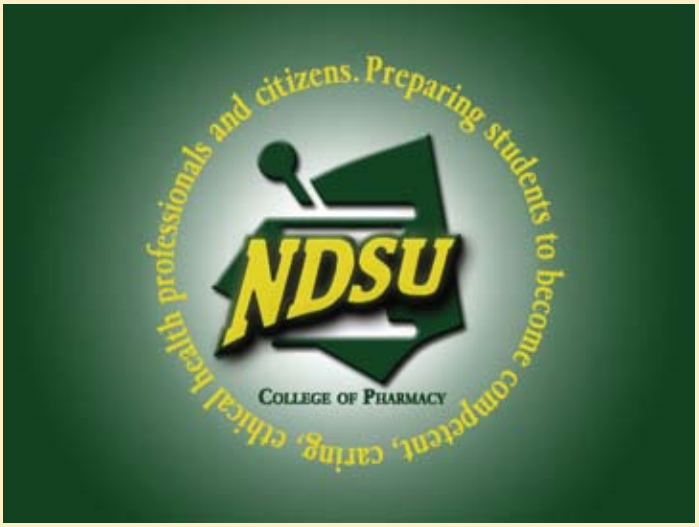
A Message from the Dean

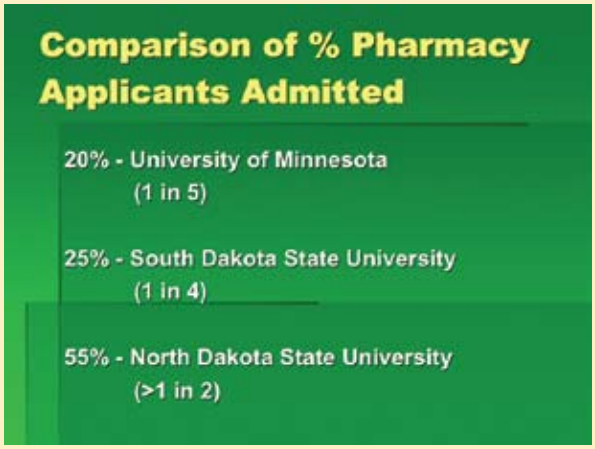
What's New In The College Of Pharmacy

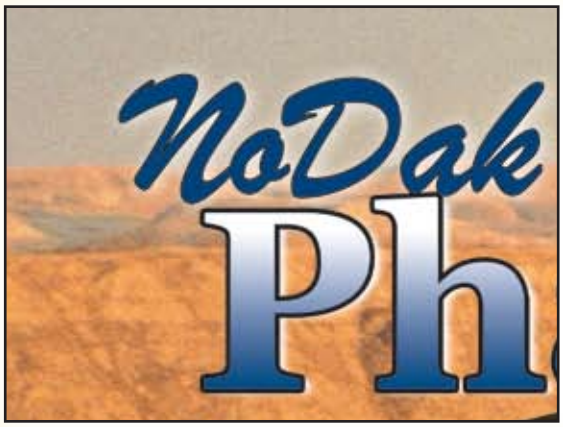
The College of Pharmacy has experienced a lot of changes recently and I thought I would share with you some of the most recent changes and highlights to our program. I recently gave a presentation (an update of the College of Pharmacy presentation including a section entitled: What's new in the College of Pharmacy) at our College of Pharmacy National Advisory Board Meeting in Scottsdale, Arizona in February. I thought you might be interested in seeing some of the highlights related to that presentation. In the last issue of the Nodak, I presented our newly revised Mission, Vision, and Core Values statements, so I will not cover that again here.

The following are some slides that represent the current status and recent changes to our program including: a new logo; current size of our human resources including student enrollment; application and admission information (including how we compare with other schools in our region related to applicant pool competition and chances of applicants being admitted); our new proposed name change (which was approved by the University Senate on March 20th and now will be forwarded to the State Board of Higher Education for their approval - this item was covered in detail in a previous Nodak Pharmacy article, September 2005); and information about our new Allied Sciences program.

These are areas I often receive the most questions about and comments on related to our program. I hope this information is of interest to you and also provides for you a good picture of who we are today as a College. If you have any questions about any of this information please feel free to contact me (email at Charles.Peterson@ndsu.edu or by phone at (701) 231-7609).







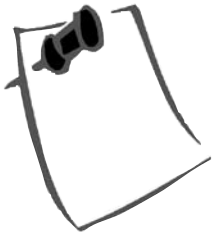
Rural Healthcare Award 2006

Front row left to right: R. Craig Schnell, Ann Rathke, John Skwiera, Patricia Hill. Back row left to right: Howard Anderson, Charles Peterson, Walter Spiese, David Scott.

Award: Outstanding Rural Health Program, 2006 Dakota Conference on Rural and Public Health, Fargo, March 23, 2006.

Photo credit: Amanda Scurry, UND School of Medicine and Health Sciences

Classifieds



Pharmacists Needed

Medical Pharmacy West (available immediately)
4101 13th Ave South
Fargo, ND 58104
Contact: John Sanger
Ph: (701) 282-6510

Relief Pharmacist Wanted
- Week of June 19 - 23, 2006
- July 3, 2006
- Week of August 7 - 11, 2006
- October 19-20, 2006
- November 24, 2006
- Week of December 25-29, 2006

Holly Rudnick
Human Resource Administrator
SCCI-Central Dakotas
1000 18th Street NW, Mandan, ND 58554
701-667-2000 Ext. 3130
Fax: 701-667-5944

PHARMACIST
PRACS Institute, Ltd., an expanding pharmaceutical research company, has a full-time opening for a Drug Inventory Control Pharmacist at the Fargo site. This position will be involved in such activities as set-up and dispensing of drug for dosing, drug inventory, correspondence, maintenance of drug room records, and occasional dosing of research participants. Requires weekday and weekend availability. Minimum credentials to qualify for the position will be a registered pharmacist eligible for licensure in ND. Please send application letter, resume and salary requirements to:

Human Resources
4801 Amber Valley Pkwy
Fargo, ND 58104

Email: pracshr@pracs.com
Fax: 701-239-4955
www.pracs.com

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(701) 284-6226 - home
(701) 331-3901 - cell
yeolde@polarcomm.com - email

RPh Needed by Mid-May
Medical Pharmacy, Fargo
Contact: John 701-282-6510

Pharmacy For Sale

Econo Pharmacy, Inc.
1190 W. Turnpike, Bismarck, ND 58501
Contact: Bill 701-224-1858
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Great location inside large grocery store

Pharmacy Technician Needed

Registered Pharmacy Technician
with at least 1 year experience for
a telepharmacy in Arthur ND
Please send resume to:
Kathy Nelson
PO Box 250
Casselton, ND 58012

Dakota Pharmacy of Bismarck
Technician wanted for sterile compounding lab work
717 E. Main Ave.
Bismarck, ND 58502-0835
Contact: Kevin Oberlander
Ph: 701-255-1881

Relief Pharmacist Available – ND & MN

Carl Benson RPh
324 S. Columbia
Morris, MN 56267

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