



# newsletter

National Association of Boards of Pharmacy®

August 2004 / Volume 33 Number 7

aid to government  
the profession  
the public  
1904 to 2004

## This Month on [www.nabp.net](http://www.nabp.net):

NABP's 101<sup>st</sup> Annual Meeting  
Travel Grant Application under  
"Special Items."

NABP/NAPRA Reissue  
Communiqué Addressing  
Importation under "Special  
Items."

NABP 2004 Officer Reports  
under "Special Items."

NABP 2003-2004 Committee  
and Task Force Reports under  
"Special Items."

Your state board of pharmacy's  
current newsletter is now  
available under "State  
Newsletters."

## Upcoming Meetings

Friday, August 27, 2004,  
Monday, August 30, 2004;  
Friday, September 10, 2004  
Board Program Review  
and Training  
NABP Headquarters  
Park Ridge, IL

Thursday-Saturday,  
September 23-25, 2004  
NABP/AACP District VI Meeting  
San Luis Resort  
Galveston, TX

Thursday-Saturday,  
October 14-16, 2004  
NABP/AACP District I Meeting  
Fairmont Algonquin Hotel  
St Andrews, New Brunswick, Canada

Wednesday-Saturday,  
October 27-30, 2004  
NABP/AACP District VII and  
VIII Meeting  
Monte Carlo Hotel  
Las Vegas, NV

Wednesday-Friday,  
November 3-5, 2004  
NABP/AACP District IV Meeting  
The Blackwell Inn  
Columbus, OH

## New Nomination Procedures for Open Executive Committee Member Positions

The NABP Executive Committee developed new nominating guidelines for open Executive Committee member positions in accordance with the amendments to the NABP Constitution and Bylaws adopted at the 100<sup>th</sup> Annual Meeting and Centennial Celebration in Chicago, IL, in April 2004. The Nominating Procedures are necessary to ensure the uniformity of procedures among NABP Districts and guarantee the validity of the nomination process.

The amendments to the Constitution and Bylaws call for Executive Committee member position nominations to occur at the District meeting of the respective open position. A maximum of two nominated candidates per District

may be slated for election to Executive Committee member positions at the following NABP Annual Meeting. Officer nominations and elections will continue to be held at the Annual Meeting.

This year, the new nomination procedures will be used by Districts I, III, IV, and VIII to designate Executive Committee member candidates. In 2005, Districts VI and VII will have open member positions on the Executive Committee.

Following is the detailed process for open Executive Committee member positions.

### Candidate Qualifications

In order to be considered for nomination, individuals

must meet three preliminary criteria:

- The individual must be an affiliated member (administrative officer or board member) of the Association serving on a board of pharmacy of an active member state at the time of nomination and election;
- The individual must not, in addition to his or her board of pharmacy activities, currently serve as an officer, official, or board or staff member for any national or state pharmacy organization; and
- The individual must not have a conflict of interest with the purpose, mission statement, and operation of NABP.

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## Executive Committee

Donna S. Wall  
*Chairperson, District IV*

Donna M. Horn  
*President, District I*

Dennis K. McAllister  
*President-elect, District VIII*

Lawrence H. Mokhiber  
*Treasurer, District II*

Charles Curtis Barr  
*Member, District V*

Michael A. Moné  
*Member, District III*

Richard A. Palombo  
*Member, District II*

Oren M. Peacock, Jr  
*Member, District VI*

Gary A. Schnabel  
*Member, District VII*

Charles R. Young  
*Member, District I*

## Nomination Procedures

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To be considered for nomination, individuals who meet these preliminary qualifications should submit to the NABP executive director/secretary, the District NABP chairperson, and the District secretary a letter of intent at least 20 days prior to the opening date of the District meeting. This includes a short (no longer than one page) narrative highlighting relevant experience and attributes that qualify the affiliated member for consideration, the expiration date for the individual’s term on the active member board, and a current curriculum vitae. NABP staff will screen applicants to determine if they are qualified; notice of qualified candidates will be forwarded to the District NABP chairperson, District secretary, and the individual nominees prior to the first day of the District meeting. Candidate information will be available for distribution at District meetings.

### District Voting

Of the candidates qualified for nomination, only two individuals per district may be slated for the final Executive Committee election at NABP’s Annual Meeting. To determine which members will be on the final ballot, each District will conduct a written-ballot election

during a Board Session at the District Meeting. Before the District’s active member delegates vote, each candidate will have the opportunity to address the boards during the Board Session for no longer than two minutes to provide additional information about themselves and their interest in serving on the Executive Committee.

Voting eligibility is similar to that used at NABP’s Annual Meeting:

- Each active member board will select one delegate.
- Active member boards may only cast one vote per board per nominee.
- The vote shall be cast by the official delegate of the active member board.
- No voting by proxy shall be permitted.
- The official delegate may be changed

by completing and submitting a change of delegate form (provided by NABP) to the NABP District chairperson prior to voting.

The two candidates receiving the majority of votes of the active member boards, provided that a minimum of four boards of pharmacy are present, shall be the District nominees. If no nominees are selected at the District meeting, individuals seeking office may do so by submitting notice to the NABP executive director/secretary to be nominated from the floor of the Annual Meeting in accordance with Article IV, Section 3(c)(iii) of the NABP Constitution and Bylaws. The results of the election must be submitted on the District Meeting Nomination Reporting Form to the NABP executive

(continued on next page)

### Quick Facts: District Nomination Procedures

- Procedures only affect Executive Committee members positions.
- Districts I, III, IV, and VIII have open member positions this year.
- Letters of intent must be submitted by interested candidates 20 days prior to opening date of the District meeting.
- Nominations will be voted upon during the District meeting’s Board Session.
- Two nominations maximum for each District’s open member position will appear on the ballot at the NABP Annual Meeting.
- Final elections for member positions will take place during the following Annual Meeting along with Executive Committee Officer elections.

## Wells Director of New Program for Canadian Health Care Decision Makers



Barbara A. Wells, BScPhm, founding executive director of the National Association of Pharmacy Regulatory Authorities (NAPRA), is leaving the position she held since 1995.

While serving as executive director, she was responsible for the development of a number of national initiatives of importance to pharmacy regulators in Canada and the US. These initiatives include the development and implementation of a national harmonized drug scheduling system for Canada, the creation

of a Mutual Recognition Agreement to support inter-provincial mobility for pharmacists, and harmonized standards of practice for pharmacists across Canada. Wells also oversaw the creation of frameworks for national model continuing competence and specialty recognition programs for Canadian pharmacists.

NABP President Donna M. Horn stated, “Barbara has been an outstanding leader in pharmacy regulation throughout the years. Her cooperation with NABP has led to such partnerships as the Canadian inception of NABP’s Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation program, VIPPS Canada™, and the reissue of the NABP/NAPRA communiqué addressing prescription drug importation. NABP wishes her much success and happiness in her new position.”

Wells accepted the director position of the Canadian Coordinating Office for Health Technology Assessment’s (CCOHTA) new program, the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS).

According to CCOHTA, the goal of COMPUS, funded by Health Canada, is to gather and evaluate best practice information and to develop tools to promote the use of best practices by health care professionals and consumers. Canadian federal, provincial, and territorial governments fund CCOHTA, an independent, not-for-profit organization that supports informed health care decision making by providing unbiased, reliable information about health technologies.

“It goes without saying that [Barbara] will be greatly missed,” said Lois Cantin, NAPRA president. “Her contribution to NAPRA over the last 10 years has been phenomenal. We thank her for that, and wish her continued success in her new position.”

Wells served as a member of the Executive Committee of the Canadian Network of National Association of Regulators. Other experience includes director of Corporate Affairs for Glaxo Canada as well as serving in community and hospital practices and holding senior management positions at the Ontario College of Pharmacists. Wells graduated from the University of Toronto’s Faculty of Pharmacy.

Recruitment of a new NAPRA executive director is now underway. Wells’ last day was June 30, 2004. ☎

## Nomination Procedures

(continued from previous page) director/secretary no later than 60 days prior to the NABP Annual Meeting.

The election and installation of Executive Committee members will

take place at the following NABP Annual Meeting.

Each spring, NABP will publish information about the nomination procedures including a list of the currently serving Executive Committee members, the Districts for which nominations are necessary, and the

requirements members must satisfy in order to be qualified for nomination. In addition, NABP staff will send a follow-up mailing to state board of pharmacy executive officers, District chairpersons, and District secretaries requesting their assistance in disseminating the nomination information

so as to encourage member participation.

For more information about the new procedures for nominating and electing Executive Committee members, please contact the Executive Office at 847/698-6227 or e-mail [custserv@nabp.net](mailto:custserv@nabp.net). ☎

## Illegal Importation Programs Under Review, HHS Seeks Solution to Safety Issues

**As support for importing prescription drugs from Canada grows among United States citizens and congressional leaders, state and city governments continue to plan – and illegally operate – Canadian importation programs. To date, the US Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) have refrained from prosecuting any of the cities or states that are operating such programs. Instead, HHS and FDA have chosen to meet with state and city officials to discuss the safety risks associated with drug importation. As a result of these discussions, some states and cities decided to forego prescription drug importation programs; however, others continue to develop programs or are beginning to implement their plans.**

### State-sponsored Drug Importation Plans

Currently, five states are operating Canadian prescription drug importation programs to varying extents (Minnesota, New Hampshire, North Dakota, Rhode Island, and Wisconsin) and eight additional states have announced plans in process to facilitate the illegal importation of drugs. Programs range from state-run Web sites that provide links to Canadian Internet

pharmacies to Web sites that provide order forms that patients must print, complete, and send to state-approved Canadian pharmacies. Rhode Island, for example, does not directly offer access to Canadian pharmacies on its Web site, but it does link to Wisconsin's Web site, which provides prescription drug order forms for select Canadian pharmacies.

At this time, none of the states are operating programs created specifically for state

employees and retirees; state plans that are in operation are open to all of each state's residents. However, Minnesota Governor Tim Pawlenty has stated that, if federal laws regarding drug importation change, state employees will be given incentives to use Canadian pharmacies. New Hampshire is considering expanding its plan to include a program for its corrections department, retired state workers, and Medicaid patients who require mental health drugs.

The eight states noted earlier, Connecticut, Illinois, Iowa, Massachusetts, Michigan, Ohio, Vermont, and West Virginia, are planning various approaches to encourage illegal importation; Massachusetts is considering utilizing a state-run pharmacy benefits manager who will advise residents on purchasing drugs from Canada. Connecticut is planning a pilot program that would allow the state's drug program to provide prescription drugs from Canada to low-income senior citizens and disabled residents. Illinois, which has been vocal about its desire to implement a Canadian prescription drug importation program, has yet to implement its plan. In early June 2004,

FDA notified Illinois that the state’s petition for a pilot program to purchase drugs from Canada had been rejected. While FDA was considering Illinois’ petition, state emissaries traveled to Europe to determine how much money could be saved by purchasing drugs overseas. The program under consideration in Illinois provides for state employees and retirees as well as Illinois residents.

**City-sponsored Drug Importation Plans**

Many cities are also aiding residents and municipal employees in purchasing prescription drugs from Canadian pharmacies. At press time, three cities – Burlington, VT; Montgomery, AL; and Springfield, MA – were operating drug importation programs; Boston, MA, was scheduled to begin operating a pilot program in July. The programs

operated by these cities all feature mail-order contracts with Canadian pharmacies for city employees and retirees.

In addition, on June 18, 2004, San Francisco, CA, launched a Web site directing residents to Canadian Internet pharmacies as a way to save money on prescription drug costs. The only three Canadian pharmacies the site lists are those that were approved by the state of

(continued on page 126)

**City-sponsored Prescription Drug Importation Plans<sup>1</sup>**

City	Status	Description
Boston, MA	Operating	Pilot program for city workers and retirees. (Began in July 2004)
Burlington, VT	Operating	Optional mail-order program for city employees. Copayments waived for those who order a three-month supply of medication from Canada.
Cambridge, MA	Planning	Pilot program for city workers and retirees.
Montgomery, AL	Operating	Optional mail-order program for city employees and retirees; purchase of Canadian drugs facilitated through a Texas-based company.
Oak Creek, WI	Planning	Pilot program for city workers and retirees.
Palm Beach County, FL	Planning	Pilot program for city workers and retirees.
San Francisco, CA	Operating	City-sponsored Web site directing residents to Canadian Internet pharmacies.
Springfield, MA	Operating	City contracts with Canadian company to provide city employees, their dependants, and retirees with long-term “maintenance” prescription medications via mail order. No copay.

1. Chart information from Trends Alert: Prescription Drug Importation, The Council of State Governments, Accessed May 2004, [www.csg.org](http://www.csg.org).

## Board Rule Ruled Unruly

By Dale J. Atkinson

The following appeared on the Missouri Board of Pharmacy Web site under a section entitled “Frequently Asked Questions-General Pharmacy Law” in an opinion dated January 2001.

**8. Does an entity have to be licensed as a pharmacy to sell veterinary legend drugs to the consumer/owner of the animal(s)?**

Yes. Veterinary legend drugs may only be sold based on the order/prescription of a veterinarian. An entity may not sell veterinary legend drugs directly to the consumer (owner of animal) based on a prescription without being licensed as a pharmacy.

This policy or interpretation of the applicable pharmacy laws in Missouri apparently represented a change in the position of the Board of Pharmacy, which had previously allowed the sale of veterinary legend drugs to consumers without the necessity of obtaining a pharmacy license from the Board. This change in “policy” by the Board was the result of an injunction entered by a circuit court preventing an entity from “practicing pharmacy” without a license. This injunction led to a

negotiated consent decree entered into between the Board of Pharmacy and a veterinary supply company.

Based upon this change of a long-standing policy of the Board regarding the sale of veterinary legend drugs by supply companies, the Missouri Board of Pharmacy investigated several additional supply companies that sold veterinary legend drugs directly to consumers/animal owners. As a result of these investigations, the Board forwarded a cease and desist letter to United Pharmacial Company of Missouri, Inc (Pharmacial). Pharmacial is a retail store that sells animal feed, other animal products, and veterinary legend drugs to owners of animals who present a valid prescription from a veterinarian.

The cease and desist letter informed Pharmacial that it was illegally selling veterinary legend drugs to consumers without holding an appropriate license as a pharmacy. Specifically, Pharmacial sold a Board inspector 1,000 tablets of Prednisone without having a licensed pharmacist on

site. The letter demanded that Pharmacial refrain from selling veterinary legend drugs without a valid pharmacy license. It included an application for a permit to operate a pharmacy and an instruction packet.

Pharmacial challenged the cease and desist letter through a declaratory judgment suit under sections of the Missouri laws that allow for challenges to the promulgation of rules. It argued, in part, that the practice act was not applicable and that the Board had promulgated a rule without following the procedural mandates required of regulatory boards under the Administrative Procedures Act (APA). The Board argued that the cease and desist letter cited only violations of the statutes, not rules, and, thus, Pharmacial’s challenge of the “rule” was misplaced. The Board also argued that the legislature, in the interim, amended the applicable statutes, which rendered the claims of Pharmacial moot.

The lower court granted summary judgment in favor of Pharmacial finding that the Board had misinterpreted the portions of the pharmacy practice act that defined the

practice of pharmacy, that the applicable Chapter of the Missouri Code relevant to the Board of Pharmacy's authority to regulate drugs applied only to drugs used by "... patients, i.e. human beings," and that the question and answer posted on the Board's Web site was a rule, but was void as not promulgated in compliance with applicable sections of the administrative procedures act. The Board appealed.

On appeal, the court first addressed the issue of whether or not the Frequently Asked Questions (FAQs) on the Web site was a rule. The Board argued that the FAQs were merely an attempt to post information frequently asked of staff and that the Board did not itself adopt nor approve the FAQs prior to placement on the site. The APA defines a rule as an agency statement of general applicability that implements, interprets, or prescribes law or practice requirements of the agency. Interpreting cases cited by the Board, the court distinguished between substantive (aka legislative rules) and interpretive rules finding both subject to the procedural requirements of adoption. The court held that "changes in statewide policy are rules." Because

the FAQs had the effect of a rule, it was void as not promulgated in accordance with applicable procedures. Accordingly, the court rejected the arguments of the Board.


Next, the court addressed the issue of whether the matter was ripe or subject to a presently existing controversy. The Board argued that the legislature, since the time of the cease and desist letter, changed the statute rendering the activities of Pharmacal under the jurisdiction of the Board of Pharmacy. The new law provided more detailed definitions of the term "pharmacy." However, the appellate court found no grounds for reversing the ruling of the lower court. In agreeing with the lower court language, the appellate court found no "... express legislative intent therein to extend the powers of the [Board] to encompass the regulation of drugs to other than patients (humans), upon the prescription by physicians and other human healthcare

professionals." Thus, whether the matter was interpreted under the old or new statute, the Board of Pharmacy did not have the authority to require a pharmacy license of entities that dispense animal legend drugs. The appellate court affirmed the holdings of the lower court in favor of Pharmacal.

**What constitutes a rule, subjecting the adoption of such regulation to the procedural aspects of an applicable administrative procedures act, is an essential concept for boards of pharmacy to comprehend.**

What constitutes a rule, subjecting the adoption of such regulation to the procedural aspects of an applicable administrative procedures act, is an essential concept for boards of pharmacy to comprehend. As illustrated in this matter, changes in board policy reflected on the Web site through an FAQ was found to constitute a rule.

*United Pharmacal Company of Missouri, Inc v Missouri Board of Pharmacy,* 2004 WL 913537 (App. Ct. MO 2004)

Notice: This Opinion has not been released from publication in the permanent law reports. 



Attorney Dale J. Atkinson is a partner in the law firm of Atkinson & Atkinson, counsel for NABP.

## Medicare Discount Drug Cards Prompt Questions from Seniors, NABP Offers Boards Assistance

**S**eniors citizens can now apply for and use Medicare prescription drug discount cards to help reduce the cost of their medications. The discount cards, which became effective June 1, 2004, were created to provide interim relief for seniors until full implementation of the newly passed Medicare Prescription Drug Improvement and Modernization Act in January 2006. Discount card providers began accepting applications for the cards in May 2004, but some seniors may still need help determining which discount card is best for them.

Some seniors may turn to their state board of pharmacy for assistance when choosing a prescription drug discount card because they assume the board has expertise concerning the federally sponsored program. NABP has compiled a detailed list of frequently asked questions concerning the Medicare prescription drug discount card to assist boards of pharmacy if they are faced with queries from senior citizens.

### What are the Medicare prescription drug discount cards?

Seniors can choose from 73 different discount cards, which provide savings of 10% to 15% on total prescription drug costs. The cards cost \$30 or less each

year; the card's cost cannot exceed \$30.

### How do I sign up for a discount card?

Senior citizens interested in signing up for discount drug cards can do so at Medicare's Web site at [www.medicare.gov](http://www.medicare.gov).

### Who should I contact if I have any questions?

Individuals with questions or concerns can contact Medicare's information service by telephone at 1-800-MEDICARE (1-800/633-4227). In addition, Medicare has created a brief tip sheet that can be found by clicking on "Search Tools" on the Medicare home page, clicking on "Publications," and clicking "Medicare-Approved Drug Discount Card Tip Sheet."

### Who qualifies for the Medicare discount cards?

Seniors who are eligible for Medicare can apply for the card.

### Can I get more than one Medicare discount card?

No. Seniors may only choose one Medicare-sponsored discount card. However, they may switch to another discount card between November 15, 2004 and December 31, 2004. Under some situations, seniors may choose a new card outside of the enrollment period. This is available to seniors who:

- move outside the card's service area;
- move to or from a long-term care facility; or
- enroll or disenroll from a Medicare private plan.

Please note that although they may hold as many non-Medicare-sponsored discount cards as they want, seniors may only use one discount card per drug purchase.

### If I have a low income, am I eligible for additional benefits?

Yes. Discount card information packets include an application for both a standard drug discount card and a special low-income card. The low-income card is for those individuals who



have an income less than \$12,569 a year (\$16,862 for couples). Seniors will not receive low-income benefits if they have other drug coverage through a current or former employer, Medicaid, the Federal Employees Health Benefits Program, Tricare, or the Veterans Benefits Administration. Seniors who receive coverage through a state pharmaceutical assistance program may still qualify for low-income benefits.

Seniors who are rejected for low-income benefits may appeal to Medicare.

Some seniors may also be eligible to receive a credit up to \$600 per year and a waiver of the initial application fee. Medicare will pay 90% to 95% of the drug costs. Unused credit will carry over to the next year.

**Who offers these cards?**

The cards are sponsored by certain pharmacies, pharmaceutical benefit management companies, insurers, Medicare private plans, and other private organizations. Some discount cards may have limited areas of use and offer different discounts on various drugs. In addition, discount card sponsors may change the drugs on which they offer discounts as well as the discount offered.

Seniors should look for the Medicare-approved seal as instances of fraud have already been reported in the media.

**What drugs are covered by Medicare discount drug cards?**

Each card is required to have a discount for at least one drug in each therapeutic category of drugs commonly used by Medicare users.

**How do the discount cards work with state pharmaceutical assistance programs?**

Each state must determine how the Medicare discount card program works with its own prescription drug programs.

**How can I determine which card is best for me?**

To optimize the benefits of the discount card, seniors should consult with their pharmacist and use the card comparison tool on the Medicare Web site at [www.medicare.gov](http://www.medicare.gov). Seniors may want to keep a log of their findings from the Medicare comparison tool so that they can contrast savings with other discount programs. In addition, seniors should be sure to call each discount card provider directly to confirm that their drugs are covered.

**When do the cards expire?**

The current program is a temporary measure until full implementation of the

prescription drug coverage program mandated in the Medicare Prescription Drug Improvement and Modernization Act in January 2006. Seniors will have the opportunity to apply for the new discount program between November 15, 2005 and May 15, 2006. The current cards expire when the new coverage begins. If seniors do not apply for new coverage, their cards will expire on May 15, 2006.

**Where can I find more information?**

Seniors can visit the Medicare Web site at [www.medicare.gov](http://www.medicare.gov) or call 1-800-MEDICARE (1-800/633-4227) if they do not have access to the Internet. Help may also be available at seniors' local community centers or their State Health Insurance Assistance Program; a listing of these programs is available on the Medicare site at [www.medicare.gov/Contacts/Related/Ships.asp](http://www.medicare.gov/Contacts/Related/Ships.asp) or <http://hiicap.state.ny.us/home/link08.htm>. Seniors can also contact the discount card provider with questions or concerns about the company's discount card policies. Another good source of information is the Medicare Rights Center Web site, located at [www.medicarerights.org/](http://www.medicarerights.org/). 

## Importation Programs

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Minnesota for its residents. A resolution set forth by the city and county of San Francisco on January 16, 2004, also called for an importation program for active and retired city employees and their dependents.

Cambridge, MA; Oak Creek, WI; and Palm Beach County, FL, are still in the planning stages of importation programs for municipal workers and retirees.

## HHS Continues to Question Safety of Drug Importation

Despite HHS Secretary Tommy G. Thompson's much reported stance on the prescription drug importation issue, FDA continues to focus on the question of the safety of importation from Canadian pharmacies. In early May, it was widely reported in national newspapers that, during a news conference on the new Medicare drug discount cards, Thompson said he would advise President George W. Bush not to stand in the way of a bill to make importing prescription drugs legal. He is quoted as saying, "I think it is coming. I think Congress is going to pass it." What is missing from these reports, however, is Thompson's caveat that a

system must be created that would assure American patients' safety if they purchase prescription drugs from Canadian pharmacies.

On May 20, 2004, John M. Taylor, FDA's associate commissioner for Regulatory Affairs, testified before the US Senate Committee on Health, Education, Labor, and

Pensions. He stated, "FDA would urge that Congress ensure that any changes to our drug regulation system do not require American citizens to give up the 'gold standard' in drug safety that has become a hallmark in this country. FDA's scientists, doctors, health care experts, and regulators must be empowered

to protect us from bad medicine."

FDA continues to study the issues surrounding drug importation through its Task Force on Drug Importation (see "HHS Task Force Studies Illegal Drug Importation" in the July 2004 *NABP Newsletter*). The Task Force expects

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## State-sponsored Prescription Drug Importation Plans<sup>1</sup>

State	Status	Description
Connecticut	Planning	Pilot program allowing state's ConnPace drug program to purchase drugs from Canadian pharmacies for low-income elderly and disabled residents.
Illinois	Planning	Pilot program for state employees and retirees; state would contract with Canadian and European sources for certain prescription drugs approved by the state. Random inspections performed by pharmacists at University of Illinois at Chicago; participants consult with local "primary care pharmacists."
Iowa	Planning	State-run Web site with links to Canadian pharmacies.
Massachusetts	Planning	State-supported pharmacy benefits manager advises and guides residents in Canadian drug purchases; does not serve as intermediary.
Michigan	Planning	State-run Web site with links to Canadian pharmacies.
Minnesota	Operating	State-run Web site listing Canadian pharmacies; order forms available for printing.
New Hampshire	Operating	First "stage": State-run Web site with link to Canadian pharmacy. Second "stage" (not yet in operation): Canadian drugs purchased by state for corrections department, retired workers, and mental illness drugs for Medicaid patients.
North Dakota	Operating	Links to two Canadian pharmacies provided on state's Web site.
Ohio	Planning	State-run Web site with links to Canadian pharmacies.
Rhode Island	Operating	State-run Web-site with links to Wisconsin's Canadian program.
Vermont	Planning	State-run Web site with links to Canadian pharmacies.
West Virginia	Planning	State-run Web site with links to Canadian pharmacies.
Wisconsin	Operating	State-run Web site listing Canadian pharmacies; order forms available for printing.

1. Chart information from Trends Alert: Prescription Drug Importation, The Council of State Governments, Accessed May 2004, [www.csg.org](http://www.csg.org).

## Compounding Accreditation Program Moving Forward

The Pharmacy Compounding Accreditation Board (PCAB), a coalition of national pharmacy professional and regulatory organizations, is moving aggressively forward to implement an accreditation program for compounding pharmacies. It was established in April 2004 to create a voluntary accreditation program for compounding pharmacies and enhance the quality of compounding practices and raise awareness of compounding. NABP is a member of PCAB's Governing Board.

In addition to NABP, PCAB's Governing Board

consists of the American College of Apothecaries, the American Pharmacists Association, the International Academy of Compounding Pharmacists, the National Community Pharmacists Association, the National Council of State Pharmacy Association Executives, the National Home Infusion Association, and the United States Pharmacopeia.

### PCAB Standards Task Force


On May 14, 2004, PCAB announced the appointment of the PCAB Standards Task

Force. The goal of this Task Force, comprised of one appointee from each PCAB Governing Board organization as well as four at-large member positions, was to set standards for a voluntary site accreditation process for compounding pharmacies. The Task Force was charged with preparing a quality compounding standards document, to be used as a foundation for an accreditation program for compounding pharmacies.

The PCAB Standards Task Force held its first meeting on May 21, 2004, where it drafted a standards document

that was submitted to the PCAB Governing Board for approval.

Once the PCAB Governing Board approves the standards for use in developing the accreditation program, NABP and PCAB will continue to structure the components of the program. These components include the application and accreditation processes as well as marketing and education programs.

For more information on PCAB, please e-mail NABP's Customer Service Department at [custserv@nabp.net](mailto:custserv@nabp.net). 

## Importation Programs

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to complete its study by December 2004.

### NABP Maintains Its Stance


NABP continues to support FDA in its position that illegal importation of prescription drugs compromises patient safety. For more than one year, NABP has been collecting data as well as consumer complaints concerning Internet pharmacy sites that appear to be located in Canada. Because of the difficulties in determining if, and where, an Internet pharmacy site is actually

licensed, the security patients feel from seeing the image of a red maple leaf, which is indicative of Canadian pharmacies, is often misguided. Complaints NABP has received range from orders that are paid for but never arrive, drugs that originate from unexpected locations, and drugs that are suspected counterfeits. Currently, NABP is discussing with the National Association of Pharmacy Regulatory Authorities the possibility of a cross-border regulatory framework. NABP is concerned that some Canadian wholesalers are buying drugs from third-world countries and then distributing them through Canadian Internet

pharmacies for the express purpose of dispensing the drugs to US patients.

If Congress passes an importation bill, NABP opposes the implementation of a federal licensure program for foreign pharmacies that bypasses state boards of pharmacy. The Association strongly believes that pharmacy regulation under such a program would prove to be unmanageable. To ensure patient safety, US federal importation legislation should require that Canadian pharmacies obtain state licensure and adhere to state regulations, encourage that Canadian governments create a basis for the Canadian pharmacy regulatory authorities to take reciprocal

disciplinary action against Canadian pharmacies that have been sanctioned in the US, and provide resources for inspecting pharmacies.

NABP held an Importation Enforcement Workshop and Task Force Meeting, June 22-23, 2004, in Arlington, VA. The Workshop and Task Force focused on how state boards can prosecute entities that are involved in illegally importing prescription drugs. For more details on NABP's Importation Enforcement Workshop and Task Force, look for the upcoming article in the September 2004 *NABP Newsletter*. 

## Around the Association

### Changes at Oklahoma Board

**Janis McAllister**, member of the Oklahoma State Board of Pharmacy since June 1, 1999, recently retired. In honor of her service, she received a commendation from Governor Brad Henry and a plaque from the Board.

In other Board news, please note that the Oklahoma State Board of Pharmacy's new e-mail address is [pharmacy@osbp.state.ok.us](mailto:pharmacy@osbp.state.ok.us).

### Bowersox New NH Board Treasurer

**George Bowersox, RPh**, was recently elected Board treasurer by members of the New Hampshire Board of Pharmacy.

### Boards Announce New Members

**Bonnie Jean Thom, RPh**, was named a member of the North Dakota State Board of Pharmacy by Governor John Hoeven on May 8, 2004. Her term will expire on May 8, 2009.

**John Lassiter, DPh**, was appointed to the Oklahoma Board on July 1, 2004, by

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## Experience NABP's Fall Educational Conference in St Petersburg, the 'Sunshine City'

**NABP's Fall Educational Conference, with selected sessions co-hosted with the American Society for Pharmacy Law, November 11-14, 2004, at the Renaissance Vinoy Resort and Golf Club in St Petersburg, FL, will continue the work begun at NABP's Importation Enforcement Workshop, held June 22-23, 2004. In addition, pharmacy members and representatives from the offices of the attorneys general will have a unique opportunity to engage in sessions exploring the future state of regulation in a regulatory arena forever changed by illegal importation and globalization.**

Meeting attendees will have the opportunity to enjoy a picturesque site and gorgeous Florida weather as well as have the chance to discover some of the attractions unique to St Petersburg.

### Retreat to St Pete

For the art connoisseur, St Petersburg offers the Museum of Fine Arts and the Salvador Dali Museum; the Renaissance Vinoy provides guests with free transportation to attractions located within a three-mile radius. The Vinoy also offers shuttle service for 10 or more people to attractions at a cost of \$4 per person each way. Located along the waterfront of downtown St Petersburg, the Museum of Fine Arts has more than 4,000

works of art in its collection extending from antiquity to the present day and features magnificent French Impressionist paintings. There is a photography gallery and collections of Steuben glass, Asian art, and pre-Columbian objects. Two gardens are also located on the grounds of the museum; one contains sculptures to encourage reflection and relaxation. Among the artists represented in the collection are Cézanne, Monet, Renoir, Whistler, O'Keeffe, and Rauschenberg. The museum is open Tuesday through Saturday from 10 AM to 5 PM; Sunday from 1 to 5 PM; and the third Thursday of each month hours are extended to 9 PM. Admission is \$6 for adults, \$5 for senior citizens 65 years of age or older, \$4 for

groups of 10 or more adults, and \$2 for students. Sundays are free, although donations are greatly appreciated. For more information on the Museum of Fine Arts call 727/896-2667 or visit its Web site at [www.fine-arts.org](http://www.fine-arts.org). Ranked as one of the top attractions in Florida, the Salvador Dali Museum houses the world's most comprehensive collection of the Spanish artist's works from 1914 to 1980. The Dali Museum is located along the waterfront, close to other museums, restaurants, and shopping. The museum's hours are: Monday through Saturday 9:30 AM to 5:30 PM; Thursday 9:30 AM to 8 PM; and Sunday noon to 5:30 PM. General admission costs \$13 and \$11 for senior citizens 65 or older. For more information on the Dali Museum call 727/823-3967 or toll-free at 1-800/442-3254, e-mail [info@salvadoralimuseum.org](mailto:info@salvadoralimuseum.org), or visit [www.salvadoralimuseum.org](http://www.salvadoralimuseum.org).

For attendees who enjoy history, St Petersburg is the home of two premier historical museums. The Florida International Museum, an affiliate of the Smithsonian Institution, houses artifacts from the Smithsonian and other museums on a rotating basis. Permanent to the museum's collection is *The Cuban Missile Crisis: When the Cold War Got Hot*, which

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## Fall Educational Conference Program

(Special Sessions Co-hosted with the American Society for Pharmacy Law [ASPL])

November 11-14, 2004

The Renaissance Vinoy Resort and Golf Club

St Petersburg, FL

### Thursday, November 11

2 - 6 PM

Registration/Information Desk Open

6 - 8 PM

Welcome Reception

Co-hosted with ASPL  
(Buffet dinner will be served.)

### Friday, November 12

7 AM - noon

Registration/Information Desk Open

7 - 8 AM

Continental Breakfast

8 - 8:15 AM

Welcome Remarks

8:15 - 9:45 AM

Federal/State Regulatory and Legislative Actions in 2004

Co-hosted with ASPL  
Program #: 205-999-04-006-L03  
(0.15 CEUs or 1.5 Contact Hours)

9:45 - 10 AM

Refreshment Break

10 AM - noon

The Changing Landscape of Importation: Patient Safety and Accessibility

Program #: 205-000-04-007-L03  
(0.20 CEUs or 2.0 Contact Hours)

Noon - 1:15 PM

Luncheon

Co-hosted with ASPL

Afternoon/Evening Free

### Saturday, November 13

7:30 AM - noon

Registration/Information Desk Open

7:30 - 8:30 AM

Continental Breakfast

8:30 - 10 AM

The Inspection and Accreditation of Wholesale Distributors: Regulating with Limited Resources

Program #: 205-000-04-008-L03  
(0.15 CEUs or 1.5 Contact Hours)

10 - 10:15 AM

Refreshment Break

10:15 AM - 12:15 PM

Recent Efforts to Address the Regulation of Pharmacy Compounding

Program #: 205-000-04-009-L04  
(0.20 CEUs or 2.0 Contact Hours)

Afternoon/Evening Free

### Sunday, November 14

7 - 10 AM

Registration/Information Desk Open

7 - 8 AM

Continental Breakfast

8 - 9:30 AM

State Efforts to Combat the Diversion of Controlled Substances

Program #: 205-000-04-010-L04  
(0.15 CEUs or 1.5 Contact Hours)

9:30 - 9:45 AM

Refreshment Break

9:45 - 11:15 AM

Medicare Prescription Drug Improvement and Modernization Act of 2003: New Opportunities in Medication Therapy Management and Electronic Prescribing

Program #: 205-000-04-011-L03  
(0.15 CEUs or 1.5 Contact Hours)

11:15 AM

Closing Remarks



NABP and the NABP Foundation are approved by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmaceutical education. ACPE Provider Number: 205. Participants may earn up to 10 hours of ACPE-approved continuing education credit from NABP. Participants in continuing pharmaceutical education programs will receive credit by completing a "Statement of Continuing Pharmaceutical Education Participation" and submitting it to the NABP office. A validated Statement will be sent as proof of participation within approximately six weeks. Full attendance and completion of a program evaluation form for each session are required to receive continuing pharmaceutical education credit and a Statement of Participation.

highlights the tense events of the Cuban Missile Crisis in October 1962. The museum's hours are Monday through Saturday 10 AM to 5 PM and Sunday noon to 5 PM. Admission is \$10 for adults, \$8 for senior citizens 65 or older, and \$5 for students age six to 18 as well as college students. Those interested in exploring the museum can visit its Web site at [www.floridamuseum.org](http://www.floridamuseum.org) or call 811/777-9882.

Located in downtown St Petersburg, the Florida Holocaust Museum is committed to providing public awareness, education, and understanding of the Holocaust. The museum honors the memory of the millions of innocent people who died in this great tragedy. The museum is open Monday through Friday, 10 AM to 5 PM, and Saturday and Sunday, noon to 5 PM. For more information contact the museum at 727/820-0100 or toll-free at 1-800/960-7448, or visit [www.fhlocaustmuseum.org](http://www.fhlocaustmuseum.org).

The Pier Aquarium is located off Spa Beach and boasts diverse marine environments from around the world including its own backyard of Tampa Bay and the California Kelp Forests, the Caribbean, and the Pacific Coral Reefs. The aquarium also offers various fun, educational, and hands-

on programs to satisfy every visitor's curiosity. Museum hours are Monday through



*Located at the St Petersburg Pier is the St Petersburg Aquarium, along with many shops and restaurants to explore. Visitors also have a beautiful view of St Petersburg from the Pier. Photo courtesy of the St Petersburg/Clearwater Area Convention and Tourism Bureau.*

Saturday, 10 AM to 8 PM, and Sunday, noon to 6 PM. Admission is \$2 – except on Sundays, which are free. For more information on the St Petersburg Aquarium call 727/821-6443 or visit [www.stpete-pier.com](http://www.stpete-pier.com).

Located in downtown St Petersburg, Sunken Gardens, a tropical paradise, is 100 years old and the city's oldest living museum. Attendees can unwind in the gardens after an invigorating morning of continuing education sessions by strolling numerous paths and watching the waterfalls cascade. The Sunken Gardens are open Monday through Saturday, 10 AM to 4:30 PM, and Sunday, noon to 4:30 PM. Admission is \$8

for adults and \$6 for seniors 55 years of age or older. Free parking is available on site.

### Shopping and Dining in St Pete


St Petersburg offers many shops and restaurants unique to the city. Located at The Pier, the same location of the St Petersburg Aquarium, are many restaurants including Captain Al's, a casual seafood restaurant and bar; Columbia Restaurant, a Spanish restaurant chain established in 1905; and Cha Cha Coconuts, a tropical bar and grill that serves Caribbean food. The Pier also has many specialty retail stores including the Crystal Mirage Gallery, an art and crystal gallery that also sells Swarovski silver crystal, and St Petersburg

Candle Gallery, where visitors can view candles being made.

Attendees may also want to explore the Courtyard Shops located near the Renaissance Vinoy. The open-air courtyard includes a restaurant and bar, florists, collectibles and gift stores, and clothing and shoe stores. Also located a short drive away is A Corner of England, an authentic British tea room serving traditional teas and British delicacies.

For those who are interested in antiques, the Gas Plant Antique Arcade is Florida's largest antique mall with four floors and more than 150 dealers. The mall features antiques and collectibles from all styles and periods. The mall is open Monday through Saturday 10 AM to 5 PM, and Sunday noon to 5 PM.

So, whether it be relaxing on one of St Pete's several beaches, exploring some of the city's eclectic museums, or spending time shopping and eating exotic food, attendees of NABP's Fall Educational Conference will have scores of options during non-programming hours.

For more information on the Fall Educational Conference, please call NABP at 847/698-6227 or e-mail [custserv@nabp.net](mailto:custserv@nabp.net). 

## New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the-counter (OTC) medications containing levels of calcium, magnesium, sodium, or potassium that are potentially harmful to persons with certain underlying medical conditions such as heart disease, hypertension, kidney disease, or other medical conditions. The final rule became effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with the above-mentioned medical conditions could worsen their condition upon consumption of these products. For example, OTC use of certain medications may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose;
- 20 mg or more of calcium in a single dose;
- 8 mg or more of magnesium in a single dose; or

- 5 mg or more of potassium in a single dose.

The new rules also require new warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult with their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium
- more than 3.2 grams calcium
- more than 600 mg magnesium
- more than 975 mg potassium.

Currently, the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes.

## FDA Requests That Antidepressant Manufacturers Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory cautioning physicians and their patients, families, and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports; however, it

is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to modify the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlafaxine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug FDA approved for use in children with major depressive disorder. Luvox, Prozac,

and Zoloft are approved for pediatric patients with obsessive-compulsive disorder.

Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely watch patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not yet been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Ⓢ

## Web Site Resources

More information on FDA's rulings about new OTC product labeling is available in the *Federal Register* on the agency's Web site:

- [www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm](http://www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm)
- [www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm](http://www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm)

Information about warnings for antidepressants can be found on FDA's Center for Drug Education and Research Web site:

- [www.fda.gov/cder/drug/antidepressants/default.htm](http://www.fda.gov/cder/drug/antidepressants/default.htm).

## Around the Association

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Governor Brad Henry. His term will expire on July 1, 2009.

**David Sumner** was recently named a member of the Pennsylvania State Board of Pharmacy by Governor Edward G. Rendell. Sumner is the Board's Bureau of Consumer Protection representative.

**W. Benjamin Fry, RPh,** and **Marcelo Laijas, Jr,** were recently named members of the Texas State Board of Pharmacy by Governor Rick Perry on April 14, 2004. Their terms will expire on August 31, 2009.

**Julie Eaton, RPh,** was named a member of the Vermont Board of Pharmacy by Governor Jim Douglas on January 23, 2004. Her term expires on December 31, 2008.

## IDPR Changes Name

The Illinois State Board of Pharmacy is one of several licensing boards that fall under the Illinois Department of Professional Regulation. The Department name recently changed and the Board now falls under the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation. 

## NABP's Web-only State Newsletter Program: Convenience and Price Number One Factors

Looking for a way to keep pharmacists and other health care professionals informed and at the same time reduce expenses? NABP is pleased to offer boards of pharmacy a new service to produce a quarterly newsletter: NABP's Web-only state newsletter program.

"I believe the Web-based newsletter is the solution [for] boards of pharmacy looking for ways to reach their licensees, but limited by resource challenges. The opportunity to provide updated information to the regulated community about such [topics] as counterfeit drug alerts, improving patient outcomes, pharmacist immunization, technician registration and standards, and a whole host of other important subjects . . . can be achieved through the Web-based application," stated Charles R. Young, executive director of the Massachusetts Board of Registration in Pharmacy and NABP Executive Committee member.

The Web-only state newsletter program is an excellent option costing only \$580 per year to produce and post on a quarterly basis. This saves boards an average of 92%; they do not incur the costs of printing, mailing, address list maintenance/label processing, and

presorted postage, which amount to more than \$7,500 per year.

According to Joshua Bolin, executive director of the Indiana Board of Pharmacy, "The switch to the Web-only state newsletters was based on funding constraints, but it is also a convenience factor. Once the pharmacy community learned of the Web-only system, the response of support was overwhelming."

Indiana was the first Board to take advantage of the Web-only newsletter program in 2002. The Board provides a link from its Web site to NABP's home page, [www.nabp.net](http://www.nabp.net), where the complete list of print and Web-only state newsletter program participants is available.

## Familiarity and Convenience


With the Web-only state newsletters, NABP continues to provide proofreading, editing, and layout services. In addition, the newsletters posted online are ready to be downloaded or printed and will still have the same familiar look – the yellow masthead with the state's seal, the symbol for law, and the bowl of hygieia symbol.

As with the hard copy newsletters, the boards

may choose the frequency of the publication of their state newsletters. Most of the boards publish their newsletters on a quarterly basis; however, boards also have the option to publish their newsletters once, twice, or three times a year. Another available option is to publish a partial list of the newsletters to mail to subscribers without Internet access and also participate in the Web-only program.

Of the 32 state boards of pharmacy that participate in NABP's state newsletter program, four states – Alaska, Indiana, Massachusetts, and North Carolina – currently participate in the Association's Web-only state newsletter program; Minnesota plans to join the program in October 2004.

According to David R. Work, executive director of the North Carolina Board of Pharmacy, "Participating in this [Web-only state newsletter] program is an excellent economic choice because the boards are still able to participate in this program at very low prices and it shows that the boards are staying contemporary with today's technology."

For more information on NABP's Web-only state newsletter program, please contact the Customer Service Department at 847/698-6227 or [custserv@nabp.net](mailto:custserv@nabp.net). 



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## NABP Featured on *Dateline NBC*'s 'Prescription for Disaster'

On Sunday, July 25, 2004, NABP was featured as an expert resource on "Dateline NBC" for a segment on the dangers of Internet drug buys. The piece reported the stories of two families, both of whom lost a loved one due to addiction to and overdoses of drugs obtained – without a prescription – from Internet pharmacies.


In December 2003, "Dateline" correspondent Victoria Corderi spent several hours interviewing NABP Executive Director/Secretary Carmen A. Catizone about the ease with which consumers can purchase virtually any type of drug, even controlled substances,

from an online pharmacy. "Doctors are offered \$5,000 or more a month to rubber-stamp prescriptions that are funneled to them," Catizone said. "By rubber stamping, we mean these doctors will receive as many as 200 e-mails a day and they simply say 'OK' to all of the e-mails without opening them or reviewing any of the patient histories."

As part of its investigations, "Dateline" contacted NABP so that Association staff could help the television news magazine purchase drugs from Internet pharmacies and arranged to have the drugs tested by the US Pharmacopeia. Drugs


purchased included Valium®, Xanax®, Roaccutane®, and Testosterone Cypionate. "Dateline" returned to NABP in January 2004 after the drugs that had been ordered were received at Association Headquarters. Catizone opened the packages on camera to show the drugs ordered were not only received, but that the packages contained no prescription label stating dose instructions or warnings.

A detailed report about NABP's undercover drugs buys that "Dateline" reported on, as well as identification test results, appears on page 97 in the July 2004 issue of the *NABP Newsletter*.

To avoid the experiences of those families profiled in "Dateline" and ensure that they receive the proper drugs with adequate information, consumers can go to NABP's Web site ([www.napb.net](http://www.napb.net)) to find a list of online pharmacies accredited through NABP's Verified Internet Pharmacy Practice Sites™ (VIPPS®) program. VIPPS-accredited online pharmacies undergo yearly reviews to ensure that they continue to maintain licenses in good standing and adhere to the rigorous 18-point criteria that is necessary to earn accreditation from NABP. 

### What Would You Like to Read About in the *NABP Newsletter*?

Do you have an interesting idea for an article that relates to the boards of pharmacy and the practice of pharmacy? Send an e-mail to the attention of the editorial manager at [custserv@napb.net](mailto:custserv@napb.net), and inform the Communications Department of your

idea for an article. Or do you want to know about a timely issue that is affecting the pharmacy profession? E-mail us and mention what topic you would like further discussed or broadened. Questions and/or comments? Send them our way; we'd be more than happy to hear them! 



In the Mail

NABP's Fall Educational  
Conference Promotional  
Brochure is nearing  
completion. The  
brochure, scheduled for  
a mailing in August,  
provides conference  
details as well as  
registration materials  
and instructions.



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