# newsletter

National Association of Boards of Pharmacy®

August 2005 / Volume 34 Number 7


aid to government
the profession
the public
1904 to 2005

## This Month on www.nabp.net:

**Special Items**
Save the Date for NABP's Fall Educational Conference: December 2-4, 2005

Frequently Asked Questions about Professional Affairs

**Headlines**
Oklahoma Passes Legislation Recognizing NABP's VAWD Program

## Upcoming Meetings

**Sunday-Tuesday, August 7-9, 2005**
NABP/AACP District III Meeting
Marriott Hotel, Knoxville, TN

**Thursday-Saturday, August 11-13, 2005**
NABP/AACP District V Meeting
Marriott Hotel, Bloomington, MN

**Thursday-Saturday, September 22-24, 2005**
NABP/AACP District I Meeting
Nathan Hale Inn, UConn Campus, Storrs, CT

**Wednesday-Saturday, October 5-8, 2005**
NABP/AACP District VI, VII, and VIII Meetings
Teton Mountain Lodge, Jackson, WY

**Thursday-Saturday, October 20-22, 2005**
NABP/AACP District II Meeting
JW Marriott, Washington, DC

**Wednesday-Friday, November 2-4, 2005**
NABP/AACP District IV Meeting
Courtyard Marriott Magnificent Mile Hotel, Chicago, IL

# States Pass Legislation, Create Rules for Pseudoephedrine

Methamphetamine, or "meth" – one of the most easily produced and highly addictive street drugs – has become more problematic for drug dealers to manufacture due to recent state laws limiting the sales of pseudoephedrine (PSE), a commonly used ingredient in the illegal production of meth that is readily available and found in such over-the-counter (OTC) medications as Sudafed®, Tylenol® Cold, Benadryl® Allergy & Cold tablets, Robitussin® Cold Sinus & Congestion, as well as many generic brands.

Currently, 25 states have meth precursor laws restricting the sales of PSE, ephedrine, and phenylpropanolamine products (see chart on page 138 for a listing of these states), and more states are in the process of writing and voting upon such legislation.

Early signs illustrate that these state laws are experiencing positive results; according to John Horton, associate deputy director for State and Local Affairs for the White House Office of National Drug Control Policy, there has been a 50% drop in the number of meth labs in Oklahoma and Oregon, two of the first states to enact laws restricting the purchase of PSE-containing products.

Many of the states' legislation are similar – limiting the sales, quantities, and time periods in which these PSE-containing products may be purchased by consumers. In addition, many of these states require the licensure of all establishments that sell PSE including convenience stores and gas stations. An example of a deviation from the norm is Montana – due to the state's rural population, if the closest pharmacy to a convenience store is located 50 miles away, the convenience store can then sell mixed PSE preparations. In such situations the stores have been given an exemption by the Montana Department of Justice and can stock PSE-containing products. In numerous cases, the state boards of pharmacy have worked closely with state legislators to establish and write PSE rules.

### Oklahoma

Oklahoma was the first state in the country to pave

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## In This Issue. . . .

The NABP Newsletter (ISSN 8756-4483) is published ten times a year by the National Association of Boards of Pharmacy (NABP) to educate, to inform, and to communicate the objectives and programs of the Association and its 66 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $35 per year.
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# PSE Legislation

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the way for other states to decrease meth labs. As reported in the March 2005 *NABP Newsletter* article "New Oklahoma Pseudoephedrine Law Causes Decrease in Illegal 'Meth' Labs," there has been a significant decrease in the number of illegal meth labs in Oklahoma due to this law. Some of Oklahoma's pharmacy requirements for Schedule V PSE include:

1. It must be kept in a locked environment (shelving unit, safe, cabinet, etc) that is within view of the pharmacy, or behind the pharmacy counter.
2. Any distributor or retailer of Schedule V PSE products must keep readily retrievable records and invoices pertaining to the receipt and sale of the substance. All records must be kept for a minimum of two years.
3. When purchasing OTC medications containing PSE, the greatest allotted amount to be purchased is 9 grams per month. This limit does not apply to Schedule V PSE products that are dispensed pursuant to a valid prescription.

All products that are either soft gelatin liquid-filled capsules or liquid preparations are exempt from the Schedule V restrictions. But all solid dosage forms of medications, including powders that contain any quantity of PSE are classified as Schedule V controlled dangerous substances.

## Oregon

On May 13, 2005, the Oregon State Board of Pharmacy adopted a permanent rule that restricted the sale of PSE, which required that products that have PSE as the sole ingredient only be sold from behind the pharmacy counter. According to this rule:

- PSE combination products may only be sold behind the counter as well; liquid and gel cap PSE products are exempt from the rule and may only be sold by a pharmacy or non-prescription drug outlet.
- The purchaser of the PSE products must produce a valid photo identification (ID), requiring the pharmacy to keep a log, either electronically or in a hard copy form, containing the purchaser's name, driver's license or other ID number, date of birth, and the amount purchased.
- PSE products must be locked in a storage space within the outlet that it is close to and within full view of a licensed pharmacy.
- Only a licensed pharmacist or registered pharmacy technician may be allowed to remove the products from the locked storage space.
- Consumers are not allowed to purchase more than 9 grams of PSE within a 30-day period.

## Kentucky

Kentucky followed suit when its legislation restricting PSE sales went into effect June 20, 2005. Senate Bill (SB) 63 requires that products with PSE, ephedrine, or phenylpropanolamine in tablet, caplet, and powder form be kept in a secure location such as behind a pharmacy counter or in a locked case. SB 63 also limits sales to three boxes of the affected products per purchase or 9 grams within a 30-day period. Customers must present a photo ID and provide their name and address in a logbook (which must be retained for two years) to purchase the medication. In addition, consumers need to be at least 18 years old to purchase PSE, ephedrine, or phenylpropanolamine in tablet, caplet, or powder form.

SB 63 not only addresses the abuse of PSE and other medications used to produce meth, but it also confronts other major meth-related problems as well as prescription drug abuse in Kentucky. Kentucky's new law:

- Makes it a felony to expose children to meth labs, with increasing penalties based on the child's injuries;

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# VAWD Provides Benefits, Cost Savings to Boards of Pharmacy; Oklahoma Signs On

Prior to and since its launch, NABP's Verified-Accredited Wholesale Distributors™ (VAWD™) program has garnered much support from state boards of pharmacy and Food and Drug Administration. All of these entities recognize the additional safety VAWD accreditation can provide to the United States' drug supply and, subsequently, the patient safety benefits. Moreover, now that boards of pharmacy have had the opportunity to evaluate the full program, they are discerning the benefits of the program in a time of waning resources.

Currently, two states have incorporated VAWD into their wholesale distributor legislation. As reported in the June-July 2005 *NABP Newsletter*, Indiana now requires all wholesale distributors to obtain VAWD accreditation in order to operate within the state. Additionally, Oklahoma's governor signed into law House Bill 1347 and Senate Bill 640, both of which recognize VAWD as an authorized outside agency for accrediting wholesale distributors and repackagers. If wholesale distributors seeking licensure in Oklahoma earn VAWD accreditation, the Oklahoma State Board of Pharmacy may exempt the company from providing the Board with certain information regarding the issuance and renewal of licenses and permits including:

1. type of ownership, whether individual, partnership, or corporation;
2. names of principal owners or officers and their Social Security Numbers (SSNs);
3. names of designated managers and their SSNs;
4. applicant's and designated managers' fingerprints;
5. criminal background check information for the applicant and designated managers as required by rule;
6. a copy of the license from the applicant's or designated managers' home state; and
7. bond requirements.

Each of the items cited in Oklahoma's law that may be made exempt on condition of VAWD accreditation are required components of the VAWD program. In an environment of strained resources and overworked compliance staffs, NABP is pleased that Oklahoma has addressed the importance of strict licensing guidelines for wholesale distributors. Furthermore, NABP is delighted that Oklahoma has recognized VAWD accreditation as an acceptable part of its licensure requirements and considers NABP's findings through the program an important part of assisting the boards in protecting the public health. By allowing NABP to perform these licensure verifications, the Board will create a safer environment for its patients yet not place more of a strain on staff due to increased investigation and inspection duties.

Bryan Potter, executive director of the Oklahoma State Board of Pharmacy, expects that many wholesale distributors will seek VAWD accreditation as it will be the simplest way for registrants to obtain a wholesale distributor license from the state board of pharmacy.

NABP estimates that boards of pharmacy that mandate VAWD accreditation are likely to realize a savings of $2.5 million on a biannual basis. Such savings may be met because boards need not fund extensive investigations and inspections of wholesale distributor facilities and personnel.

Aside from the cost savings, there are many other benefits that VAWD offers the state boards of pharmacy such as criminal and financial background checking; wholesale distributor disciplinary information from NABP's National Clearinghouse of Licensure, Certification, and Accreditation; and the comprehensive criteria for accreditation.

NABP has contracted with a third party to perform financial and criminal background checks on designated persons within those companies that apply for VAWD accreditation. The background checks focus on those people who are involved in the day-to-day operations and decisions at the wholesale distribution facility. At a minimum, background checks will be performed on the facility's warehouse manager and his or her supervisor.

NABP's Clearinghouse will be utilized to access disciplinary information that likely will not be accessible through background checks. Searches will be performed for both the wholesale distribution facility and the designated persons. While state boards investigating a distributor would have to contact each state individually to uncover disciplinary actions, NABP's national database allows staff to quickly and efficiently obtain disciplinary records from boards throughout the country.

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# Caught in a Web

By Dale J. Atkinson, JD

The public health and legal issues surrounding the proliferation of Internet accessibility to prescription medications and the origin of such drugs has placed immense pressure on the regulatory boards. Pharmacy boards, medical boards, as well as many other regulatory agencies, face legal and political issues addressing access to medications while not compromising the health, safety, and welfare of the citizens of the respective states. Additionally, the interplay between federal and state laws further exacerbates these already complex issues. However, the state practice acts do exist and must be enforced by the respective regulatory boards in order to carry out the public protection intent of the legislatures. Related boards must also coordinate their efforts to best carry out their vital mission.

A physician in North Dakota had credentials that included licensure in numerous states and board certification in clinical and anatomic pathology and forensic pathology. The physician also owned and operated related consulting businesses that provided services throughout the United States, served as a director of two laboratories in Illinois and Georgia, and was an emergency physician. Approximately 75% of his time was spent performing autopsies, 15% was devoted to his director responsibilities, and 5% to medical-legal consulting. The remaining 5% of his efforts involved the practice of Internet medicine.

Related to the Internet practice, the physician served as medical director of Net Doctor International, which operated two Web sites, www.net-dr.com and www.maleclinic.com. The physician had a loose arrangement with the organization that paid him based upon the cash flow of the company. Net Doctor is a private company that uses a physician-designed Web site to collect patient information and medical history relevant to prescribing certain prescription drugs. The company uses a questionnaire or information form to gather such information. The physician reviewed the medical histories of the patients and prescribed the medications, but was not an employee of the company. Apparently, additional doctors also reviewed submitted questionnaires.

Prospective patients visit the Web site seeking one of six Food and Drug Administration (FDA)-approved, non-narcotic medications (Celebrex®, Cipro®, Propecia®, Vaniqa®, Viagra®, or Xenical®) and are asked to fill out a questionnaire. Appropriately completed questionnaires are electronically forwarded to the physician for review as to whether or not and how much to prescribe to the patient. No face-to-face consultations take place and rarely are follow-up telephone conversations undertaken.

An undercover agent for the North Dakota Bureau of Criminal Investigations completed a questionnaire using a fictitious name. He placed an Internet order for Cipro from Bismarck, ND. The drug was dispensed by Community Drug of Pittsburgh, PA, and was prescribed by the physician. Based upon these actions and

additional prescriptions of the physician obtained from the Pennsylvania company and elsewhere, the medical board charged the physician with dishonorable, unethical, or unprofessional conduct. Specifically, the board alleged that the physician repeatedly wrote prescriptions for patients over the Internet without examination and/or without obtaining sufficient information.

After a hearing at which the physician was not present nor represented by counsel, the Administrative Law Judge (ALJ) recommended licensure revocation. This recommendation was accepted by the board and the physician appealed the matter to the district court. The district court granted the physician's request for leave to present evidence and the matter was remanded to the board for an additional hearing.

At the additional hearing before the same ALJ, the physician was represented by an attorney and expert testimony on behalf of the physician and cross-examination of the board's witnesses took place. Thereafter, the ALJ recommended that the physician be fined and censured and informed that if such activities occur again his license would be revoked.

Before the ALJ recommendation was heard by the board, the physician requested that he be allowed to personally appear before the full board. The physician was informed that the board was meeting telephonically to discuss the case and he declined to participate. The board adopted the ALJ recommended findings of fact and conclusions of law, but rejected the recommended sanction. Instead, the board affirmed the original revocation sanction initially made by the ALJ and ordered the license revoked. The district court affirmed the board order and sanction and the physician appealed the matter to the North Dakota Supreme Court.

The Supreme Court rejected the physician's argument that the refusal to allow him to personally appear before the full board when it considered the ALJ recommendation violated his due process rights. The court reviewed the applicable North Dakota law and noted that the board "may" allow oral arguments on recommendations from an ALJ. It held that the physician was afforded the necessary procedural due process.

The court also rejected the physician's arguments that the verdict was not supported by a preponderance of the evidence. In fact, the court noted that the physician admitted to approving 15,000 prescriptions in 2002, which, if calculated using the 5% allocation of time by the physician spent on Internet medicine, amounted to reviewing 72 questionnaires per hour. The court agreed with the ALJ that processing 72 questionnaires per hour would not provide the time necessary to legitimize any professional assessment.

Finally, the physician argued that the board did not sufficiently justify its reasons for rejecting and increasing the ALJ-recommended sanction. The court held that North Dakota law requires the reversal of a board order that does sufficiently explain the rationale for not adopting the recommended findings or order. Because the board did not provide its explanation, the court reversed and remanded the matter to the board to explain its reasons for rejecting the ALJ-recommended sanction.

Pharmacy boards must understand the procedural aspects of administrative actions and, where necessary, meticulously follow such procedures. While this matter was remanded to the board providing an opportunity to justify its reasoning, the expenditure of time can still be taxing on board operations.

*Jones v North Dakota State Board of Medical Examiners*, 691 N.W. 2d 251 (ND 2005)

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

# State, Federal Legislation Seeks to Protect Patients from Counterfeit Drugs; NABP Aids Officials in Fight

Since the *NABP Newsletter* last ran an article on the efforts to protect the United States' medication distribution system in October 2004, concern with the issue of counterfeit drugs has surged again due in part to the publicity surrounding the May 2005 release of a book on the topic by medical/health journalist Katherine Eban, *Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply*. For the most part, both the book and the mainstream press attention it has spurred deal with the counterfeiting situation as it stood when NABP last summarized it, focusing on diversion and counterfeiting that had occurred among Florida's many secondary wholesale distributors, which led directly to Florida's new, vastly stricter wholesaler regulations. Since that time, regulators, lawmakers, and others have continued to be far from idle in the fight against counterfeit drugs, in such areas as new and proposed legislation on the state and federal levels, law enforcement operations, data collection projects, and action on the part of wholesalers.

## A Continuing Problem

Not surprisingly, the problem of diverted and counterfeit medications has continued to garner attention from the public, regulators, and the wholesale distributor industry. According to the Pharmaceutical Security Institute, a private firm reportedly funded by the drug industry, there was a 16% increase during 2004 in the worldwide incidence of counterfeit, stolen, or diverted drugs from the previous year. The US led all countries with 76 reported incidents of counterfeit, stolen, or diverted drugs. (The US ranked fifth when only counterfeit drugs were considered, with a total of 32 reported incidents.) Since under-reporting is assumed and US reporting efforts have intensified, the worldwide total is likely much higher.

The World Health Organization (WHO) reported that, in a 2001 study undertaken in the Mekong region of Southeast Asia, more than one-third of anti-malarial artesunate products contained no active ingredients. A 2004 follow-up study indicated a deterioration of the situation, as 99 out of 188 samples were found to be counterfeit. In May of this year, WHO announced a new Web-based system called the Rapid Alert System, which will transmit reports on the distribution of counterfeit medications to a country's relevant authorities so countermeasures may be taken.

While a critical issue for industry concerns is intellectual property theft when patented medications are copied without permission, NABP and the US regulatory community are primarily focused on the public health hazards of counterfeit or adulterated

drugs entering the US distribution system. These medications often reach US consumers when a patient orders the drug from a Web site, sometimes one alleging to be a Canadian site or allegedly connected with Canada, in order to increase consumer confidence.

NABP, in conjunction with the pharmaceutical company Eli Lilly, and Food and Drug Administration (FDA) ordered and arranged to analyze a sample of medications, deemed *similares*, that are threatening to enter or may already have entered the US drug distribution system through the Internet and other sources. Similares are available in countries all over the world, particularly in Latin America, and purportedly contain the same active ingredients as brand-name medications in the US. Similares are considered in many countries outside the US as legal and inexpensive alternatives to patented drugs. They are not generic medications nor do they meet US standards of safety and efficacy for brand-name or generic medications.

In late 2004, NABP ordered several different medications including Cialis®, Evista®, and Zyprexa® from a total of 13 Web sites. No prescriptions were required by the sites. FDA performed an analysis of the submitted medications; two, in particular, were highly suspicious. Some of the sampled drugs far exceeded the level of allowed in the US medication. The amount of active ingredient present varied widely, and in at least one case, Fenilox (the "generic Evista"), no active ingredient was present. In addition, Lilly, the manufacturer of these drugs, performed a regulatory analysis on the products obtained by NABP and found that several were in fact similares and did not meet the company's US standards.

In May 2005, FDA issued a consumer advisory after conducting comparable tests on counterfeit versions of Lipitor® and Viagra® purchased in border towns of Mexico. (The advisory also referred to the Evista tested in conjunction with NABP.) Like the Evista similare in the NABP project, neither the counterfeit Lipitor nor the counterfeit Viagra contained any active ingredient. (For more information on counterfeit Evista see the Professional Affairs article on page 143.)

## Law Enforcement Actions

The Internet, of course, not only provides an ideal avenue by which US consumers can obtain medications outside the legal distribution channels, increasing the chances of receiving counterfeit or adulterated drugs, but also increases their opportunities to purchase controlled substances (counterfeit or not) that they might not otherwise be able to obtain.

In one highly publicized case, Drug Enforcement Administration (DEA), in conjunction with other federal and state agencies, announced in April 2005 the successful culmination of Operation "Cyber Chase," a year-long investigation that targeted Internet pharmaceutical traffickers operating in the US, Europe, the Caribbean, and India and other parts of Asia, resulting in 20 arrests in eight US cities and four other countries.

According to a news release issued by DEA, the investigation began after the identification of a Philadelphia-based international Internet drug trafficking organization that allegedly obtained controlled substances

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## PSE Legislation

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- Allows law enforcement officials to charge individuals with manufacturing meth if they show intent to make the drug and possess two or more chemicals or items of equipment necessary for its production;
- Forces Internet pharmacies to register with the state's board of pharmacy to do business in the state;
- Requires Verified Internet Pharmacy Practice Sites™ accreditation for online pharmacies
- Calls for Internet pharmacies to use the drug-tracking system commonly known as KASPER (Kentucky All Schedule Prescription Electronic Reporting);
- Requires a prescription to fill an Internet pharmacy order;
- Allows prosecutors to seek civil remedies against persons trafficking in precursors of or making meth; and
- Penalizes those who use firearms in furtherance of drug-related crimes.

States are not alone in the battle to fight meth abuse. Recently, meth production has drawn much attention and become a concern on a national legislative level. On June 12, 2005, Senator Ron Wyden (D-OR) announced that, in his opinion, federal legislation is needed to combat "the methamphetamine epidemic sweeping my state and much of the country." He began his brief address by highlighting the breakup of an Oregon-based meth lab "capable of producing 400,000 doses of pure meth at a time – enough to intoxicate the entire adult population of Portland." Senator Wyden said that although the bust is good news, the bad news is that the lab had been in business for at least five months, producing and distributing thousands of doses of deadly meth. The subject of meth is being discussed more and more in the halls of Congress as is federal meth legislation to more effectively deal with this national drug problem.

Senator Wyden also produced another interesting and bothersome fact: Drug Enforcement

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## History of Meth

A derivative of amphetamine, meth is a potent stimulant that affects the central nervous system; it was first synthesized in 1887 in Germany as amphetamine. In the 1930s, amphetamine was marketed as Benzedrine, an over-the-counter inhaler to treat nasal congestion. During this time, and probably in direct correlation to the United States' Depression and Prohibition eras, this drug was abused by many looking for a way to get "high." By 1937 amphetamine was available by prescription in tablet form. Methamphetamine (meth), a more potent and easier-to-manufacture drug, was discovered in Japan in 1919 and is still legally produced in the US, sold under the trade name Desoxyn® and used to treat such symptoms as Attention Deficit Hyperactivity Disorder and exogenous obesity. Amphetamines were widely used during World War II by soldiers for endurance and used mainly by American soldiers during Vietnam.

The 1950s saw legally manufactured tablets of both dextroamphetamine (Dexedrine) and methamphetamine (Methedrine) becoming readily available and used nonmedically by college students, truck drivers, and athletes – with the increased use of these drugs came the escalated abuse of the drugs.

Increased availability of injectable meth in the 1960s further spurred the utilization of the drug for non-medical purposes, but the 1970 Controlled Substances Act strictly limited the legal production of injectable meth, causing its use to decrease greatly. However, due to its easy-to-access ingredients, meth began gaining popularity again in the 1990s.

During the past decade the trafficking and abuse of meth has risen; clandestine production accounts for nearly all of the meth trafficked and abused in the US.

According to the US Department of Health and Human Services' report *Results From the 2002 National Survey on Drug Use and Health: National Findings*, more than 12 million people age 12 and older, 5.3%, reported that they had used meth at least once in their lifetime. In addition, from October 1, 2000, to September 30, 2001, there were 3,932 federal drug arrests for amphetamine/methamphetamine use, representing 12% of all federal drug arrests.

# Counterfeit Update

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smuggled into the US, repackaged them, and distributed them throughout the US and around the world. The substances included hydrocodone, anabolic steroids, and amphetamines.

DEA is approaching the issue of counterfeit and diverted drugs in other ways. The agency established an international toll-free hotline last January that allows the public to anonymously report the illegal sale or abuse of prescription drugs; as of April, DEA reported that it had received "hundreds" of tips.

In addition, DEA is keeping up-to-date on NABP's anti-counterfeiting efforts targeting wholesalers, including the Association's recently launched Verified-Accredited Wholesale Distributors™ (VAWD™) program. NABP Professional Affairs Department staff gave a presentation discussing the VAWD program at DEA's Fourteenth National Conference on Drug and Chemical Diversion, held this past May in Savannah, GA.

## Secondary Wholesalers

The VAWD program is gaining a higher profile as critics continue to finger wholesalers – particularly the secondary wholesale market – as the other major potential entry point for counterfeit drugs into the US medication distribution system. As Eban's *Dangerous Doses* book demonstrates, much domestic attention has focused on this area, and both industry and government efforts have targeted secondary wholesalers in recent months.

Activist New York Attorney General Eliot Spitzer grabbed headlines in April when the "big three" US wholesalers – Cardinal Health, Inc; McKesson Corp; and AmerisourceBergen Corp, which distribute up to 90% of the nation's medications – made it known in regulatory filings that Spitzer had subpoenaed documents pertaining to the pharmaceutical secondary wholesale market. While there was some initial speculation that the information might be used as part of Spitzer's concerns with drug pricing, later reports pegged the subpoenas as Spitzer gathering information for an ongoing investigation into the secondary drug marketplace.

Both McKesson and AmerisourceBergen emphasized through spokespersons their comparatively small purchases – about half of 1% of the companies' total – from the secondary wholesale market. Cardinal, meanwhile, announced in May that it would shut down a unit that trades in the secondary drug marketplace. Through a spokesperson, the company denied that this decision came as a result of Spitzer's investigation, but rather was based on the unit's poor financial performance over the last year.

Secondary wholesalers took another blow at the end of May when CVS/Pharmacy announced that it would no longer do business with pharmaceutical wholesalers that obtain medications in the secondary drug market. "CVS will only purchase pharmaceuticals directly from the manufacturer, or from wholesalers who certify that they are not trading in the secondary drug market," said Chris Bodine, CVS's executive vice president of merchandising and marketing, in a company press release. "If we are unable to receive those assurances, those wholesalers' contracts will not be renewed." At press time, the impact of this policy change on the "big three" wholesalers was unclear.

## Legislation

In May, US Representative Steve Israel (D-NY) introduced legislation in the House of Representatives intended to counteract the proliferation of counterfeit medications. Dubbed "Tim Fagan's Law" in honor of a young patient who had received counterfeit Epogen® following his liver transplant in 2002, the bill contains several provisions, many affecting FDA. The bill's provisions include:

- an increase in criminal penalties;
- a two-day period in which manufacturers must alert FDA about a counterfeited drug;
- authority for FDA to require companies to use anti-counterfeiting technology as it becomes available and feasible;
- a requirement that FDA implement the paper pedigree originally mandated in 1988 and postponed since that time;
- money for spot-checking for counterfeits and for the education of public and health care professionals on counterfeit drug identification; and
- recall authority for FDA in relation to prescription drugs.

As of press time, the bill remained in the Committee on Energy and Commerce's Subcommittee on Health.

Meanwhile, the states continue to see legislative activity in this area as well. One notable legislative accomplishment occurred in Indiana in May, when Governor Mitch Daniels signed into law a bill that expands requirements for wholesale pharmaceutical

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## State Methamphetamine Precursor Laws*

| State | Effective Date | Sales Limits |
|---|---|---|
| Alabama | July 1, 2005 | • Sales limited to no more than two packages/6 grams per transaction<br>• Individual purchase of more than 6 grams by an individual within a 30-day period with intent to manufacture is unlawful |
| Arizona | October 31, 2005 | Prohibits retailer from selling more than three packages, not to exceed nine grams of ephedrine, PSE, norpseudoephedrine, or PPA products in a single transaction unless the person has a valid prescription |
| Arkansas | March 20, 2005 | No more than three packages containing one or more products; or a single package containing more than 96 pills, tablets, gel caps, capsules or individual units; or a single package containing more than 3 grams of ephedrine (EPH)/PSE/phenylpropanolamine (PPA); may not purchase more than 5 grams EPH, or 9 grams PSE/PPA, in any 30-day period |
| Colorado | July 1, 2005 | No more than three packages in a single retail sale |
| Florida | July 1, 2005 | May not sell the lesser of more than 9 grams or three packages of single entity PSE, EPH, and PPA products |
| Georgia | July 1, 2005* | Three package/9 grams limit for all products, except for those that have been exempted<br>*Except for ordinances in effect before December 31, 2004, and for those, preemption beginning January 1, 2006 |
| Illinois | January 1, 2005 | • Sales of nonexempt EPH and PSE products are limited to two packages per transaction<br>• Retail distributors utilizing self-service checkout stations may do so only if stations are programmed to prevent sales of nonexempt products in an amount that exceeds the limit. When purchasers attempt to buy three or more products, neither the self-service checkout station nor the store employee may allow purchases |

## PSE Legislation

(continued from page 136)

Administration officials state that superlabs operated in Mexico by drug trafficking organizations now produce about 65% of all meth sold in the US, thus making the job of American agents more difficult because of the necessity of American-Mexican cooperation. The extent of corruption among Mexico's anti-drug police and other agents is well known both in Mexico and abroad.

The US Congress is currently considering legislation intended to make processes to obtain the ingredients needed to manufacture meth more intricate and complicated. Committee hearings are discussing a bill that will sharply restrict the sale of cold and allergy products containing PSE; SB 103 will be modeled after an Oklahoma law that took effect in April 2005.

The bill would also expedite Food and Drug Administration-approval of reformulated drugs, allowing alternate products to reach store shelves more quickly than the usual three to five years. One drug company is already working to reformulate up to half of its line of pseudoephedrine-based line of cold products with phenylephrine by January 2006. Reportedly, other drug manufacturers are considering similar changes to their medications; however, the Associated Press notes that companies are moving cautiously to make sure that substitutes are effective.

Time and resources are being utilized on a state and national level, all with the right focus in mind – that eventually the illegal production and harmful abuse of meth will be halted.

Please refer to future issues of the *NABP Newsletter* to learn about NABP's involvement with the latest developments concerning pseudoephedrine and the Association's stance on the regulation of PSE products.

| State | Effective Date | Sales Limits |
|---|---|---|
| Kansas | June 1, 2005 – Schedule V provisions* | Sales limited to no more than four packages or containers to a specific customer within a seven-day period<br>*all others upon publication of the *Kansas Register* |
| Kentucky | June 20, 2005 | • May not sell more than 9 grams of EPH, PSE, or PPA in solid dose products to an individual within a 30-day period<br>• May not sell more than three packages of solid dose EPH, PSE, or PPA products per transaction |
| Minnesota | July 1, 2005 for non-veterinary transactions | • Packages may not contain more than 3 grams of EPH/PSE, or for nonliquids, sales in blister packs where each blister contains no more than two dosage units, or if use of blister packs is technically infeasible, sales must be in unit dose packaging<br>• Single transactions limited to no more than two packages or 6 grams per transaction, and purchaser may not acquire more than 6 grams per 30 days |
| Mississippi | July 1, 2005 | Sales limited to two packages or no more than 6 grams of EPH or PSE in a single retail transaction |
| Missouri | June 15, 2005 | • 9 grams per person per 30-day period for all products except liquid or liquid-filled gel capsule, and for drug products that DHSS determines are not used to manufacture meth<br>• 9 grams per transaction for liquid or liquid-filled gel capsule, and for drug products that DHSS determines are not used to manufacture meth |
| Montana | July 1, 2005 | Sales limited to no more than 9 grams of nonexempt PSE or EPH products per 30 days |
| Nebraska | September 1, 2005 | No more than 1,400 mg of PSE/PPA to be sold to or purchased by a customer per 24 hours, unless pursuant to a prescription or medical order |
| North Dakota | June 1, 2005 | • Limits sales to packages of no more than 2 grams of one or more meth precursor drugs calculated in terms of ephedrine HCI and PSE HCI<br>• Limits sales in blister packs to no more than two dosage units<br>• Limits sales to no more than two packages containing one or more meth precursor products<br>• Limits sales to person under 18 years old |
| Oklahoma | November 1, 2005 | Limits sales to 9 grams of PSE per 30-day period |
| Oregon | May 14, 2005 | • Restricts the sale of PSE; products that have PSE as the sole ingredient may only be sold from behind the pharmacy counter<br>• Purchaser must produce a valid photo identification<br>• Consumers are not allowed to purchase more than 9 grams of PSE within a 30-day period |
| South Dakota | July 1, 2005 | No person may purchase, and no retailer may sell, in a single transaction, more than two packages of PSE or EPH products |
| Tennessee | March 31, 2005 – pharmacy only sales* | Sales limited to three packages of nonexempt products or no more than 9 grams of any EPH, PSE, or PPA product per 30 days, unless dispensed pursuant to a valid prescription<br>*April 29, 2005, for implementing sales limits, restrictions, identification, record keeping, and placement restrictions |
| Texas | August 1, 2005 | Sales limited to no more than two packages or 6 grams per transaction |
| Washington | Varies | • Effective January 1, 2006, the law will prohibit sales of more than two packages or a single package of more than 3 grams in a single transaction or in a 24-hour period<br>• Prohibits sale of more than 3 grams of EPH, PSE, or PPA in a single transaction or in a 24-hour period |
| Wisconsin | October 1, 2005 – Schedule V designation* | May not sell more than 4 ounces per 48 hours of a product containing PSE in combination with another Schedule-V substance<br>* June 22, 2005, for all other provisions |
| Wyoming | July 1, 2005 | Retail sale of nonexempt EPH, PSE, and PPA products are restricted to packages containing no more than 3 grams of one or more precursors calculated in terms of active base and in blister packs containing no more than two dosage units in each blister of blister packs technically infeasible, sales in unit dose packets or pouches |

*Source: National Association of Chain Drug Stores

# After Attending FEC Educational Sessions, Visit Sunny Isles Beach Local Attractions

NABP's 2005 Fall Educational Conference (FEC), December 2-4, 2005, at the Trump Sonesta Hotel, Sunny Isles Beach, FL, offers attendees the chance to earn continuing education credit as well as experience the warmth and sophistication of South Florida. Sunny Isles Beach's central location and easy access make it the best regional shopping area; the city is within 30 minutes of virtually all of South Florida's attractions.

After FEC participants attend timely and informative educational sessions there is something for everyone to do, from relaxing by the pool at the Trump Sonesta Hotel to shopping at the exclusive shops of Bal Harbour to taking a walking tour of the Art Deco District. Awarded Four-Diamond recognition by the American Automobile Association, the Trump Sonesta Hotel is an adventure in itself with a grotto-style pool and sun deck with fountains, rock formations, and waterfalls as well as air-conditioned cabanas at the pool and beachfront. Or enjoy the hotel's world-class spa, which offers traditional as well as cutting-edge treatments and service.

Once you have enjoyed the amenities of the Trump Sonesta Hotel, explore the beauty of the Art Deco District in South Beach. Begin your tour of Mediterranean Revival and Art Deco architecture at the Miami Design Preservation League Welcome Center; 90-minute guided walking tours and self-guided audio tours are available. In this area, along Ocean Drive and 10th Street, art galleries and shops abound and local artists sell their wares.

© Greater Miami Convention and Visitors Bureau

*The South Beach Art Deco District houses local artisans in historic buildings. Enjoy coffee at a sidewalk cafe or browse the many boutiques and art galleries.*

If it is ancient architecture you crave, stop by the 10th Century Spanish Monastery that now calls North Miami Beach its home. Built in the Province of Segovia, Spain, during the period 1133-1141, the Cloisters and the Monastery's outbuildings were purchased by publishing magnate William Randolph Hearst in 1925.

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## Area Attractions

**10th Century Spanish Monastery**
Phone: 305/945-1461
Web site: www.spanishmonastery.com/
Address: 16711 W Dixie Hwy,
North Miami Beach, FL 33160

**Aventura Mall**
Phone: 305/935-1110; Fax: 305/935-9360
Web site: www.shopaventuramall.com
19501 Biscayne Blvd, Aventura, FL 33180

**Bal Harbour Shops**
Phone: 305/866-0311
Web site: www.balharbourshops.com
Address: 9700 Collins Ave, Bal Harbour, FL 33154

**Charles Deering Estate**
Phone: 305/235-1668
Web site: www.flheritage.com/magazine/summer00/deering.html
Address: 16701 SW 72nd Ave, Miami, FL 33157

**Gulfstream Park**
Phone: 954/454-7000
Web site: www.gulfstreampark.com
Address: 901 S Federal Hwy, Hallandale, FL 33009

**MDPL & The Art Deco Welcome Center**
Phone: 305/672-2014; Fax: 305/672-4319
Web site: www.mdpl.org/
Address: 1001 Ocean Dr, Miami Beach, FL 33139

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# Fall Educational Conference Program*

*Program subject to change.

**December 2-4, 2005 Trump Sonesta Hotel Sunny Isles Beach, FL**

## Thursday, December 1

*2 - 6 PM*

**Registration/Information Desk Open**

## Friday, December 2

*6:30 AM - 1 PM*

**Registration/Information Desk Open**

*7 - 7:45 AM*

**Continental Breakfast**

*7:45 - 8 AM*

**Welcome Remarks**

*8 - 11 AM*

**Educational Session**
*(0.30 CEUs – 3.0 contact hours)*

*11 - 11:15 AM*

**Refreshment Break**

*11:15 AM - 12:45 PM*

**Educational Session**
*(0.15 CEUs – 1.5 contact hours)*

*12:45 - 2 PM*

**Lunch Break (On your own.)**

*2 - 3:30 PM*

**ACPE Open Hearing on Improving the Quality of CE**

*6:30 - 8:30 PM*

**Welcome Reception**
(Buffet dinner will be served.)

## Saturday, December 3

*7 AM - 12:45 PM*

**Registration/Information Desk Open**

*7:30 - 8:30 AM*

**Continental Breakfast**

*8:30 - 10:30 AM*

**Educational Session**
*(0.20 CEUs – 2.0 contact hours)*

*10:30 - 10:45 AM*

**Refreshment Break**

*10:45 AM - 12:15 PM*

**Educational Session**
*(0.15 CEUs – 1.5 contact hours)*

*12:30 - 2 PM*

**Lunch Break (On your own.)**

## Sunday, December 4

*6:30 AM - noon*

**Registration/Information Desk Open**

*7 - 8 AM*

**Continental Breakfast**

*8 - 9:30 AM*

**Educational Session**
*(0.15 CEUs – 1.5 contact hours)*

*9:30 - 9:45 AM*

**Refreshment Break**

*9:45 - 11:15 AM*

**Educational Session**
*(0.15 CEUs – 1.5 contact hours)*

*11:15 - 11:30 AM*

**Closing Remarks**

*NABP and the NABP Foundation are approved by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmacy education. ACPE Provider Number: 205. Participants may earn up to 11 hours of ACPE-approved continuing education credit from NABP. Participants in continuing pharmacy education programs will receive credit by completing a "Statement of Continuing Pharmacy Education Participation" and submitting it to NABP. A validated Statement of Continuing Pharmacy Education Credit 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 pharmacy education credit and a Statement of Continuing Pharmacy Education Credit.*

# NABP Offers an Advanced Pharmacy Clerkship

NABP has offered to the academic community the opportunity to participate in an advanced pharmacy clerkship with an emphasis in association management during the 2005-2006 academic year. The clerkship is designed for senior professional pharmacy students and will allow students to learn how NABP assists the state boards of pharmacy in achieving their goal of protecting the public health through its various programs, services, and activities.

The student(s) will work closely with staff by identifying current issues of concern to the state boards of pharmacy, contributing articles for inclusion in various NABP publications, and researching and compiling reference materials necessary for NABP task forces and committees to complete their assigned responsibilities.

Although students will be primarily assigned to the Professional Affairs Department, he or she will still gain exposure to other departments within the Association.

For more information on NABP's pharmacy clerkship, please contact the Customer Service Department at 847/391-4406 or custserv@nabp.net.

## FEC

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Unfortunately, Hearst was never able to reassemble the structure due to the onset of his financial difficulties shortly after the shipment arrived. It was not until 1952, one year after Hearst's death, that the stones were purchased and the monastery was rebuilt as a tourist attraction.

Only a 10-minute complementary shuttle ride from the hotel, history was made in the form of the first exclusive high-fashion shopping center. Built in 1965, Bal Harbour was scoffed at by retail experts who expected the concept to fail. Bal Harbour's internationally renowned shops are surrounded by a tropical garden setting. The chic open-air mall features 100 first-class boutiques and flagship stores including Bulgari, Cartier, and Gucci. Another popular nearby shopping destination is Aventura Mall. This 2.3 million square-foot complex features 250 stores, a 24-screen movie theater, and a large indoor playground complete with a life-size ship. Upon arriving at the mall, be sure to pick up the "Ultimate Shopping Folio," which includes a welcome letter, directory of service, and a 20% discount card plus a booklet of coupons.

For an evening out, visit South Beach and experience its lively and exciting night life. The area is famous for its variety of entertainment including the theater, symphony, night clubs, and restaurants.

There is so much to do in the Sunny Isles Beach area, you might want to stay after the FEC to get your fill of activities.

- Beaches abound, but be sure to stop at South Beach, voted one of the 10 best beaches in the world by the Travel Channel in 1999 and 2001.
- Golf lovers can get in a few rounds at one of several of South Florida's country clubs with which the Trump Sonesta Hotel has affiliations. These include The Presidential and the Miami Beach Golf Club, which are only a 15- to 20-minute ride from the hotel.
- Run to Gulfstream Park for thoroughbred racing and weekend concerts featuring top-name musical artists and sports celebrities.

For more information about NABP's 2005 Fall Educational Conference, contact the Customer Service Department at 847/391-4406 or e-mail custserv@nabp.net.

### Area Attractions (continued from page 140)

**Metro Zoo**
Phone: 305/251-0400; Fax: 305/378-6381
Web site: www.miamimetrozoo.com
Address: 12400 SW 152 St, Miami, FL 33177

**Miami Art Museum**
Phone: 305/375-3000; Fax: 305/375-1725
Web site: www.miamiartmuseum.org
Address: 101 West Flagler St, Miami, FL 33130

**Miami Seaquarium**
Phone: 305/361-5705
Website: www.miamiseaquarium.com/
Address: 4400 Rickenbacker Causeway, Miami, FL 33149

**Museum of Science & Planetarium**
Phone: 305/646-4200
Web site: www.miamisci.org
Address: 3280 South Miami Ave, Miami, FL 33129

## FDA Releases Update on Combating Counterfeit Drugs

On May 18, 2005, Food and Drug Administration (FDA) released "Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update" (Update). This Update follows up on the agency's initial February 18, 2004 report addressing counterfeit drugs. Since the 2004 report, which identified measures that can be taken to better protect Americans from counterfeit drugs, FDA has worked with manufacturers, wholesale distributors, pharmacies, consumer groups, technology specialists, standard-setting bodies, state and federal agencies, international governmental entities, and others to advance the measures outlined in the 2004 report. Activities include the development and implementation of electronic product codes and radio frequency identification. In its 2005 Update, FDA notes that significant progress is being made in securing drug products and packaging, securing the movement of product, enhancing regulatory oversight, increasing penalties for counterfeiters, heightened vigilance and awareness of counterfeits, and increasing international collaboration. However, more work needs to be done to further secure the United States' drug supply.

In 2004, FDA's Office of Criminal Investigations initiated 58 counterfeit drug cases, a significant increase over the 30 cases in 2003; however, the agency notes that this is likely due to increased vigilance. FDA also states that most of the suspect counterfeits discovered in 2004 were found in smaller quantities than those found in 2003.

The Update reviews steps taken and future actions required for track-and-trace technology, authentication technology, regulatory oversight and enforcement (electronic pedigree), state efforts, secure business practices, heightened vigilance and awareness, counterfeit alert network, and education. The full Update can be accessed at www.fda.gov/oc/initiatives/counterfeit/update2005.html.

## DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from www.access.gpo.gov/su_docs/fedreg/a050401c.html.

## FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medications online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to ensure that a Web site has met all applicable state and federal laws and regulations. Consumers will also be able to determine if an online pharmacy is VIPPS accredited by visiting the NABP Web site; VIPPS accredited online pharmacies also display the VIPPS Seal on their Web sites.

For more information on these PSAs, visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

## FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico

FDA is warning consumers about the sale of counterfeit versions of Lipitor®, Viagra®, and an unapproved product promoted as "generic Evista" to US consumers at pharmacies in Mexican border towns. The counterfeit Lipitor product purchased in Mexico was associated with several reports of high cholesterol in consumers who had used the product. Women who take the substandard generic Evista product that contains no active ingredient may be at risk for developing osteoporosis or for having their osteoporosis worsen.

FDA, in coordination with NABP, analyzed the generic Evista and found it to contain no active ingredient. The counterfeit Lipitor and counterfeit Viagra were analyzed by Eli Lilly and were also found to contain no active ingredient. The generic Evista product was purchased from Agua Prieta, Sonora, Mexico, and

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## Around the Association

### Florida Names New Executive Director

**Rebecca R. Poston, RPh, CPh,** has been named executive director of the Florida Board of Pharmacy. Poston has 23 years of experience in pharmaceutical services including 13 years as president and owner of Pharmaceutical Health Care Consultants and six years as the director for the Orange County Medical Clinic. She is a former chair of the Florida Board of pharmacy.

A graduate of the University of Georgia with a bachelor of science in pharmacy degree, Poston has been an active member of numerous professional organizations including the American Pharmacists Association.

### New Board Members

Two new board members were appointed to the Alaska Board of Pharmacy:

- **Mary Drue Mundell, RPh;** term expires March 1, 2009.
- **Leona Oberts**, term expires March 1, 2009.

**Dorothy Neal Gourley, RPh**, has been named a member of the Oklahoma State Board of Pharmacy. Her term expires June 30, 2010.

# NABP Accepting Item Writer Applications for All Examinations

Calling all pharmacy practitioners, educators, and regulators! NABP is seeking item writers for the North American Pharmacist Licensure Examination™ (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), and Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) programs. Pharmacists chosen to serve as item writers must hold an active license in good standing. All applicants will have their licenses verified through NABP's National Clearinghouse of Licensure, Certification, and Accreditation. Interested pharmacists should send or fax a letter of interest indicating current practice setting, specialties, and years of experience, along with a current resume or curriculum vitae to NABP's Executive Director/Secretary, Carmen A. Catizone, at 1600 Feehanville Drive, Mount Prospect, IL 60056; fax 847/391-4502. Applications are accepted on a continual basis.

Item writers will be selected based on the specific needs of the examination programs. Those who are chosen will be asked to attend a weekend workshop at NABP Headquarters or an area hotel, with travel and lodging expenses paid by NABP. Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP's competency assessment programs.

State board of pharmacy members and community pharmacists are particularly encouraged to participate in the item-writing process. For more information about item writing, contact the Competency Assessment Department at 847/391-4406.

# Professional Affairs

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is labeled as "Raloxifeno, fenilox, 50 tabletas, 60 mg," made or distributed by Litio and labeled as manufactured in Monterrey, Nuevo Leon, Mexico. The label has red triangles across the top and bottom; photographs of the products can be viewed online at www.fda.gov/bbs/topics/news/photos/border.html.

Counterfeit Lipitor and Viagra were purchased in the Mexican border towns of Juarez, Los Algodones, Nogales, and Tijuana. The counterfeit Lipitor and counterfeit Viagra products were labeled only in English, whereas legitimate Mexican pharmaceuticals are usually labeled in Spanish. In addition, the counterfeit Lipitor was provided in round white plastic bottles; however, authentic Lipitor in Mexico is sold only in boxes of blister packs. FDA and Mexican federal health officials are continuing to work together to address the issue of counterfeit human drug products, especially along our common border. Recently, health officials in Mexico's Federal Commission for the Protection from Sanitary Risks have undertaken several specific operations to target illegal drugs including counterfeit drugs in Mexican drug stores. These operations, throughout Mexico including the areas that border on the US, have resulted in the suspension of 19 pharmacies and the confiscation and recall of over 105 tons of medicines.

Reports of suspected counterfeit drugs can be submitted to FDA at www.fda.gov/medwatch.

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# Canada to Ban Bulk Drug Exports to United States

On June 27, 2005, Canada's Health Minister, Ujjal Dosanjh, announced that the country would change its regulations on exporting prescription drugs and would no longer export prescription drugs in bulk to the United States. The change is an attempt to protect the country's drugs supply should the US Congress legalize Internet and bulk importation of prescription drugs from Canada.

Dosanjh stated in a news conference in Toronto that the proposed legislation will allow for a temporary ban on bulk prescription drug trade to the US if supplies are running low in Canada. Two facets of prescription drug exportation that will not be affected are Internet pharmacy practice and sales to Americans who travel by car or bus across the border to fill prescriptions. While Dosanjh has no plans to eliminate the Canadian-US Internet pharmacy business, he did note that he would consider regulations that would curb the practice of Canadian doctors signing off on prescriptions without any real relationship with American patients.

After this announcement, the Ontario Pharmacists' Association (OPA) praised Dosanjh, but qualified its support. In a news release, the association stated that the legislation needs to be strengthened in order to meet the health minister's objective to no longer be a cheap "drug store to the United States."

A poll commissioned by OPA in May 2005 found that 83% of Canadians want the federal government to act to prevent drug exports before US laws are changed to legalize this trade.

In recent years, several US cities, states, and municipalities have implemented Canadian drug programs, but Canada's proposed regulations will not discourage these governments from utilizing importation programs. The city of Montgomery, AL, has operated its importation program for two years, and the mayor's office has been preparing for the change in policy, reported the *Montgomery Advertiser*. The city has already experienced limited supplies of some popular drugs due to restricted sales to Canada by pharmaceutical companies in an attempt to prevent resales to Americans. To combat this, and in anticipation of Canada preventing drugs sales to US citizens, the city of Montgomery incorporated an international drug program six to eight months ago to replace the Canadian program.

## VAWD

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The criteria that wholesale distributors must meet to achieve VAWD accreditation are comprehensive. Of particular note are the criteria addressing security, drug product handling and storage, drug product authentication and due diligence, as well as record keeping, which includes pedigree requirements. Through on-site inspections, VAWD inspectors will be able to determine if the VAWD applicant has taken the proper steps to protect against counterfeit drugs and prevent theft and diversion as well as fraud. In addition, the inspectors will verify that key employees have the ability to discern counterfeit medications and identify fake pedigrees.

For more information about the VAWD program, visit NABP's Web site at www.nabp.net/vawd/intro.asp.

## Counterfeit Update

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distributor licensing, based on NABP's Model Rules for the Licensure of Wholesale Distributors, which is part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. Notably, the new law also requires wholesalers to obtain and maintain accreditation from NABP's VAWD program, and lays the groundwork for the Indiana Board of Pharmacy to establish an electronic pedigree program.

Clearly, the issue of counterfeit, diverted, and adulterated drugs making their way into the US medicine distribution system will not dissipate anytime soon. But with efforts continuing like those described here, regulators, lawmakers, enforcement officials, and other stakeholders will continue to have an impact on the problem, and will continue to help ensure the safety of US medications.

## Executive Committee Treasurer, Members Attend New Executive Committee Member Orientation

*Pictured with Charles R. Young (left), NABP's new treasurer, are new Executive Committee Members Reginald B. "Reggie" Dilliard, Patricia F. Harris, John R. Dorvee, Jr, and William T. Winsley, at NABP's Headquarters in Mount Prospect, IL, on July 6, 2005.*

### Reminder

Save the Date: NABP's program review and training sessions for board of pharmacy staff will be held August 29, 2005, and September 9, 2005, at NABP Headquarters in Mount Prospect, IL.

nabp newsletter

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