NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

newsletter

AID TO GOVERNMENT - THE PROFESSION - THE PUBLIC - 1904 TO 2003

NABP Intensifies Activities to Counter Illegal Prescription Drug Importation

As state officials from Illinois, Iowa, Minnesota, and Wisconsin attempt to set up state-sponsored plans to import prescription drugs, NABP has increased its activities to send the message to consumers and politicians that importing medications from Canada and other countries is dangerous and illegal. While NABP has consistently provided interviews to print and television media concerning this issue, the Association recently intensified its activities and participated in a media tour.

On Tuesday, October 21, 2003, NABP participated in a press conference at Beacon Hill, in Boston, MA, with representatives from the United States Department of Health and Human Services (HHS) and the Massachusetts College of Pharmacy and Health Sciences. The event took place at 9:30 AM, immediately prior to Springfield, MA Mayor Michael Albano loading buses for a statewide bus tour to raise support for his illegal effort to obtain prescription drugs from Canada.

NABP Executive Director/Secretary Carmen A. Catizone (right) hosted a news conference about the dangers of reimporting prescription drugs with Brian Cresta (center), regional director for the United States Department of Health and Human Services, and Dennis Lyons (left), director of Government Affairs, Massachusetts College of Pharmacy and Health Sciences.

The groups participating in the press conference strongly expressed their concern that expanding Albano's proposal would circumvent Food and Drug Administration's (FDA) approval and safety processes. FDA Commissioner Mark McClellan has warned that the proposal "creates a wide channel for large volumes of unapproved drugs and other products to enter the United States that are potentially injurious to public health and pose a threat to the security of our nation's drug supply."

"If Mayor Albano continues with his program in Springfield and convinces other municipalities to join, the

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FDA Commissioner Discusses Illegal Drug Reimportation at NABP's FLC

Attendees of NABP's 2003 Fall Legislative Conference, held September 14-16 in Washington, DC, enjoyed the opportunity to hear Food and Drug Administration (FDA) Commissioner Mark McClellan, MD, PhD, provide an update on the recent actions FDA has taken to curb illegal reimportation of prescription drugs.

McClellan stated, "Our two organizations [NABP and FDA] are facing more serious challenges and issues related to the safety and integrity of the nation's pharmaceutical supply."

McClellan went on to explain that FDA's main concern regarding the illegal reimportation issues is keep-

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integrity of the US medication system will be further challenged and more problems will arise than the program will resolve. Because the source and safety of these medicines cannot be guaranteed, unknowing patients may become ill due to unapproved medications, incorrect dosages, and improperly stored and shipped medications. Patients may save on their prescription costs, but the trailing hospital, emergency room, and additional prescription costs will more than negate any savings," Carmen A. Catizone, NABP executive director/secretary, stated at the press conference.

Brian Cresta, regional director for HHS, added, "Secretary [Tommy G.] Thompson has the authority to allow these medications to be imported from Canada, but he has refused to do so because of concerns about the safety of the imported medicines. We continue to feel that the best and most appropriate way to make prescription medicines affordable to our nation's seniors is through a comprehensive Medicare drug benefit."

Later that day, Catizone participated in a satellite tour with 16 television stations stressing that importation of prescription medications is unsafe and illegal. During this tour, Catizone responded to questions from television reporters from cities on the East Coast, in the Midwest, and in the South.

NABP will continue to contact media outlets about the danger and illegality of drug importation. Currently, the Association is working on a response to Illinois Governor Rod R. Blagojevich's recent study that reports that importing prescription drugs from Canada is safer then purchasing medication in Illinois. Look in the January 2004 *NABP Newsletter* for a full article on this topic.

For more information on actions NABP has taken to speak out against illegal importation, visit the "Headlines" section of the Association's Web site at www.nabp.net.

FPGEE Winter Administration Approaching, Pre-FPGEE Aids Candidates

The winter administration of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) will be held on December 6, 2003. The paper-and-pencil examination is being offered in three United States locations: Brooklyn, NY; Northlake (Chicago area), IL; and San Mateo (San Francisco area), CA.

In early October, candidates accepted to sit for the December FPGEE received admission tickets and information and procedures including the test day schedule, test center restrictions, examination instructions, policies on changes and/or cancellations, and result notification procedures.

Candidates who wish to prepare themselves for the examination can take the Pre-FPGEE™, a Web-based practice examination for the FPGEE that was launched by NABP on October 1, 2003.

The Pre-FPGEE consists of previously scored and calibrated FPGEE items that have subsequently been retired. Two unique forms, each with 66 questions, are available; the fee for each attempt is $50. After completing the examination, candidates receive a score report with an estimated scaled score and range. Like other practice examinations, a candidate's score on the Pre-FPGEE is similar to what he or

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ing the United States' drug supply safe and secure and assisting patients in using drugs effectively.

FDA's challenge is helping senior citizens and patients who purchase prescription drugs on a regular basis gain access to affordable drugs while ensuring that these medications are safe and effective and encouraging the development of even better treatment in the future. According to McClellan, the price of pharmaceuticals in the US differs from around the world and this fact alone should command the public's attention but not override safety concerns.

"Americans should not have to choose between affordability and safety [when purchasing prescription medications]. My number one goal is to make drugs safe and affordable for all of us," explained McClellan.

The Illegal Reimportation Factor

Concerning the illegal reimportation of prescription drugs, McClellan stated, "With these threats today, our agency has to be more committed than ever to stopping those who endanger public health by illegally selling unapproved and risky prescription drugs. . . ."

When patients purchase illegal reimported drugs, they bypass FDA's ability and purpose to act as the consumer's drug safety "watch dog." FDA bases its drug approval on scientific data that demonstrates the benefits of the drug(s) and that these benefits outweigh any risks of the product. FDA also approves these drugs based upon a careful analysis of the production, labeling, and distribution of the drug(s) to make sure patients [receive] the intended benefits without excessive risks.

The risks are real. FDA's recent investigations of illegally reimported medications uncovered drugs that were expired, of the wrong strength, contaminated, wrong drug, incorrectly labeled, and improperly packaged and stored. According to McClellan, in a recent "blitz" of four locations in three days FDA intercepted 1,100 violative products with products of Canadian origin encompassing 14% – the highest percentage of any other foreign products.

Concerning foreign Internet pharmacy sites, McClellan offered the warning "buyer beware" because the agency currently does not have the resources or authority to provide assurances of safety for drugs that are imported.

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FDA Efforts to Contain Counterfeit Drug Growth

Food and Drug Administration Comissioner Mark McClellan also spoke about the rise in counterfeit drugs at the 2003 Fall Legislative Conference held September 14-16 in Washington, DC. According to McClellan, since 2000, counterfeit drug cases have increased to 20 per year compared to the 1990s, when cases averaged five per year. FDA created a task force on this topic and published its Counterfeit Drug Task Force Interim Report.

In response to the FDA's report, NABP developed its own Task Force on Counterfeit Drugs and Wholesale Distributors. Revisions to NABP's Model Rules for Licensure of Wholesale Distributors will be considered in order to deal with the increasing threat of counterfeit drugs. This Task Force is an outgrowth of NABP's work with FDA to update state requirements for wholesale distributor licensure.

The commissioner outlined ways that FDA is working with the pharmaceutical industry to make prescription drugs more affordable.

- New generic initiatives, which took effect in August 2002, including a new rule to give patients access to generic drugs. It is estimated that this effort could lower drug costs by over $3 billion annually.
- Expansion of generic drug review program – speed up the process to approve generic drugs.
- Lowering the cost of developing and having new medications approved.

Patient safety is FDA's number one concern. Currently, the agency is working to preserve the agency's "gold standard" for safety and effectiveness.

Legal *Briefs*

You Can't Tell the Players Without a Scorecard

By Dale J. Atkinson, JD

Main Street Pharmacy, an Internet pharmacy, maintained an office in Norman, OK, a town situated in Cleveland County. The office processed prescriptions but had no walk-in customers and was operated by a pharmacist who was not a resident of Oklahoma, but was licensed to practice pharmacy in that state.

Prescriptions were dispensed through a worldwide Web site at nationpharmacy.com. A notice was placed on the Web site stating that the pharmacy would not ship drugs to Oklahoma or Texas.

The Oklahoma State Board of Pharmacy filed a complaint against the pharmacist individually and as manager of Main Street Pharmacy. The complaint (which demonstrates the breadth of the Oklahoma Practice Act and Board rules) contained the following counts:

Count 1:

a. Respondent conducted himself in a manner which does not entitle him to the respect and confidence of the pharmacy community.

b. Respondent operates Main Street Pharmacy that utilizes the worldwide Web site and is responsible for all aspects of the operation of Main Street including the Web site.

c. Respondent employs two physicians who did not establish face-to-face patient contact and who prescribed controlled, dangerous substances.

d. Public complaints have been filed that the pharmacy is not reachable, that refills are not being provided, and that false identifications have been used to obtain controlled, dangerous drugs.

e. Respondent is using Oklahoma as a haven for selling drugs extra-territorially, specifically excluding the citizens of Oklahoma and Texas.

Counts 2 through 9 involve allegations in regard to improper pricing, the failure of the respondent to establish and maintain effective controls against diversion of prescription drugs, prescribing excessive quantities of drugs, dispensing drugs on prescriptions issued by a physician who had withdrawn his authorization for these prescriptions, failure to comply with federal and state laws, failure to address possible addiction or dependency of certain patients of the pharmacy, and violation of various rules of the Board.

After the hearing, the Board revoked the permit of the pharmacy and the professional license of the pharmacist based on findings under the multiple counts. The pharmacist, on behalf of himself and the pharmacy, appealed the case to district court located in Cleveland County, the site of the pharmacy office. On motion of the Board, however, the appeal was transferred to the district court in Oklahoma County, the county in which the Board is located and, therefore, where the license and permit were issued.

For reasons not stated in the opinion, the administrative record of the Board hearing was not filed with the district court in Oklahoma County. Despite not having the record, the district court in that county accepted briefs, oral arguments, and affirmed the revocations of the Board. The matter was then appealed by the pharmacist to the Court of Civil Appeals of Oklahoma.

The court of appeals ruled that the Board did not have the authority to seek a change of venue and effectively disposed of the case by transferring it to the district court in Cleveland County for disposition. It further held, however, that an appeal involving factual findings by a board and its disciplinary decision cannot be correctly disposed of if the district court does not have the record of the administra-

tive proceedings. The review by a trial court in the state of Oklahoma is basically confined to a review of the administrative record. The appellate court emphasized that the absence of the record prevented the district court from properly determining the issues raised on appeal by the pharmacist, thus causing the remand of this case to the District Court of Cleveland County for consideration.

Certainly, disgruntled individuals subject to administrative disciplinary actions by regulatory boards should have a full opportunity to seek judicial review of the ultimate board decision. Due process demands this. The "record" established during an administrative proceeding forms the basis for review by the judicial tribunal in the vast majority of cases. Parties appealing an administrative decision have the right to argue legal error by the board using the record as a mechanism for substantiating such claims.

This case is of great interest, however, because of the breadth of the complaint against what appears to be a storefront operation. Many states have been confronted with operations of this nature, questioning whether storefronts should be licensed as pharmacies and, if so, what restraints are placed upon these pharmacies by the practice acts of both pharmacy and medicine. This case is further complicated by the fact that, while located in Oklahoma, the Web site pharmacy shipping the drugs, which was not located in Oklahoma, could not dispense drugs in Oklahoma. The Board alleged in the complaint that the pharmacist-in-charge of the office in Oklahoma was also responsible for the acts of the out-of-state dispensing entity, thus placing his license in jeopardy for acts of the Web site. The question of the necessity of face-to-face contact with a physician with respect to the issuance of prescriptions, particularly those involving controlled dangerous drugs, was also a part of the Board's consideration. This question should also be of interest to the medical board.

We have often emphasized the importance of a board establishing a good record at the administrative level to be wholly prepared to meet any appeal. The absence of a record is certainly a problem as this case indicates. It also appears that in Oklahoma, venue shopping is not an option of the Board.

Mainstreet Pharmacy v Oklahoma State Board of Pharmacy, 2003 WL 22076461, 76 P.3d 91, 2003 OK CIV APP 68 (2003)

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

FDA Commissioner Discusses Reimportation

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Legal Strings

Under current law, the Prescription Drug Marketing Act, FDA approves foreign drugs after facilities have been inspected by FDA officials, adequate documentation of manufacturing and pedigree for products have been supplied, and when FDA is sure of the drug manufacturer's identity.

But, according to McClellan, the US Congress' proposal would simply assume that these less expensive drugs from abroad are as effective and safe as FDA-approved drugs and that FDA should let imported drugs in under certain circumstances. The proposed House Bill HR 2724 does not ensure drug safety and adds prohibitions on FDA's ability to perform inspections, McClellan commented.

"It [HR 2724] would create . . . poor channels and create a conflict with pharmacy laws in every state," said McClellan. He added, "Other entities try to save money for employees by [forming] a partnership with a storefront Canadian pharmacy. State and local governments can't provide reliable safety assurances when they purchase drugs from foreign sources."

Ephedra Dangers, State Bans Sale of Ephedra

When professional athletes use ephedra and experience severe side effects or even death, these occurrences gain national attention. Yet, when the average person experiences the same consequences, there is little, if any, call for action.

More than 18,000 reports of adverse reactions by ephedra users, including strokes, seizures, heart attacks, and deaths, have been received by United States Food and Drug Administration (FDA) – with 60% of these adverse events experienced by people under the age of 40, according to the US Department of Health and Human Services Inspector General Joseph E. Schmitz.

A popular ingredient in weight loss and athletic performance enhancement dietary products, ephedra is a naturally occurring substance derived from the Chinese herb Ma Huang. Ephedra's main active ingredient is ephedrine, which, when chemically synthesized, is regulated as a drug. Currently, only two states, Illinois and New York, have passed legislation to eliminate this harmful substance from store shelves.

The Move to Ban Ephedra

On May 28, 2003, Illinois became the first state in the nation to ban the sale of ephedra. The movement to ban this dietary supplement began when 16-year-old Sean Riggins of Lincoln, IL, died of a heart attack after consuming an ephedra product to help him make the high school football team. Currently in effect, the bill makes it a misdemeanor to sell ephedra supplements in Illinois, an act punishable by up to one year in jail and a $5,000 fine. Those who are repeat offenders could face up to five years and a $20,000 fine.

"Members of the [Illinois] legislature and Governor Rod R. Blagojevich saw what was going on with ephedra and took the bold step of banning it," states Ron Gottrich, manager, Drugs and Medical Devices Programs of the Division of Food, Drugs and Dairies in the Illinois Department of Public Health.

The Illinois ban is the first win for those who have lobbied for the ban of ephedra. US Department of Health and Human Services Secretary Tommy G. Thompson has called for FDA warning labels on ephedra products since October 2002, but the politics of the nutritional supplement industry have triumphed over health care activists. Labels stating that ephedra can cause heart attacks and strokes is an issue the industry has blocked for many years. As stated on National Public Radio's June 23, 2003 edition of *All Things Considered*, Senator Dick Durbin (D-IL) says, "The producers of these supplements can put anything on the shelf. It is up to the FDA to prove it is unsafe."

According to a March 1, 2003 article in *The Salt Lake Tribune*, "Nutritional supplement makers in Utah, self-described 'Silicon Valley of the supplement industry,' are wary of federal calls . . . for warning labels – and possibly limits – on . . . ephedra."

Due to the Dietary Supplement Health and Education Act of 1994 and the help of Senator Orrin Hatch (R-UT), herbal supplements can be marketed more freely than prescription medications, unless FDA can prove the substance is dangerous. In 1999, FDA proposed to limit ephedra sales to 8 mg doses, a plan Hatch challenged. But, since the possible ephedra-linked death of Baltimore Orioles pitcher Steve Bechler in February 2003, Hatch has changed his stance and now supports FDA, calling for a "prompt federal review of ephedra."

However, the federal warning labels and a bill banning ephedra have not yet become a reality. In June 2003, though, FDA issued warning letters to six marketers of products containing ephedrine compounds. There are, however, organizations, corporations, and some companies who have decided to move forward and ban their members from using any nutritional supplements containing ephedra. In 2001, the National Football League became the first professional US sports league to ban the use of ephedra, following the lead of the National Collegiate Athletic Association and the International Olympic Committee. Major League Baseball banned ephedra use in its minor league divisions.

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RxWEST Earns VIPPS Certification

RxWEST.com is the latest online pharmacy to receive NABP's Verified Internet Pharmacy Practice Sites™ (VIPPS®) certification. RxWEST is located at www.rxwest.com.

As a VIPPS-certified site, RxWEST may display the VIPPS hyperlink Seal of Approval on its Web site. By clicking on the VIPPS Seal, consumers will be able to find the verified information they need to make informed decisions regarding their choice of online pharmacies. Consumers may also access the VIPPS database directly via NABP's Web site at www.nabp.net, under "VIPPS," and "Verified Internet Pharmacies List." Currently, 14 online pharmacies have qualified for VIPPS Certification.

"RxWEST elected to participate in the VIPPS program because of VIPPS' reputation and high standards," says Mike Woodley, RPh, RxWEST director of pharmacy operations. "At RxWEST, we maintain high industry standards and welcome the opportunity to demonstrate those standards through participation in the VIPPS program."

RxWEST was founded in 1995. The pharmacy benefit manager designs and administers comprehensive and flexible prescription benefit programs for self-insured clients. Prescription services include access to both retail and mail-order pharmacy programs.

Participation in the VIPPS certification program is voluntary. Developed in 1999, the program provides consumers with a reliable means to identify those online pharmacies that have proven their preparedness to meet the unique challenges of the practice of pharmacy via the Internet.

For more information about the VIPPS program, call NABP at 847/698-6227 or visit the Association's Web site at www.nabp.net.

Ephedra Dangers, State Bans Sale of Ephedra *(continued from previous page)*

Other examples that illustrate that a ban is necessary include:

- Major dietary supplement manufacturer, Twinlab Corp, halted sales of ephedra products because of "escalating insurance costs and regulatory uncertainties";
- Canada, the United Kingdom, and Germany prohibit ephedra sales;
- US Army and Air Force military exchanges have removed ephedra-related products from military commissary shelves worldwide; and
- The 7-Eleven Corp and EAS (a major dietary supplement supplier) have ended sales of ephedra products.

Dangers of Ephedra

According to a February 28, 2003 RAND (a contraction of the words research and development) Study, products containing ephedra can cause such side effects as nausea, vomiting, the jitters, and heart palpitations. Also, evidence exists between these products and such catastrophic events as heart attack, stroke, or sudden death.

RAND's press release concerning the study states, "With regard to catastrophic events, these findings are a strong signal that there is a link between use of ephedra or ephedrine and the occurrence of death, heart attack, stroke, seizures, and serious psychiatric symptoms," says Paul Shekelle, the RAND and US Department of Veterans Affairs physician who headed the study.

Researchers also discovered no evidence that ephedra products boost athletic performance, one of the main reasons people take these products.

NABP supports the ban on ephedra and will assist those state boards of pharmacy who are trying to pass legislation (state or federal) to ban the substance.

FLC Session Highlights Technician Diversion, NABP Clearinghouse

NABP's 2003 Fall Legislative Conference (FLC) featured a session on "Technician Diversion and Monitoring," in which state boards discussed technician registration and diversion programs and NABP outlined the value of reporting technician actions to its Disciplinary Clearinghouse. Presenters stressed the importance of registering pharmacy technicians to help control drug diversion and having a centralized database for monitoring technician disciplinary actions.

Jerry Moore, executive director of the Alabama State Board of Pharmacy, and James R. Weiss, NABP's information technology and services director, shared their knowledge at the session held on Monday, September 15, 2003.

According to Moore, on January 1, 1997, the state of Alabama passed legislation allowing the Board of Pharmacy to register technicians. Since the legislation was enacted, almost 15,000 technicians have been registered. He explained at the FLC that this legislation was necessary because technicians were diverting drugs, but the state had no jurisdiction over them, and pharmacy owners rarely pressed charges. Although diversion by technicians still occurs, the Board now has recourse and pharmacies have a way to discern if technicians have been disciplined before managers make a final hiring or firing decision.

Moore says that state boards may not think technician diversion is problematic, but his investigations have determined that it is a serious concern. The problem of technician diversion is, in fact, 10 times worse than what state boards believe. Investigations in Alabama uncovered an organized ring of people that paid people to obtain employment as pharmacy technicians for the sole purpose of diverting drugs. He notes that in the past three years, 212 technician disciplinary cases have come before the Board. Of those cases, 60 licenses were revoked and seven were put on probation for drug diversion. Other violations included working without a current registration; theft of merchandise or money; conviction of a felony or misdemeanor; working while under the influence of drugs or alcohol; unauthorized possession of a pharmacy key; or fraudulent claims submission.

The Alabama Board's technician registration program helps prevent unregistered technicians, and those who have been disciplined for diversion, from moving from pharmacy to pharmacy and diverting drugs as they go. However, Moore continued, this will not prevent some technicians from seeking employment in another state. Weiss explained how using NABP's Disciplinary Clearinghouse can create a national database of technician disciplinary actions for boards of pharmacy and help states monitor the interstate movement of technicians.

Since the development of NABP's Disciplinary Clearinghouse in 1983, state boards of pharmacy have routinely submitted pharmacist disciplinary action information. Now, however, the Clearinghouse has the capability to process technician information. In the past two years, 42 boards have sent reports of pharmacist disciplinary action electronically and by hard copy

2004 PTCB Examination Dates Announced

The Pharmacy Technician Certification Board (PTCB) recently announced the dates for its nationally recognized Pharmacy Technician Certification Examination (PTCE) to become a certified pharmacy technician (CPhT). The 2004 PTCE dates are March 20, July 17, and November 13; and the examination is available at test centers in all 50 states.

PTCB certification is included in regulations by 20 state boards of pharmacy (see "Survey Shows State Board Embracing Technician Certification" on next page for more information about state requirements for certification) and by employers across all 50 states. Once technicians become a CPhT, their certification moves with them.

Those who sit for the PTCE can register online at www.ptcb.org. The fee for the examination is $120. For more information, visit PTCB's Web site or call 202/429-7576. NABP

for NABP to process in the database. NABP collects and organizes information from the boards and reports are provided to the boards monthly. The same data management reporting can be done with technician information.

Information entered into NABP's Clearinghouse includes identity, licenses, adverse action classifications, and basis for action categories. Adverse action classifications include board actions such as:

- revocation;
- probation;
- suspension;
- denial of renewal; and
- publicly available fine/monetary penalty; etc.

The basis for action categories have a total of 55 codes that identify a specific basis for action. The categories are:

- noncompliance with federal, state, or contractual requirements;
- criminal conviction or adjudication;
- confidentiality, consent, or disclosure violations;
- misconduct or abuse;
- fraud, deception, or misrepresentation; and
- unsafe practice or substandard care.

State boards that submit licensure and disciplinary information to NABP's Clearinghouse can designate NABP as the boards' Health Integrity and Protection Data Bank (HIPDB) agent. Presently, 21 states have designated NABP as their reporting agent for the HIPDB. Other benefits of utilizing NABP's Clearinghouse include:

- uniformity of information;
- NABP manages information on behalf of all boards free of charge;
- Clearinghouse information used by the Electronic Licensure Transfer Program® when preparing official applications for license transfer; and
- crosschecking licenses.

As the role of technicians in pharmacies grows, boards of pharmacy are seeing the importance of registering technicians for patient safety and preventing diversion. NABP's Disciplinary Clearinghouse is an ideal tool for boards that can aid them in processing and housing technician information. For more information on submitting information to NABP's Disciplinary Clearinghouse, contact NABP at 847/698-6227.

Survey Shows State Boards Embracing Technician Certification

Recently, NABP conducted a survey to determine the status of technician certification requirements among state boards of pharmacy. Results show that a majority of boards are currently considering legislation to register or license pharmacy technicians. Forty boards responded to the survey.

- Twenty-six states are considering legislation to register or license technicians, while 14 are taking no action at this time.
- Twenty-two states are considering recognizing or currently recognize the Pharmacy Technician Certification Board (PTCB) certification program or some other mechanism; the other 18 states either do not recognize PTCB certification or recognize some other mechanism.
- Fifteen states requested more information about PTCB certification and the Pharmacy Technician Certification Examination (PTCE).

NABP recognizes the PTCE as a valid assessment mechanism and the PTCB as a credible certification process. Since PTCB's inception in 1995, the organization has certified more than 100,000 pharmacy technicians through the national PTCE and transfer process. The goal of the PTCB national certification program is to enable pharmacy technicians to assist the pharmacist more effectively to offer safe and effective patient care and service.

For complete survey results, contact NABP's Executive Office at 847/698-6227.

Board Training Sessions Receive High Ratings from Attendees

NABP recently hosted 21 staff members from 17 state boards of pharmacy at its annual Program Review and Training sessions held on Friday, August 22, 2003; Monday, August 25; and Friday, September 5, at NABP Headquarters in Park Ridge, IL. Board of pharmacy staff agreed that they enjoyed the chance to learn more about NABP and to network with members of other state boards of pharmacy.

Regina Devine of the Missouri Board of Pharmacy (bottom right) and Wendy Watson (left) and Deborah Stump (right) both of the North Carolina Board of Pharmacy, listen as NABP staff explain the programs and services offered by the Association.

"I really enjoyed coming to NABP and meeting other board of pharmacy employees," says Regina Devine from the Missouri Board of Pharmacy. "It gave us a chance to compare [the] requirements of our boards and also ask questions about NABP. This is a valuable program that should continue."

Suggestions board staff had to make the next training sessions even better included providing more information about the Healthcare Integrity and Protection Data Bank and where and how that data is used, new NABP programs that have been developed, and NABP staff background. One other suggestion was that the training sessions be expanded to a two-day seminar because so much information is covered in one day. The purpose of the sessions is to review the programs and services offered by NABP, how NABP collects and provides information to the boards, and how computer software is integrated into and utilized by NABP's programs.

All attendees were given an *NABP Program Review and Training User Manual* to use as a reference for NABP's programs and computer software programs. In addition, copies of the *User Manual* were sent to all member boards for their review and use.

Next year's program may be held in conjunction with NABP's 100th Annual Meeting and Centennial Celebration, April 24-27, 2004, at the Fairmont Hotel in Chicago, IL.

2003 Program Review and Training Agenda

The following topics were covered during NABP's annual Program Review and Training sessions held in August and September 2003.

NABP Program Review

- North American Pharmacist Licensure Examination™ (NAPLEX®)
- Multistate Pharmacy Jurisprudence Examination® (MPJE®)
- Pre-NAPLEX™
- Foreign Pharmacy Graduate Examination Committee™ (FPGEC®)/Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®)
- Communications/Customer Service Departments (ie, State Newsletter Program and other publications; customer service call statistics; and Annual Meetings and Fall Conferences)
- Electronic Licensure Transfer Program® (ELTP®)/Verified Internet Pharmacy Practice Sites™ (VIPPS®)
- NABP Disciplinary Clearinghouse/Healthcare Integrity and Protection Data Bank (HIPDB)
- Renewal and Application Process

Computer Software

The session also included instruction on computer software for the following programs and services:

- Lotus Notes™ E-mail
- NAPLEX/MPJE
- ELTP/VIPPS
- Clearinghouse/HIPDB

Certified Disease Managers Compensated for Services

According to a study performed by the National Institute for Standards in Pharmacist Credentialing (NISPC), more than half of all pharmacists certified in disease management report compensation for their services. Certified disease managers (CDMs), credentialed by NISPC, receive compensation for their services 57% of the time either personally or at their place of work. Of the 300 survey respondents, 22% are compensated as individual practitioners for disease state management (DSM) services. Results also indicated that 64% of CDMs currently provide DSM to the patients they serve.

Nearly 70% of respondents in the nationwide survey practice in a community independent or chain setting. DSM services offered included diabetes (59%), dyslipidemia (20%), anticoagulation (13%), and asthma (8%). CDMs also provide services in smoking cessation, hypertension, congestive heart failure, osteoporosis, immunization, depression, headache management, weight management/nutrition, and hormone replacement therapy.

Other key findings include:

- Thirty-four percent of CDMs spend between 1% to 10% of their time on patient care activities, while more than 66% of CDMs spend more than 10% of their time directly with the patient.
- More than half of the respondents spend less than 51% of their time on administrative activities related to the provision of these cognitive services.
- Nearly half of the respondents said that less than 10% of their businesses deal with DSM activities. Twenty-two percent mentioned that more than half of their business comes from the DSM services they provide.
- While 80% of CDMs use a paper system to document clinical activities, the majority of respondents would be interested in an electronic documentation system for both clinical and billing activities.
- Sixty-four percent mentioned that private or state-sponsored DSM programs exist that utilize pharmacists as the health care provider.
- Lack of time, compensation, and employer support were the main reasons that 33% of respondents do not offer DSM to their patients.

Currently, 964 pharmacists are credentialed in diabetes, 343 credentialed in asthma, and 178 and 136 credentialed in dyslipidemia and anticoagulation, respectively.

FDA Approves New Cholesterol-lowering Drug

Food and Drug Administration (FDA) recently approved Crestor® (rosuvastatin calcium) to lower cholesterol. In the class of HMG-CoA reductase inhibitors, or statins, rosuvastatin was approved based on multiple trials of at least six weeks duration. It was compared to a placebo and other marketed statins. In these trials, rosuvastatin reduced total cholesterol, bad cholesterol (LDL-C), and triglycerides and increased good cholesterol (HDL-C) with therapeutic response occurring within one week and maximum response seen at four weeks. Approximately 12,000 patients received rosuvastatin at different doses in clinical trials submitted to FDA.

The most frequent side effects seen in patients treated with rosuvastatin included muscle aches, stomach pain, constipation, nausea, and weakness. In rare instances, severe muscle pain and muscle weakness resulting in kidney damage have been associated with statin drugs. Patients should be monitored for abnormalities of liver function before treatment, at 12 weeks following initial therapy, and with any elevation of dose. Monitoring is recommended periodically thereafter.

Rosuvastatin is available in 5, 10, 20, and 40 mg tablets. In clinical trials, the majority of patients reached target LDL-C levels as recommended by the National Cholesterol Education Program on either the 5 or 10 mg starting dose. The 20 mg dose can be the start dose for patients who have very high cholesterol levels, while the 40 mg dose should be reserved only for those individuals who are not adequately treated with the 20 mg dose. MMP

Judge Orders Rx Depot to Cease Business

A United States District Court judge has ordered Rx Depot to cease operations until a trial determines if they flouted a ban on importing and re-importing prescription medications. This ruling follows a suit filed on September 11, 2003, by the US Department of Justice alleging that Rx Depot, Inc, and Rx of Canada violate federal law by importing prescription drugs.

In her ruling, Judge Claire Eagan stated, "The fact that there are currently no known cases of someone being harmed by a drug received as a result of using Rx Depot, ... or that plaintiff is currently unaware of anyone being harmed by prescription medications ordered through Rx Depot and imported from Canada ... does not diminish the legitimate safety concerns of the FDA [Food and Drug Administration] with unregulated commercial reimportation of US-manufactured drugs by someone other than the manufacturer and importation of foreign-manufactured drugs not approved by the FDA."

FDA initially requested that the justice department seek an injunction against the Tulsa, OK-based storefront chain. Before contacting the Department of Justice, FDA sent a warning letter to Rx Depot on March 21, 2003, informing the firm that, "Your actions also present a significant risk to the public health, and you mislead the public about the safety of the drugs obtained through Rx Depot," and that Rx Depot risked possible enforcement action if it continued to promote sales of unapproved drugs, claiming that they were "FDA-approved" and "exactly the same as if purchased in the United States."

Rx Depot plans to appeal this latest ruling. Earlier in the case, despite insisting that it would keep its doors open, Rx Depot shut its eight units located in Oklahoma. Rx Depot operates 85 storefront drugstores that fax patient information to Canadian pharmacies, which then ship prescription drugs to American patients. In addition to FDA's actions, the states of Oklahoma, Arkansas, and Montana have taken action against the company's practices.

Iowa Board Files Emergency Action Against Pharmacy

Union Family Pharmacy, a community pharmacy located in Dubuque, IA, surrendered its pharmacy license after the Iowa Board of Pharmacy Examiners filed an emergency action to suspend its pharmacy license. Charges were brought against the pharmacy following a Board inspection that found that Union Family Pharmacy failed to comply with the "minimum standards for the practice of pharmacy in the State of Iowa and has, thereby, placed patients at high risk for harm."

The Board filed the emergency action on September 12, 2003, and scheduled a hearing for October 9, 2003.

"Union Family Pharmacy indicated to us that it did not want a hearing and would surrender its license," says Iowa Board Executive Director Lloyd K. Jessen. "The pharmacy surrendered its pharmacy license effective October 10. Now the Board will bring disciplinary action against all the pharmacists involved."

According to the Board's report, the pharmacy's general license number, with Charles Wiebke as pharmacist-in-charge, was renewed on December 11, 2002. However, after an investigation performed in early September 2003, the Board found that the alleged wrongdoings of Union Family Pharmacy include:

- Shipping prescription drugs to 47 states outside of Iowa; Union Family Pharmacy was not licensed as an Internet pharmacy and did not hold licensure in any other state.
- Dispensing Schedule III and IV substances that were prescribed through the Internet without a valid doctor-patient relationship. These prescriptions make up nearly all of the 5,000 prescriptions filled through its Web site. In addition, the 5,000 prescriptions were written by the same four doctors.
- Using pharmacy technicians to fill prescriptions without final checks made by pharmacists.

Constitutional Amendment Deadline Set

Proposed amendments to NABP's Constitution and Bylaws must be submitted between January 26, 2004, and March 11, 2004. To be considered during NABP's 100th Annual Meeting and Centennial Celebration, April 24-27, 2004, at the Fairmont Hotel in Chicago, IL, amendments must be submitted in writing to the Office of the Executive Director/Secretary at NABP, 700 Busse Hwy; Park Ridge, IL, 60068. Submission dates are established by NABP's Constitution, which specifies that proposed amendments may be accepted no earlier than 90 days and no later than 45 days before the Annual Meeting's First Business Session.

For more information about the amendment procedure, contact NABP Executive Director/Secretary Carmen A. Catizone at ceo@nabp.net.

Around the *Association*

Dennis Receives Merit Award

Betty Dennis, PharmD, MS, a member of the North Carolina Board of Pharmacy, received the Kappa Epsilon Award of Merit at the 44th National Kappa Epsilon Convention in Kansas City, MO. The Award of Merit recognizes an alumni member who is active within the profession of pharmacy. Currently, Dennis has an active clinical practice at the Ambulatory Care Center at the University of North Carolina (UNC) Hospitals and has an appointment as clinical associate professor at the UNC School of Pharmacy. Other honors and awards she has received include North Carolina Association of Pharmacists' Pharmacist of the Year Award, North Carolina Pharmaceutical Association Presidential Award, and American Society of Hospital Pharmacists Fellow.

Boards Elect New Officers

The New Jersey Board of Pharmacy announced that it has elected two new officers. Edward McGinley, RPh, is now president of the Board and Edith Micale, RPh, is treasurer.

The Oklahoma State Board of Pharmacy has elected new officers for 2003-2004. Jerry Allen, RPh, is now president and James Spoon, RPh, is vice president.

Boards Name New Executive Directors

- Bonnie Rampersaud has replaced James Granger as executive director of the District of Columbia Board of Pharmacy.
- Joanne Boyer, RPh, was appointed executive director of the New Jersey Board of Pharmacy effective September 2, 2003. Before joining the Board, Boyer served as manager of clinical operation services at Aventis Pharmaceuticals in Bridgewater, NJ.
- Debra L. Billingsley, BS, JD, was appointed executive director of the Kansas State Board of Pharmacy on September 15, 2003. She replaces Susan Linn.

New Board Member at NH Board

Vahrij Manoukian, RPh, was appointed to the New Hampshire Board of Pharmacy effective August 19, 2003. His term expires September 6, 2008.

New Mexico Board Moves

The New Mexico Board of Pharmacy moved to a new location in September. The Board is now located at 111 Lomas Blvd, Suite 412, Albuquerque, NM 87102. The phone and fax numbers remain the same.

NABP Centennial Capsule

Join Us for NABP's 100th Anniversary and Centennial Celebration

Where: Fairmont Hotel, Chicago, IL
When: April 24-27, 2004

Through April 2004, the NABP Newsletter *will feature the "NABP Centennial Capsule" that will highlight notable events in NABP's 100-year history.*

1981 – Two states were added to the Bureau of Voluntary Compliance state newsletter program.

1982 – NABP member boards instruct the Association to "fund, develop, and produce . . . an equivalency examination to qualify graduates of foreign institutions to sit for NABPLEX [National Association of Boards of Pharmacy Licensure Examination]." Today, this examination is known as the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). NABP also creates the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) at this time.

1983 – The reciprocity fee is raised to $100; 3,810 applications are processed. The Federal Drug Law Examination (FDLE) is administered by 15 states.

1984 – NABP administers its first FPGEE on April 1. The Association announces the implementation of the Disciplinary Clearinghouse, a service for state boards of pharmacy.

1985 – Three hundred and fifty candidates sit for the FPGEE in three different cities. A $1.5 million budget is approved for NABP; budgets for the FPGEC and NABP Foundation bring the total budget to $2 million.

1986 – NABP changes the NABPLEX from a five-part test to an integrated examination. In June, for the first time, candidates are tested on their practice abilities, not their ability to understand separate disciplines. NABP Headquarters moves to the O'Hare Corporate Center in Park Ridge, IL.

1987 – Carmen A. Catizone succeeds Fred T. Mahaffey as NABP executive director/secretary. Mahaffey served the Association for 32 years.

1988 – The NABPLEX becomes an "in-house" program, joining the FPGEE and FDLE; the Testing and Measurement Department staff expands to accommodate new duties. Nova Scotia, Canada, and Victoria, Australia, become NABP associate members.

1989 – NABP processes a record 4,431 license transfer applications. The previous record was set in 1986 with 4,367 applications.

1990 – Indiana joins the NABPLEX score transfer program, bringing the total number of participants to 38 states. In addition, the score transfer program expands to process requests filed from candidates sitting for the NABPLEX or FDLE in any active or associate member state.

FPGEE Winter Administration Approaching, Pre-FPGEE Aids Candidates

(continued from page 142)

she can expect to receive on the FPGEE, but may not be the actual score attained, nor is it a guarantee of passing the actual examination.

The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

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NABP Meeting Dates

Thursday, December 11, 2003
Committee on Law Enforcement/Legislation Meeting
Hyatt Rosemont Hotel, Chicago, IL

Friday-Sunday, January 9-11, 2004
NAPLEX and MPJE Item Writing Workshops
Hyatt Rosemont Hotel, Rosemont, IL

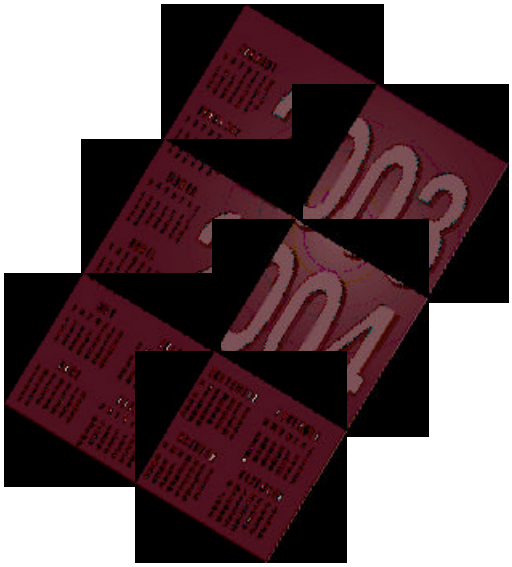
Friday-Sunday, January 23-25, 2004
MPJE State Specific Review Meeting
Hilton Scottsdale Hotel, Scottsdale, AZ

Thursday-Friday, February 12-13, 2004
New Executive Officers Orientation Program
NABP Headquarters, Park Ridge, IL

Friday, March 12, 2004
Committee on Constitution and Bylaws Meeting
NABP Headquarters, Park Ridge, IL

Saturday-Tuesday, April 24-27, 2004
NABP's 100th Annual Meeting and Centennial Celebration
Fairmont Hotel, Chicago, IL

Thursday-Sunday, November 11-14, 2004
NABP/ASPL Joint Fall Conference
Renaissance Vinoy Resort and Golf Club,
St Petersburg, FL



newsletter
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