newsletter

National Association of Boards of Pharmacy®

AWARE GET INFORMED. PRESCRIPTION DRUG SAFETY®

September 2012 / Volume 41 Number 8

aid to government
the profession
the public
1904 to 2012

Upcoming Events

September 19-20, 2012
NABP Interactive Member Forum
Northbrook, IL

September 29, 2012
DEA National Drug Take-Back Day

October 14-16, 2012
NABP/AACP Districts 1 & 2 Meeting
Skytop, PA

October 21-24, 2012
NABP/AACP Districts 6, 7, & 8 Meeting
Little Rock, AR

October 31-November 2, 2012
NABP/AACP District 4 Meeting
Ann Arbor, MI

November 13-14, 2012
NABP Interactive Executive Officer Forum
Northbrook, IL

Pill Mill Laws and Enforcement Efforts Make Progress; New Laws Aim to Shut Down More Illegal 'Pain Clinics'

©iStockphoto.com/sjlocke

As states work to pass and implement legislation in hopes of curbing prescription drug abuse and misuse, they are taking into consideration sophisticated pill mill operators and including components to combat these schemes. Pill mill scheme operators will educate themselves on which states have a prescription monitoring program (PMP) and the state's PMP rules and adopt strategies to avoid detection of doctor shopping as pointed out by the Honorable Roger W. West, JD, in his presentation at the April 2012 National Rx Drug Abuse Summit. West presented this information as part of a detailed overview of organized prescription drug trafficking in Kentucky and related investigations spanning from 2000 to 2011. West explained how Kentucky pill mill operators sent individuals to Pennsylvania, Ohio, and Florida to obtain pills from illegally operating clinics for sale back in Kentucky. As this example shows, the illegal distribution of prescription drugs through pill mill operations is a problem affecting numerous states across the country. Such illegal activity has contributed to the rise in prescription drug abuse, with deaths due to overdose of prescription painkillers at epidemic levels, as stressed by the Centers for Disease Control and Prevention (CDC). In fact, CDC has indicated that the number of fatal overdoses associated with prescription painkillers is now greater than the number of overdose deaths from heroin and cocaine combined.

To address the illegal distribution of prescription controlled substances through large scale operations, including shutting down illegal "pain clinics," or pill mills, and reducing doctor shopping, several states, including Ohio, Tennessee, Georgia, Kentucky, and West Virginia, have adopted new laws to regulate pain management clinics and targeted, multi-agency enforcement efforts such as those in Florida continue. New laws also aim to protect public health by ensuring the legitimate pain management clinics can safely provide treatment to patients with legitimate need. More states have also adopted laws to establish or enhance a PMP.

(continued on page 166)

In This Issue. . .

The *NABP Newsletter* (ISSN 8756-4483) is published 10 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 63 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.

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
847/391-4406
www.nabp.net
custserv@nabp.net

Carmen A. Catizone
Executive Director/ Secretary

Larissa Doucette
Communications Manager

Pill Mill Laws

(continued from page 165)

Ohio's Pill Mill Bill

Ohio's comprehensive "Pill Mill Bill" (HB93) includes several provisions to deter doctor shopping and prevent abuse. Under the new law, effective October 27, 2011, a prescriber's practice must be licensed as a pain management clinic with a Terminal Distributor of Dangerous Drugs license if the majority of his or her patients are being treated for pain or chronic pain with controlled substances. The Ohio State Board of Pharmacy oversees this licensure process, and must coordinate with the State Medical Board of Ohio in certain cases. In addition, the Board promulgated a rule that requires all pharmacists to check the state's PMP, known as OARRS (Ohio Automated Rx Reporting System), if the prescription exceeds 12 weeks of continuous treatment of a controlled substance or if "red flags" arise while dispensing the prescription to the patient. Effective November 30, 2011, the State Medical Board of Ohio also implemented a rule requiring that prescribers check OARRS.

Tennessee Adopts New Pain Clinic Requirements

To curb doctor shopping, Tennessee adopted a law regarding provisions for the registration of pain management clinics, and a law strengthening PMP reporting and use requirements.

According to the National Conference of State Legislatures, Tennessee "ranks second in the nation in the number of prescription medications dispensed," due to the number of pill mills.

Effective January 1, 2012, all pain management clinics in Tennessee must be registered with the state. Under the new law, "pain management clinic" is defined "as a privately-owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse or a physician assistant provides pain management services to patients, a majority of whom are issued a prescription for, or are dispensed, opioids, benzodiazepine, barbiturates, or carisoprodol, but not including suboxone, for more than 90 days within a 12-month period." The clinic must be run by a medical director who is a physician licensed to practice medicine in the state. Tennessee's law also prohibits cash transactions and increases penalties on clinic employees that violate regulations. Effective March 26, 2012, rules promulgated by the Tennessee Department of Health Division of Pain Management Clinics specify responsibilities and training requirements for pain clinic medical directors.

Tennessee has also adopted a law requiring that pharmacists submit required data to the state's PMP database every seven days. The law also requires physicians to query the database prior to writing new prescriptions for opioid pain drugs to help ensure the patient is not doctor shopping.

Georgia to Implement Similar Law

In January 2012, the North Carolina Board of Pharmacy made its licensees aware that numerous pharmacies in the state had been presented with suspicious prescriptions issued by pain clinics in Georgia. The Board explained that these prescriptions were usually issued to people living outside the state, and were usually prescriptions for various controlled substances. Also, pharmacists contacting facilities to verify the prescriptions were typically unable to reach the prescriber, but told on the phone that the prescription is "legitimate." The Board cautioned pharmacists that "most, if not all, such prescriptions are not written for a legitimate medical purpose in the ordinary course of medical practice."

To address such activity in Georgia and to "better protect the public from criminal activities associated with the illegal distribution of controlled substances as well as provide for a safer place for people to obtain appropriate medical treatment," on March 27, 2012, the Georgia Legislature passed the Georgia Pain Management Clinic Act, which will implement provisions for the licensure and regulation of pain management clinics in Georgia. The law defines pain management clinics as a clinic or medical practice where more than 50% of the patients are treated for chronic pain for nonterminal conditions with Schedule II or Schedule III drugs. Practices advertising

(continued on page 170)

NABP Encourages Boards to Participate in 2012 Triathlon, a Series of Fall Meetings

In the spirit of the 2012 Summer Olympics, NABP is reaching out to the state boards of pharmacy encouraging participation in a triathlon of meeting events this fall.

The trio of events include:

- **NABP Interactive Member Forum**
  September 19-20, 2012
  Northbrook, IL
- **Tri-Regulator Symposium**
  October 17-18, 2012
  Washington, DC
- **NABP Interactive Executive Officer Forum**
  November 13-14, 2012
  Northbrook, IL

Member Forum

The first leg of the triathlon, the NABP Interactive Member Forum, will provide board of pharmacy members with the opportunity to network with their peers while discussing regulatory trends and challenges faced by their boards. The forum will take place over two days – September 19-20 – and programming will focus on timely topics based on member input prior to their arrival at the forum.

In July, NABP invited each board of pharmacy to designate one member from the board to attend the forum at no charge. As with previous forums, travel, hotel accommodations, and meals will be paid by NABP. In addition, there is no registration fee for the meeting. Questions may be directed to Penny Moroney, NABP meeting services manager, at nabpmeetings@nabp.net.

Tri-Regulator Symposium

As the second leg of the triathlon, the Tri-Regulator Symposium offers the boards of pharmacy a chance to discuss opportunities for interprofessional cooperation and the challenges facing state pharmacy, medical, and nursing boards. On October 17-18, the symposium will join together NABP, Federation of State Medical Boards, and National Council of State Boards of Nursing in the first-ever meeting of its kind. Attendance is open to board executive directors and board members; however, space is limited. Registration ends August 21. Questions may be directed to Dana Oberman, NABP executive meeting planner, at exec-office@nabp.net.

Executive Officer Forum

The third and final leg of the triathlon, the NABP Interactive Executive Officer Forum, is tailored specifically to board of pharmacy executive officers. Like the Member Forum, each executive officer is invited to attend the forum at no charge, with travel, hotel accommodations, and meals covered by NABP, in addition to no registration fee. Invitations for the November 13-14 forum will be forthcoming.

Executive Committee

Malcolm J. Broussard
Chairperson
One-year term

Michael A. Burleson
President
One-year term

Karen M. Ryle
President-elect
One-year term

Joseph L. Adams
Treasurer
One-year term

James T. DeVita
Member, District 1
Serving third year of a three-year term

Edward G. McGinley
Member, District 2
Serving third year of a three-year term

Mark T. Conradi
Member, District 3
Serving second year of a three-year term

William John Cover
Member, District 4
Serving second year of a three-year term

Lloyd K. Jessen
Member, District 5
Serving third year of a three-year term

Jeanne D. Waggener
Member, District 6
Serving first year of a three-year term

Mark D. Johnston
Member, District 7
Serving first year of a three-year term

Hal Wand
Member, District 8
Serving second year of a three-year term

NABP Executive Committee elections are held each year at the Association's Annual Meeting.

Incidentally: Incident Reports Limited Disclosure

By Dale J. Atkinson, JD

Boards of pharmacy are created and empowered to protect the public through the regulation of the profession. In order to carry out this essential mission, boards generally have the authority to accept and initiate complaints and conduct administrative investigations related thereto. The scope of such investigative powers may, however, be subject to limitations set forth in law through the practice act, administrative procedures act, or other legislation. Confidentiality laws and other legislation designed to promote internal review and quality improvements may prevent the disclosure of valuable information to the investigating regulatory board. Such prohibition from disclosure is potentially countered by the public protection mission of the board of pharmacy and its obligations to the consuming public. Consider the following.

In July 2010, the Illinois Department of Financial and Professional Regulation (Department) issued three administrative subpoenas to Walgreen Company (Walgreens) seeking "All incident reports of medication error involving" three named pharmacists employed by Walgreens. While the judicial opinion did not state the basis for the subpoenas, it is presumed that the Department was investigating alleged wrongdoing regarding the three pharmacists.

In response, Walgreens filed written objections to the subpoenas, arguing that the requested documents were privileged under the Patient Safety and Quality Improvement Act (Patient Safety Act) and the Medical Studies Act (MSA). Specifically, the Patient Safety Act is federal legislation that creates patient safety organizations (PSO) in order to collect, aggregate, and analyze confidential information reported by health care providers. In addition, the Patient Safety Act creates a legal privilege and confidentiality protections regarding certain patient safety work product for reports "assembled or developed by a provider for reporting to a patient safety organization." The legal privilege significantly limits the use of these reports in criminal, civil, and administrative proceedings.

The MSA is an Illinois State law, which also protects certain peer review information conducted by hospitals and other health care providers and prevents disclosure in criminal, civil, and administrative proceedings. The MSA is intended to encourage the disclosure of medication errors to allow for improvement of patient care and safety.

Under policies related to the occurrence of medication errors, Walgreens pharmacists are required to complete a report and submit it to the Walgreens internal Strategic Tracking and Analytical Reporting System (STARS).

Pursuant to an affidavit filed with Walgreens' objections to the subpoenas, STARS reports are transmitted to the Patient Safety Research Foundation, Inc, a federally certified PSO. The affidavit also stated that Walgreens "does not create, maintain, or otherwise have in its possession documents which are specifically entitled 'incident reports'

pertaining to 'medication error.'" Finally, the affidavit stated that STARS reports contain information about an improperly processed or filled prescription that is dispensed to a customer and are considered strictly confidential.

In response, the Department countered that the language of the subpoena was sufficiently broad to require the submission of all incident reports within and outside of STARS. The Department also argued that the privilege under the Patient Safety Act, which would prohibit submission via a subpoena only applied to documents created e**xclusively** for the purpose of being transmitted to a PSO. Because the STARS reports had the potential for use in a non-privileged manner, the Department argued such potentiality removed them from protection.

Walgreens submitted a second affidavit whereby the company reaffirmed that it did not gather or require any incident reports other than the STARS reports. Again in response to this Walgreens averment, the Department submitted an affidavit disputing the facts regarding the lack of any other incident reports. The Department personnel stated that medication error reports from pharmacist activities had been submitted by Walgreens in previous administrative actions casting doubt on the stated Walgreens policies.

After hearing oral arguments on Walgreens' motion to dismiss the subpoenas, the lower court ruled in favor of the company and against the Department. It found that the incident reports of medication error constituted patient safety work product and were privileged and protected from disclosure under the Patient Safety Act. The court also held that the MSA applied to pharmacies. The Department appealed the ruling.

On appeal, the Department argued that the Patient Safety Act does not prohibit a state regulatory agency from seeking disclosure of incident reports documenting medication errors. It also argued that the record before the lower court did not establish that **every** incident report is privileged and that the MSA did not apply to pharmacies.

After addressing the standard of review on a motion to dismiss, the appellate court turned its attention to the legislative intent of the Patient Safety Act and its sweeping evidentiary protections for qualified materials. The court summarized that the Patient Safety Act provides that patient safety work product is privileged and "shall not be subject to discovery in connection with a Federal, State, local civil criminal, or administrative proceeding." It also noted that information collected, maintained, or developed separately from a patient safety evaluation system to be submitted to a PSO is excluded from the discovery protections.

First, the court noted that Walgreens' affidavit clearly identified the fact that the incident reports were gathered solely for the purpose of submission to a PSO. Next, the court noted that the narrow scope of the language in the subpoena was limited to incident reports of a nature which were subject to the Patient Safety Act privilege protections. Finally, the court noted that the documents submitted by Walgreens in previous actions involving the Department were about policy violations such as failing to follow directions from supervisors or providing medications for free and did not constitute incident reports of medication errors.

In a minor segment of the opinion, the appellate court did agree with the Department that the lower court erred in finding that the MSA applied to pharmacies. This portion of the opinion did not give rise to a need for a reversal or remand of the lower court dismissal of the Department petition.

(continued on page 186)

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

Pill Mill Laws

(continued from page 166)

"treatment of pain" or using the word "pain" in its name are also considered pain clinics under the new law.

The Georgia law will require pain clinics to apply for a license with the Georgia Composite Medical Board and renew the license every two years. Such pain clinics must be "wholly owned" by physicians licensed in Georgia, and an authorized prescriber, such as a physician, must be on site when the clinic provides treatment or services. The medical board may initiate investigations of applicants for pain clinics as part of the application process.

Kentucky and West Virginia Laws Adopted

To address the proliferation of pill mills in Kentucky, including the organized prescription drug trafficking described by West, a bill (HB1) including a "broad spectrum of aggressive measures needed to fight the problem of prescription drug abuse" was signed into law by Governor Steve Beshear in April 2012. As with the Georgia law, in Kentucky, pain management clinics must "be owned and operated by a licensed medical practitioner." As noted by *Kentucky Health News*, prior to the law, 33 of 77 pain clinics in Kentucky were owned by people without a medical background. Under the law, the owner, or a designee who is a physician, must be physically present practicing medicine in the facility during at least 50% of the hours of operation. Also, the owner or designee must have training in pain management such as having completed a certification or accredited residency. The law also requires medical licensure boards to investigate prescribing complaints immediately.

In addition, the law requires all prescribers to register to use the state's PMP, known as the Kentucky All Schedules Prescription Electronic Reporting (KASPER) System. Further, prescribers are required to query KASPER prior to the initial prescribing of Schedule II or Schedule III medications. When prescribing controlled substance medications, prescribers are also required to discuss risks and benefits with the patient and obtain written consent for treatment.

Approved by Governor Earl Ray Tomblin on March 29, 2012, a new law in West Virginia will require specific regulations for pain clinics. The law defines pain management clinics as those privately owned clinics where in any month more than 50% of patients are prescribed or dispensed opioids or other controlled substances, as specified in rules, for chronic pain resulting from non-malignant conditions. At least one owner of a pain clinic must be a physician actively licensed to practice medicine, surgery, or osteopathic medicine or surgery in West Virginia, and the West Virginia Office of Health Facility Licensure and Certification must inspect each facility prior to licensing a pain clinic. Only a physician or pharmacist may dispense controlled substance medication at a pain clinic, and prior to prescribing or dispensing a new prescription, they must consult the state's PMP to ensure the patient is not doctor shopping.

These laws in neighboring Georgia, Kentucky, Tennessee, and West Virginia are likely to enhance enforcement efforts as well as prevent the establishment of new pill mills, as shown by the progress made in Florida.

Florida's Progress

Florida's comprehensive bill to fight pill mills was signed into law in June 2011 and, effective July 1, 2011, the law banned most physicians from dispensing Schedule II and III drugs and increased fines on doctors who violate standards of care.

This new law, along with a 2010 Florida law requiring all pain management clinics to register with the Florida Department of Health, saw results with the number of registered pain clinics dropping by 41% in one year. As of March 31, 2011, there were 854 registered pain clinics in Florida and as of March 2012, there were 508 registered pain clinics.

Further, Drug Enforcement Administration (DEA) data showed a 97% decrease in oxycodone purchases by doctors in Florida from 2010 to 2011, following the implementation of the new state laws. DEA notes that in 2010, Automation of Reports and Consolidated Orders System data showed that 90 of the top 100 oxycodone purchasing physicians in the nation were located in Florida, and that in 2011 only 13 prescribers on that list were located in Florida. DEA attributes this drop to the enforcement of new Florida laws that "stripped doctors of their ability to dispense controlled substances, including opioid based pain relievers, at rogue pain clinics," as indicated in a DEA news release.

Florida's new law also required the implementation of a state PMP with pharmacies and those prescribers authorized to dispense required to report certain Schedule II through IV prescriptions within seven days of the dispensing date. Law enforcement have been able to request PMP reports related to active investigations since November 14, 2011. Prescribers and pharmacies are not required to use the PMP prior to prescribing a controlled substance, but may register to use the database.

At the federal level, increasing enforcement – against pill mills, doctor shopping, and other instances of prescribing outside of standard medical practice – is among the four goals of the 2012 National Drug Control Strategy. The strategy report explains that throughout 2011 several multi-agency operations successfully shut down numerous pill mills and arrested prescribers engaged in related illegal activity. In Florida, for example, three operations targeting pill mills resulted in 22 arrests and several indictments against doctors and others involved in pill mill schemes, as well as the closure of 40 pill mills.

Operation Oxy Alley, which resulted in the arrests

(continued on page 178)

Drugs Marketed Without FDA Review and Approval: Public Health Implications and Roles for Pharmacists

Contributed by Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Office of Unapproved Drugs and Labeling Compliance: Kim Tran Simmons, JD, RPh; Tara P. Turner, PharmD, MPH; Spencer Salis, PharmD; Anuj A. Shah, MA, JD; and Sara Rothman, BA.

Did you know that there are thousands of drugs on the market that have never been reviewed by Food and Drug Administration (FDA)? Some prescription drug products are marketed illegally, without FDA approval. In addition, commonly used over-the-counter (OTC) preparations can be legally marketed without FDA premarket review or approval if they are marketed in accordance with pre-determined conditions (as described in the OTC monograph system) set forth by FDA; however, it is the responsibility of the firms that bring these products to market to ensure that they are legally compliant drug products. Therefore, pharmacists can not assume that all marketed drugs have been reviewed by FDA to be safe and effective. The existence of unapproved drugs impacts the public health and creates vital roles for the practicing pharmacist.

Background

The Federal Food, Drug, and Cosmetic Act generally requires that drugs marketed in the United States be shown to be both safe and effective prior to marketing.[1] The New Drug Application (NDA) process, required for introducing a new drug into the marketplace, includes a product-specific review of a drug's safety and efficacy; drug specific labeling, including review of a drug's indications, dosing, directions for use, and safety information; inspections of the drug manufacturing facilities to ensure compliance with current Good Manufacturing Practices; and additional post-marketing requirements, such as reporting of adverse drug events.[2]

In addition, while all new prescription and OTC drugs require FDA approval prior to marketing, FDA established the OTC monograph system (also referred to as the OTC Drug Review) as a way for OTC drug products to come to market without individual FDA evaluation and approval if they meet FDA's established conditions for Generally Recognized As Safe and Effective (GRASE).[3] Those products that do not meet the conditions set forth by FDA still require an NDA.

With many laws in place to ensure that drugs are safe and effective, why do illegally marketed unapproved drugs exist? There have been progressive changes to the drug laws since the passage of the 1906 Pure Food and Drug Act.[4] These changes to the law were primarily a response to address tragedies that occurred from drugs, resulting in the implementation of stronger drug laws.[5] Yet some drugs are currently marketed as if the laws never changed. These drugs are not FDA approved, nor do they conform to an OTC monograph or otherwise qualify to be marketed under the OTC monograph system. The lack of evidence demonstrating safety and effectiveness poses a significant public health concern.

Furthermore, although OTC drugs often pose fewer safety hazards than prescription drug products, it is the responsibility of firms to ensure that the OTC drug products they bring to market under the OTC monograph system are monograph compliant. Only after such OTC medications come to market is FDA able to identify and remove from the marketplace noncompliant and unapproved OTC products. It is especially important that pharmacists and their patients do not entertain a false sense of security regarding OTC products, particularly since they are not required to be administered under the supervision of a health care professional.[6]

(continued on page 172)

1. Federal Food, Drug, and Cosmetic Act, §505(a) (21 USC §355(a)).
2. For more information about the drug approval process, including different types of applications (investigational new drug, NDA, abbreviated new drug application, and biologics license application), see the FDA Web site, *www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm.*
3. OTC drug monographs are a kind of "rule book" of conditions for each therapeutic category covering acceptable ingredients, indications, doses, formulations, labeling, and testing. A marketed drug that is consistent with the conditions set forth under a final monograph and all other general applicable OTC requirements is considered GRASE under the monograph. In addition, there are certain categories of OTC products where FDA has not published a final monograph but has published a Tentative Final Monograph (TFM). For OTC products that fall under a TFM, FDA also does not object to the marketing of a product that meets the proposed conditions of that TFM when such marketing does not present a public health concern. Furthermore, if an OTC product qualifies for evaluation under the OTC Drug Review, because as formulated and labeled it was marketed OTC at the inception of the OTC Drug Review (ie, is "eligible for the OTC Drug Review"), but is not yet covered by a final monograph, the product may be marketed pending completion of a final monograph absent any public health concern.
4. For more information, see *A History of the FDA and Drug Regulation in the United States, www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/UCM093550.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=drug law history&utm_content=3.*
5. For information on the sulfanilamide disaster, see *www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm.*
6. For more information about OTC drug marketing requirements, see the FDA Web site, *www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm209647.htm.*

FDA Review and Approval

(continued from page 171)

Public Health Impact

Illegally marketed unapproved drugs raise public health concerns for a variety of reasons, including:

- **Safety risks** Unapproved drugs may be unsafe. They have not undergone the rigorous FDA review process, so their safety has not been demonstrated; the absence of reported safety problems does not mean that these problems do not exist. For example, carbinoxamine, a sedating antihistamine, was labeled for use in children as young as one month of age. Its use was associated with 21 infant deaths. FDA ordered companies to stop manufacturing unapproved carbinoxamine-containing products in 2006.[7]
- **Lack evidence of effectiveness** Unapproved drugs may be ineffective. For example, trimethobenzamide hydrochloride suppositories, indicated for the treatment of nausea and vomiting, were found to lack evidence of effectiveness and in 2007, FDA ordered all companies to stop manufacturing and distributing this drug product.[8]
- **Labeling deficiencies** Unapproved drugs may have labeling deficiencies, including inadequate directions for use and inadequate information regarding potentially serious side effects. For example, approved versions of ergotamine, for the treatment of vascular headaches and migraines, have a boxed warning in their labeling regarding a possibly fatal drug-drug interaction with CYP 3A4 inhibitors. However, labeling of most of the unapproved versions did not contain this warning. In 2007, FDA sent warning letters to eight manufacturers and 12 distributors of ergotamine-containing drug products.[9]
- **Drug quality issues** Unapproved drugs may not be of expected identity, strength, quality, and purity. For example, between 1987 and 1994, FDA received complaints of potency problems with orally administered levothyroxine sodium products. None had approved NDAs. In 1997, FDA issued a *Federal Register* notice announcing its finding that levothyroxine sodium products were new drugs and gave manufacturers three years (later extended to four) to submit and obtain approval of NDAs.[10]
- **Challenge the integrity of the new drug approval and OTC drug monograph system** Unapproved drugs challenge the integrity of the drug approval system by competing with approved versions of products. Illegal marketing of unapproved drug products reduces incentives for research to prove safety and effectiveness and promotes an uneven playing field through unfair competition between manufacturers of approved and unapproved drugs. Some unapproved drugs are marketed as generics, when in fact an approved reference or innovator product does not exist. For example, in 2009, FDA warned companies to stop marketing unapproved versions of codeine sulfate tablets, which directly competed with approved versions of the drug.[11]
- **Limited post-marketing surveillance** Another problem with unapproved drugs is limited post-marketing surveillance. Manufacturers of unapproved prescription products who are not complying with pre-market requirements are also not likely to adhere to post-marketing requirements. Although drug manufacturers are required to report unexpected, serious adverse events to FDA, there is no requirement for periodic reporting.

To address the problem of unapproved drugs, in June 2006, FDA announced the Marketed Unapproved Drugs Initiative and published a final guidance titled *Marketed Unapproved Drugs – Compliance Policy Guide (CPG),* outlining enforcement policies aimed at efficiently and rationally bringing all illegally marketed unapproved drugs into the approval process.[12] Through the *CPG,* FDA encourages companies to comply with the drug approval

7. *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#carbinoxamine.*
8. *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#trimethobenzamide_hydrochloride.*
9. *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#ergotamine.*
10. 62 *Federal Register* 43535; August 14, 1997.
11. *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm#codeine_sulfate.*
12. US Department of Health and Human Services, FDA, Center for Drug Evaluation and Research, *Guidance for FDA Staff and Industry: Marketed Unapproved Drugs – Compliance Policy Guide:* Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs. US FDA Web site, *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf* .

or appropriate regulatory process, while seeking to minimize disruption to the marketplace. The *CPG* provides notice that any product that is being marketed illegally is subject to FDA enforcement action at any time.

Since the *CPG's* publication in 2006, FDA has taken enforcement action against 19 classes of prescription drugs, notifying manufacturers and distributors of an unapproved drug to stop manufacturing and distributing affected products.[13] Firms who do not comply are subject to additional actions such as seizures and injunctions.

- In 2007, FDA took action against unapproved timed-release dosage forms containing the expectorant guaifenesin. Timed-release drugs require FDA approval to ensure that the product releases its active ingredients safely and effectively, sustaining the intended effect over the entire time in which the product is intended to work. Currently, there are several firms who market approved versions of timed-release products containing guaifenesin, including OTC products under the trade names Mucinex® and Mucinex D.[14]
- In 2011, FDA took action against approximately 500 unapproved oral drug products labeled for prescription use and offered for relief of cold, cough, or allergy symptoms because of potential safety risks, lack of evidence of effectiveness, and the presentation of direct challenges to the new drug approval and OTC drug monograph system. Some products were extended release formulations while others were inappropriately labeled for use in infants and young children. In fact, some of the immediate-release drug products subject to this action could potentially be legally

(continued on page 174)

FDA Prompts Companies to Remove Certain Unapproved Oxycodone Products from Market

On July 5, 2012, Food and Drug Administration (FDA) announced its intent to take enforcement action against companies that manufacture or distribute unapproved single-ingredient, immediate-release oral drug products containing oxycodone hydrochloride, including tablets, capsules, and oral solutions (77 *Federal Register* 16475; July 6, 2012). These products have not been evaluated by the FDA for safety, effectiveness, manufacturing quality, or appropriate labeling, and cannot be legally marketed in the United States.

Oxycodone is listed under Schedule II of the Controlled Substances Act (21 U.S.C. 801, et seq.) with an abuse liability similar to other opioid agonists. Improper labeling and use of oxycodone can lead to overdose and death. FDA recognizes that opioid medications are associated with prescription drug misuse, abuse, and addiction, which have resulted in an increase in injuries and deaths across the US over the last 10 years.

FDA took this recent action because unapproved single-ingredient, immediate release oral oxycodone products have been associated with reports of medication errors causing serious adverse events. In addition, some of these unapproved products omit important warning information in their labeling.

Consumers will continue to have access to FDA-approved oxycodone products. There are FDA-approved versions of these drug products on the market that contain the same active ingredient, strength(s), and dosage forms as the unapproved products. Manufacturers of the approved versions of these products have given FDA assurance that they can adequately supply the market. Pharmacists should be prepared to assist affected patients by working with prescribers to recommend approved alternatives, as needed.

Companies with products that are subject to this action are expected to stop manufacturing the products within 45 days (August 20, 2012) and stop shipping the products within 90 days (October 4, 2012). Companies that continue to market products that fall within the scope of this *Federal Register* notice are subject to enforcement action including seizure, injunction, or other judicial or administrative proceeding.

13. FDA Unapproved Drugs Enforcement page: *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm.*

14. 72 *Federal Register* 29517; May 29, 2007.

FDA Review and Approval

(continued from page 173)

marketed without FDA approval if reformulated to comply with the OTC cold cough final monograph. Firms could remove the labeling for prescription use only, alter products' indications, and remove the ingredients not covered by the OTC monograph.[15]

Despite FDA's efforts, firms continue to introduce unapproved new drugs to the market. The unapproved drug business model generates large profits for companies who avoided the costs of research and development or the costs involved in the drug approval process. Yet, for all the aforementioned reasons, drug products need to be either FDA approved or conform to an OTC monograph to protect the public from the risks of unsafe, ineffective, or poor quality products. To address this issue, FDA published a revised *CPG* in September 2011, stating that manufacturers or distributors that begin marketing unapproved drugs after September 19, 2011, are subject to immediate enforcement action without regard to the enforcement priorities set forth in the original *CPG*.

Although OTC drug products generally pose fewer safety hazards than prescription drug products, in part because most OTC drugs are intended to alleviate symptoms rather than to treat disease, OTC medications have much easier consumer access and can still be associated with safety concerns. The following are examples of actions that FDA has taken against firms that illegally marketed OTC medications:

- In 2009 FDA issued a warning letter to the manufacturer of three Zicam® Cold Remedy products, marketed as OTC homeopathic cold remedies, because the agency had received more than 130 reports of loss of sense of smell related to the use of these products. In some cases, loss of smell may be a permanent condition that significantly impacts a consumer's quality of life.[16]
- In 2011, FDA issued four warning letters to companies that manufacture and market OTC drug products, including hand sanitizers, that claim to prevent infection from Methicillin-resistant Staphylococcus Aureus bacteria (MRSA). In addition, the labeling of some of the firms' hand sanitizing drug products make claims related to preventing infection from E coli and/or H1N1 flu virus. These organisms are significant public health threats and FDA does not have sufficient evidence demonstrating that these products are safe and effective for these purposes.[17]

Pharmacist Roles

As FDA continues its work to help secure the nation's drug supply by eliminating illegally marketed unapproved drugs, pharmacists play a vital role in protecting the American public in a number of ways. Health care providers, including pharmacists, have a responsibility to promote quality health care and preserve patient safety.

Pharmacists need to be aware of the problem of marketed unapproved drugs, as well as potential safety issues related to marketed OTC drug products. FDA provides a variety of resources, including videos, podcasts, and a WebLearn course, to convey the message to pharmacists and other health care providers, as well as to consumers.[18]

Drug product labels are not required to document FDA approval status. Pharmacists can not assume that because a drug is listed in commonly used references or is available on pharmacy shelves, it has been FDA reviewed or approved. FDA provides various resources to determine the approval status of drugs:

- Drugs@FDA contains a listing of most FDA-approved drug products, including prescription and OTC human drugs with an approved drug marketing application (NDA or abbreviated new drug application (ANDA)) and most therapeutic biologic products with an approved biologics license application. OTC monograph products are not included.[19]
- The *Orange Book* contains a listing of all prescription and OTC drug products with an approved NDA or ANDA, as well as discontinued products.[20]
- The National Drug Code (NDC) Directory is a reflection of those products that are

(continued on page 187)

15. 76 *Federal Register* 11794; March 3, 2011.
16. FDA Advises Consumers Not To Use Certain Zicam Cold Remedies: Intranasal Zinc Product Linked to Loss of Sense of Smell, *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm167065.htm.*
17. FDA Warns Companies to Stop Making MRSA Claims for Over-the-Counter Products, *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm252127.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=mrsa%20warning%20letters&utm_content=1.*
18. Unapproved Drugs Initiative Web page, Resources for You, *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=unapproved%20drugs&utm_content=4.*
19. Drugs@FDA, *www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.*
20. *Orange Book, www.accessdata.fda.gov/scripts/cder/ob/default.cfm.*

Amended *Model Act* Addresses Pharmacy Security and Provides New *Model Rules* for Medical Gases

As part of its effort to assist the boards of pharmacy as they work to protect the public health, NABP recently amended the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* by increasing security provisions for pharmacies, adding *Model Rules* for medical gases, updating electronic prescribing language, and adding language intended to help improve quality and safety in patient care. These changes were incorporated as a result of the Executive Committee-approved recommendations of the Task Force on the Control and Accountability of Prescription Medications and the Committee on Law Enforcement/Legislation.

Revisions recommended by the Task Force on the Control and Accountability of Prescription Medications included adding a state and federal fingerprint-based criminal background check for applicants for pharmacist, pharmacy, pharmacy technician, and pharmacy intern licensure. For clarification, the Committee on Law Enforcement/Legislation added "as specified by Board rule," so as to provide flexibility for the boards. Along those lines, licensees, upon renewal, are required to attest to the fact that they have no criminal convictions or arrests. Additionally, a notification provision was added requiring all licensees to report to the board any criminal conviction or pleas of guilty or *nolo contendere*.

The task force also suggested several revisions to the facility provisions in the *Model Rules for the Practice of Pharmacy* to clarify certain requirements related to separation of employment of an employee and the Committee on Law Enforcement/Legislation revised this provision slightly so as to be less proscriptive in certain instances. Additionally, the task force increased the security provision for a pharmacy that ships medications by mail or common carriers to aid in the prevention of diversion by employees and added requirements for the tracking of all shipments from such pharmacies to deter and help prevent theft in transit.

Lastly, a comment was added addressing increased vigilance on the part of the pharmacist-in-charge to prevent and detect drug diversion by implementing policies and procedures that provide various methods to accomplish tighter controls over inventory management and employee access such as inspection of shipments, reconciliation of orders, and periodic reviews of alarm codes, passwords, and access badges.

Along with reviewing and suggesting some revisions to the task force's recommendations, the Committee on Law Enforcement/Legislation also recommended the adoption of the *Model Rules for the Licensure of Medical Gas and Medical Gas Related Equipment Wholesale Distributors*. The existing *Model Rules for the Licensure of Wholesale Distributors* did not fully encompass the traditional practices of medical gas distributors, prompting the Executive Committee to recommend that the Committee on Law Enforcement/Legislation review the proposed rules after seeking input from the Compressed Gas Association. Ultimately, the committee approved 16 sections that mirror the *Model Rules for the Licensure of Wholesale Distributors* while incorporating specific language pertaining to the distribution of medical gases.

The Executive Committee also requested that the Committee on Law Enforcement/Legislation amend the *Model Act* to reflect revisions to 21 Code of Federal Regulations (CFR) 1311 with regard to electronic prescribing. In response, the Committee on Law Enforcement/Legislation approved amendments that revised the *Model Rules for the Practice of Pharmacy*, specifically the provision for the Manner of Issuance of a Prescription Drug Order by replacing "by way of Electronic Transmission," which pertained to both facsimile transmission and electronic transmission, with either "via facsimile" or "issued electronically," which is necessary because the federal requirements for each are now different.

Finally, the Committee on Law Enforcement/Legislation agreed to amend the *Model Act* to remove the licensure and renewal provisions for the practice of telepharmacy across state lines as it was deemed to be included in the practice of pharmacy in many states and therefore not requiring special licensure or language indicating such.

The updated *Model Act* is available for free download in the Publications section of the NABP Web site at *www.nabp.net/publications/model-act.*

Newly Approved e-Advertiser

The following entity was accredited through the NABP e-Advertiser Approval[CM] Program:

The Kroger Co
www.kroger.com

A full listing of NABP-approved e-Advertisers is available on the NABP Web site at *www.nabp.net.*

NABP Field Survey Staff Works With Boards of Pharmacy to Customize Specialized Programs, Accommodate Unique State Needs

Through specialized programs, NABP has customized survey services to support board of pharmacy efforts to protect the public health. Specialized programs in Iowa, Maryland, and Idaho were customized to meet the needs of each state board of pharmacy, and, when necessary, refined to accommodate situations and objectives unique to each project.

NABP Services Support Two Iowa Projects

Launched in 2011, two survey programs in Iowa are supporting Iowa Board of Pharmacy efforts to help ensure that controlled substances (CS) are managed properly by CS registrants, and that patient care and dispensing services provided by pharmacies meet state requirements.

In the CS registrant program, the Board contracted NABP to provide inspections of providers in Iowa registered with Drug Enforcement Administration (DEA) and the state to prescribe or dispense CS medications. NABP surveyors were trained to evaluate compliance with Iowa's criteria and conducted inspections using the official forms of the Board. During a pilot of 50 registrants, surveyors interviewed CS registrants as assigned by the Iowa Board and surveyed to ensure that CS drugs are handled, stored, and tracked in compliance with federal and Iowa State regulations.

This specialized survey program has been ongoing for two years, giving NABP staff the opportunity to work with the Board to further refine logistics of the program to better serve the changing needs of the Board. Specifically, during the first year of the program surveyors were assigned to interview CS registrants in geographically dispersed locations across Iowa that included several rural providers across the state.

Logistics of assigned surveys during the second year evolved to include inner city areas where many assigned providers are co-located in the same hospital or larger facility. To complete the 2012 survey process efficiently, NABP staff made survey assignments against a master list of registrants provided by the Board with the goal of surveying 500 CS registrants in the first six months of 2012. In some cases, 10, 20, or 30 CS providers worked at the same hospital, allowing surveyors to focus on conducting all the surveys required for that location, rather than revisiting that facility at multiple times over several months.

A requirement that the registrant must be present to conduct the inspection added another dimension to the challenge, sometimes requiring more than one visit by a surveyor to find the assigned provider. With the registrant present, NABP surveyors checked licenses, documentation, and inventories. At the request of the Iowa Board, the surveyor also provided limited but relevant training to select registrants.

NABP surveyors completed 50 CS registrant inspections in 2011 and, as of June 30, 2012, successfully met the goal of completing and submitting an additional 500 CS registrant inspection reports to the Iowa Board of Pharmacy.

Iowa Pharmacy Shopper Program

The Iowa Board of Pharmacy has also con-

tracted with NABP to provide a pharmacy shopper program for surveying pharmacy dispensing practices. Specifically, assigned surveyors, in the role of patients, present prescriptions to be filled at a pharmacy. While having the prescription filled as a new patient at the assigned pharmacy, they make observations about the entire dispensing process. Elements evaluated include:

- Whether patient history was conducted and what questions were asked
- Evaluating the patient experience in the assigned pharmacy
- Whether patient counseling services were provided and the quality of the information provided
- Whether the pharmacy adhered to Health Insurance Portability and Accountability Act requirements
- Whether the prescription was dispensed accurately

Maryland Survey Project

Since 2009, NABP has provided customized surveys on behalf of the Maryland Board of Pharmacy following the implementation of a Maryland law requiring that out-of-state wholesale distributors be inspected as a condition of licensure.

The Maryland Board appointed NABP as its designee for these inspections and surveyors use a Maryland inspection form.

For this project, NABP surveyors record their observations of the facility, and the Board makes the ultimate decision as to whether the wholesale distributor passes inspection.

This arrangement has helped the Maryland Board to meet the mandate for wholesale distributor inspections, while freeing up Board resources and staff for other projects. In this case, Maryland contacts NABP when they receive an application that requires a survey in order to be processed.

Idaho Project

NABP recently worked with the Idaho State Board of Pharmacy on a project involving inspections related to drug outlets where telepharmacy across state lines was being practiced. NABP field staff used an inspection form provided by the Board and conducted surveys at two locations practicing telepharmacy. After providing the inspection reports for the specified locations to the Board, NABP also made recommendations to the Board for revising the reporting form to better meet the Board's needs.

Customized and Flexible Surveying and Reporting

As evidenced by the programs in Iowa, Maryland, and Idaho, NABP customizable survey services are developed to complement the work of boards of pharmacy, assisting boards to meet mandates and accomplish goals when shrinking budgets or other issues might otherwise limit the board from using resources and staff for such projects. For example, when NABP surveyors complete specialized surveys and submit reports to the board, board staff can then focus on any needed follow-up inspections or investigations. NABP remains available to help with any questions an applicant might raise about the inspection report and surveyors can be made available should legal or other issues arise from inspection findings.

An additional advantage for boards is that NABP surveyors are located across the country. Further, while some boards are not able to support staff travel, the NABP surveyors are able to travel, which may be needed in the case of out-of-state inspections.

As illustrated by the current programs, NABP staff work closely with state

(continued on page 178)

NABP Field Survey

(continued from page 177)

boards to develop survey programs that meet their unique needs. The following are some of the elements that may vary from state to state:

- *Location where surveys need to be conducted.* Some sites may be in rural areas and several hours apart, while in other states sites surveyed may be in close proximity.
- *Provider or personnel to be interviewed or on hand during the survey.* Issues of provider's availability can present the need for flexibility when scheduling or conducting unannounced surveys.
- *Type of surveyor most appropriate for the particular project.* To help meet the needs of different surveys, NABP surveyors have varying backgrounds, ranging from pharmacy practice to law enforcement, such as background at DEA and Food and Drug Administration's Office of Criminal Investigations.
- *Reporting tools and time frame requirements.* A board may have in place survey or inspection forms, or the board may request assistance in developing or updating reporting forms. Some boards require a handwritten survey to be submitted to the registrant, while other boards require a typed report to be submitted to the board.

These are some of the many factors considered when customizing the survey process with a board. And, as illustrated with the Iowa project, NABP staff assesses the process after the initial implementation and works with the board to make any changes needed to ensure the most efficient process. Mid-course assessments are also made to help ensure that the required information is captured accurately through the reports, and that changes are made if needed to accomplish this goal.

NABP survey staff works closely with boards – from planning, to implementation, to assessing results – to ensure that such specialized projects are accomplished correctly and will meet board needs. Further, NABP staff is always available to both the assigned surveyors and board of pharmacy staff. This flexibility and availability support the accurate and efficient completion of surveys and projects when questions arise during off-hours, for example.

Customized surveys and inspection services are available as a fee-based program. Inquiries about these services may be sent via e-mail to GovernmentAffairs@nabp.net.

Pill Mill Laws

(continued from page 170)

and convictions of the George brothers in Florida, is one of the most highly publicized instances of multi-agency collaboration to shut down a large-scale pill mill operation. In September 2011, the Department of Justice announced that twin brothers Christopher George and Jeffrey George faced federal charges related to the operation, management, and financing of four alleged pain management clinics in Florida that illegally distributed approximately 20 million oxycodone pills, among other drug products. As of April 30, 2012, 28 of the 32 defendants indicted in this case – including the George brothers – had pleaded guilty.

DEA Tactical Diversion Squads and High Intensity Drug Trafficking Areas task force groups will continue efforts to shut down illegally operating pain clinics, as indicated in the 2012 National Drug Control Strategy.

PMP Laws

To assist prescribers and pharmacists with making the best treatment and dispensing decisions, more states are adopting laws to implement PMPs, or to enhance the capabilities of existing PMPs. In addition to Florida, since 2010, the states of Delaware, Georgia, Maryland, and New Hampshire have enacted laws to require the establishment of a PMP.

In May 2012, New York State adopted the I-STOP bill aimed to prevent doctor shopping. The law will require the creation of a new, real-time PMP, and both pharmacists and prescribers will be required to submit information about controlled substance medications to the database immediately.

Four states – Idaho, Louisiana, Tennessee, and Utah – adopted legislation allowing the sharing of PMP data with PMPs in other states. These laws position these state PMPs to participate in the NABP PMP InterConnect℠, enhancing efforts to prevent doctor shopping and identify patients in need of help with addiction or misuse.

Increasing the number of PMPs and improving their effectiveness is also among the four goals of 2012 National Drug Control Strategy. As part of this objective, national projects – in which NABP is participating – are supporting efforts to enhance access to PMP data among authorized users such as physicians and pharmacists. (For more information on NABP InterConnect, see page 182 of this *Newsletter.*) Such collaboration among lawmakers, regulators, law enforcement, and other stakeholders at the federal, state, and local levels is vital as efforts to fight prescription drug abuse and diversion, including combatting illegal pain clinics, move forward.

NABP Report Stresses Need for International Collaboration to Combat Online Counterfeit Drug Distribution

In late July, NABP issued a report about the continually increasing online counterfeit drug supply and the urgent need for international collaboration among regulators and other public agencies as well as private sector entities. As described in the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: July 2012,* counterfeit drugs sold online often make their way to unwary consumers through a complex chain of international transactions by multiple parties, and international, public-private collaborative efforts are needed to combat this illegal activity.

NABP continues to review and monitor Web sites selling prescription drugs and its findings are also presented in the July report – of more than 10,000 Web sites analyzed, 97% operate out of compliance with pharmacy laws and practice standards established in the United States, and many other developed countries, to protect public health. Such sites provide an outlet for counterfeit medicines to enter the US drug supply, endangering the health and safety of Americans.

The report provides an overview of collaborative strategies from pharmacy experts to stop online counterfeit drug distribution. Public and private sector experts on international health law and global pharmaceutical security assert that rogue online drug sellers work with a network of private sector entities – some legitimate and some rogue – to obtain, market, collect payment for, and distribute drug products that are often counterfeit or substandard. Experts call for public-private partnerships to promote the adoption of effective laws, regulations, and policies addressing all levels of this complex chain, along with effective enforcement efforts. Additionally, consumer education about rogue online drug sites and counterfeit drug dangers is necessary.

NABP is committed to fostering opportunities for international collaboration, and, with the support of the global pharmacy community, NABP has applied for the .pharmacy generic Top-Level Domain, which would offer consumers around the globe a trusted means for obtaining the safest medications online. As Internet commerce becomes increasingly commonplace, NABP President Michael A. Burleson, RPh, also expressed the need to raise awareness about counterfeit medicine and rogue online sellers, giving special emphasis to recent endeavors including international pharmacy initiatives and the AWAR$_X$E® Consumer Protection Program. President Burleson stated, "Focusing on the topics of safe drug disposal, online pharmacies, and counterfeit drug dangers, AWAR$_X$E educates consumers on prescription drug safety."

> . . . rogue online drug sellers work with a network of private sector entities – some legitimate and some rogue – obtain, market, collect payment for, and distribute drug products that are often counterfeit or substandard.

The reviewed sites found to be operating out of compliance with US pharmacy laws are listed as Not Recommended on NABP's consumer protection Web site, *www.AWARERX.ORG*. As stated in the report, the 9,734 Internet drug outlets currently listed as Not Recommended are characterized as follows:

- 9,261 appear to be affiliated with a network that obtains drugs from questionable sources
- 4,828 offer foreign or non-Food and Drug Administration-approved drugs
- 8,497 do not require a valid prescription
- 2,271 have a physical address located outside of the US (most rogue sites post no address whatsoever)
- 3,614 have server locations in foreign countries

To help consumers find the safest sources for purchasing medicine online, NABP developed the VIPPS® (Verified Internet Pharmacy Practice Sites^{CM}) accreditation program. Consumers should look for the VIPPS Seal on an accredited site, or check NABP's database on its consumer protection Web site, *www.AWARERX.ORG*. As part of its continued efforts to combat these rogue sites, NABP and the state boards of pharmacy are stepping up their efforts to educate the public through the AWAR$_X$E Consumer Protection Program. The AWAR$_X$E Web site provides information on safely obtaining medications and includes updated news, tips, information, and links to relevant NABP resources. Plus, state-specific information is available in the Get Local section of the site including medication drop box locations for unwanted prescription drugs.

For the full report with detailed findings on the characteristics of rogue Web sites, visit *www.AWARERX.ORG/not_recommended_sites.*

AWARxE Online Purchasing and Counterfeit Dangers Messages Reach Millions; Program Encourages Participation in Fifth DEA Take-Back Day

Unsuspecting Americans have suffered health consequences such as strokes, heart attacks, addiction, and even death due to taking drugs purchased from Internet drug outlets. These rogue outlets often sell counterfeit drugs containing too much, too little, or the wrong active ingredient, and often these products contain toxins such as glue, chalk, and rat poison. In fact, Food and Drug Administration recently warned consumers about a potentially dangerous counterfeit version of Adderall® tablets being sold on the Internet – the tablets contained the painkillers tramadol and acetaminophen rather than the active ingredients of the authentic attention deficit hyperactivity disorder drug, Adderall. These disturbing facts were highlighted for consumers in an AWARxE® Internet public service announcement (PSA) campaign that launched June 12, 2012, and runs through mid-August.

The campaign raised awareness about the dangers of buying medications from rogue Internet drug outlets, and encouraged consumers to make an informed choice when buying their prescriptions online. AWARxE messaging provided links to the VIPPS® (Verified Internet Practice Pharmacy Sites℠) list on *www.AWARERX.ORG* and explained why using a VIPPS-accredited site is the safest means of purchasing prescription drugs on the Internet.

The campaign brought these messages to consumers via Web site banners, guest articles posted by bloggers, and a social media press release. All of these interactive Internet vehicles included links back to the AWARxE Web site and the AWARxE PSAs.

Web sites were provided with AWARxE banners linking to AWARxE PSAs with a potential audience reach of almost 26 million to date (see sidebar). In addition, NABP provided guest articles to bloggers writing about legislation, health care, caregiving, and parenting, potentially reaching over 205,000 additional consumers. Finally, the AWARxE social media press release distributed the week of July 9, 2012, was distributed to 2,800 Internet channels with a potential reach of over 11,800,000 consumers. The social media press release can be viewed at *www.marketwire.com/press-release/Counterfeit-Drugs-Endanger-Consumers-Unknowingly-Using-Fake-Pharmacy-Sites-1677902.htm*. An update on the campaign's success will be provided in future NABP communications.

AWARxE Promotes DEA Take-Back Day

AWARxE – through multiple communication vehicles – also continues to encourage consumer participation in the fifth Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day to take place Saturday, September 29, 2012. Announcements on the AWARxE Web site, on the AWARxE Facebook page, and in the *AWARxE Prescription Drug Safety News*, the program's new electronic newsletter, encourage consumers to rid their homes of any unneeded, unwanted medications by bringing them to a nearby DEA Drug Take-Back site. The AWARxE Web site provides a link to the DEA collection site locator, and the AWARxE Facebook page is updated continuously with state and local news about collection sites as information becomes available. Along with encouraging safe disposal of medications to prevent misuse and abuse, AWARxE alerts consumers to the importance of securely storing all needed medications.

School leaders and staff learned about prescription drug abuse among teens, including AWARxE facts on where teens obtain drugs and the scope of the problem, during a presentation by Jesse Wimberly, compliance agent, Ohio

(continued on page 181)

PSA Banners Widen AWARxE Audience

AWARxE Internet PSA banner exposures include USA Today, Yahoo! Finance, Reuters.com, MSNBC, International Business Times, Pharmacy Choice, Goodhousekeeping.com, Health.com, The Caregiver's Voice, and eCare Diary.

PCOA Undergoes Changes to Benefit Schools and Colleges; NABP to Offer Added Testing Flexibility

Responding to the needs expressed by the schools and colleges of pharmacy, NABP will be changing the administration of its Pharmacy Curriculum Outcomes Assessment® (PCOA®) to three testing windows. Beginning in 2013, schools and colleges of pharmacy can choose testing dates within three testing windows to administer the PCOA to their students. Schools and colleges will be asked to notify NABP at least 90 days in advance of their desired testing date to ensure adequate planning time for a successful administration.

In addition to more flexibility in scheduling, the PCOA will also be able to provide score reports to the schools more quickly. Schools will receive score reports approximately four weeks after the close of the testing window.

Further expediting the process of how information is provided to the schools and colleges, NABP plans to move its PCOA communications and registration materials to an electronic format. Information will be posted to the NABP Web site where schools can download the registration materials and informational brochures. All materials are expected to be posted on the NABP Web site in early September. Schools and colleges can expect to receive an e-mail when the PCOA materials have been posted.

These changes to the PCOA are in large part a response from the forum held in April, at NABP Headquarters. The forum provided the opportunity for representatives from schools and colleges of pharmacy, the American Association of Colleges of Pharmacy, and the Accreditation Council for Pharmacy Education (ACPE) to communicate with one another about the PCOA and share their own perspectives and experiences regarding the assessment.

Launched in 2008, the PCOA was developed by NABP in response to requests from schools and colleges of pharmacy to produce a psychometrically sound, standardized assessment that could be used as formative and summative measures of student learning outcomes. The valuable data provided in the students' score reports allow participating schools to compare the results of their students' performance to those of students across the United States and fulfill some of ACPE's recommendations for assessment.

Since the assessment began, more than 14,000 students from 46 different schools and colleges of pharmacy have participated in the PCOA.

The cost of the assessment is $75 per student, which includes the cost of the administration materials, personnel to supervise the administration, thorough analysis of resulting data, and score reports. Schools have the option to administer the assessment in a computer-based format or a paper-based; however, only one format may be offered at each school.

Interested schools and colleges of pharmacy are encouraged to contact Maria Boyle, competency assessment senior manager, at 847/391-4406 or via e-mail at NABP_Comp_Assess@nabp.net.

More information about the PCOA, including upcoming testing dates, will be available in the Programs section of the NABP Web site at *www.nabp.net/programs/assessment/pcoa.*

AWAR$_X$E

(continued from page 180)

State Board of Pharmacy, at the 2012 School Resource Officer and D.A.R.E. Officer Combined Conference in Ohio, June 24-26, 2012. Information from AWAR$_X$E resources was presented in a slide show to over 140 attendees composed of school administrators, teachers, principals, school counselors, school-based police officers, juvenile probation officers, and detectives. Attendees also received AWAR$_X$E flyers and bookmarks alerting them to visit the AWAR$_X$E Web site for additional information.

Participants found the AWAR$_X$E information very valuable and will likely be sharing the information with students at schools throughout Ohio. Further, Wimberly was invited to deliver his presentation at two training events for new Ohio school resource officers, one on August 6, 2012, and the second to be held on October 26, 2012.

To receive *AWAR$_X$E Prescription Drug Safety News,* complete the sign up form available on the AWAR$_X$E Web site at *www.AWARERX.ORG/newsletterSignup.php.*

Over 670,000 Continuing Pharmacy Education Activity Records Now Tracked Electronically through the CPE Monitor System

CPE Monitor™ integration is well underway, with over 670,000 continuing pharmacy education (CPE) activity records now stored in the system. More than 105 Accreditation Council for Pharmacy Education (ACPE)-accredited providers have begun to electronically transmit CPE data through the CPE Monitor service and soon all ACPE-accredited providers will require pharmacists and pharmacy technicians to submit their NABP e-Profile ID and date of birth (MMDD) in order to obtain CPE credit.

As of press time, more than 170,000 pharmacists and 95,000 technicians have created NABP e-Profiles and registered for the CPE Monitor service, allowing them to electronically track CPE activity from participating providers.

A national collaborative service from NABP, ACPE, and ACPE providers, CPE Monitor is expected to provide the boards of pharmacy with a streamlined process to verify their licensees' and registrants' compliance with CPE requirements. It is anticipated that in 2013 the boards of pharmacy will be able to request reports on the CPE activity of their licensees, eventually eliminating the need for them to collect printed statements of credit for ACPE-accredited CPE.

To obtain an e-Profile ID, licensees may visit *www.MyCPEmonitor.net*, create an e-Profile, and register for CPE Monitor.

NABP Explores New Pilot Partnerships to Enhance PMP Data Access; SAMHSA Funding Supports Interoperability Efforts

NABP is exploring the potential for two new pilot projects that would enhance access to prescription monitoring program (PMP) data by authorized users in the pharmacy and general practitioner settings, as the current project in the state of Indiana moves forward. A new grant funding opportunity for PMPs from Substance Abuse and Mental Health Services Administration (SAMHSA) may help to initiate these projects.

In the first potential pilot, NABP would partner with an Indian Health Service pharmacy in North Dakota, and the North Dakota PMP, an NABP PMP InterConnect℠ participant, to make PMP data more easily accessible to authorized users in the participating pharmacy. Similar to the current pilot in the state of Indiana, this project would leverage the NABP InterConnect technology. Specifically, queries from PMP users in the pharmacy would pass through the NABP InterConnect to a third-party system where it would be analyzed. The resulting report would provide the PMP user in the pharmacy with a "red light, green light" type of signal, indicating that the prescription can be dispensed based on the PMP data, or that further information should be obtained before the prescription is dispensed.

In the second potential pilot, NABP and the Michigan Automated Prescription System, also an NABP InterConnect participant, would partner to make PMP data more readily available to physicians or authorized users in the general practitioner setting. In this effort, PMP data would be integrated into electronic medical records so that doctors or other authorized users in participating medical practices could query PMP data without leaving the patient's primary medical record.

SAMHSA PMP Funding Opportunity

Announced in June 2012, a new SAMHSA program will enable states to undertake such projects. SAMHSA announced that the Prescription Drug Monitoring Integration and Interoperability Expansion Grant program, along with a Centers for Disease Control and Prevention program evaluation, will be funded with $4 million from the Prevention and Public Health Fund.

Targeting prescription drug abuse, this program supports efforts to integrate PMPs into electronic health records and other health information technology systems. The program goals are to expand and enhance the use of PMPs by facilitating the secure and timely transmission of prescription drug information to prescribers, dispensers, and other entities. SAMHSA indicates that grant funds will also be used by states to allow for modification of their systems to expand interoperability. The deadline to apply was July 31, 2012. Updates on these potential pilots and recipients of the SAMHSA grant will be included in upcoming NABP communications.

Board Staff, New Executive Officers Attend Annual Program Review and Training to Network and Learn of NABP Programs and Services

To further familiarize themselves with NABP programs and services, board of pharmacy staff, both new employees and those seeking a refresher course, attended the NABP Annual Program Review and Training Session on July 24-25, 2012, at NABP Headquarters.

Thirteen participants representing 12 state boards of pharmacy attended this two-day interactive session that provided board staff with information about NABP's examinations, licensure transfer, accreditation programs, and more. In addition, these informational sessions provide board staff with a unique opportunity to network with other board of pharmacy staff.

Held in conjunction with the Program Review and Training was the New Executive Officers Orientation Program, which is designed to acquaint new executive officers with NABP membership and governance, NABP programs and services, and how those programs and services may help in assisting the state boards of pharmacy.

Both events began with a group dinner on July 24, which provided the board staff and new executive officers with the opportunity to network with one another and NABP representatives.

On July 25, both groups convened for breakfast and a brief welcome. After the welcome, board staff and the new executive officers parted ways to begin the educational portion of the meeting. The educational portion provided attendees with an overview of the following NABP programs and services:

- Electronic Licensure Transfer Program® (ELTP®), license verification, e-mail, and data transfer functions
- NABP Clearinghouse/ Healthcare Integrity and Protection Data Bank reporting
- North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®), including eligibility and score reporting
- Pharmacist Assessment for Remediation Evaluation℠ (PARE℠)
- Application, examination, and certification processes for the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program
- Verified Internet Pharmacy Practice Sites℠ (VIPPS®), Vet-VIPPS®, Verified-Accredited Wholesale Distributors® (VAWD®), durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation programs, and the NABP e-Advertiser Approval℠ Program
- Pharmacy Curriculum Outcomes Assessment® (PCOA®) program
- Internet Drug Outlet Identification program
- Pharmacist and Pharmacy Achievement and Discipline® database (PPAD®)
- AWAR$_X$E® Consumer Protection Program
- CPE Monitor™ service
- NABP PMP InterConnect℠
- Government Affairs

For more information about future training sessions or to obtain training materials provided at the session, please contact NABP at custserv@nabp.net.

NABP Holds Training for Board Staff, New Executive Officers

(Above) Board of pharmacy staff learn of the various programs and services offered by NABP while also having the opportunity to network. Pictured above left to right: Janine Burkett, RPh, member, Missouri Board of Pharmacy; Karen MacLean, administrative director, Oregon State Board of Pharmacy; and Tanya Styles, administrative assistant, South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy.

(Below) New board executive officers get acquainted with NABP membership and governance. Pictured left to right: Kyle Parker, MBA, RPh, executive director, Ohio State Board of Pharmacy; and Gregory Pachmayr, JD, MPA, director, Indiana Board of Pharmacy.

PTCB Certification Exam Blueprint Updated

The Pharmacy Technician Certification Board (PTCB) announced in June 2012 the update of the Pharmacy Technician Certification Exam (PTCE) Blueprint, which includes the reorganization of current PTCE content into nine knowledge areas. The areas are as follows:

- Pharmacology for Technicians
- Pharmacy Law and Regulations
- Sterile and Nonsterile Compounding
- Medication Safety
- Pharmacy Quality Assurance
- Medication Order Entry and Fill Process
- Pharmacy Inventory Management
- Pharmacy Billing and Reimbursement
- Pharmacy Information Systems Usage and Application

PTCB indicated that "Changes to the PTCE resulted from a Job Analysis Study completed in February 2012. The profession-wide study, in which over 25,000 pharmacy technicians from every state and practice setting participated, identified the entry level knowledge and skills needed to perform tasks that are most important to protecting public health. A panel of expert pharmacists and pharmacy technicians used the findings to develop the revised PTCE blueprint." PTCB noted further that "While much of the PTCE's content remains unchanged, extensive work has gone into reorganizing the blueprint and creating more specific knowledge domains." PTCB has provided a crosswalk document for those familiar with the current blueprint; the document helps to identify where knowledge listed under the current blueprint will be organized within the new blueprint. Additional information and a link to the crosswalk document is available in a PTCB press release at *www.prnewswire.com/news-releases/ptcb-announces-updated-pharmacy-technician-certification-exam-blueprint-157468045.html.*

AHRQ Toolset Can Assist Pharmacies with e-Prescribing

A new toolset released by the Agency for Healthcare Research and Quality (AHRQ) can assist independent pharmacies with the implementation of e-prescribing and may also provide useful guidance to those pharmacies already using e-prescribing. The toolset for independent pharmacies consists of seven chapters that provide guidance on topics ranging from planning the implementation process and launching the system, to troubleshooting common problems and moving into more advanced pharmacy services, states AHRQ. Flyers for use in communicating the launch to patients, templates for communicating with providers about the launch, tools for assessing pharmacy workflow, and a spreadsheet to determine return-on-investment, among other tools, are also available to pharmacies. The toolset can be downloaded from the AHRQ Web site at *http://healthit.ahrq.gov/portal/server.pt/community/health_it_tools_and_resources/919/a_toolset_for_e-prescribing_implementation_in_independent_pharmacies/30595.* AHRQ also released a toolset designed to assist physician offices with the implementation of e-prescribing.

Suspicious Offers Make Following FDA Purchasing Guidelines Important

Several pharmacies in the Charlotte, NC, area have been approached by questionable drug wholesalers attempting to sell them drug supplies that may be fake, reports WSOC-TV. One pharmacy owner indicated that he received calls from companies claiming to be new wholesalers on a daily basis.

In an April 2012 Food and Drug Administration (FDA) statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." The statement was issued following FDA's action requesting that medical practices in several states stop administering drugs purchased from any foreign or unlicensed source. FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business. Also, suspected criminal activity can be reported to FDA's Office of Criminal Investigations (OCI) by calling 800/551-3989 or completing the online form on the OCI Web Site. The statement is available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for NABP's Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply. Information on VAWD is available in the Programs section of the NABP web site, *at www.nabp.net/programs/accreditation/vawd.*

Delaware PMP Begins Collecting Data

The Delaware Prescription Monitoring Program (PMP) started collecting data from pharmacies on March 1, 2012. The data includes all transactions for controlled substances (CS) dispensed in the state of Delaware in an effort to prevent and detect prescription drug misuse and diversion, as well as enable better coordination of patient care.

The data is reported to the PMP on a daily basis by Delaware-licensed pharmacies and prescribers who dispense CS. This database is available online to prescribers and dispensers and is a free service through the Office of Controlled Substances in the Delaware Division of Professional Regulation. The database is searchable online, available 24/7 with full mobile device access. Delaware-licensed prescribers are encouraged to register to request patient reports and can use the program to check the history of a new patient and to monitor ongoing treatment. These patient reports, and the automatically sent threshold reports, enhance the ability of health care providers to coordinate care.

Additional information is available on the Delaware PMP Web site at *www.delawarepmp.com*.

Kentucky PMP Reporting Changes to Be Implemented

Signed by Governor Steve Beshear, a new law (HB 1) will require all Kentucky-licensed pharmacists to be registered with Kentucky All Schedule Prescription Electronic Reporting, known as KASPER, and to report within three business days any theft to local law enforcement. In addition, the bill requires all pharmacies to report the dispensing of CS within 24 hours beginning in July 2013. Also, the bill will require the Kentucky Board of Pharmacy to establish by September 1, 2012, a regulation that will address issues related to pharmacist licensure restrictions and requirements. More information about these regulation changes is available in the Board's June 2012 *Newsletter*.

Wyoming's Online PDMP to Streamline Data Processing

WORx, the Wyoming online prescription database program, is expected to go online soon and will streamline the process of the current prescription drug monitoring program (PDMP). The Wyoming State Board of Pharmacy notes that the PDMP has had much success since the program began in 2004. Currently reports generated from the PDMP are available Monday through Friday, 8 AM to 5 PM. The move of the PDMP to the online version, WORx, will streamline the process and allow solicitors almost instant access to the PDMP program at any time, day or night. With the goal of reducing the inappropriate use of prescription drugs, the program monitors patients' prescriptions of CS in Schedules II, III, and IV from all community pharmacies licensed with the state of Wyoming, with some exceptions. As WORx continues to increase in utilization and as practitioners recognize the importance of the program, the Board hopes the amount of unsolicited profiles, those generated by WORx when a predetermined threshold has been met, and the rates of doctor shoppers will continue to decline.

Tennessee Background Check Rules in Effect

The Tennessee Board of Pharmacy has passed rules that require criminal background checks for pharmacists before approving licensure and pharmacy technicians before approving registration. All applicants applying for initial licensure in Tennessee (not renewal or reinstatement) are required to obtain a criminal background check conducted by the Tennessee Bureau of Investigation and the Federal Bureau of Investigation.

The Board notes that this requirement is not to be confused with the health related Board criminal background check, which requires that before any person who will be providing direct patient care is hired, health care facilities, emergency medical services, and individual health professionals are

(continued on page 186)

Around the Association

Executive Officer Change

Gregory Pachmayr, JD, MPA, is now serving as the director of the Indiana Board of Pharmacy. Prior to this, he served as a litigation specialist for the Board. Pachmayr was also a contractor for the Indiana Department of Correction. In addition, Pachmayr has experience as a teaching assistant and student law clerk, and he was an HIV/AIDS advisor for the United States Peace Corps. He earned his bachelor of arts degree in English and political science from the State University of New York at Buffalo, a doctor of jurisprudence degree from Indiana University Maurer School of Law, and a master of public affairs from Indiana University School of Public and Environmental Affairs.

Board Member Appointments

- **Anita Young, EdD, RPh,** has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Young's appointment will expire on November 30, 2016.
- **Marian Jensen, EdD, MEd,** has been appointed a public member of the Montana Board of Pharmacy. Jensen's appointment will expire on July 1, 2017.

(continued on page 186)

Around the Association

(continued from page 185)

- **Joseph Gerdes III, BA,** has been appointed a public member of the Pennsylvania State Board of Pharmacy. Gerdes' appointment will expire on June 11, 2018.

Board Officer Changes

The Virginia Board of Pharmacy has elected the following officers to the Board:

- **David Kozera, RPh,** Chairperson
- **Jody Allen, PharmD,** Vice Chairperson

State Board News

(continued from page 185)

required by law to conduct background checks using the state sex offenders registry, the state abuse registry, and the other abuse registries for states in which the prospective employee has lived in the previous seven years. More information is available at *http://health.state.tn.us/CBC/index.htm*.

Kansas Pharmacy Practice Act Changes Implemented

Effective July 1, 2012, amended Kansas law (SB 211) allows a pharmacist to provide up to a three-month supply of a prescription drug that is not a CS or psychotherapeutic drug when a practitioner has written a drug order to be filled with a smaller supply but included sufficient numbers of refills for a three-month supply.

Kansas adopted legislative changes applying to the state's PMP, K-TRACS, effective May 17, 2012, that authorize the Board to accept grants, donations, gifts, or bequests that further the K-TRACS program. Also, the Board is authorized to provide data from the K-TRACS data to medical examiners, coroners, or other persons authorized under law to investigate or determine causes of death.

In addition, the K-TRACS Advisory Committee is now authorized to review and analyze data from K-TRACS for purposes of identifying patterns and activities of concern. The committee can now notify prescribers and dispensers if there appears to be misuse or abuse of CS or drugs of concern and can notify the appropriate law enforcement agency if there is a reasonable suspicion of criminal activity. Other committee activities were also implemented.

More information is available on the K-TRACS Web site, *www.hidinc.com/kansaspmp*.

Legal Briefs

(continued from page 169)

Based upon the factors referenced above, the appellate court affirmed the lower court dismissal of the Department's petition to enforce the administrative subpoenas and prohibited the disclosure of the Walgreens STARS reports.

The ability of boards of pharmacy to engage in discovery when investigating or prosecuting administrative matters may be curtailed by the protection of certain medication error incident reports generated for submission to identified PSOs.

Department of Financial and Professional Regulation v. Walgreen Company, 2012 Ill. App. LEXIS 423 (App. Ct Ill 2012)

Newly Accredited VIPPS Facility

The following Internet pharmacy was accredited through the NABP Verified Internet Pharmacy Practice Sites℠ (VIPPS®) program:

Triplefin Specialty Services dba Triplefin Specialty Pharmacy
www.triplefinrx.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies is available on the NABP Web site at *www.nabp.net*.

Newly Accredited DMEPOS Facilities

The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

Baydoun Pharmacy
St Petersburg, FL

City Discount Pharmacy
Pocomoke City, MD

Empire Pharmacy
West New York, NJ

Harinam Rx Inc
Newburgh, NY

Pocomoke Discount Pharmacy
Pocomoke City, MD

R.O.R. Madison Pharmacy, Inc
New York, NY

Vita-Care Pharmacy, Inc
Houston, TX

A full listing of the nearly 1,000 accredited DMEPOS companies representing close to 30,000 facilities is available on the NABP Web site at *www.nabp.net*.

FDA Review and Approval

(continued from page 174)

properly listed with FDA and includes both approved and unapproved products. Therefore, the presence of an NDC number on the product label does **not** denote a drug's approval status. If a drug product is approved, the associated application number will appear in the NDC Directory.[21]

Although it may be more difficult for pharmacists to determine if OTC drug products are FDA approved or monograph compliant, pharmacists are a vital link in the consumer health information chain, and as such, there are important safety factors to consider when recommending or counseling consumers about OTC drug products. It is important for pharmacists to be keenly aware of an OTC drug product's formulation. FDA is concerned about medication mix-ups due to an increasing amount of brand-name extensions (eg, products that have the same names or portions of the same name but contain different active ingredients). Therefore, it is important to refer to OTC drug products not only by their brand or trade name, but by the full name of the OTC drug product. It is also important to educate consumers about the importance of checking the active ingredients in the "Drug Facts" panel prior to purchase to ensure correct product selection.

Pharmacists should also be knowledgeable about pharmacy laws in the state(s) in which they practice. Pharmacists should understand that FDA's enforcement actions, including *Federal Register* notices and warning letters, do not result in recall notices, unless otherwise initiated. Therefore, drug products affected by an enforcement action may still be found on pharmacy shelves for a short period of time.

Pharmacists should work with decision-makers to eliminate or minimize the number of unapproved prescription drugs on a pharmacy's shelves or on an institution's formulary, to the extent possible. Pharmacists should also consult with health care providers who prescribe unapproved drugs to seek approved alternatives for their patients. When appropriate, pharmacists should counsel affected patients about why their medication has been changed and what they should expect from any new medications.

For OTC drug products, it is also important for pharmacists to be aware of the available strength and concentration of these drug products. For example, there are currently multiple concentrations of infant acetaminophen on the market and it is important for consumers to know the concentration of the product and follow the directions provided for that particular product. Pharmacists should encourage consumers to exactly follow the dosing directions provided on the specific product or as otherwise directed by a health care provider.

Another important area for pharmacists to consider is orally ingested OTC liquid drug products that are packaged with dosage delivery devices (eg, cups, droppers, syringes, and spoons to measure and dispense the doses of medication). In May 2011, FDA released a final guidance to firms that manufacture, market, or distribute these drug products in response to ongoing concerns about the potential for accidental drug overdoses that can result from the use of dosage delivery devices with markings that are confusing, unclear, or inconsistent with the products' labeled dosage directions. Pharmacists should take note of the key recommendations in this guidance when counseling patients.[22]

Pharmacists are encouraged to report adverse events, side effects, or product quality problems related to prescription and OTC drugs to FDA's MedWatch Safety Information and Adverse Event Reporting Program.[23] By engaging in active communication with other health care providers and consumers about drug products, pharmacists can play a vital role in alerting FDA about potential public health problems and are essential in helping the consumer achieve safe and effective drug therapy.

Conclusion

Certain drug products that have not been reviewed by FDA can pose risks to the American consumer. Pharmacists can play a vital role in protecting the public health by staying informed and alerting other health care providers to the concerns of illegally marketed unapproved drugs, and by reducing consumer exposure to them through formulary and inventory management. For OTC drug products, patient education and counseling are critical to ensure safe and effective use.

The agency will continue to do its part by encouraging companies to obtain approval for their products, by monitoring industry for compliance to applicable laws and regulations, and taking enforcement action when necessary.

21. NDC Directory, *www.accessdata.fda.gov/scripts/cder/ndc/default.cfm.*

22. Guidance for Industry: Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products, *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM188992.pdf?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=Guidance liquid delivery device&utm_content=1.*

23. FDA MedWatch, *www.fda.gov/MedWatch/report.htm.*

nabp newsletter

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

First Class
U.S. POSTAGE
PAID
Permit #583
Schaumburg, IL 60173

Newly Accredited VAWD Facilities

The following facilities were accredited through the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program:

Johnson & Johnson Sales and Logistics Company, LLC
Lititz, PA

Medical Specialties Distributors, LLC
City of Industry, CA

Midway Dental Supply, Inc
Lakeville, IN

Mission Pharmacal Co
Boerne, TX

Moore Medical, LLC
Bolingbrook, IL

Patterson Logistics Services, Inc
Blythewood, SC
Kent, WA

A full listing of more than 525 accredited VAWD facilities is available on the NABP Web site at *www.nabp.net*.