National, International Stakeholders Develop New Strategies for Fighting Counterfeit Drugs

“It is shocking to realize that, in some parts of the world, somewhere between 30 and 50 percent of drugs to treat serious diseases are actually counterfeit,” said Food and Drug Administration (FDA) Commissioner Margaret A. Hamburg, MD, in remarks at the Partnership for Safe Medicines’ Exchange 2010 conference held last October. Hamburg noted that “Estimates . . . vary a lot and we do need better surveillance and data to truly define the magnitude and scope of the problem. But what we do know is that it is growing every day.”

The scope and danger of the counterfeit drug problem gained additional attention from federal legislators and other stakeholders following a CBS 60 Minutes investigative report that aired March 13, 2011. In addition to presenting remarks from Hamburg and other government officials, the program gave an inside look at the bust of a counterfeit drug operation in Peru, stressing the deceptive appearance of the products, which closely mimicked authentic, brand-name drugs, and the unsanitary conditions of the location.

Many actions have been taken to address the counterfeit drug problem over the past two decades, initiated by both private organizations and United States government agencies, as well as international organizations and regulators. Yet, as Hamburg’s words suggest, the problem of counterfeit medications remains a serious threat to public health, and developed countries are not exempt. In the US and Europe, patients directly receiving counterfeit medications – which may include products with wrong ingredients, without active ingredients, or with insufficient active ingredients – via unscrupulous Internet sites operating illegally remains common. And the increasingly complex and international supply chain that includes global manufacturing raises concerns about adulterated ingredients infiltrating even well-controlled pharmaceutical markets.

The World Health Organization (WHO) notes that “the true extent of the [counterfeit drug] problem (continued on page 90)
Feature News

Counterfeit Drugs

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is not really known since no global study has been carried out." Still, in the past, WHO has estimated that up to 1% of drug sales in developed countries may be composed of counterfeits. The figure remains much higher in the developing world.

In the US, rogue Internet drug outlets continue to be the most common avenue for counterfeits to find their way to patients. In NABP’s January 2011 Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators, the Association reported that about 96% of Internet drug outlets reviewed were not operating in compliance with state and federal laws or patient safety and pharmacy practice standards, a percentage that has remained fairly consistent over the past four years.

At the same time, the security of the legitimate supply chain has been strengthened as states have continued to improve regulation of drug wholesalers. Most states have increased regulation of wholesalers, and 22 states now recognize wholesaler accreditation by NABP’s VAWD® (Verified-Accredited Whole- sale Distributors®) program; three of those states (Indiana, North Dakota, and Wyoming) require VAWD accreditation as part of licensure. While the drug supply chain is not impregnable – in a well-publicized case in 2009, for example, stolen insulin found its way back into the system and into patients’ hands – such breaches are comparatively rare.

But US regulators are not complacent about the security of the US supply chain. In her Interchange 2010 address, FDA’s Hamburg laid out a large part of the problem: Today, nearly 40 percent of the drugs Americans take are imported and nearly 80 percent of the active ingredients in the drugs on the American market come from overseas sources. . . the supply chain – from raw material to finished product – has become more complex and mysterious involving a web of repackers and distributors in a variety of locations. Like any chain, the drug supply chain is only as strong as its weakest link, and the proliferation of additional handlers, suppliers and middlemen creates new entry points through which contaminated, adulterated and counterfeited products can infiltrate the drug supply. Results include incidents like the deaths caused in 2008 by heparin that contained an adulterated ingredient, oversulfated chondroitin sulfate. At the Pew Health Group Conference, March 14-15, 2011, John Taylor III, Esq, acting principal deputy commissioner, FDA, stated that “another public health crisis like Heparin seems inevitable.” In combating such a global and complex problem, Hamburg noted, “[O]ur success or failure in this effort will depend on the relationships we establish and maintain with our foreign partners.”

International Stumbling Blocks

A number of stumbling blocks of varying magnitude make international cooperation on counterfeits easier said than done. Lack of legal and regulatory infrastructure in many developing countries form perhaps the largest blocks. WHO notes that only about 20% of its 191 member states have well-developed drug regulation, and 30% “either have no drug regulation in place or a very limited capacity that hardly functions.” According to WHO, few of its member states have enacted national legislation addressing counterfeit drugs, and weak sanctions against counterfeiters prevail, serving as little or no deterrent.

Disagreement between countries on the definition of “counterfeit drug” further muddies the waters, and makes it difficult to gather definitive global statistics on the problem. In short, do counterfeits include products that mimic brand-name products as closely as approved generics – even if they violate a patent? Or do they only include sub-standard or entirely fake medicines intended to defraud? Developed and developing countries are split on the answer. In developed countries, notably the US, counterfeiters are intrinsically linked with intellectual property (IP) rights. (Indeed, much inter-agency coordination of the US government’s fight against counterfeit drugs is happening under the auspices of the Office of the Intellectual Property Enforcement Coordinator (IPEC).) Develop-
Participants Prepare to Use CPE Monitor Service

The new CPE Monitor service launched in March 2011, and will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. CPE Monitor will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012.

Pharmacists and pharmacy technicians may visit www.MyCPEmonitor.net or the NABP Web site, www.nabp.net, to create an e-Profile and obtain their permanent identification number. At press time, more than 3,470 pharmacists and pharmacy technicians had created their NABP e-profile and obtained their permanent identification number.

Boards of pharmacy may wish to encourage their licensees and registrants to create their NABP e-Profile if they have not already done so. It is important for pharmacists and technicians to create their NABP e-Profiles soon because in the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

In order to help educate licensees, NABP answered questions about CPE Monitor at the American Pharmacists Association (APhA) Annual Meeting and Exposition, March 25-28, 2011, in Seattle, WA. More information about the CPE Monitor service is available in the April 2011 NABP Newsletter. Pharmacists and technicians may access additional information by visiting the Programs section of the NABP Web site at www.nabp.net/programs.

CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Pharmacists and Technicians -

Get Ahead of the Game! Prepare Now.

In the latter part of 2011, you will need to submit your NABP e-Profile ID to ACPE-accredited CPE course providers. Prepare now and set up your NABP e-Profile!

Go to www.MyCPEmonitor.net to obtain your identification number.

Executive Committee

Gary A. Schnabel
Chairperson
One-year term

William T. Winsley
President
One-year term

Malcolm J. Broussard
President-elect
One-year term

Michael A. Burleson
Treasurer
One-year term

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

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

Mark T. Conradi
Member, District 3
Serving first year of a one-year term

Gregory Braylock, Sr
Member, District 4
Serving third year of a three-year term

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

Joseph L. “Joe” Adams
Member, District 6
Serving second year of a three-year term

Cathryn J. Lew
Member, District 7
Serving second year of a three-year term

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

NABP Executive Committee elections are held each year at the Association’s Annual Meeting.
Providing members of the boards of pharmacy, along with administrative staff, inspectors, and attorneys with certain immunity protections is essential to the efficient and undeterred operations of any such administrative agency. In short, regulatory board personnel acting within the scope of authority and in good faith will likely be provided with protections from liability based upon challenges from disgruntled licensees.

Of course, in addressing complex legal issues as applied to equally complex fact patterns, mistakes may be made in the administrative process providing a basis for challenging the decision of the regulatory board. Substantiating on appeal a legal basis for reversing and/or remanding an administrative ruling does not consequently provide a basis for subjecting the administrative board and/or its members to liability in the form of damages. Importantly, the agency personnel must act within the scope of authority and in good faith. Consider the following.

The Washington State Board of Pharmacy conducts periodic inspections of pharmacy permit holders to determine compliance with applicable laws regulating the practice of pharmacy. Board inspectors assign numeric grades to each facility resulting in recognition as “class A” (score of 90 to 100), “conditional” (score of 80 to 90), or unsatisfactory (score below 80). A pharmacy receiving an unsatisfactory grade is subject to disciplinary action if its score does not increase to 90 or better within 14 days of the unsatisfactory finding. Thus, such pharmacies are subject to re-inspections on short notice. Further, the Board is authorized to summarily suspend a pharmacy’s permit for an unsatisfactory classification if the pharmacy’s conditions “represent a clear and present danger to the public health, safety, and welfare.” A summary suspension results in immediate loss of the permit (or pharmacist’s license) without a hearing. Shortly after such a summary suspension, the licensee and/or permit holder will be afforded a hearing on the merits.

An individual (licensee) was licensed as a pharmacist in 1980. In 1995, the licensee purchased a pharmacy (facility) and acted as its sole pharmacist. In December 1998 while undertaking routine inspections, the facility was the subject of an unsatisfactory score of 79. In February 1999, the facility had improved its conditions and received a class A score of 94. Despite these improved conditions, the Board’s two inspectors (collectively referred to as inspectors) re-inspected the facility in July 1999 and provided an unsatisfactory score of 48. In August 1999, the inspectors graded the facility unsatisfactory with a score of 56.

The licensee alleged that the inspectors subjected him to non-stop harassment, including yelling and pounding on the counters while the licensee was attempting to select, count, and prepare medications. Based upon the record established in the ensuing litigation, the licensee and Board had had numerous interactions related to citations for dispensing in non-child-resistant containers and without a written request, failing to obtain chronic conditions of patients from pharmacy, incorrect National Drug Code numbers, improper recordkeeping, and others.
Many of the encounters involved the inspectors and some of the interactions resulted in lost points during the facility inspections.

Based upon the unsatisfactory inspection reports, the executive director of the Board filed an *ex parte* motion for summary suspension of the facility permit and license, effectively closing the pharmacy. A summary suspension occurs without a hearing and is granted under circumstances whereby the public are placed at serious risk of significant harm. Under circumstances where a summary suspension is granted, the license holder will be provided with a hearing within a time period specified in law. The potential or imminent risk to the public provides a basis for the immediate suspension of the license.

On August 17, 1999, and without a hearing, the facility permit and pharmacist license were summarily suspended by the Board. The licensee was notified of the suspensions and the docketing of a September 10, 1999 hearing date. Specifically, the notice provided to the licensee stated that if a written motion to challenge the summary suspension were filed, he would waive his right to the September 10, 1999 hearing.

On August 30, 1999, the licensee waived his right to the expedited hearing by filing a motion to modify and stay the ruling of the Board. This motion was denied and a hearing was eventually set for December 7, 1999. The summary suspension caused the licensee and his business to incur substantial financial losses. Based upon his inability to fund a defense, the licensee entered into a consent agreement whereby the license and facility permit were suspended for a five-year period. In addition, the consent agreement “acknowledge[d] that the evidence is sufficient to justify the . . . findings” and he waived his right to a full hearing and was accepted and entered by the Board in February 2000. The consent agreement did not address a right to sue.

In 2002, the licensee filed suit against the state of Washington, the Washington State Department of Health, the Board, the two inspectors, and the executive director. The lower court granted summary judgment in favor of the defendants on multiple issues, but allowed certain counts related to negligent supervision and interference with a business were also allowed to proceed. The Board appealed the lower court ruling and the appellate court dismissed under summary judgment all counts against the defendants based upon immunity, the fact that no due process violations occurred, and failure to exhaust administrative remedies. Note, summary judgment basically means that the litigation can be decided under matter of law in that there are no material issues of fact under dispute. Thus one issue on appeal would be whether there exists a genuine issue of material fact. The licensee appealed the matter to the Washington Supreme Court.

Initially, the Supreme Court noted that the licensee did not appeal the finding of absolute immunity related to the actions of the executive director and affirmed the dismissal of him from the litigation. Next, the court turned to the issue of whether the inspectors were entitled to qualified immunity. The court identified two questions to consider. First, whether the licensee’s allegations establish a connection between the actions of the inspectors and a violation(s) of a constitutional right. Second, whether the conduct of the inspectors was objectively reasonable in light of clearly established law.

Before addressing the specific two questions above, the court analyzed (continued on page 94)
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the due process rights to which the licensee may be entitled. In its review, the court held that, in spite of the fact that the inspectors were not the ultimate decision-makers regarding the fate of licensees, such inspectors can cause the violation of due process rights through their actions. That is, the actions of those involved in the investigative process can, under certain circumstances, form the basis for liability. Indeed, the federal statute under which the litigation was pursued states that persons who, under color of any statute subjects or causes to be subjected, any citizen to be deprived of certain rights may be subject to liability. Thus, if the inspectors wrongfully fabricated evidence of an emergency causing the summary suspension of the licenses, such may subject the defendants to liability.

Turning its attention to the issue of whether there exists a genuine issue of material fact, the court held in favor of the licensee/permit holder. The court noted that a reasonable juror could infer that the inspectors arbitrarily lowered the inspection scores of the licensee under the facts known to the court. The opinion reviewed the numerous facts regarding the 1998 and 1999 inspections of the pharmacy and, “in a very close case,” found that a genuine issue of material fact existed as to whether the inspectors wrongfully fabricated an emergency and knew or should have known such fabrication would cause the immediate suspension of the license or permit without a hearing.

Likewise, the court found the existence of issues of material fact when assessing the constitutional claims of the licensee. It noted that the Board did not present irrefutable evidence that the violations discovered by the inspectors during the 1998 and 1999 inspections would have typically resulted in inspections scores of 48 and 56. Based upon the allegations of the complaint, the court held that a reasonable juror may credit the licensee’s version of the events, rather than that of the inspectors.

Next, the court addressed the issue of qualified immunity and whether the defendants should be afforded protections thereunder. It stated that government officials performing discretionary functions are immune “if their conduct is objectively reasonable when measured against clearly established law.” The court held that the inspectors should have known under these circumstances that their actions (perhaps fabricating circumstances which would result in an emergency suspension without a hearing) could reasonably result in a violation of constitutional rights. Accordingly, the court held that the inspectors were not entitled to qualified immunity.

Finally, the court held that the licensee did indeed exhaust his administrative remedies, a prerequisite to pursuing the litigation. It stated that the Board arrived at a final determination defined as a definitive act of the agency, which is binding until and unless set aside by a court. The court noted that the waiver by the licensee of a right to a prompt hearing did not change the fact that the Board reached a final determination as it agreed to the entry of the consent agreement.

Accordingly, the Washington Supreme Court reversed the appellate court and found that there exist genuine issues of material fact, which preclude summary judgment.

Pharmacy board members, staff, and other agency personnel must be aware of their duties and responsibilities and operate under the delineated authority of the board and in good faith at all times. Immunity principles will generally protect regulatory persons who follow this mantra. There are many additional facts surrounding the above case, which cannot be described in this Newsletter article. However, to the extent discretionary acts are undertaken, agency personnel, such as inspectors, need to be fully trained and aware of the application of these acts.


Newly Accredited DMEPOS Facilities

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

Hancock Pharmacy VII LLC
New Haven, CT

neighboRx
Middletown, NY

The Medicine Shoppe Pharmacy
Port Orange, FL

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.
Leaders whose support and initiatives have furthered the NABP mission of protecting the public health will be honored during the NABP 107th Annual Meeting, which will be held May 21-24, 2011, at the San Antonio Marriott Rivercenter in San Antonio, TX. The 2011 awards will be presented on Tuesday, May 24, during the Annual Awards Dinner and will include the NABP Lester E. Hosto Distinguished Service Award, the Honorary President Award, the Fred T. Mahaffey Award, the Henry Cade Memorial Award, and the John F. Atkinson Service Award.

**Lester E. Hosto Distinguished Service Award**

The highest honor bestowed by NABP is the Lester E. Hosto Distinguished Service Award, named in honor of the late 1990-1991 NABP President Lester E. Hosto. Receiving the 2011 award is Susan Ksiazek, RPh, for her exemplary service in protecting the public health and significant involvement in NABP. Ksiazek is an active member of NABP having served on many of the Association’s committees and task forces including the Committee on Law Enforcement/Legislation, the Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions, and the Task Force to Examine NABP’s Data Resources. In addition, Ksiazek has served as the NABP District 2 secretary for the past four years.

Since 1998, Ksiazek has served as a member on the New York State Board of Pharmacy, serving as chair in 2007. A senior pharmacist at the Erie County Medical Center since 1988, she is responsible for clinical services and performance improvement. From 2004 to 2005, she also served as acting director of the Department of Pharmaceutical Science. She began her career as a community pharmacist before moving into the institutional practice setting.

Ksiazek also serves as preceptor for experiential rotations at the State University of New York at Buffalo, where she also serves as a clinical adjunct professor and as a student mentor.

**Honorary President**

Receiving the 2011 honorary president award is Kim A. Caldwell, RPh, for his exemplary service in protecting the public health and significant involvement in NABP. Caldwell has been an active member of NABP having participated in numerous NABP task forces. Caldwell also took on the position of chair for many of the NABP task forces including the Task Force to Review Accreditation Standards for Community Pharmacy, the Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety, and the Task Force to Examine NABP’s Data Resources.

First appointed to the Texas State Board of Pharmacy in 1997, Caldwell served as the Board president from 1999 to 2000. Currently, he is the director of the Center for Outcomes Research at Humana Pharmacy Solutions. Prior to this position, he served as senior director of pharmaceutical outreach/reimbursement at Abbott Laboratories from 2005 to 2008. In addition, he held a position with the Centers for Medicare & Medicaid Services as division director of Clinical and Economic Performance Medicare Drug Benefit Group, where he led the development and implementation of the Medicare prescription drug benefit.

**Fred T. Mahaffey Award**

In recognition of their exemplary service and dedication to NABP’s mission of protecting the public health, the members of the Ohio State Board of Pharmacy will be honored with the 2011 Fred T. Mahaffey Award for their strong commitment to the development of rigorous regulation requirements related to e-prescribing. Holding the nation’s strictest laws and regulations on e-prescribing, the Ohio State Board of Pharmacy has advanced the efforts on providing a thorough authentication process for all electronic prescription transmission systems, keeping in conjunction with Drug Enforcement Administration’s interim final rule, which became effective June 1, 2010. The Board’s authentication approval process includes reviewing that each system has true “positive identification” of the prescriber sending the prescription pursuant to the Ohio Administrative Code, that every system has security and accountability of all confidential information, that the pharmacist receiving the prescription can identify that the system has approvable status with the Ohio State Board of Pharmacy, and that the

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Boards of Pharmacy, State Legislators, and Law Enforcement Continue to Tackle Methamphetamine Problem

On February 23, 2011, Sheriff Joe Guy of McMinn County, TN, released a community memorandum requesting retailers in his jurisdiction to stop selling pseudoephedrine (PSE) products for 100 days – his plea illustrates the severity of the methamphetamine problem still plaguing many communities with meth labs and meth-related crimes. On a national level, recent data shows that use of the drug has increased between 2008 and 2009. For example, the number of recent new users ages 12 and older of meth increased 62% from 95,000 in 2008 to 154,000 in 2009, according to the 2009 National Survey on Drug Use and Health. The problem continues to demand the attention of law enforcement, lawmakers, and pharmacy regulators across the country as they take various actions to control the sale in their states of PSE products, the key precursor ingredient in the illegal manufacture of meth.

All states require that PSE product sales are logged in order to enforce federal restrictions on PSE sales limits under the federal Combat Methamphetamine Epidemic Act of 2005, which became effective nationwide in September 2006. The adoption of laws and implementation of electronic tracking systems for PSE sales in several states helps to put a dent in meth production by centralizing PSE sales data to help prevent the practice of smurfing (individuals traveling from store to store, each time purchasing the legal limit of PSE for use in meth production).

In 2010, several states passed laws requiring the implementation of electronic tracking systems, bringing the total to 13 states, and other state legislatures are currently debating similar bills. Following the lead of Oregon and Mississippi, a few state legislatures are also considering PSE by prescription only laws.

Amendments under the federal Combat Methamphetamine Enhancement Act of 2010 (Public Law 111-268) went into effect April 11, 2011, and require that sellers of PSE products self-certify that they understand and are in compliance with related requirements for selling these drug products. The law also requires the Attorney General to develop a list of all self-certified individuals and to publish the list on the Drug Enforcement Administration (DEA) Web site. Further, distributors of listed chemical products are required to sell only to self-certified regulated sellers.

Under the new law, mail-order distributors must follow consistent regulations in order to help ensure that individuals are not exceeding their legal limit for PSE product purchases. Specifically, mail-order distributors must receive from the purchaser a copy of an identification card that provides a photograph and is issued by a state or the federal government. The name and address on the identification must be verified to correspond to the name and address provided by the purchaser.
States With Electronic Tracking Requirements

Thirteen states currently have laws requiring that PSE sales are tracked electronically, with three recently adopting the laws and/or implementing their tracking systems. Under emergency rules developed by the Missouri Department of Health and Senior Services, the National Precursor Log Exchange (NPLEx) was implemented in Missouri on September 28, 2010. The Kansas State Board of Pharmacy adopted the Kansas Electronic Methamphetamine Precursor Logging tracking system, also part of NPLEx, through rules and regulations on August 24, 2010. In addition, the South Carolina Law Enforcement Division (SLED) joined the NPLEx to develop a tracking program that was implemented in South Carolina in January 2011 (see “State Board News” on page 110).

In the state of Washington, a bill to implement statewide electronic tracking of PSE retail sales of methamphetamine precursors, specifically pseudoephedrine, ephedrine, and phenylpropanolamine passed in the 2010 legislature. The law went into effect on June 10, 2010 and the Washington State Board of Pharmacy has approved rule language to implement the law.

The states of Alabama, Arkansas, Florida, Illinois, Iowa, Kansas, Kentucky, Louisiana, Oklahoma, Tennessee, and West Virginia also have adopted and implemented laws requiring the electronic tracking of products containing PSE. A new law in Arkansas (Act 588) passed in March 2011, strengthening PSE laws by requiring that a pharmacist use professional judgement, patient medication history, and patient screening to determine that a PSE product is for a legitimate medical need.

A bill (LB 20) to require electronic tracking was introduced to the Nebraska legislature January 2011 and was approved by Governor Dave Heineman on April 14, 2011.

Success with Electronic Tracking

Much data demonstrating the results of tracking programs and other actions to combat meth production is relatively new and there is still some debate as to which actions are the most effective.

Electronic tracking can provide an advantage over paper logs as data is centralized and can be shared among pharmacies in a state, and, in many instances, across state lines. Sharing aggregate data in real time helps stop the practice of smurfing, because pharmacists are able to more accurately determine if a PSE purchase would exceed an individual’s legal limit. For example, South Carolina’s implementation of NPLEx facilitates this process as the system provides a “do not sell” recommendation if appropriate at the time of purchase. Customers can then be directed to a public Web site that provides information explaining why they were unable to make their purchase. In Kentucky, where NPLEx was developed and first implemented, the system helps to block the illegal purchase of about 10,000 grams of PSE per month, enough to manufacture about 5,000 grams of meth. Iowa’s NPLEx, implemented in September 2010, quickly demonstrated success in this regard. The system approved 200,000 purchases of PSE products, but blocked over 10,000 sales between September and December 2010. As noted by the Kansas State Board of Pharmacy, blocking illegal purchases across state lines helps prevent meth cooks from obtaining the precursor ingredient from any retailer connected to their system, including those in neighboring or nearby states.

New data and evidence continues to show the impact of tracking systems in some states. For example, as of February 28, 2011, SLED, South Carolina’s implementation of the NPLEx tracking system, which launched January 1, 2011, had blocked more than 6,000 boxes of PSE from being sold to consumers who

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had already reached their legal purchasing limit.

In other states, the real time data provides a more accurate picture of activity for law enforcement to take appropriate action. The NPLEX system offers the capability for states to share PSE purchase data and has shown success in aiding law enforcement. For example, using NPLEX, a detective with the District Attorney's Office in Delaware County, OK, was able to begin tracking smurfers in neighboring Missouri, increasing his success in shutting down meth labs in Oklahoma.

The state of Georgia does not require electronic tracking, but some pharmacies voluntarily participate in the Georgia Methamphetamine Intelligence System (GMIS) used by the Georgia Bureau of Investigation (GBI). Law enforcement officers told the Times-Georgian that within the first 30 days of operation GMIS data enabled GBI to identify 126 people who had purchased more than the legal limit of PSE.

Counterpoints

According to an Associated Press report, Missouri State Highway Patrol statistics indicate that 1,960 meth lab incidents occurred in the state in 2010, a 10% increase from 2009. Some interpret that meth lab incident increases indicate that the meth problem is getting worse, despite precursor tracking laws. Another interpretation could be that tracking systems allow law enforcement to identify, locate, and shut down meth labs more frequently using the real time aggregate data.

Prescription Only PSE

Two states – Oregon and Mississippi – have adopted the strictest PSE laws to date, requiring patients to present a prescription in order to purchase the products. The Mississippi Bureau of Narcotics reports a nearly 70% decrease in meth-related cases statewide since the implementation of the law in its state. Comparing data from the periods of July 2009 to February 2010 (prior to the prescription only law) with data from July 2010 to February 2011 (after implementation of the prescription only law) shows a reduction from 607 meth lab incidents to 203 meth lab incidents in Mississippi.

Oregon, the first state to adopt a PSE by prescription only law, with rules adopted in April 2006, and effective July 1, 2006, has seen a steady reduction in the amount of meth lab incidents. According to DEA, Oregon had only 12 meth lab incidents from January 1, 2009 to December 31, 2009, a 94% decrease from the year prior to the prescription only law. There were 191 incidents in 2005, prior to the Oregon law. In 2006 there were 51 incidents; in 2007, 23; and in 2008, 21 incidents.

While not requiring a prescription for all PSE purchases, the state of Oklahoma has implemented tougher restrictions for meth offenders. The Oklahoma State Board of Pharmacy has implemented a regulation stating that any person with a previous meth-related drug offense may not possess PSE at all. If a pharmacy sells PSE over the counter, then the customer's name is automatically checked against the Meth Registry and the sale will be blocked if the individual has a meth-related drug offense. In addition, the state has classified all PSE-containing medications as Schedule V prescriptions and requires that they be submitted to the prescription monitoring program database.

PSE Prescription Only Legislation

Legislators in several states are considering PSE by prescription only bills.

Two bills to require a prescription for PSE products have been introduced in Kentucky. House Bill 281 would make meth precursor drugs Schedule IV controlled substances and prohibit a practitioner from dispensing more than 9 grams of PSE to an ultimate user per month. The similar Senate Bill 45 was also introduced in Kentucky.

Bills introduced in Indiana (Senate Bill 474), in Tennessee (House Bill 181), and in Arkansas (House Bill 1444) would classify meth precursor ingredients as Schedule III drugs, thus requiring a prescription for PSE products. In these states the bills have been referred to committee in the 2011 legislative session.

Senate Bill 40 in Hawaii would reclassify pseudoephedrine as a Schedule V drug that may only be dispensed with a prescription with certain exceptions; the bill is currently being considered by the state's legislators.

Public Safety at Stake

Although recent tracking data shows improvements on a local basis, the National Drug Threat Assessment 2010 indicates that overall domestic methamphetamine production in 2009 showed no decline and was fueled primarily by organized smuggling. The report also indicates production in Mexico increased in 2009 and there was a 58% increase from 2008 to 2009 in the amount of meth seized at the United States southwest border. This may seem disheartening as it suggests the difficulty of controlling meth use by controlling domestic production.

Even if PSE laws do not have an immediate impact on meth use nationwide, assessing which federal and state laws and programs are most effective at preventing illegal meth production in the US is vital to eliminating the scourge of meth labs that harm communities in numerous ways.
Board of Pharmacy Staff, New Executive Officers Invited to Attend Annual Training on NABP Programs and Services

Are you a board of pharmacy staff member interested in learning about NABP programs and related Internet-based processes? Learn all you need to know about NABP’s examinations, licensure transfer, accreditation programs, and more by attending the annual Program Review and Training session on July 26-27, 2011, at NABP Headquarters. Both new board of pharmacy staff, as well as those seeking a refresher course, are invited to attend.

To assist the boards of pharmacy with expenses, NABP offers to cover travel, one night’s hotel accommodation, and three meal expenses for one participant per board.

Held concurrently with the Program Review and Training session is 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 will begin with a group dinner on July 26, at 6 PM, giving both groups, the board of pharmacy staff and the new executive officers, the opportunity to network with one another and NABP representatives. On July 27, attendees will convene at 8 AM for breakfast then, from 8:30 AM to 4 PM, board of pharmacy staff and the new executive officers will part ways and begin the educational portion of the session. This portion of the event will provide attendees with an overview of the following 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
- Application, examination, and certification processes for the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program
- Verified Internet Pharmacy Practice SitesCM (VIPPS®), Vet-VIPPSCM, Verified-Accredited Wholesale Distributors® (VAWD®), durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation programs, and the NABP e-Advertiser ApprovalCM Program
- Pharmacy Curriculum Outcomes Assessment® (PCOA®) program
- Internet Drug Outlet Identification program
- Pharmacist Assessment for Remediation Evaluation (PARE)
- Pharmacist and Pharmacy Achievement and Discipline® (PPAD®) database
- CPE MonitorTM service
- PMP InterconnectTM

Last year 15 participants representing 11 state boards of pharmacy attended the Annual Program Review and Training session. NABP asks that interested state boards of pharmacy contact NABP at their earliest convenience to ensure a space for staff members as space is limited to 20 participants.

To participate in the session or for more information about future training sessions, please contact the Customer Service Department at 847/391-4406 or custserv@nabp.net.

Are you a board of pharmacy staff member interested in learning about NABP programs and related Internet-based processes? Learn all you need to know about NABP’s examinations, licensure transfer, accreditation programs, and more by attending the annual Program Review and Training session on July 26-27, 2011, at NABP Headquarters. Both new board of pharmacy staff, as well as those seeking a refresher course, are invited to attend.

To assist the boards of pharmacy with expenses, NABP offers to cover travel, one night’s hotel accommodation, and three meal expenses for one participant per board.

Held concurrently with the Program Review and Training session is 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 will begin with a group dinner on July 26, at 6 PM, giving both groups, the board of pharmacy staff and the new executive officers, the opportunity to network with one another and NABP representatives. On July 27, attendees will convene at 8 AM for breakfast then, from 8:30 AM to 4 PM, board of pharmacy staff and the new executive officers will part ways and begin the educational portion of the session. This portion of the event will provide attendees with an overview of the following 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
- Application, examination, and certification processes for the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program
- Verified Internet Pharmacy Practice SitesCM (VIPPS®), Vet-VIPPSCM, Verified-Accredited Wholesale Distributors® (VAWD®), durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation programs, and the NABP e-Advertiser ApprovalCM Program
- Pharmacy Curriculum Outcomes Assessment® (PCOA®) program
- Internet Drug Outlet Identification program
- Pharmacist Assessment for Remediation Evaluation (PARE)
- Pharmacist and Pharmacy Achievement and Discipline® (PPAD®) database
- CPE MonitorTM service
- PMP InterconnectTM

Last year 15 participants representing 11 state boards of pharmacy attended the Annual Program Review and Training session. NABP asks that interested state boards of pharmacy contact NABP at their earliest convenience to ensure a space for staff members as space is limited to 20 participants.

To participate in the session or for more information about future training sessions, please contact the Customer Service Department at 847/391-4406 or custserv@nabp.net.

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Counterfeit Drugs
(continued from page 90)

ing countries wish to separate the concepts. For example, WHO came under fire at the 2010 World Health Assembly from countries including Brazil, India, and Thailand, which disagreed with WHO’s working definition of the term “counterfeit” and urged WHO to step down from its role as secretariat of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), which helps lead international efforts against counterfeiting. According to news reports, the dissidents felt that IMPACT had a hidden agenda to protect intellectual property rights of brand-name drug manufacturers even in countries with no effective IP rights, and was therefore going to endanger patients’ access to necessary drugs in the developing world. Although a preliminary report from WHO’s Working Group of Member States on Substandard/Falsified/Falsely-Labelled/Falsified/ Counterfeit Medical Products was released in March 2011, containing recommendations intended to clarify WHO’s role to “ensure the availability of quality, safe, efficacious and affordable medical products,” and “the prevention and control of medical products of compromised quality, safety and efficacy,” the issue remained unresolved heading into the 2011 World Health Assembly’s May meeting.

Progress

Among these difficulties lies consensus: All parties do agree that counterfeit medications are a major public health hazard throughout the world. And many countries demonstrate a growing will to tackle problems within their borders and to collaborate internationally. For example, the European Union is seeking to attack the sale of counterfeit drugs and to alert the public as to the dangers of purchasing unauthorized drugs over the Internet; the European parliament’s environment and public health committee voted to take measures to address criminal networks that exploit loopholes in existing controls. In late 2010, China announced a plan to increase its monitoring of Internet sites appearing in search results for counterfeit and illegal drugs, as part of a campaign to crack down on the trafficking and promotion of those products. The World Customs Organization, which represents customs administrations from 176 countries, last year signed the Chirac Foundation’s Cotonou Declaration, which calls for taking cooperative action against falsified or counterfeit medications.

Significant efforts to collaborate internationally and domestically have also continued within the US. Just in the last couple of years, FDA, the US Immigration and Customs Enforcement, and US Customs and Border Protection, among other federal agencies, have participated in a number of law enforcement actions in cooperation with other countries’ governments. These have included such actions as:

- Operation Mercury (2009) and Mercury II (2010), which targeted the importation and distribution of substandard and counterfeit medications;
- Operation Apothecary, frequent enforcement surges (12 in fiscal year 2010) at international mail and express carrier facilities, designed to address, measure, and attack potential vulnerabilities in the entry process that could allow smuggling of counterfeits; and
- Operation Pangea III, a worldwide “week of action” targeting online sales of counterfeit and illegal medications and resulting in arrests around the world and the seizure of thousands of medications.

As noted by Victoria Espinel, the US intellectual property enforcement coordinator, in a White House blog post, Progress on the Intellectual Property Enforcement Strategy, one of these law enforcement sweeps also resulted in nearly 300 Web sites used to sell counterfeit drugs being taken down.

In yet another victory in the fight against rogue Internet pharmacies, Federal Bureau of Investigation agents arrested a Russian man who allegedly masterminded a botnet that sent billions of spam e-mails per day for counterfeit prescription medications and non-FDA-approved herbal remedies, among other products. For the last year, coordination of federal efforts to combat counterfeit drugs in the US has fallen to IPEC. IPEC’s Counterfeit Pharmaceutical Inter-Agency Working Group released a report in March 2011 detailing strategic plans going forward and highlighting recent enforcement actions. (The report is available for downloading at www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma_Report_Final.pdf.)

One of IPEC’s emphases has been on encouraging increased private sector support for anti-counterfeiting measures, particularly in addressing rogue Internet drug outlets. Last December, IPEC announced significant private-sector cooperation in the form of 11 major Internet commerce companies planning to establish a nonprofit organization “dedicated to promoting information sharing, education and more efficient law enforcement of rogue Internet pharmacies,” now referred to as the Center for Safe Internet Pharmacies (CSIP). Information sharing would focus on spreading the word about rogue Internet sites selling pharmaceuticals in violation of federal law; as part of this effort, the organization would support an expansion or “White List” of NABP’s VIPPS® (Verified Internet Pharmacy Practice Sites®)-accredited pharmacies. The IPEC educational piece would fund campaigns underscoring the dangers of purchasing drugs on the Internet from unauthorized pharmacies. To assist with enforcement, CSIP members would share information with law enforcement where appropriate, and also take such enforcement actions (when appropriate) as stopping payment or shutting down a site.

Prior to the IPEC meeting that initiated the formation of CSIP, NABP was able to announce progress in efforts to fight rogue Internet drug outlets. In the first half of 2010, three major Internet search engines limited their advertising to Internet pharmacies in the US that are accredited

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Counterfeit Drugs
(continued from page 100)

through NABP’s VIPPS program. Google subsequently filed a lawsuit against individuals who allegedly violated their new AdWords policy.

In her remarks at Interchange 2010, FDA Commissioner Hamburg discussed current and planned FDA activities to secure the US drug supply. The agency is developing risk models, she said, in order to target its enforcement efforts. FDA had already systematically ranked more than 1,000 active drug ingredients, she said, “in order of their respective risk of economically-motivated adulteration, based on a multi-factorial risk-based model.” A subset of high-risk ingredients would be subject to additional sampling and testing at the border. Hamburg also announced a new Drug Integrity and Security Program that would focus on threats to the supply chain. The program is intended to “take a life-cycle approach by identifying vulnerabilities for products and the supply chain starting with the raw ingredients, continuing through when the finished drug reaches the patient and, working with stakeholders, to put measures in place to mitigate these threats,” she said.

On a national and state level, law enforcement, regulatory bodies, nonprofits, and the media play an ongoing role in numerous anti-counterfeiting activities, from cooperating in investigations shutting down illegal Internet drug outlets, to helping stop licensees from participating in Internet drug outlet scams, to alerting the public as to safe Internet pharmacy usage.

Indeed, while the fight against counterfeit drugs may seem Sisyphean, momentum on both national and international fronts has been building. With hard work, cooperation, and ingenuity, public and private stakeholders can continue to make progress as they combat those who would jeopardize the public health with falsified, substandard medications.

States, FDA Pressing Forward with Pedigree, Track and Trace Rules and Regulations

One method of helping ensure the integrity of the US drug supply chain is through the use of drug pedigrees, verifiable written or electronic documents that track each move in a drug’s journey from manufacturer to patient. When enforcement of federal drug pedigree requirements, originally established by the Prescription Drug Marketing Act of 1987, was put on hold by a legal challenge, some states opted to move ahead with their own requirements. As of March 2011, according to the Healthcare Distribution Management Association, 18 states had adopted final rules regarding distributor licensing and pedigree requirements, three states had enacted legislation but rules were pending, eight states had enacted legislation, one state had proposed pedigree legislation, and 20 states had no legislation or regulations on the topic.

California’s pedigree law has arguably drawn the most attention nationwide; its comprehensive requirements include those for an electronic pedigree, product serialization, and track-and-trace capability from manufacturer to point of sale. Industry concerns that the legislation would require a supply chain infrastructure and standards not currently in place have led to a delayed implementation date. Currently, the requirements are scheduled to take effect on a staggered basis starting in 2015 through 2017.

In another example, Idaho enacted legislation requiring wholesale drug distributors of prescription drugs “that leaves, or has ever left, the normal distribution channel” to provide a pedigree to the person receiving the drug; the Idaho State Board of Pharmacy was tasked with determining an implementation date for electronic track and trace pedigree technology, and allowed to extend the date “in one . . . year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.” The Board extended the implementation date once, to July 2011, when it is currently scheduled to go into effect.

In a report issued at the end of 2010, the National Council for Prescription Drug Programs predicted that “state level pressure for electronic pedigrees will intensify should preemptive federal legislation not materialize in a timely fashion.”

While such federal legislation is still pending, FDA did issue during 2010 the first of several intended guidances and regulations required by the Food and Drug Administration Amendments Act of 2007, which instructs the Health and Human Services Secretary “to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.” The guidance addresses the standardized numerical identification (SNI) for prescription drugs at the “package” level – that is, the smallest unit placed into interstate commerce by the manufacturer or repackager intended for individual sale to a pharmacy (or other dispenser). FDA Commissioner Hamburg compared the SNI to a “license plate” for individual packages of drug products as they travel through the supply chain.” She flagged the guidance as “an important first step in developing a track and trace authentication system in the US.”
Are You AWARxE?

New Resources Available on the AWARxE Web Site

Four out of 10 teens think that prescription medications are much safer to abuse than illicit drugs, even if they are not prescribed by a doctor, and teens often combine prescription and over-the-counter drugs with alcohol.

Share the news to raise AWARxEness among colleagues, friends, and family.

- The AWARxE™ Web site (AWARErx.org) has been updated with inviting, easy-to-read, and timely content to more effectively reach consumers seeking information on prescription drug misuse and abuse, counterfeit drug dangers, illegal Internet drug outlets, and medication safety.
- The Pharmacists section provides links to patient medication safety materials and information on safe medication disposal, as well as information on prescription monitoring programs as tools to fight prescription drug abuse and the NABP PMP Interconnect™ system, which is currently scheduled to launch in summer 2011. The Pharmacists section also includes links to relevant NABP documents and resources from relevant government agencies.
- Related AWARxE news articles are updated weekly and include an item that links to a March 6, 2011 CBS 60 Minutes report on counterfeiting.
- Suggestions for additional content, resources, or topics for the AWARxE Web site Pharmacists section may be sent by e-mail to AWARErx@nabp.net.

Boards of pharmacy addressing the problems of prescription drug abuse, rogue Internet drug sites, and counterfeit drugs may recommend to their licensees and registrants that they use the AWARxE Web site as a resource for educating their patients about these alarming issues.

Boards of pharmacy that wish to place the AWARxE logo on their Web site, hyperlinked to www.AWARErx.org, may obtain information by sending an e-mail to AWARErx@nabp.net.

GET INFORMED | www.AWARErx.org

Travel Grant Applications Still Being Accepted for Annual Meeting

NABP continues to accept travel grant applications from qualified voting delegates to attend the 107th Annual Meeting held May 21-24, 2011, at the San Antonio Marriott Rivercenter in San Antonio, TX. The travel grant assists boards in sending voting delegates to the Annual Meeting so they may participate in important business sessions where they discuss and vote upon resolutions and amendments to the NABP Constitution and Bylaws and elect NABP Executive Committee members and officers. In addition, they can attend educational sessions regarding current issues facing pharmacy regulators.

Qualified voting delegates can receive up to $1,500 in grant monies that may be used to lessen the costs for travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. The travel grant does not include Annual Meeting registration fees.

Travel grant applications may be obtained from NABP upon the direct requests of executive officers of the state boards of pharmacy. Applications can be submitted by mail to Dana Oberman, executive meeting planner supervising coordinator, at NABP Headquarters or via fax at 847/391-4502. NABP requests that applications be submitted prior to the Annual Meeting. All applicants will be informed of whether or not they have qualified for the travel grant.

For more information on the Annual Meeting travel grant, contact the NABP Executive Office at exec-office@nabp.net.
Saturday, May 21, 2011

9 AM - 7 PM
Registration/Information Desk Open

2 - 4 PM
Pre-Meeting CPE

International Pharmacy Practice - Bridging the Globe
Sponsored by Medco Health Solutions, Inc
ACPE #205-000-11-001-L03-P
(0.2 CEUs – 2 contact hours)

5 - 6 PM
Annual Meeting and District Meeting Orientation

7 - 10 PM
President’s Welcome Reception
Sponsored by Medco Health Solutions, Inc
Honoring NABP President William T. Winsley, MS, RPh, and his wife Betsy
Dinner will be served
Dress: business casual

Sunday, May 22, 2011

6:30 AM - 5:15 PM
Registration/Information Desk Open

7:30 - 8:30 AM
Fun Run/Walk
Sponsored by Celgene Corporation

8 - 11:30 AM
Hospitality Brunch
Sponsored by Omnicare, Inc

Educational Table Top Displays

8 - 11:30 AM
Joint CPE

Educational Poster Session - Strengthening Public Protection
Sponsored by Pearson VUE
ACPE #205-000-11-002-L04-P
(0.1 CEU – 1 contact hour)

Noon - 4 PM
First Business Session
Presiding: William T. Winsley, MS, RPh, NABP President

- Welcome Remarks
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
  Presentation of Colors
  National Anthem
  Keynote Address
  Steven Squyres, PhD, Principal Investigator, Mars Exploration Rover Project
  Call to Order
  Greetings from the Host State
  Jeanne D. Waggener, RPh, President, Texas State Board of Pharmacy

- Report of the Executive Committee
  Gary A. Schnabel, RN, RPh, Chairperson, NABP Executive Committee
  Recognition of Sponsors
  President’s Address
  William T. Winsley, MS, RPh, NABP President
  Report of the Treasurer
  Michael A. Burleson, RPh, NABP Treasurer
  Announcement of Candidates for Open Executive Committee Officer and Member Positions

4 - 5 PM
Joint CPE

Legal and Government Affairs Update - San Antonio Confidential
Sponsored by Walgreen Co
ACPE #205-000-11-003-L03-P
(0.1 CEU - 1 contact hour)

Monday, May 23, 2011

7 AM - 2 PM
Registration/Information Desk Open

7 - 8:15 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention

8:15 - 10:15 AM
Joint CPE

DEA Update - What’s New at the Agency?
Sponsored by Walgreen Co
ACPE #205-000-11-004-L03-P
(0.2 CEUs – 2 contact hours)

10:30 AM - noon
Second Business Session
Presiding: William T. Winsley, MS, RPh, NABP President

- Report of the Executive Director/Secretary
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary

- Report of the Committee on Resolutions
  Chairperson, Committee on Resolutions
  - First Reading of Resolutions

- Report of the Committee on Constitution and Bylaws
  Edith G. Goodmaster, Chairperson, Committee on Constitution and Bylaws
  - Presentation of Proposed Amendments to the Constitution and Bylaws

- Candidate Speeches for Open Executive Committee Officer and Member Positions

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nabp newsletter

107th Annual Meeting

Monday, May 23, 2011 (cont)

Noon - 12:30 PM
Informal Member/Candidate Discussion

1:30 - 5:15 PM
Optional Tour

History and Merriment: San Antonio Style
Reservation required

Tuesday, May 24, 2011

7:30 AM - 4:15 PM
Registration/Information Desk Open

7:45 - 8:45 AM
Continental Breakfast

8:45 - 10:15 AM
Executive Officer and Board Member CPE

Social Media - To Tweet or Not to Tweet?
Sponsored by CVS Caremark
ACPE #205-000-11-005-L05-P
(0.15 CEUs - 1.5 contact hours)

8:45 - 10:15 AM
Compliance Officer CPE

FDA Update - A Guide for APIs and INDs
ACPE #205-000-11-006-L03-P
(0.15 CEUs - 1.5 contact hours)

10:30 AM - noon
Joint CPE
Rogue Internet Pharmacies - Can Collaboration Break the Link?
ACPE #205-000-11-007-L05-P
(0.15 CEUs - 1.5 contact hours)

Noon - 1:30 PM
Lunch Break
On your own.

1:30 - 4 PM
Final Business Session
Presiding: William T. Winsley, MS, RPh, NABP President
• Election of 2011-2012 Executive Committee Officers and Members
• Remarks of the Incoming President Malcolm J. Broussard, RPh, NABP President-elect
• Installation of 2011-2012 Executive Committee Officers and Members
• Final Report of the Committee on Constitution and Bylaws
  Edith G. Goodmaster, Chairperson, Committee on Constitution and Bylaws
  • Discuss and Vote on Proposed Amendments to the Constitution and Bylaws
• Final Report of the Committee on Resolutions
  Chairperson, Committee on Resolutions
  • Discuss and Vote on Resolutions
• Invitation to the 2012 Annual Meeting in Philadelphia, PA
  Michael A. Podgurski, RPh, Member, Pennsylvania State Board of Pharmacy

5:45 - 6:45 PM
Awards Dinner Reception

7 - 11 PM
Annual Awards Dinner
Presiding: Malcolm J. Broussard, RPh, 2011-2012 NABP President
• Presentation to 2011 Honorary President
• Presentation to William T. Winsley, MS, RPh, 2011-2012 Chairperson, NABP Executive Committee
• Presentation of the 2011 Fred T. Mahaffey Award
• Presentation of the 2011 Henry Cade Memorial Award
• Presentation of the 2011 John F. Atkinson Service Award
• Presentation of the 2011 Lester E. Hosto Distinguished Service Award

Dress: semiformal

Note: Additional information on the continuing pharmacy education sessions is available at www.nabp.net/meetings. The 107th Annual Meeting schedule is subject to change.

NABP and the NABP Foundation is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). ACPE Provider Number: 205. Participants may earn ACPE-accredited CPE credit by completing a Statement of Continuing Pharmacy Education Participation online and submitting it to NABP. Full attendance and completion of the program evaluation for each session are required to receive CPE credit and a Statement of Continuing Pharmacy Education Credit.

Continuing Legal Education (CLE) Policy: NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending CPE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.
Award Winners
(continued from page 95)
pharmacist receiving the
prescription can identify that
the prescription is legitimate.
Currently, the Ohio State
Board of Pharmacy is the
only state that requires a
second layer of authentica-
tion and documentation on
e-prescriptions in its effort to
prevent forgery.
Accepting this award
on the Board’s behalf is
Ohio State Board of Phar-
macy President Richard F.
Kolezynski, RPh.

Henry Cade Memorial
Award
For her exemplary service
in protecting the public
health and her significant
involvement with NABP,
Mary J. Ryan, RPh, MBA,
will receive the 2011 Henry
Cade Memorial Award.
Ryan has been a long-
time supporter of NABP’s
mission and purpose having
participated in numerous
task forces including the
Task Force on Telephar-
mary and the Implementa-
tion of the Medicare Drug
Benefit Medication Therapy

John F. Atkinson Service
Award
In recognition of her ef-
forts in protecting the public
health through her commit-
tment to the Texas State Board
of Pharmacy’s Enforcement
Division, Carol E. Fisher,
RPh, MPA, will receive the
John F. Atkinson Service
Award. Since 2000, Fisher has
served as the director of en-
fforcement at the Texas State
Board of Pharmacy where she
is responsible for managing
the enforcement division,
the agency’s largest division,
which inspects pharmacies
throughout the state.
Fisher joined the Texas
State Board of Pharmacy in
1978 when she was hired as
one of the two pharmacistsof
operations planning, vice
president/general manager
of PAID Prescriptions, and
director of claims process-
ing.

John F. Atkinson
Service Award
In recognition of her ef-
forts in protecting the public
health through her commit-
tment to the Texas State Board
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is responsible for managing
the enforcement division,
the agency’s largest division,
which inspects pharmacies
throughout the state.
Fisher joined the Texas
State Board of Pharmacy in
1978 when she was hired as
one of the two pharmacists
to serve as the agency’s first
compliance officers. As one
of the first in this position,
she was instrumental in
laying the foundation for
the new compliance pro-
gram. In 1982, when the
compliance program was
expanded, Fisher became
the first director of compli-
ance where she established
the procedures for operation
of the program as well as
procedures for inspection
of pharmacies in the state.
After serving as director of
compliance for five years,
Fisher became the director
of adjudication and legal
support services until be-
coming the first director of
enforcement for the agency.
On many occasions,
Fisher has helped the Texas
Board develop and improve
existing rules due to her dili-
genence in studying the details
of all her cases. Through
it all, her focus is on the
protection and welfare of
patients.
By exemplifying the
Association’s mission, these
leaders have shown their
dedication to protecting
public health and will be
honored at the NABP An-
nual Awards Dinner to be
held Tuesday, May 24, 2011,
from 7 - 11 PM.

For more information
on the NABP 107th Annual
Meeting, “Boards of Phar-
macy and NABP – Bridg-
ing to Unity and Strength”
visit the Meetings section of
the NABP Web site at www
.nabp.net/meetings.
NABP congratulates the Pharmacy Compounding Accreditation Board (PCAB) for reaching a major milestone in its voluntary accreditation program for compounding pharmacies this year when it passed the “100” mark, and as of March 11, 2011, has accredited 112 pharmacies. The PCAB accreditation program was developed to improve quality practices and patient care in compounding pharmacies.

Earlier this year, PCAB named Joe Cabaleiro, RPh, as the new executive director of the organization, replacing Tom Murry, PharmD, Esq, who was elected to the North Carolina legislature in November 2010. Playing a vital role in the initial development of PCAB and having served as the organization’s director of standards interpretation for five years prior to accepting this position, Cabaleiro’s expertise will lead PCAB’s mission to promote, develop, and maintain principles, policies, and standards for the practice of pharmacy compounding. He intends to continue the support of compounding pharmacies through PCAB accreditation programs and initiatives as these pharmacies strive to improve quality practices and enhance patient care.

PCAB released revised standards for pharmaceutical compounding accreditation in September 2010. This is the first time the standards have been revised since they were originally drafted in May 2004 by the PCAB Standards Task Force, which was composed of one expert from each PCAB governing board as well as four at-large members. To coincide with the release of the revised standards and to educate the public and pharmacy community, and promote the accreditation program, PCAB has also taken steps to form a social media presence on LinkedIn, Facebook, and Twitter.

Pharmacies wishing to achieve PCAB accreditation are asked to complete an extensive application, document their written policies, and provide analyses of their quality procedures. The pharmacy also provides a pharmacy profile, ownership information, and state license information for both the pharmacy and pharmacist-in-charge.

NABP, with its wide-ranging experience in accreditation, works closely with PCAB and its accreditation program. The Association performs licensure verification to assist PCAB in ensuring that any applicant pharmacy or pharmacist-in-charge has the appropriate licenses and has not had disciplinary action that would be grounds to deny accreditation.

NAPLEX Item Writers Convene
Volunteers discuss and review examination items during a North American Pharmacist Licensure Examination® (NAPLEX®) Item Writing Workshop held at NABP Headquarters. Pictured from left to right: Winter J. Smith, PharmD, BCPS, assistant professor, University of Oklahoma College of Pharmacy, and Eric Schneider, PharmD, BCPS, associate professor, University of Arkansas for Medical Sciences College of Pharmacy.
2011-2012 FPGEE Review Committee Members Announced

NABP is pleased to introduce six new members and commend the 17 returning members of the 2011-2012 Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) Review Committee. The FPGEE Review Committee, developed in order to ensure the integrity and validity of the NABP examination, acts under the policy and planning guidance of the NABP Advisory Committee on Examinations and the NABP Executive Committee. The dedicated volunteers contribute their time and expertise to reviewing and verifying the examination questions and assisting with the development of new test questions.

The FPGEE Review Committee requires individuals from academia who teach in areas of preclinical, clinical, pharmaceutical, and biomedical sciences; social and behavioral sciences; and pharmaceutical services management or pharmacy administration. Previous experience in writing examination questions is required for this committee.

In addition, volunteers are needed to serve as item writers for the PCOA. Requirements for PCOA item writers include being from an academic setting and having a strong interest in assessment and curriculum. Previous experience in writing examination questions is preferred.

Participation in these review committees typically require a commitment of two to four meetings per year, which are generally held from Thursday to Saturday, with all travel and meal expenses covered by NABP.

Those interested in serving as a member on any of these committees may submit a letter of interest and a current resume or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone, via mail to NABP Headquarters; e-mail at exec-office@nabp.net; or fax at 847/391-4502 no later than Friday, July 15, 2011.

NABP is accepting submissions for volunteers interested in serving on the Association’s three examination review committees including the North American Pharmacist Licensure Examination® (NAPLEX®), the Multistate Pharmacy Jurisprudence Examination® (MPJE®), and the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). In addition, item writing volunteers are needed for the NABP Pharmacy Curriculum Outcomes Assessment® (PCOA®).

If chosen, volunteers will write, edit, and assess potential questions for the competency assessment programs, as well as assist in establishing passing standards.

Ideal candidates for the NAPLEX Review Committee are practitioners from community and hospital settings, educators, and regulators who have previous experience as NAPLEX item writers.

The MPJE Review Committee has openings for volunteers familiar with state and federal jurisprudence requirements. Participation in this review committee is limited to individuals from those states that participate in the MPJE program. Though not a requirement, previous experience in writing examination questions is beneficial and would be helpful to the committee.

FPGEE Review Committee Members

- Barbara Adamcik, Idaho State University, College of Pharmacy
- *Sally A. Arif, Midwestern University, Chicago College of Pharmacy
- *Kimberly Burns, Lake Erie College of Osteopathic Medicine School of Pharmacy

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Committee on Law Enforcement/Legislation Convenes at NABP Headquarters to Review and Discuss Proposed Edits to the *Model Act*

The Committee on Law Enforcement/Legislation convened March 8, 2011, at NABP Headquarters to review and discuss a variety of proposed edits to the *Model State Pharmacy Act* and the *Model Rules of the National Association of Boards of Pharmacy*. Pictured from left to right: Susan DelMonico, JD, RPh, member, Rhode Island Board of Pharmacy; Philip P. Burgess, RPh, MBA, member, Illinois Department of Financial and Professional Regulation, State Board of Pharmacy; Wendy Anderson, RPh, program director, Colorado State Board of Pharmacy; William Cover, RPh, member, Indiana Board of Pharmacy; Charles Wetherbee, JD, member, Texas State Board of Pharmacy; Buford Abeldt, Sr, RPh, member, Texas State Board of Pharmacy; Committee Chairperson Patricia Donato, RPh, member, New York State Board of Pharmacy; Lee Ann Bundrick, RPh, administrator, South Carolina Department of Labor, Licensing and Regulation – Board of Pharmacy; and Hal Wand, MBA, RPh, NABP Executive Committee liaison.
Unapproved Drugs Seized by US Marshals at FDA Request

As part of the Food and Drug Administration (FDA) Unapproved Drugs Initiative, US Marshals seized all lots of Auralgan® Otic Solution, a prescription drug used to treat pain and inflammation associated with ear infections, from Integrated Commercialization Solutions Inc (ICS) in Brooks, KY, on February 15, 2011. Auralgan is manufactured for Deston Therapeutics, located in Chapel Hill, NC, and is warehoused at ICS. The product does not have FDA approval and its labeling does not include adequate directions for use; thus, Deston’s sale of the product in the US violates federal law. The action followed several warnings sent by FDA to Deston in 2010, regarding the company’s distribution of unapproved new drugs and misbranded drugs, as reported in an FDA News Release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm243638.htm.

FDA Warns Not to Use Terbutaline in Pregnant Women

FDA warns health care providers and patients that injectable terbutaline should not be used in pregnant women for prevention or prolonged treatment (beyond 48-72 hours) of preterm labor in either the hospital or outpatient setting because of the potential for serious maternal heart problems and death. In addition, FDA warns, oral terbutaline should not be used for prevention or any treatment of preterm labor because it has not been shown to be effective and has similar safety concerns. Death and serious adverse reactions, including increased heart rate, transient hyperglycemia, hypokalemia, cardiac arrhythmias, pulmonary edema, and myocardial ischemia have been reported after prolonged administration of oral or injectable terbutaline to pregnant women.

FDA is requiring the addition of a boxed warning and contraindication to both the terbutaline injection label and the terbutaline tablet label to warn against this use. FDA explains that terbutaline, approved to prevent and treat bronchospasm (narrowing of airways) associated with asthma, bronchitis, and emphysema, is sometimes used off-label (an unapproved use) for acute obstetric uses, including treating preterm labor and treating uterine hyperstimulation. Terbutaline has also been used off-label over longer periods of time in an attempt to prevent recurrent preterm labor. Based on the FDA review, FDA has concluded that the risk of serious adverse events outweighs any potential benefit to pregnant women receiving preventative or prolonged treatment with terbutaline injection (beyond 48-72 hours), or acute or prolonged treatment with oral terbutaline. More information is available in an FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm243539.htm.

One Lot Jantoven Warfarin Sodium Tablets Recalled

FDA is notifying health care providers that Upsher-Smith Laboratories has recalled one lot of Jantoven® Warfarin Sodium, USP, 3 mg Tablets, an anticoagulant, after a single bottle labeled as Jantoven Warfarin Sodium, USP, 3 mg Tablets was found to contain tablets at a higher 10 mg strength. The product lot was distributed to wholesalers, retail chains, and independent pharmacies throughout the US. The primary risk of substituting 10 mg warfarin for 3 mg warfarin is overdosing more than three times the labeled amount, which leads to excessive anticoagulation that could be expected to result in life-threatening hemorrhage in patients. The number of the recalled lot is 284081, with an expiration date of September 2012. Upsher-Smith notes that the two Jantoven tablets can be readily identified by color: the 3 mg tablet is tan and the 10 mg tablet is white. In addition, the manufacturer advises that the 3 mg tablet is imprinted with the letters WRF, a line, and the number 3 below the line. The reverse side of the 10 mg tablet carries the number 832. A press release on the FDA Web site, at www.fda.gov/Safety/Recalls/ucm243811.htm, provides more information and links to photographs of the 3 mg and 10 mg tablets.

PTCB Reports Record Number of Candidates

The Pharmacy Technician Certification Board (PTCB) reports that over 400,000 pharmacy technicians nationwide have earned the PTCB Certified Pharmacy Technician credential since 1995, with more than 55,000 candidates having taken the Pharmacy Technician Certification Exam in 2010 alone. PTCB notes that an increasing number of states have decided to allow only pharmacy technicians certified through PTCB to be employed by pharmacies. Thomas E. Menighan, BSPharm, MBA, FAPhA, chair, PTCB Board of Governors stated that “America’s evolving health care system calls for qualified support personnel that will enable pharmacists to provide patient-centered care with authority and autonomy.” The PTCB press release, available at https://www.ptcb.org/AM/Template.cfm?Section=Press_Releases1&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=3974&utm_content= Professional Affairs Update
SC Board Requires Participation in Real-Time PSE Monitoring Program

In its effort to track the illegal sale of pseudoephedrine (PSE) products, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy requires all pharmacies and retailers in the state to participate in a statewide, real-time electronic PSE monitoring program, known as the National Precursor Log Exchange (NPLEx). Pursuant to Combat Methamphetamine Epidemic Act (CMEA) of 2005, pharmacies and retailers are currently required to capture certain data regarding PSE sales.

In compliance with 2010 South Carolina Code of Laws Act 242, South Carolina Law Enforcement Division joined the NPLEx, which enables pharmacies to easily enter PSE sales data online, rather than recording the information into a manual log or in-store computer system.

Data will be stored in a secure, central repository that treats the data collected as if it were Health Insurance Portability and Accountability Act data. Furthermore, the collected data will be viewable by law enforcement, in keeping with CMEA and the South Carolina Code of Law.

Pharmacies will be required to enter PSE sales data into NPLEx prior to completing the sale and the database will provide a “Do Not Sell” recommendation if a sale would exceed state and/or federal laws on PSE purchase limits. Customers can be directed to a public Web site that provides more information as to why they were unable to purchase.

OH Board Changes Rules on Serial Numbering of Prescriptions and Prescription Copy

On January 1, 2011, the Ohio State Board of Pharmacy made two rule changes regarding serial numbering of prescriptions and prescription copy.

Rule 4729-5-19 Serial Numbering of Prescriptions was changed to mandate that, after the refills authorized on an initial prescription are used up, any additional “refills” authorized by the prescriber must be assigned a new prescription number. In the past, it was permissible to use the same number by just adding additional refills to the first prescription, as long as the time limit on refills had not expired. This option is no longer allowed. The Board notes that once the original prescription and its authorized refills have run out, a new prescription and a new prescription number are required.

The Board notes that the changes to rule 4729-5-19 are important because rule 4729-5-24, Prescription Copy, was also changed so that each prescription will be limited to one transfer during the life of that prescription. A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription. These actions must be in accordance with laws requiring that copies of prescriptions for dangerous drugs, including both non-controlled substances and controlled substances, shall only be transferred one time and that pharmacies electronically sharing a real-time, online database may transfer a prescription up to the maximum number of refills permitted by law and the prescriber’s authorization pursuant to paragraph (A) (5) of this rule. The Board’s overall goal is to ensure patient safety due to the greatly increased chances of error when patients are requesting multiple transfers to multiple pharmacies month after month.

SC Protocol Regarding Out-of-State CS Prescriptions Addressed

In an effort to protect the citizens and the pharmacists of South Carolina, the Department of Health and Environmental Control (DHEC) Bureau of Drug Control reminds pharmacists of steps for pharmacists to take regarding out-of-state controlled substances (CS).

DHEC continues to receive reports of numerous South Carolina pharmacies being presented with prescriptions for CS issued by various Florida and Georgia practitioners. The individuals presenting the prescriptions have provided positive identifications and addresses from numerous states including Kentucky, Tennessee, West Virginia, and Ohio.

DHEC recommends that pharmacists refer to South Carolina regulations regarding dispensing CS prescriptions. Regulations state the responsibility for the proper prescribing and dispensing of CS is upon the prescribing practitioner, but a corresponding liability rests with the pharmacist who fills and ultimately dispenses the prescription. Further, an order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of the act. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to CS.

In addition, in the event of telephone inquiries as to availability of specific stock, it is advisable that the pharmacist not disclose to the caller current inventory levels or strengths available, unless the patient is known to the pharmacist.

DHEC also reminds South Carolina pharmacists that regulations prohibit pre-printed CS prescriptions.

WA’s Health-PACT Project Fosters Communication to Improve Patient Safety

Supported in part by a grant from the Agency for Healthcare Research and Quality (AHRQ), the state
of Washington plans to implement its Patient Advocacy through Communication and Transparency (Health-PACT) project as a means of advocating for patients to receive safe and effective health care. AHRQ’s three-year, $3 million grant will support Health-PACT projects aimed to improve patient safety and promote medical liability reform. The AHRQ grant will support the development, distribution, and evaluation of communication training to avoid adverse events and errors. Health-PACT goals are to create a platform for stakeholders across the spectrum of health care to forward shared interests around communication and transparency, with a focus on patient advocacy; to serve as a clearinghouse for member organizations for best practices on communication and transparency in health care; to assist interactions between health care and patient advocacy communities on communication and transparency in health care; and pursue specific joint projects on promoting patient advocacy through communication and transparency. The project will integrate ideas, teamwork, and communication from all health professions, including pharmacy. Health-PACT’s initial launch meeting is planned for spring 2011. More information about Health-PACT may be obtained by contacting Amelia Chappelle, research coordinator, at amchappe@uw.edu.

Board Member Reappointments

Shirley Wheat, has been reappointed a public member of the California State Board of Pharmacy. Wheat’s reappointment will expire on June 1, 2014.

Board Officer Changes

The Alabama State Board of Pharmacy has elected the following officers to the Board:

- Robert Nelson, PharmD, President
- Donnie Calhoun, RPh, Vice President

The Arizona State Board of Pharmacy has elected the following officers to the Board:

- Steven Haiber, RPh, President
- Daniel Milovich, RPh, Vice President

The California State Board of Pharmacy has elected the following officers to the Board:

- Stanley Weisser, RPh, President
- Randy Kajioka, PharmD, Vice President

The Oregon State Board of Pharmacy has elected the following officers to the Board:

- Ann Zweber, RPh, President
- Larry Cartier, RPh, Vice President

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

- Albert Hill, DPh, President
- Brenda Warren, DPh, Vice President

The Utah Board of Pharmacy has elected the following officer to the Board:

- Dominic DeRose, Jr, RPh, Chairperson

Newly Approved e-Advertisers

The following entities were accredited through the NABP e-Advertiser Approval Program:

Deerfield Veterinary Hospital, PC
www.deerfieldvetrx.com

Rapid Drug Detox Marketing, LLC
www.rapiddrugdetox.com

A full listing of NABP approved e-Advertisers is available on the NABP Web site at www.nabp.net.
NABP 107th Annual Meeting
May 21-24, 2011
See pages 103 and 104 for more details.
Quick and easy registration is available in the Meetings section of the NABP Web site, www.nabp.net/meetings.