Board Compliance Officers Share Experiences at Interactive Forum, Network with NABP Surveyors

Thirty-nine compliance officers gathered at the Interactive Compliance Officer Forum and Surveyor Training Program, held December 1-2, 2011, to discuss with their colleagues the challenges they face on a daily basis. Held in conjunction with the Forum, the annual Surveyor Training Program hosted 30 NABP accreditation consultant surveyors as they received updates and training on NABP accreditation programs. In addition, the surveyors joined the compliance officers during some of the Forum sessions and the two groups were given plenty of opportunities for networking. The Forum was the third in a series of three meetings themed “Prescription for Shared Future: The Partnering Plan to Protect Public Health through AWAREness,” that were developed to reinforce the partnership between the boards of pharmacy and NABP, and the shared mission to protect public health.

The Interactive Compliance Officer Forum featured panel discussions on topics of high interest to participants, as well as plenty of attendee discussion time on these and other topics suggested during the course of the meeting. In each discussion, compliance officers gained valuable new ideas as fellow participants posed challenging questions and offered a variety of relevant experiences, perspectives, and information.

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Interactive Forum and Surveyor Training
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Though the surveyors attended sessions on the NABP durable medical equipment, prosthetics, orthotics, and supplies accreditation program on Thursday morning, the Forum was officially kicked off in the afternoon by William T. Winsley, MS, RPh, chairperson, NABP Executive Committee, when he welcomed compliance officers and surveyors and reiterated the purpose of the meeting. Winsley stressed the importance of this unique opportunity for board of pharmacy compliance officers to discuss with their colleagues—in closed sessions—important and timely issues related to pharmacy regulation. He added that NABP takes seriously its role of assisting the boards of pharmacy, and that this meeting, as well as the forums for the members and executive officers, is just one of the many ways that the Association strives to support and create value for the boards.

The first joint session of the day—”What’s New in the World of Compliance?”—covered four areas of pharmacy that are creating new challenges for compliance officers, inspectors, and investigators. These areas included drug shortages, counterfeit drugs and pedigrees, pill mills and detox centers, and medication storage compliance. Throughout the Forum, scheduled topics were introduced by board of pharmacy compliance officers who had noteworthy experiences with a particular topic. After the brief overview by the panelist, attendees engaged in lively discussions regarding issues in their states.

At the conclusion of the first afternoon’s programming, compliance officers were taken to NABP Headquarters for a tour of the building and staff presentations, and a welcome from NABP President Malcolm J. Broussard, RPh. Next, compliance officers joined the NABP surveyors for a networking dinner.

The Forum continued on Friday morning with more networking events and programming. Compliance officers and surveyors attended separate sessions in the morning, but came together again for a final joint session in the afternoon. Surveyors received information on the Verified-Accredited Wholesale Distributors® program, while compliance officers started the day in the session “Trends and Technology.” In this session, attendees focused on the areas of employee diversion, cargo theft, and electronic inspection forms. Again, short introductions provided by compliance officers were followed by audience discussions. The next session, entitled “Shared Topics,” featured topics that were suggested by compliance officers in response to a survey that was sent prior to the event. The topics covered included USP Chapter 797, inspecting for public safety, and secondary and virtual wholesale distributors. In the time remaining, attendees began discussing some of the topics that were suggested by attendees during Winsley’s welcome remarks the previous day, including access to controlled substances during inspections; coupons, incentives, or guarantees that impact or distort pharmacists in community pharmacies; re-importation; unapproved uses of domperidone; and dealing with limited resources at the board level.

During the final session of the meeting, surveyors joined the compliance officers again for “Scarce Resources – State Inspection Services.” This session focused on how tight board resources have affected compliance officers and innovative ways to deal with this issue. The session also included time to finish discussion of the additional topics that were brought up by attendees at the beginning of the meeting.

NABP President-elect Michael A. Burleson, RPh, closed the meeting with some additional information about NABP programs and services that are available to the attendees. He thanked attendees for their participation and for their dedication to protecting public health.

In 2012, forums will be held for both board of pharmacy members and executive officers. The Interactive Board Member Forum will be held September 19-20, and the Interactive Executive Officer Forum will be (continued on page 30)
PSM Honors NABP with Guardian Award for Efforts to Fight Counterfeit Medicines

The Partnership for Safe Medicines (PSM) presented NABP with the inaugural Guardian award, recognizing the Association's efforts in raising awareness of and combating unlicensed online pharmacies. The award was presented at the PSM Interchange, October 27, 2011, an annual conference bringing together investigators, regulators, patient advocates, counterfeit drug victims, and law enforcement to address issues related to fighting counterfeit drugs.

Over 120 stakeholders participated in the 2011 PSM Interchange “to discuss ways to stem the rising tide of counterfeit and unsafe medicines not only in the United States, but around the globe,” as noted in a PSM press release. Speakers included United States Under Secretary of State Robert D. Hormats, who stressed the importance of collaboration among US government agencies, international governments, and private sector and stakeholder groups, in making progress in the fight against counterfeit and substandard medicines. Dr Marv Shepherd, president of PSM and director of the Center for Pharmacoeconomic Studies at the University of Texas-Austin, stated that the goal of the Interchange conference was to “send a message of empowerment – empowering consumers and medical professionals to identify and avoid unsafe medicines, empowering lawmakers and regulators to develop policies to keep our drug supply safe, and empowering global stakeholders to join together to develop a unified, collaborative effort to fight the growing counterfeit drug risk.” Other PSM Interchange speakers included Senator Michael Bennet (D-CO), Congressman Jim Matheson (D-UT), Deputy Director of Immigration and Customs Enforcement Kumar C. Kibble, Maryland Attorney General Douglas Gansler, and representatives from Food and Drug Administration, the White House Office of the US Intellectual Property Enforcement Coordinator, and a variety of domestic and international patient and health advocacy organizations.

The Guardian will be an annual award presented by PSM to an individual or organization that has demonstrated outstanding leadership in the fight to stop counterfeit medicines.

NABP Partnering with APhA to Develop Community Pharmacy Accreditation Program

NABP is partnering with the American Pharmacists Association (APhA) to develop the voluntary community pharmacy accreditation program. The associations are working together to develop, test, and implement standards and the accreditation process, and the program is expected to launch this year. The program standards will be focused on assisting pharmacies in the ongoing patient safety and quality initiatives that support the best interest of patients.

Further, both APhA and NABP see the developing community pharmacy accreditation program as supporting the realization of the Joint Commission of Pharmacy Practitioners’ (JCPP) 2015 Future Vision of Pharmacy Practice, which envisions that “Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.” The NABP 2011 Report of the Executive Committee, presented by 2010-2011 NABP Executive Committee Chairperson Gary A. Schnabel, RN, RPh, at the Association’s 107th Annual Meeting, stressed that the change in pharmacy practice envisioned in the JCPP statement “can be realized with the community pharmacy accreditation program.”

Executive Committee

- William T. Winsley, Chairperson
  One-year term
- Malcolm J. Broussard, President
  One-year term
- Michael A. Burleson, President-elect
  One-year term
- Karen M. Ryle, Treasurer
  One-year term
- James T. DeVita, Member, District 1
  Serving second year of a three-year term
- Edward G. McGinley, Member, District 2
  Serving second year of a three-year term
- Mark T. Conradi, Member, District 3
  Serving first year of a three-year term
- William J. Cover, Member, District 4
  Serving first year of a three-year term
- Lloyd K. Jessen, Member, District 5
  Serving second year of a three-year term
- Joseph L. “Joe” Adams, Member, District 6
  Serving third year of a three-year term
- Kathryn J. Lew, Member, District 7
  Serving third year of a three-year term
- Hal Wand, Member, District 8
  Serving first year of a three-year term

NABP Executive Committee elections are held each year at the Association’s Annual Meeting.
Legal Briefs

Arrested Development
By Dale J. Atkinson, JD

The proliferation of technological advancements enables boards of pharmacy to provide the public with virtually immediate access to information about applicants and licensees, including persons subject to administrative discipline. This ease of availability of public information enhances opportunity for an informed public and allows consumers not only to verify a professional’s credentials, but also to assess such practitioner’s administrative background.

On the other hand, licensees may not appreciate the public nature of certain adverse information and, based upon the ease of public access, may seek to have such information removed from public availability. Requests to delete administrative discipline from public access may be justified based upon the completion of the sanctions set forth in the order, the mere passage of time, as well as other legal or equitable grounds. One such mechanism is to have a record “expunged.” Expunction effectively destroys the records and treats the impacted person, for purposes of the official records, as if the event (generally a crime) had never occurred. The admissibility of information that led to criminal action of a now expunged record may, however, remain relevant. As mentioned, most likely the expunged record addresses a criminal matter. But, to what degree is information related to the events of an expunged criminal conviction relevant and admissible in an administrative proceeding? Or perhaps more difficult, what about an expunged record related to a criminal arrest that did not result in a conviction? Consider the following.

An officer of the Texas Alcoholic Beverage Commission was conducting an inspection of a bar. While on the premises he was approached by a patron who reported a male alone near the dance floor was engaged in lewd acts. The inspector observed the lewd acts and immediately removed the patron from the establishment. As a result of the incident, the patron was arrested and charged with indecent exposure. Some time later, the charges were dismissed and eventually his arrest records were expunged. He was never convicted of a crime.

The patron (Licensee) was a teacher who held an active Texas Educator Certification at the time of the incident and was employed by a public school district. Eventually, the State Board for Educator Certification (Board) filed a petition against the Licensee with the State Office of Administrative Hearings. The petition alleged that the actions of the Licensee at the bar indicated that he was a person “unworthy to instruct or supervise the youth of the State of Texas.” The Board sought to have his educator certification permanently revoked.

Prior to the administrative hearing, the Licensee filed a motion arguing that because his arrest record had been expunged the Board could not produce any evidence to support its claim. An expunction order under the Code of Criminal
Procedure prohibits the use of any records or files concerning the Licensee’s arrest. The Board responded that it intended to use the testimony of the inspector who was an eyewitness to the events and it would not use nor rely upon the arrest records.

At the hearing, the administrative law judge allowed the inspector to testify but did not admit such testimony into the record until the conclusion of the proceedings. In overruling the Licensee’s objections to the testimony of the inspector and allowing such to be made of record, the administrative law judge noted that the inspector did not refresh his memory from the arrest record or any other record subject to the expunction order. The Licensee testified and admitted he was escorted out of the nightclub but denied engaging in lewd acts. Two additional character witnesses testified on behalf of the Licensee.

The administrative law judge found that the Licensee engaged in the lewd acts at the nightclub and concluded that such conduct was an act of moral turpitude and that an act of moral turpitude can preclude a finding of good moral character. However, the administrative law judge concluded that the Board did not have the basis for discipline because the Board’s definition of “unworthy to instruct or supervise the youth of the state of Texas” basically required the educator to have been convicted of one of the enumerated crimes set forth in that section of the cited law.

The Board adopted the findings of the administrative law judge with the exception of the two conclusions of law related to the interpretation of what constitutes unworthy to instruct or supervise. The Board found the administrative law judge’s interpretation to be inconsistent with applicable law, agency rules, and prior administrative decisions. The Board concluded that the conduct of the Licensee established that he was unworthy to instruct or supervise the youth of the state of Texas and revoked his license.

On appeal, the Licensee argued that the Board exceeded its statutory authority by rejecting the administrative law judge conclusion regarding her interpretation of the phrase “unworthy to instruct,” the court held that the Administrative Procedure Act (APA) specifically allows for the Board to change a finding of fact or conclusion of law. It held that the Board complied with the APA requirement of explaining the reasons and legal basis for its rejection of the administrative law judge conclusions. The court also reiterated its role under the standard of review as assessing whether the Board’s interpretation was reasonable and did not contradict the plain language of the statute or rule.

The court held that requiring a criminal conviction of one of the two cited criminal sections in order to find one unworthy to instruct was inconsistent with the public protection intent of the statute. In deferring to the Board’s authority, the court held that the Board’s interpretation was reasonable, consistent with the statute, and was delineated in its order. Thus, the Board acted within its statutory authority.

Addressing the admission of the eyewitness testimony, the Licensee argued that the expunction statute “precludes a person who acquires knowledge of an arrest while a state employee and who knows of an order expunging the

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Interactive Forum and Surveyor Training
(continued from page 26)

held November 13-14. NABP will again cover all expenses for one member from each board in order to facilitate participation by as many boards as possible and allow for increased opportunity for networking as attendees use the Forum to share ideas and develop potential solutions to meet common challenges.

Legal Briefs
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records and files relating to that arrest from disseminating or using the records or files.” In rejecting this argument and upholding the allowance of the inspector’s testimony, the court held that such testimony relied upon personal observation, not on an expunged record or file. Indeed, the inspector testified to the fact that his recollection of the events of that evening were based upon his direct knowledge and that he did not refresh his memory using the expunged records or files. In interpreting the statute, the court noted “the legislature’s intent in enacting the expunction statute was not to eradicate all evidence of the conduct underlying the expunged arrest.” Thus, the allowance of the inspector’s testimony was affirmed and this argument of the Licensee was rejected.

Finally, the court addressed the Licensee’s argument that the Board erred in denying his request to supplement the record with additional evidence not presented to the administrative law judge. The Licensee had sought to have an additional order entered by the expunging court made of record in the administrative proceedings. This additional court order called for the Texas Education Agency to return to the court all files related to the Licensee and was based upon allegations of noncompliance by such agency. The court noted that to allow on appeal the submission of additional evidence outside the administrative record, the requesting party must show the evidence is material and that there were good reasons for its failure to be presented in the proceedings before the administrative law judge. In this case, the court held that the Licensee failed to argue that the agency was not complying with the expunction order but, instead, merely argued that the admission of the testimony of the inspector was improper. Accordingly, this argument by the Licensee was rejected.

Rejecting all arguments of the Licensee, the court affirmed the findings of the Board and the revocation of the license. Due to the implication of criminal laws related to pharmacists accused of wrongdoing and the potential for criminal arrests, boards of pharmacy may be confronted with the admissibility of information related to an expunged criminal record. This can be a complicated legal arena and advice from counsel is essential.


Newly Approved e-Advertiser

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

Catlin Enterprises, Inc dba Withdrawal-Ease
www.withdrawal-ease.com

A full listing of NABP approved e-Advertisers is available on the NABP Web site at www.nabp.net.
Federal and State Governments Take Action to Stem Onslaught of Two New Classes of Synthetic Drugs

With claims of offering users a means of altering consciousness without running afoul of the law, two relatively new classes of synthetic drugs are sweeping through the country. Despite its comparatively recent arrival in the United States, cannabinoid-laced “incense” alone is estimated to be a $5 billion industry. Synthetic cannabinoids supposedly mimic the effects of marijuana use, while synthetic cathinones have been touted as a “legal” alternative to such drugs as cocaine or methamphetamine. As evidence of the increasingly widespread use and harm caused by these substances has mounted, local, state, and federal governments have taken swift action to legally constrain their manufacture, possession, and use. At the same time, manufacturers and sellers of the synthetic drugs are taking steps to circumvent new regulations and continue to grow a lucrative new industry.

Incense & Bath Salts

The histories of synthetic cannabinoids and synthetic cathinones are similar. Both drug types became widespread in Europe before being documented in the US around 2008 (cannabinoids) or 2009 (cathinones). Both are marketed as small packets of “not for human consumption” items – usually “herbal incense” for cannabinoids and “bath salts” for cathinones – but are clearly understood by both buyer and seller to be intended for ingestion by those seeking a psychoactive result. Both are widely available over the Internet and from brick-and-mortar stores ranging from head shops to gas stations. Both have triggered a dramatic upsurge in related visits to emergency rooms and calls to poison control centers. US poison control centers received 2,915 calls related to synthetic cannabinoids in 2010; for 2011, the number had risen to 5,741 for the first 10 months of the year. As for synthetic cathinones, related calls to poison centers shot up from 303 in 2010 to 5,625 in 2011 through the end of October alone.

Synthetic cannabinoids are chemically engineered substances functionally similar to delta-9-tetrahydrocannabinol (THC), the principal psychoactive component in marijuana. Originally developed for research purposes, they have never been approved by Food and Drug Administration for therapeutic purposes, and according to Drug Enforcement Administration (DEA), “there is little information regarding the pharmacology, toxicology, and safety of these substances in humans.” Producers of herbal incense products often dissolve the substance in solvents and spray it in liquid form onto a mixture of dried, chopped, or crushed herbs and other botanical materials; users primarily smoke the “incense” to achieve the psychotropic effects. Analysis has found extensive variation across different samples, including those from the same supplier: different chemical variations, differing potency varying from two to more than 500 times stronger than THC, and even difference in the brain receptors targeted.

While synthetic cannabinoids reportedly often trigger the same physiological responses as marijuana, this is not always the case. Adverse health effects associated with synthetic cannabinoids include agitation, anxiety, nausea, vomiting, tachycardia, hypertension, tremors, seizures, hallucinations, paranoid behavior, and loss of consciousness. News reports and researchers have linked a number of psychotic episodes and deaths to the ingestion of “herbal incense,” including a teenager in Illinois who drove his vehicle into a house and a Nebraska student who killed an assistant principal at his school and himself.

Synthetic cathinones, meanwhile, are central nervous system stimulants structurally and pharmacologically similar to substances such as amphetamine, 3,4-methylenedioxy-methamphetamine, and cathinone (which occurs naturally in the khat plant). At least two synthetic cathinones, methylenedioxypyrovalerone (MDPV) and methylone, were originally derived from products developed in pharmaceutical research; however, as DEA points out, there are currently no accepted medical uses for these products in the US. Most users reportedly ingest “bath salts” (which are often sold in granular form reminiscent in appearance to real bath salts) by snorting them in powder form or swallowing them, usually in capsule or tablet form.

Synthetic cathinones reportedly trigger physical and psychological responses similar to cocaine or meth; some of the many adverse health effects include extreme agitation or anxiety, hallucinations, paranoia, aggression or disturbed behavior, palpitations, seizures, vomiting, headaches, and hypertension. A number of atrocities and deaths have been attributed to ingestion of synthetic cathinones, including a 21-year-old in Louisiana who shot himself, deaths attributed to driving under the influence of the substances, and users’ violent behavior toward themselves or others.

Moving Quickly

Lawmakers and regulators have acted quickly in response to the situation. On the federal level, in

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March 2011, DEA issued a final order temporarily designating five chemicals used in synthetic cannabinoid products – referred to as JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol – as Schedule I substances. Their placement into the Controlled Substances Act (CSA) makes illegal their manufacture, distribution, possession, importation, and exportation. The designation lasts for one year, and may be extended for an additional six months during “pendency of proceedings” for a more permanent placement. Likewise, on October 21, 2011, DEA issued a final order temporarily placing three synthetic cathinones – mephedrone, methylone, and MDPV “and their salts, isomers, and salts of isomers” – in Schedule I of the CSA.

Meanwhile, US legislators in early 2011 introduced two bills in each the House of Representatives and the Senate dealing with synthetic cannabinoids and synthetic cathinones. Senate Bill 409, the “Combating Dangerous Synthetic Stimulants Act of 2011,” proposed to amend the CSA to include mephedrone and MDPV as Schedule I controlled substances. At press time, it had passed through committee and had been placed on the Senate Legislative Calendar; an identical bill remained in committee in the House. Senate Bill 605, the “Dangerous Synthetic Drug Control Act of 2011,” addressed synthetic cannabinoids; it would put a broad list of “any material, compound, mixture or preparation which contains cannabimimetic agents (or the salts, isomers, or salts of isomers thereof)” into Schedule I of the CSA, and would also extend temporary listing of substances in CSA Schedule I to up to two years, with a one-year extension. At press time, the bill had also been placed on the Senate Legislative Calendar; the House version, which would also ban a number of synthetic cathinones, passed in the House on December 8, 2011, and has been referred to the Senate Committee on the Judiciary.

Local and state legislators and regulators have acted even faster. Kansas outlawed the use, possession, and sale of synthetic cannabinoids in 2010 – the first state to pass legislation doing so. By the end of October 2011, at least 40 states had adopted laws or departmental rules banning chemical substances related to synthetic cannabinoids. At least three additional states had similar legislation pending. The drugs have been addressed throughout the country on a more local level, as well. In November 2011, for example, Chicago prohibited the sale of “synthetic marijuana.” States have also taken action against bath salts: by the end of October 2011, at least 33 states had adopted laws or departmental rules outlawing substances related to synthetic cathinones.

The complex nature of the synthetic drugs, however, makes regulation difficult. The manufacturers of the products subtly change the compounds to sidestep laws. In Kansas, for example, the original 2010 law banned three compounds; almost immediately, new compounds began appearing. The state more recently passed legislation taking a broader approach, banning the general chemical classes associated with synthetic cannabinoids. The state’s laws related to synthetic cathinones are likewise broad and attempt to include substitutions or variations the producers might come up with. Other states’ laws vary widely in their specificity, but a number of states are considering legislation adding additional compounds to their original bans, or broadening language to encompass more potential formulations.

Most of the legislation, particularly the more recent broad designations of chemical classes, has been enacted too recently to judge its impact. With large profits, manufacturers and retailers of the substances, meanwhile, have a significant incentive to continue their activities. Enough incentive, no doubt, to keep the cat-and-mouse game between regulators and illicit drug manufacturers going for some time to come.

**Newly Accredited DMEPOS Facilities**

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

- **Austin Pharmacy Inc**
  Forest Hills, NY
- **Belew Drugs Asheville Highway LLC**
  Knoxville, TN
- **NMB Generics, Inc**
  Miami, FL
- **Pharmacy Depot LLC**
  Brooklyn, NY
- **St Jude Pharmacy**
  Brooklyn, NY

A full listing of the nearly 1,000 accredited DMEPOS companies representing more than 29,000 facilities is available on the NABP Web site at [www.nabp.net](http://www.nabp.net).
Currently wrapping up the last of the CPE Monitor™ data transmission pilot, the Accreditation Council for Pharmacy Education (ACPE) has reported that all three modes of transmission – manual, Web-based, and file transfer protocol (FTP) – were successfully tested with the assistance of 42 providers and NABP.

Soon, ACPE plans to provide an updated technical specifications document to all ACPE-accredited providers to assist with their transition to CPE Monitor. Many providers have already begun integrating CPE Monitor into their systems. Those providers who choose to transmit data manually will be able to begin utilizing the service immediately. Those who choose to transmit data through the Web service or via FTP, will first need to contact ACPE directly in order to set up the transmission services.

As providers implement the system, anyone registering for ACPE-accredited continuing pharmacy education (CPE) with that provider will be required to provide his or her NABP e-Profile ID and birth date (MMDD) to receive credit. With the majority of the ACPE providers projected to have completed the integration of CPE Monitor into their systems by July 2012, it is strongly recommended that all pharmacists and pharmacy technicians set up their e-Profiles to avoid any delays in the processing and tracking of CPE data. All accredited providers will be required to transmit their CPE data through the system by December 31, 2012, in order to continue to issue ACPE-accredited CPE units.

Since the initial launch of CPE Monitor, more than 100,000 pharmacists and 43,000 pharmacy technicians have set up their e-Profiles to prepare for the shift to electronic data transmission. Licensees may obtain more information on CPE Monitor and set up their e-Profiles at www.MyCPEmonitor.net.

Another 188 Tons of Unneeded Medications Collected During Third Drug Enforcement Administration Take-Back Day

Consumers disposed of more than 188 tons of unneeded, unwanted, or expired medications on the third National Drug Enforcement Administration (DEA) Prescription Drug Take-Back Day coordinated by DEA on October 29, 2011. Law enforcement and community organizations partnered with DEA to provide 5,327 take-back sites across all 50 states and the United States territories. DEA reports that the three take-back days combined collected a total of 995,185 pounds (498.5 tons) of unwanted medication.

By providing consumers with a safe and authorized method of medication disposal, DEA take-back events help to prevent prescription drug misuse and abuse, and the events are part of the White House strategy for preventing prescription drug abuse. The plan, outlined in the document, “Epidemic: Responding to America’s Prescription Drug Abuse Crisis” also includes:

- education of health care providers, patients, parents, and youth;
- establishing prescription drug monitoring programs in all the states; and
- increased enforcement to address “doctor shopping” and pill mills.

Further, DEA Administrator Michele M. Leonhart stated that the agency “remains hard at work” developing a permanent process for people to safely and conveniently dispose of unneeded medications, as authorized by the Safe and Secure Drug Disposal Act of 2010. Leonhart noted that the “amount of prescription drugs turned in by the American public during the past three Take-Back Day events speaks volumes about the need to develop” such a drug disposal process. The next DEA take-back day will be held April 28, 2012.

For information on local programs that accept medications for disposal year round, consumers can visit www.AWARERx.ORG, and click on Get Local.
Task Force to Consider Next Steps in Fighting Illegal Internet Distribution of Medications

An estimated 36 million Americans, or one in six people, have ordered prescription drugs from Internet Web sites without a prescription, according to a Partnership at Drugfree.org survey. Consistent with this finding, NABP has found that approximately 80% of the sites on the Association’s Not Recommended list do not require a valid prescription. Consumers using rogue sites continue to be at risk as regulators look for new ways to combat this issue.

As stressed in the October 2011 NABP Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators, the operators of rogue sites, “take advantage of patient confidence in trusted brands to sell pills that may contain too much or too little, if any, of the approved drug’s active ingredient, an entirely different active ingredient, or contaminants ranging from talcum powder to printer ink.” Indeed, cases of consumers, both in the United States and abroad, harmed by counterfeit drugs ordered from such rogue sites have been documented. Further, rogue Internet drug outlets put patients at risk by distributing controlled substance (CS) drugs without requiring prescriptions, raising the potential for drug-drug interactions, overdose, and drug abuse or addiction. In fact, Drug Enforcement Administration (DEA) has indicated that rogue sites contribute to the prescription drug addiction epidemic.

Federal regulators have had some success, at times in collaboration with their international regulatory counterparts, in shutting down rogue Internet drug outlets. Congress is considering bills to address the problem, one by way of protecting intellectual property, and another by adopting tougher penalties for counterfeit trafficking.

On the state level, boards of pharmacy have had an impact by disciplining licensees engaged in dispensing drugs based on invalid prescriptions associated with Internet drug outlets. Boards have also partnered with DEA in cases where licensees are involved in larger scale Internet drug distribution schemes. In some states, laws requiring board of pharmacy oversight for the registration of Internet pharmacies, and laws or rules that recognize VIPPS® (Verified Internet Pharmacy Practice Sites®) as fulfilling certain state requirements also help to protect patients.

Through establishing programs such as VIPPS, Vet-VIPPS® (Veterinary-Verified Internet Pharmacy Practice Sites®), and the NABP e-Advertiser Approval Program, providing research on rogue sites to federal and state regulators, and through consumer education initiatives, NABP has taken several steps to protect patients from the harmful products peddled by rogue Internet drug outlets. And to determine whether additional action should be taken by boards of pharmacy and the Association to address the illegal distribution of drugs via Internet sites, the NABP Task Force on Internet Pharmacy Practice will convene March 6-7, 2012.

Boards of Pharmacy Actions

State legislatures and state boards of pharmacy continue to take steps to protect their residents from rogue drug outlets operating via the Internet.

In Iowa, legislation adopted in 2009 required that the Iowa Board of Pharmacy develop rules for the registration of Internet pharmacies, including rules to define “Internet pharmacies” and “Internet pharmacy sites,” and to establish requirements for site registration, site content, and other relevant matters. The rules must also cover the...
requirement that Internet pharmacies doing business in Iowa must be accredited through the VIPPS program. The Board is currently developing the rules.

As reported in the 2012 NABP Survey of Pharmacy Law, at least 14 states, in addition to Iowa, recognize VIPPS accreditation as fulfilling certain requirements of Internet pharmacies dispensing to patients in their state. And at least four states, Florida, Hawaii, Missouri, and Utah, have a separate category for licensing Internet pharmacies. At least one state, Indiana, requires that in-state Internet pharmacies are licensed as mail order pharmacies.

Boards are also able to have an impact on illegal Internet drug outlets by disciplining licensees, both pharmacies and pharmacists, who facilitate their business by dispensing invalid prescriptions. Boards of pharmacy in California, Minnesota, and Ohio have issued fines and put pharmacist licenses on probation for such violations, as reported in the December 2010 NABP Newsletter article “State Boards of Pharmacy Take Action to Stop Licensees Involved in Unlawful Internet Drug Outlet Schemes.” As detailed in the same article, the boards in Iowa and Kansas also took emergency actions against pharmacies involved in larger scale Internet drug distribution schemes.

**NABP Actions**

NABP continues to keep federal and state regulators and other stakeholders informed via the quarterly reports of the Internet Drug Outlet Identification program. As of October 2011, the program had reviewed almost 8,500 Internet drug outlets, finding that over 96% of the sites are operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards.

NABP shared such information at a White House meeting on rogue Internet drug outlets November 9, 2010, and also presented information about the VIPPS accreditation program. The US Office of the Intellectual Property Enforcement Coordinator (IPEC) that coordinated the meeting, as well as meeting participants, were supportive of developing a “White List” of legitimately operating online pharmacies based on expanding the VIPPS list. Subsequently, NABP participated in a panel discussion, “Dangers of Counterfeit Pharmaceuticals,” coordinated by the IPEC office December 14, 2010.

NABP also participated in a Congressional Briefing coordinated by the Partnership for Safe Medicines (PSM) and Senator Chris Coons on June 23, 2011, to discuss the problem of rogue Internet drug outlets. Participants at the meeting discussed challenges regulators face and strategies to solve the problem.

To raise awareness among consumers, NABP issued a public health alert warning Americans about the dangers associated with medications purchased through fake online pharmacies, and presented some of the Association’s research statistics. NABP also continues to educate the public via e-News announcements and via the AWAREx™ consumer protection program Web site, www.AWARERx.ORG, and outreach events.

**Federal Actions, Successes, and New Challenges**

The Ryan Haight Online Pharmacy Consumer Protection Act, by amending the Controlled Substances Act (CSA) with a definition of “valid prescription,” allowed for the prosecution of individuals distributing CS via the Internet without requiring a valid prescription. The law went into effect April 13, 2009, and DEA announced the first charges in violation of the law in May 2010.

In addition, federal law enforcement and regulators, often in partnership with international regulators and with private US entities, have been able to shut down thousands of such Web sites.

However, new challenges in both arenas continue to arise. IPEC explains, in a report released in March 2011, that the definition applied to the CSA “was designed to (continued on page 36)
address the practice of online pharmacies that dispensed controlled substances without a prior prescription or on the basis of a purported review by a physician who reviewed a questionnaire.” However, many online sellers market prescription drugs other than CS. Thus, IPEC recommends, that the Federal Food, Drug, and Cosmetic Act (FD&C Act) be amended to use the Ryan Haight definition of valid prescription so that non-CS prescription drugs sold online may be regulated. IPEC indicates that a similar amendment to the FD&C Act can “help reduce the number of online pharmacies evading prescription requirements and, in turn, selling counterfeit drugs.”

Bryan Liang, PhD, MD, JD, vice president of the PSM, agrees with IPEC’s recommendation and stressed at the Congressional Briefing in June 2011 that current federal regulations address only online pharmacies that are based in the US and that distribute CS.

Liang and other industry experts point out another challenge; specifically, while thousands of rogue Internet drug outlets have been shut down, the operators of such sites can easily set up shop again. Further, if investigations result in arrests and convictions related to distributing counterfeit drugs via the Internet, the penalties are not tough enough to deter others from engaging in counterfeit manufacture or distribution. Liang has also noted that it is “difficult to attribute patient death or injury to online drug consumption or purchase.” Meanwhile, counterfeiters and rogue site operators are motivated by hefty profits. For example, “When sold at market price, counterfeit ED [erectile dysfunction] drugs reportedly can generate 2,000% profit margins – approximately 10 times the profitability of heroin,” as indicated in the October 2011 NABP Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators. Industry experts, both represented by the Alliance for Safe Online Pharmacies (ASOP) and by IPEC, have stressed that increasing penalties for convictions related to the manufacture and distribution of counterfeit drugs can help to prevent this crime.

Liang indicates another challenge for customs and law enforcement – with the millions of illegal imports being shipped into the US, it is impossible for every package to be screened for the presence of counterfeit drugs. And, as highlighted in a March 2011 60 Minutes report, even with the thousands of packages seized, under current law, many packages must be shipped back to overseas senders, giving another chance for the package to be reshipped and possibly evade detection. Customs and Border Protection told PSM that many such packages are the result of Internet orders with the counterfeiters being shipped directly to patients.

Lawmakers Act

Consistent with the IPEC recommendation, the Online Pharmacy Safety Act of 2011 (S 2002), introduced to the Senate on December 15, 2011, would amend the FD&C Act to use the Ryan Haight definition of valid prescription so that non-CS prescription drugs may only be ordered and dispensed from an Internet pharmacy pursuant to a valid prescription. The bill is also intended to protect Americans from counterfeit drugs sold over the Internet by requiring the establishment of a registry of legitimate online pharmacy Web sites, which would include Internet pharmacies accredited by the NABP VIPPS program. In addition, the legislation would allow Internet service providers – such as domain name registrars, financial transaction providers, and Internet advertising services – to cease or refuse to provide services to Internet drug outlets not included on the registry.

Other legislation has been drafted to specifically target the trafficking of counterfeit drugs and was introduced by Senator Patrick Leahy (D-VT) to the Senate on November 17, 2011. The Counterfeit Drug Penalty Enhancement Act of 2011 would increase penalties for trafficking counterfeit drugs, with convicted individuals facing penalties of up to $4 million and 20 years imprisonment, and up to $8 million for multiple offenses. Entities convicted of trafficking counterfeit drugs could face fines as high as $10 million for a single offense or as much as $20 million if convicted of multiple offenses. One supporter of the bill stated that under current US law, individuals convicted of trafficking counterfeit drugs typically face prison sentences of three years, while the products they peddle can cause serious health issues for unsuspecting purchasers.

Attempts to fight counterfeiters with legislation protecting intellectual property have been met with much debate. In May 2011, the “Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property Act of 2011” was introduced to the US Senate. This legislation was developed with the intention of targeting the worst-of-the-worst Internet intellectual property infringers by eliminating financial viability of a site, rather than blocking access. While the bill was developed to respond to concerns voiced by various parties over 2010 intellectual property legislation, it also faced much criticism.

In addition, another bill, the Stop Online Piracy Act (SOPA), which was introduced to the House in October 2011, and as of press time has been deferred to a House committee. SOPA builds upon the two previous pieces of legislation and includes provisions intended to fight rogue Internet drug outlets by encouraging private companies to stop doing business with them, as summarized by ASOP. The bill also includes provisions that would increase penalties for convictions related to trafficking counterfeit drugs.

Global Perspective

Along with federal and state legislation, industry experts and government agencies have recognized the need for a global perspective and for international partnerships to...
Task Force Convenes to Discuss Pharmacy Technology Systems

On November 1-2, 2011, the Task Force on Pharmacy Practice Technology Systems convened at NABP Headquarters to review and discuss existing state laws and regulations addressing the use of technology systems and relevant Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy language. Pictured from left to right: James T. DeVita, RPh, Executive Committee liaison; Task Force Chairperson Patricia D’Antonio, RPh, MS, MBA, CGP, executive director, District of Columbia Board of Pharmacy; Dennis McAllister, RPh, FASHP, member, Arizona State Board of Pharmacy; Amy Mattila, RPh, past member, Wisconsin Pharmacy Examining Board; Danna Droz, RPh, JD, prescription monitoring program administrator, Ohio Automated Rx Reporting System; Michael Podgurski, RPh, member, Pennsylvania State Board of Pharmacy; Lee Ann Bundrick, RPh, administrator, South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy; and Kenneth Saunders, RP, PharmD, member, Nebraska Board of Pharmacy.

Task Force
(continued from page 36)

make headway in regulating rogue Internet drug sites.

Food and Drug Administration (FDA) joined regulatory agencies from 81 countries for the International Internet Week of Action, September 20-27, 2011. The collaborative effort aims to curb online distribution of counterfeit medications, and in 2011 INTERPOL reports that “almost 13,500 websites engaged in illegal activity were shut down.” FDA reports that at least 578 sites selling unapproved drug products to US citizens were shut down as a result of the global action.

The World Health Organization and other international health groups have taken serious steps to fight counterfeits and protect the quality of drugs. At a November 21, 2011 meeting called by the World Health Professions Alliance (WHPA), participants focused on reducing the impact of counterfeit drugs on patients and the public in central Europe and acknowledged the role of the Internet in disseminating counterfeit drugs. The resulting WHPA Prague Call to Action, among its four objectives for action, called for fostering regional collaborative initiatives, including attention to the illegal Internet distribution of counterfeit drugs.

Closer to home, the Canadian regulatory agency, Health Canada, has taken steps to protect its citizens from the dangers of counterfeit drugs sold on the Internet. In November 2010, Health Canada issued a warning to consumers about three specific sites found to be peddling counterfeit drugs. As explained in the warning, the sites had been reviewed by the Ontario College of Pharmacists and it was determined that they were not associated with pharmacies licensed in Ontario. Health Canada has also provided a section of its Web site devoted to raising awareness among Canadians about the risks of ordering drugs online.

Task Force to Invite Partners, Consider Global Perspectives

The NABP task force is committed to taking a global view, as it also considers the future steps of state boards of pharmacy and the Association. The charge of the task force will be to:

1. Review existing Internet pharmacy practices;
2. Review current state laws and regulations, VIPPS standards, and NABP Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy language; and
3. Examine future opportunities and challenges in an emerging global environment.

At least one representative from a Canadian pharmacy regulatory body will participate on the task force, and recommendations from the task force may help bring about global cooperation. The report of the task force will be the topic of a future NABP Newsletter article.
Forum Offers Compliance Officers, Surveyors Chance to Network While Attending Timely and Relevant Sessions

New this year, the annual NABP Surveyor Training Program was held in conjunction with the first ever NABP Interactive Compliance Officer Forum. Initial feedback on the Forum and Training Program was very positive. Attendees expressed their appreciation of the joint event, which provided board of pharmacy compliance officers, inspectors, and investigators a chance to share information and network with NABP accreditation consultant surveyors. The programming took place over a period of two days and included both surveyor and compliance officer-specific sessions as well as joint sessions. More information on the Forum can be found in the cover story of this Newsletter.

NABP Surveyors Convene for Annual Training, Joint Interactive Forum
Thirty NABP accreditation consultant surveyors participated in the annual Surveyor Training Program, which took place in conjunction with the NABP Interactive Compliance Officer Forum on December 1-2, 2011. The surveyors attended specialized training sessions led by NABP staff each morning prior to joining board of pharmacy compliance officers, inspectors, and investigators in the afternoon. The surveyor-specific sessions covered various topics relating to NABP accreditation programs including “Surveyor Fundamentals/What’s on the Horizon?”, “DMEPOS Magnified in 2012”, “VAWD: New Twists”; and “VAWD: Nitty Gritty.”

Panelists Explore the World of Compliance, Share Insights
During the December 1, 2011 joint session, “What’s New in the World of Compliance?” panelists shared and led discussions on timely compliance-related topics. Pictured from left to right: session moderator James T. DeVita, RPh, member, NABP Executive Committee; Gregg Jones, BPharm, RPh, CPh, compliance manager, NABP (Recognizing and Addressing Counterfeit Drugs/Pedigrees); Tim Thomas, compliance officer, Indiana Board of Pharmacy (The Impact of Drug Shortages); Tom Glenski, RPh, chief inspector, Missouri Board of Pharmacy (Storage Compliance Stories); and Chris Reed, compliance supervisor, Ohio State Board of Pharmacy (Pill Mills & Detox Centers).
President Broussard Welcomes Attendees
NABP President Malcolm J. Broussard, RPh, welcomed the state board of pharmacy compliance officers, investigators, and inspectors to NABP Headquarters on December 1, 2011, prior to a joint networking dinner with the NABP accreditation consultant surveyors.

Examining Trends and Technology in Pharmacy
Board of pharmacy compliance officers began day two of the Forum with the session “Trends and Technology.” Pictured from left to right: Steve Hart, RPh, inspections and investigations coordinator, Kentucky Board of Pharmacy (Electronic Inspection Forms); Gary Karel, pharmacy inspector, South Dakota State Board of Pharmacy (Employee Diversion); session moderator Hal Wand, MBA, RPh, member, NABP Executive Committee; and Ben Kesner, RPh, state drug inspector, New Mexico Board of Pharmacy (Cargo Theft).

Experts Speak on Public Safety Inspections, USP Chapter 797, and Virtual Wholesalers
The second compliance officer session held on December 2, 2011, “Shared Topics,” focused on issues previously suggested by attendees. Pictured from left to right: session moderator Mark T. Conradi, RPh, JD, member, NABP Executive Committee; Joe Depczynski, board inspector/investigator, Nevada State Board of Pharmacy (Inspecting for Public Safety); Paul Holder, RPh, PharmD, assistant director of enforcement, Texas State Board of Pharmacy (USP Chapter 797); and Judi Nurse, PharmD, supervising inspector, California State Board of Pharmacy (Secondary/Virtual Wholesaler Case Studies).

Working with Limited Resources
Jim Wolfe, RPh, investigator, Iowa Board of Pharmacy (right) provided his insight during the December 2, 2011 joint session “Scarce Resources – State Inspection Services.” The moderator for this session was William T. Winsley, MS, RPh, chairperson, NABP Executive Committee (left).
AWARxE Continues Outreach Efforts to Educate Consumers Across America

The death rate from overdoses of drugs such as hydrocodone (Vicodin®), methadone, oxycodone (OxyContin®), and oxymorphone (Opana®) has more than tripled in the past decade, as stressed in a Centers for Disease Control and Prevention Vital Signs report released in November 2011. In response to these statistics, Gil Kerlikowske, director of National Drug Control Policy, stated that “Health care providers and patients should be educated on the risks of prescription painkillers,” and that “parents and grandparents [should take time to properly] dispose of any unneeded or expired medications from the home and to talk to their kids about the misuse and abuse of prescription drugs.” The AWARxE™ consumer protection program continues to focus on both objectives highlighted by Kerlikowske:

- educating the public about prescription drug abuse, and
- encouraging participation in medication disposal events and programs.

Further, AWARxE alerts consumers to the dangers of counterfeit medications, often marketed by Internet drug outlets, and the steps they can take to protect their loved ones.

State agencies, health care organizations, and community groups across America are using AWARxE educational materials to help inform consumers about the dangers of prescription drug abuse and the importance of proper disposal of unneeded drugs.

In Nevada, the Clark County Water Reclamation District in Las Vegas will be distributing at least 5,000 bookmarks to consumers at a variety of agency events. The district has partnered with three local police departments to provide medication disposal programs. The programs encourage safe disposal of unneeded medications to help prevent misuse of the drugs, and to help protect the environment.

NABP staff shared AWARxE resources and facts with attendees of the 10th annual symposium of the Managed Healthcare Providers Association (MHPA), Oak Brook Terrace, IL, November 18, 2011. Health care organization administrators visited the AWARxE booth to learn about information resources that can help inform patients. Attendees were encouraged to create opportunities for health care providers to alert patients to AWARxE.org resources by ordering and distributing bookmarks.

After learning about AWARxE, MHPA members shared about AWARxE resources in its monthly newsletter that is distributed to 700 physicians and other health care providers.

Cardinal Health will reach out to its pharmacy patients by broadcasting the AWARxE public service announcements (PSAs) on its in-store television network, Pharmacy Health Network.

The Cardinal Pharmacy Health Network in-store media system presents health care information to patients in 912 Cardinal pharmacies, and the programming will include one of the four AWARxE PSAs every hour. You can view the PSAs on the AWARxE YouTube channel at www.youtube.com/user/AWARxE.

AWARxE promotional efforts and partnerships have brought more consumers to the program’s Web site – site visits were up 85% in November, when compared with August and September statistics. To more effectively engage and inform these visitors, the AWARxE Web site content has been expanded to offer direct access to:

- The NABP list of VIPPS® (Verified Internet Pharmacy Practice Sites™) recommended pharmacies
- The NABP list of Vet-VIPPS® (Veterinary-Verified Internet Pharmacy Practice Sites™) recommended pharmacies
- The NABP Not Recommended list
- The article stressing the dangers of counterfeit drugs distributed by Internet drug outlets. The article encourages consumers to use only VIPPS sites when purchasing prescription drugs online, and to get informed with AWARxE resources.

The article is available on the NABP Web site, www.napsnet.com, under the Health & Fitness section.

To share information about medication disposal events or programs in your state, to order bookmarks at no charge to the board, or to obtain the AWARxE logo for a Web site, send an e-mail to AWARxE@NABP.NET.
FDNY Chief to Share Gripping, First-Hand Encounter with 9/11 World Trade Center Attacks During Annual Meeting Keynote

It was the morning of September 11, 2001, and New York City Fire Department (FDNY) Battalion Commander Richard Picciotto answered the call heard around the world. In minutes, he was at Ground Zero of the worst terrorist attack to ever hit American soil, acting boldly to save innocent lives as the Twin Towers began to burn and, a short time later, buckle. Rushing into the North Tower to rescue those inside, Picciotto soon found himself trapped in the smoldering rubble on the stairwell between the sixth and seventh floors after its collapse. Buried for more than four hours, he emerged almost unscathed.

In a presentation modeled after his New York Times best-selling book, Last Man Down, Picciotto will offer Annual Meeting attendees an eye witness account of one of the nation’s darkest hours. He will speak during the First Business Session of the NABP 108th Annual Meeting, to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA.

Providing a firefighter’s view of the 9/11 attacks, his book chronicles the harrowing experience, providing a tribute to the 343 firefighters and 2,400 civilians who lay dead in the rubble that surrounded him on that day. Picciotto will share with attendees his heartfelt remembrance of that day of infamy and profound humanity. Picciotto will also share how 9/11 renewed his sense of personal values and his perspective on what is important and how hope and positivity can emerge out of tragedy and adversity. Through his experiences with FDNY, Picciotto will share how others can lead effectively and achieve optimal teamwork and goals as well as the training, preparedness, risk management, and decision-making skills needed to tackle any problem.

Picciotto was the highest-ranking firefighter to survive the World Trade Center collapse and the last firefighter to escape the devastation. He played a vital role in the massive operation, testified in front of the 9/11 Commission, and has additionally appeared on many major networks including CNN, the History Channel, and National Geographic Channel.

Prior to surviving 9/11, Picciotto was already a veteran of terrorist attacks having fought a similar battle after the World Trade Center bombing in 1993. Picciotto is a former New York City police officer, and has served as a fire marshal, an arson investigator, a lieutenant, and captain prior to becoming chief in 1992. He is a 28-year veteran of the FDNY, and for the past nine years, has presided over the department’s Battalion 11, covering Manhattan’s Upper West Side. He is the recipient of departmental awards and commendations for his bravery and meritorious service.

The Annual Meeting Keynote Address is sponsored by Humana Pharmacy Solutions. Additional information about the 108th Annual Meeting is available in the Meetings section of the NABP Web site at www.nabp.net/meetings.

Visit NABP.net in February 2012 for Quick and Convenient Online Annual Meeting Registration

Online registration will be available beginning February 1, 2012, for the NABP 108th Annual Meeting to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA. To maintain the accuracy of attendee information and streamline the registration process, all registrations will be handled electronically. Attendees are encouraged to register early to receive reduced registration rates. In order to receive the early registration rate, attendees must register on or before April 9, 2012. Registration may be accessed via the Meetings section of the NABP Web site at www.nabp.net/meetings.

NABP offers attendees three payment options:
1. Mailing in the payment
2. Using a credit card (American Express, MasterCard, or Visa)
3. Paying in Philadelphia

Attendees who do not have access to a computer may contact the NABP Customer Service Department at 847/391-4406. More information about the 108th Annual Meeting is available in the Meetings section of the NABP Web site at www.nabp.net/meetings.
Meeting Program

May 19-22, 2012
Sheraton Philadelphia Downtown Hotel
Philadelphia, PA

Saturday, May 19, 2012
9 AM - 7 PM
Registration/Information Desk Open
2 - 4 PM
Pre-Meeting CPE
5 - 6 PM
Annual Meeting and District Meeting Orientation
7 - 10 PM
President’s Welcome Reception
Honoring NABP President Malcolm J. Broussard, RPh
Sponsored by Medco Health Solutions, Inc
Dinner will be served
Dress: business casual

Sunday, May 20, 2012
6:30 AM - 5:15 PM
Registration/Information Desk Open
7:30 - 8:30 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention
8 - 11:30 AM
Hospitality Brunch and Educational Table Top Displays
8 - 11:30 AM
Joint CPE
Educational Poster Session – Embracing Knowledge for Public Protection

Monday, May 21, 2012
Noon - 3:15 PM
First Business Session
12:30 - 1:30 PM
Keynote Address
Chief Richard Picciotto, FDNY
Sponsored by Humana Pharmacy Solutions
3:30 - 4:30 PM
Joint CPE

Tuesday, May 22, 2012
7:30 AM - 4:15 PM
Registration/Information Desk Open
7:45 - 8:45 AM
NABP Breakfast
8:45 - 10:15 AM
Executive Officer and Board Member CPE
8:45 - 10:15 AM
Compliance Officer CPE
10:30 AM - noon
Joint CPE
Noon
Lunch Break
On your own.
1:30 - 4 PM
Final Business Session
5:45 - 6:45 PM
Awards Dinner Reception
7 - 11 PM
Annual Awards Dinner
Dress: semiformal

Note: The 108th 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 and learning assessment 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.
March Deadline Approaching to Reserve a Spot for the NABP 108th Annual Meeting’s Educational Poster Session

The deadline to reserve a spot as a presenter for the NABP Annual Educational Poster Session is March 9, 2012. State boards of pharmacy members and staff, as well as schools and colleges of pharmacy, are invited to participate.

The poster session, which focuses on “Embracing Knowledge for Public Protection,” will take place on Sunday, May 20, from 6:30 - 7:45 AM, during the NABP 108th Annual Meeting, May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA.

The session will offer those displaying posters the opportunity to share information about their organization’s latest legislative issues, technology, policy development, and/or disciplinary cases as they relate to “Embracing Knowledge for Public Protection,” with other pharmacy professionals.

Participants may earn one contact hour (0.1 CEU) of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education (CPE) credit for their attendance and participation. Presenters and participants are not automatically qualified for CPE. To earn CPE, both presenters and participants must spend at least one hour interacting with other Poster Session presenters and complete a post-session test.

Posters must coincide with the Poster Session theme, “Embracing Knowledge for Public Protection.”

Participating boards and schools and colleges of pharmacy will be provided with one four-foot by six-foot bulletin board, which should be manned by a qualified pharmacist, during display times. Assembly time will be available on Sunday, May 20, from 6:30 - 7:45 AM. Student presenters are welcome and must be accompanied by a licensed pharmacist. Pharmacy school students will receive a free voucher valued at $50 to take the Pre-NAPLEX®, a practice examination for students preparing for the North American Pharmacist Licensure Examination®.

Those interested in participating should contact NABP Professional Affairs Manager Eileen Lewalski via e-mail at elewalski@nabp.net by the March 9 deadline.

Annual Meeting Travel Grants Available to Boards’ Member, Administrative Officer, or Voting Delegate

NABP continues to offer active member state boards of pharmacy travel grant opportunities to attend the 108th Annual Meeting to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA. New this year, the travel grant is no longer restricted to the board’s voting delegate. Now, a grant may be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board’s administrative officer regardless of whether or not they are a voting delegate. In the past, only the voting delegate of each board was qualified to apply for the grant.

One individual per active member board of pharmacy is eligible to receive the grant. Though the individual applying for the travel grant need not be the voting delegate, his or her board of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

The Association established the grant to assist boards in sending voting delegates to the Annual Meeting so they may participate in important business including discussing and voting upon resolutions and amendments to the NABP Constitution and Bylaws, electing NABP Executive Committee members and officers, and attending educational sessions regarding current issues facing pharmacy regulators.

The NABP Annual Meeting Travel Grant program lessens the costs for qualified individuals by providing funds for travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. Eligible individuals can receive up to $1,500 in grant monies to attend the NABP 108th Annual Meeting. The grant may not be applied to Annual Meeting registration fees.

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 Sarah Fowle, at NABP Headquarters or via fax at 847/391-4500. NABP requests that applications be submitted prior to the Annual Meeting. Applicants will be informed of whether or not they have qualified for the grant. Last year, NABP provided 41 state boards of pharmacy with grants to attend the NABP 107th Annual Meeting.

For more information on the Annual Meeting Travel Grant, contact the NABP Executive Office at executive@nabp.net.
Ohio Board Promulgates Rules on Mandatory Access to OARRS

The Ohio State Board of Pharmacy promulgated rules addressing mandatory access to the Ohio Automated Rx Reporting System (OARRS) as required by the passage of Ohio HB 93, dealing mainly with pain management facilities. In the past, pharmacists and prescribers were not required to use OARRS and were not liable if they did or did not obtain reports. Prescribers and pharmacists now must review OARRS reports under conditions defined by the licensing boards. The Medical and Pharmacy Boards were each required to promulgate rules defining the reasons that their respective licensees would be required to access OARRS and review the resulting reports.

Another significant change under HB 93 is that prescribers may no longer personally furnish (ie, dispense) controlled substances to their patients for more than a 72-hour period at one time. Furthermore, if prescribers do provide reported drugs (controlled substances, tramadol, and carisoprodol) to their patients, they are now required to report that dispensing to OARRS. In the past, pharmacies reported, but prescribers did not.

In addition, wholesalers are now required to report all sales of reported drugs to OARRS. In the past, they only reported sales to prescribers. Now they will be reporting pharmacy sales as well. As a result, the OARRS database will have a more complete picture of the balance between the reported drugs purchased as well as the reported drugs dispensed, if review of this information is necessary.

These rules became effective October 27, 2011, and the text of the rules reflecting the current language is available on the Ohio State Board of Pharmacy Web site under “Laws & Rules.”

Oregon’s Qualified Users May Now Access PDMP Data

The Oregon Prescription Drug Monitoring Program (PDMP), operated by the Oregon Health Authority (OHA) is now available online for qualified users to look up patient information. Licensed pharmacists and health care practitioners may apply for an account to become qualified to view their patient’s controlled substance dispensing record. Pharmacists have been uploading controlled substance prescription information into the PDMP system since June, but the online lookup availability marks the final implementation phase of the PDMP.

However, the Board notes that a number of pharmacies required by statute to upload information are not yet reporting. The OHA will be conducting outreach with pharmacies to see what assistance may be needed to increase compliance with the reporting law, which may include connecting pharmacy software vendors with the PDMP vendor to facilitate electronic reporting, educating pharmacies about how to submit “zero reports” if no controlled substances were dispensed during a given week, or completing a reporting waiver request if a pharmacy feels it is not required to report under the law.

More information about the Oregon PDMP is available on the program Web site at www.orpdmp.com.

Iowa Board Holds First Outreach Meeting

The Iowa Board of Pharmacy held its first Pharmacy Outreach Meeting on September 13, 2011, as a means to review new laws and administrative rules with pharmacists and pharmacy technicians. The meeting also included a discussion of current pharmacy projects and study groups, and a town hall meeting that allowed participants to provide input to the Board on topics of concern. Approximately 100 pharmacists and 50 pharmacy technicians attended the meeting. A second Pharmacy Outreach Meeting was held on November 10, and a Pharmacy Outreach Breakfast Meeting is scheduled to be held on January 22, 2012, during the Iowa Pharmacy Association Expo.

New Iowa Legislation Permits the Use of Pharmacy Pilot Projects

New legislation has been approved, permitting the Iowa Board of Pharmacy to allow pharmacy pilot projects. The Board may only consider projects that expand pharmaceutical care services that contribute to positive patient outcomes. The Board may not consider any project intended only to provide a competitive advantage. In addition, pilot projects may not expand the definition of the practice of pharmacy. Projects will be approved for a specified period of time and may not exceed 18 months. New administrative rules will identify the procedures for applying for approval of pilot or demonstration research projects. The Board will review all applications and either approve or deny them. The pharmacist who is responsible for any approved project must file a written summary of the project results with the Board within three months after the completion of the project. The Board must submit reports to the legislature.

Iowa Board to Provide Annual Funding for its Drug Disposal Take-Away Program

New legislation in Iowa allows the Board to provide annual funding for the administration of the pharmaceutical collection and disposal program – the TakeAway Environmental Return System – that was established in 2009. The Board may allocate up to $125,000 of its license fees per year for this purpose. The program provides for the management and disposal of unused, excess, and expired pharmaceuticals.
NABP Foundation Board of Directors Approves Funding for Utah School on Alcoholism and Other Drug Dependencies

The NABP Foundation Board of Directors approved at its November 30, 2011 meeting travel grants to help underwrite some of the costs associated with attending the University of Utah School on Alcoholism and Other Drug Dependencies. The grants will be available to qualified board of pharmacy members and staff for up to 10 states (one individual per state) on a first-come, first-served basis.

Held annually on the University of Utah campus in Salt Lake City, the school is recognized internationally and provides training on current issues and trends in substance abuse education, prevention, and treatment. The school continually expands its scope to keep pace with increasing awareness of the health and social problems of alcoholism and other drug dependencies. Group sections, including for pharmacists, provide specialized information and techniques for working effectively with substance abuse problems in various disciplines. The next session is scheduled to take place June 17-22, 2012.

Additional information about the Utah School on Alcoholism and Other Drug Dependencies is available at http://medicine.utah.edu/uas/index.htm. More information about the travel grant program will be provided in the NABP Electronic Mailbag, which is sent to the board of pharmacy executive officers each week, as well as a forthcoming NABP Newsletter article.

Around the Association

Executive Officer Changes

Andrew Holt, PharmD, has been selected to serve as the executive director of the Tennessee Board of Pharmacy. Prior to this he served in various capacities as a pharmacy manager for Walgreens and then Target. He also worked as a nuclear pharmacist for GE Healthcare in Memphis, TN, and holds American Pharmacists Association certifications in medication therapy management and immunization delivery. In addition, Holt was a member of the University of Tennessee (UT) National Alumni Association’s Board of Governors from 2006-2009 and served as president of Memphis/Shelby County Chapter of the UT Alumni Association from 2005-2006. Holt completed his pre-pharmacy curriculum at the University of Memphis and earned his doctor of pharmacy degree from the UT Health Science Center.

Debra Hobbins, DNP, APRN, LSAC, is now serving as the bureau manager, Division of Occupational and Professional Licensing, Utah Board of Pharmacy. She is board certified as both an addictions and women’s health care nurse practitioner. In addition, Hobbins is a licensed substance abuse counselor and has been working in the field of addiction medicine for more than a decade. Most recently she was appointed to the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment group, assigned to develop modules and provide national training with these modules for opioid treatment professionals. She has received many awards for excellence in clinical practice and has authored numerous journal articles and text book chapters. Hobbins received her doctor of nursing practice degree from the University of Utah.

Dan Williams is currently serving as the bureau director, Division of Board Services, for the Wisconsin Department of Safety and Professional Services.

Board Member Appointments

● Mitra Gavgani, PharmD, has been appointed a member of the Maryland Board of Pharmacy. Gavgani’s appointment will expire on April 30, 2014.

● Stephanie Hammond, PharmD, has been appointed a member of the Maryland Board of Pharmacy. Hammond’s appointment will expire on April 30, 2015.

● Zeno St Cyr II, MPH, has been appointed a public member of the Maryland Board of Pharmacy. St Cyr’s appointment will expire on June 30, 2014.

● Kenneth Saunders, RP, PharmD, TTS, has been appointed a member of the Nebraska Board of Pharmacy. Saunders’ appointment will expire on November 30, 2015.

● Jack Dalton, RPh, has been appointed a member of the Nevada State Board of Pharmacy. Dalton’s appointment will expire on October 31, 2014.

● Michael Bullek, RPh, has been appointed a member of the New Hampshire Board of Pharmacy. Bullek’s appointment will expire on September 6, 2016.

● Helen Pervanans, PharmD, RPh, has been appointed a member of the New Hampshire Board of Pharmacy. Pervanans’ appointment will expire on September 6, 2016.

● Fran Gronberg has been appointed a public member of the North Dakota Board of Pharmacy. (continued on page 46)
NABP to Discuss AWARxE, CPE Monitor Programs at 2012 APhA Meeting

NABP representatives will be available at Booth 1012 during the American Pharmacists Association (APhA) Annual Meeting and Exposition to provide information about the Association, its consumer protection program AWARxE™, and CPE Monitor™. The meeting will be held March 9-12, 2012, in New Orleans, LA.

Newly Accredited Vet-VIPPS Facilities

The following veterinary Internet pharmacies were accredited through the NABP Veterinary-Verified Internet Pharmacy Practice Sites™ (Vet-VIPPS®) program:

- Agropec Trading, Inc dba Allivet  
  www.allivet.com
- Heartland Veterinary Supply, Inc dba Heartland Veterinary Pharmacy  
  www.heartlandvetsupply.com
- Lambert Vet Supply dba Pet’s Choice Pharmacy  
  www.lambertvetsupply.com

A full listing of the accredited Vet-VIPPS sites is available on the NABP Web site at www.nabp.net.

Around the Association

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State Board of Pharmacy. Gronberg’s appointment will expire on May 8, 2016.

- **Greg Adams, DPh**, has been appointed a member of the Oklahoma State Board of Pharmacy. Adams’ appointment will expire on June 30, 2016.
- **Stephen Dudley** has been appointed a public member of the Oklahoma State Board of Pharmacy. Dudley’s term is coterminous with the governor.
- **Rebecca Long, PharmD**, has been appointed a member of the South Carolina Board of Pharmacy. Long is serving at the discretion of the appointing body.
- **Robert Hubbard, RPh**, has been appointed a member of the South Carolina Board of Pharmacy. Hubbard’s appointment will expire on June 30, 2016.

- **Diane Dady, RPh**, has been appointed a member of the South Dakota State Board of Pharmacy. Dady’s appointment will expire on October 1, 2014.
- **Will Bunch, DPh**, has been appointed a member of the Tennessee Board of Pharmacy. Bunch’s appointment will expire on September 7, 2017.
- **Joyce McDaniel** has been appointed a public member of the Tennessee Board of Pharmacy. McDaniel’s appointment will expire on December 31, 2015.

Board Member Reappointments

- **Sara St Angelo, PharmD, RPh**, has been reappointed a member of the Indiana Board of Pharmacy. St Angelo’s reappointment will expire on August 26, 2014.
- **Donald Accetta, MD**, has been reappointed a member of the Massachusetts Board of Registration in Pharmacy. Accetta’s reappointment will expire on December 1, 2013.
- **Steven Budish** has been reappointed a public member of the Massachusetts Board of Registration in Pharmacy. Budish’s reappointment will expire on December 1, 2014.
- **James T. DeVita, RPh**, has been reappointed a member of the Massachusetts Board of Registration in Pharmacy. DeVita’s reappointment will expire on November 29, 2014.
- **Pamela Marshall, RPh**, has been reappointed a member of the Missouri Board of Pharmacy. Marshall’s reappointment will expire on September 24, 2015.
- **Robert Marshall, RP, PharmD**, has been reappointed a member of the Nebraska Board of Pharmacy. Marshall’s reappointment will expire on November 30, 2016.
- **Danny Cross, RPh**, has been reappointed a member of the New Mexico Board of Pharmacy. Cross’s reappointment will expire on June 30, 2015.
- **Gayle Ziegler, RPh**, has been reappointed a member of the North Dakota State Board of Pharmacy. Ziegler’s reappointment will expire on May 8, 2016.
- **Jeanne Waggener, RPh**, has been reappointed a member of the Texas State Board of Pharmacy. Waggener’s reappointment will expire on August 31, 2017.
- **Alice Mendoza, RPh**, has been reappointed a member of the Texas State Board of Pharmacy. Mendoza’s reappointment will expire on August 31, 2017.
Providers Should be Cautious When Ordering Vaccines Online, Study Concludes

Web sites marketing certain biologic vaccines to providers and consumers were analyzed in a recent study that stressed patient safety dangers, particularly in the context of vaccine shortages. The study evaluated online sellers appearing in the top five Internet search results for Hepatitis B, Pediatric and Adult Hepatitis A, and Zoster vaccines. The study determined that none of these sites appeared in these results were VIPPS® (Verified Internet Pharmacy Practice Sites®) accredited and most were on the NABP Not Recommended list. Details about the study and its conclusions are available in the article "Vaccine shortages and suspect online pharmacy sellers," published in Vaccine, and available at www.sciencedirect.com/science/article/pii/S0264410X1101783X.

NICHD Encourages Patient Education on SIDS Risk Reduction

The National Institute of Child Health and Human Development (NICHD) encourages pharmacists to educate parents and caregivers on Sudden Infant Death Syndrome (SIDS) risk reduction. NICHD provides a free, online educational opportunity that presents to pharmacists the latest SIDS research and SIDS risk reduction steps. The training also outlines how pharmacists can help to educate parents and caregivers. The training is available on the NICHD Web site at www.nichd.nih.gov/SIDS/PharmacistCE.cfm, and consumer resources are also available on the Back to Sleep Public Education Campaign Web page at www.nichd.nih.gov/SIDS.

FDA Releases ‘Use Medicines Wisely’ Video

Food and Drug Administration (FDA) Office of Women’s Health has released a public service announcement video titled, “Use Medicines Wisely,” to help raise awareness about safe medication use. As stated in an FDA news release, “Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented.”

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:
- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

‘Script Your Future’ Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at a regional launch event in Baltimore, MD, for the campaign, “Script Your Future,” on November 2, 2011. A survey released by the National Consumers League, the organization that developed Script Your Future, indicates that “patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence.”

The Script Your Future campaign brings together “stakeholders in health care, business and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients.” The campaign is targeting six regional areas with outreach activities and advertising, and more information is available at www.ScriptYourFuture.org.

Training Video Provides Tips on Preventing Pharmacy Robbery

RxPATROL (Pattern Analysis Tracking Robberies and Other Losses) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at http://rxpatrol.org/TrainingVideos.aspx.
Newly Accredited VAWD Facilities

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

DSC Logistics, Inc
Rancho Cucamonga, CA

Exel, Inc
Elizabeth, NJ

Weeks, Inc
Ontario, CA

Masters Pharmaceutical, Inc
Fairfield, OH

McKesson Medical-Surgical

Minnesota Supply, Inc

RPS, Inc dba RPS Imaging
Michigan City, IN

A full listing of more than 510 accredited VAWD facilities is available on the NABP Web site at www.nabp.net.