The Joint Commission of Pharmacy Practitioners (JCPP) brings together the chief executive and chief elected officers of national pharmacy associations, including NABP, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice. Established in 1977, the JCPP meets quarterly and forms workgroups that focus on priority projects. The JCPP has facilitated strategic planning efforts that have shaped positive change in the practice of pharmacy for more than 30 years, and will continue to influence pharmacy practice through its vision articulated in “Future Vision of Pharmacy Practice.”

Past Impact

Recommendations resulting from JCPP conferences and quarterly meetings have been aimed to ensure public health and safety by optimizing the medication use process. Working collaboratively through the JCPP, leaders in the profession “acknowledged that the focus of pharmacy must move beyond the important but narrow aspect of ‘right drug to the right patient’ and encompass the responsibility for assuring that appropriate outcomes are achieved when medications are part of a patient’s individual treatment plan.” This perception of the function and responsibility of pharmacy practice helped to facilitate changes such as the shift to a universal doctoral level of education, and practice and legal changes that have helped pharmacists to increase their scope of services.

Also as a result of JCPP collaborations, coalitions among pharmacy organizations and other stakeholders have been formed, and have helped to shape new state and national legislation and regulations. For example, JCPP coalitions helped influence changes that resulted in Medicare’s prescription drug benefit requirement for medication therapy management services as of 2006.

Future Impact

Through the “Future Vision of Pharmacy Practice,” adopted by JCPP member organization (continued on page 26)
Joint Commission
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executive officers in 2004, the JCPP will continue to influence positive change in the practice well into the next decade. The JCPP “Future Vision of Pharmacy Practice,” endorsed by each JCPP member organization’s board of directors, envisions what pharmacy practice should look like in 2015, as summarized in the document’s opening statement: “Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.”

In his incoming speech at the NABP 105th Annual Meeting in May 2009, President Gary A. Schnabel, RN, RPh, endorsed the future vision outlined in the JCPP “Future Vision of Pharmacy Practice,” stating, “As boards of pharmacy, I feel that it is also imperative for us to embrace this future vision, and through our statutes and regulations define and advance that vision in the context of patient care and protection of the public health . . . If the boards of pharmacy can provide the regulatory environment that fosters the vision on behalf of the patient and the protection of the public health . . . If the boards of pharmacy can provide the regulatory environment that fosters the vision on behalf of the patient and the protection of the public health, then this collective vision of practitioners and regulators will serve as one of the pillars of a new foundation for the practice of pharmacy first proposed some 30 years ago and discussed ad nauseam every year since those words were first spoken and captured in the pharmacy journals.”

The 2015 future vision is detailed in the document in three sections: the foundations of pharmacy practice, how pharmacists will practice, and how pharmacy practice will benefit society. The first section outlines the foundations of pharmacy education that prepares pharmacists “to provide patient-centered and population-based care that optimizes medication therapy.” The second section explains that the pharmacist’s scope is to include managing medication therapy, accounting for patients’ therapeutic outcomes, and promoting patient wellness. The section also emphasizes that as they work with other health care professionals, pharmacists will be the most trusted source of medications and supplies, and the primary resource for advice regarding medication use. Finally, the last section stresses that, by realizing the expanded scope of their practice, pharmacists will achieve public recognition as practitioners who are essential to providing effective health care.

In January 2008, the JCPP released the final version of “An Action Plan for Implementation of the JCPP Future Vision of Pharmacy Practice.” In the plan, the JCPP identifies three critical areas for initial focus as they work toward achieving the vision. Specifically, practice model, payment policy, and communication are deemed areas that must be articulated and planned. The action plan details success factors, objectives, and recommended action steps that should be met for each critical area.

Three workgroups were formed to focus on each critical area, helping to realize the future vision of pharmacy practice. The action plan document makes clear that JCPP anticipates more discussions to help align the action steps of the implementation plan and the policies of participating organizations. Thus, in keeping with the organization’s mission, JCPP continues to implement its initiatives, including the “Future Vision of Pharmacy Practice,” through the collaborative efforts it fosters.

NABP, State, and Federal Actions Help Fight Cybercrime Linked to Internet Drug Outlets

On November 30, 2009, the Federal Trade Commission (FTC) announced the charges and settlements – topping $15.15 million – against two individuals behind an expansive international spam network responsible for promoting the fraudulent "Canadian Healthcare" brand name. Spamhaus, an independent anti-spam research group, called this network the largest "spam gang" in the world. FTC, Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) continue to fight such cybercrimes through investigations, warning letters, and public awareness efforts. Several state boards of pharmacy and states’ attorney general offices have also taken steps to fight rogue Internet drug outlets and raise awareness. And, in addition to actions taken to fight rogue Internet drug outlets, NABP has undertaken several initiatives to help educate, and thus help protect, the public from related cybercrimes.

The January 2010 NABP Newsletter reported on the rise in cybercrimes – such as malware attacks, phishing schemes, and online identity theft – that are facilitated by deceptive spam e-mail messages promoting questionable pharmaceutical Web sites. As explained, such crime is also facilitated by deceptive brand name abuse and cybersquatting, and Canadian pharmacies suffer the highest volume of such brand abuse. As verified by Internet security experts and the prosecutors in the recent FTC case, Canadian pharm spam campaigns are capable of sending massive volumes of spam e-mail because they are run by organized crime networks and employ sophisticated technological methods.

Using ‘Canada’ to Lure Patients

Spam promoting supposed Canadian online pharmacies, which are trusted as safe by some Internet consumers hoping to purchase discount drugs, in fact, makes up the largest portion of spam promoting questionable online pharmacies, and spammers use deceptive domain names and brandjacking tactics to lure consumers to click on links to fraudulent Web sites. In fact, the October 2009 Spam Report from McAfee states, “Canada is the largest victim of brand identity theft in the world.” In reality, most of these fraudulent Web sites are not hosted in Canada, nor do the millions of spam e-mails promoting “Canadian” pharmacies originate from Canada. This deception puts at serious risk those United States patients, who – despite federal regulations – seek Canadian online pharmacy products that they perceive to be as safe as US pharmacy products, at a fraction of the cost.

‘Canadian Pharmacy’

Internet security experts and anti-spam researchers have identified Web sites touting the name “Canadian Pharmacy” as the oldest, largest, and most spammed of Internet drug outlets. By some estimates, in September 2009, 60-70% of spam promoted the fraudulent Canadian Pharmacy “brand,” which is part of a network affiliate program. Such programs provide links, Web page templates, and the e-mail addresses to be spammed to their affiliates. Affiliates then direct traffic to those Web pages through spammed links, and they receive commissions on any resulting sales. Stefan Savage, an associate professor of computer science and engineering at the University of California, San Diego, and Cisco’s chief security researcher, Patrick Peterson, told Network World, a publication for network and IT professionals, that Canadian Pharmacy may be linked to the GlavMed affiliate program. In fact, Peterson indicated that GlavMed.com is fueled by the infamous Storm botnet, a vast network of personal computers compromised with software that enables hackers to send spam (See January 2010 NABP Newsletter). He explained to Network World that the Storm botnet makes a request to GlavMed every hour to acquire spam (continued on page 30)
Boards of pharmacy are created and empowered to protect the public by carrying out the intent of the legislation to regulate the profession in the interest of public protection. Regulatory boards are state agencies and enjoy numerous legal powers and protections designed to allow enforcement of the laws, while at the same time recognizing the legal rights of the applicants and licensees. Examples of board powers and protections include the right to issue, deny, and renew licenses; fully investigate allegations of wrongdoing; gather and present evidence at a formal hearing; and discipline or sanction individuals found to have violated the laws, all under the protection of immunity in the event of a challenge to the process.

Past newsletter articles have addressed the importance of coordinating investigations with law enforcement authorities to ensure that evidence gathered will be admissible in the event the matter proceeds to a trial or administrative hearing on the merits. In addition to the interplay between the criminal and administrative investigations is the use or admissibility of evidence and/or convictions (or judgments) previously secured in administrative and/or criminal proceeding(s) in subsequent civil matters (e.g., malpractice). Consider the following.

An emergency room physician (licensee) was accused of negligence in a medical malpractice case, specifically failing to diagnose and treat a spinal cord injury resulting in continuing pain and discomfort in the patient’s back. In a previous decision, the Nebraska Supreme Court affirmed a lower court ruling that excluded the patient’s expert witness, but reversed and remanded the lower court’s ruling that awarded summary judgment in favor of the licensee.

While the matter was awaiting a trial on the merits, the licensee surrendered his medical license to the Nebraska Department of Health and Human Services (DHHS) in resolution of an administrative investigation. DHHS had alleged that during the years 2000 through 2008, the licensee engaged in inappropriate sexual touching of other patients during non-gynecological examinations. The licensee waived his rights to a hearing, pleaded no contest to the allegations, and surrendered his license for a minimum of two years.

Based upon the licensure surrender in an administrative proceeding, the patient amended her civil complaint in the malpractice proceedings and sought to obtain through discovery the complaint and investigative files of the DHHS which resulted in the licensure surrender. The patient also sought to take a second deposition of the licensee to inquire about the licensure surrender and the acts which precipitated the administrative prosecution. In short, the patient argued that she did not give informed consent to allow the licensee to render medical care because the licensee

found that an affidavit of another expert for the patient created a factual issue that precluded summary judgment in favor of the licensee.
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Attorney Dale J. Atkinson is a partner in the law firm of Atkinson & Atkinson, outside counsel for NABP.

did not disclose his “compulsions and unfitness” to the patient. The licensee argued against turning over the requested documents in that the administrative complaint and investigative files were irrelevant to the civil proceedings and were statutorily privileged.

The lower court judge overruled the objections of the licensee and continued the civil malpractice trial so that additional discovery could be conducted regarding the allegations and surrender of the licensee’s medical license. The licensee sought a judicial order from the Nebraska Supreme Court in the form of a mandamus preventing the additional discovery.

The court first addressed that a mandamus is an action at law whereby a writ is issued compelling the performance (or non-performance) of certain acts upon a lower court. A writ of mandamus can also be imposed upon a person or corporation. The person seeking the mandamus has the burden of proof and must establish clearly and conclusively the entitlement of the remedy. In the current matter, the court narrowed the issues to:

1. whether the patient was entitled to additional discovery on information held by the board,
2. whether the complaints and investigatory information held by the board was privileged, and
3. whether the additional information related to the licensee’s unprofessional conduct was relevant to the civil malpractice proceedings.

The court reviewed the procedural issues relative to the filing and administrative prosecution of licensees accused of wrongdoing under the practice act. The Attorney General’s Office determines whether to file a petition with the DHHS against a licensee based upon a complaint. As set forth under law, the petition, once filed, becomes a public record. If there is a contested hearing, the complaint and investigative materials that are made part of the record are also public and subject to disclosure. Further, reports within the investigative materials are public to the extent they are admitted and become a part of the record of a contested hearing. But if materials are not included in the contested hearing, the DHHS’s incident reports, underlying complaints, and investigative records are statutorily privileged from discovery.

In its analysis, the court noted that evidentiary privileges are narrowly construed. It also emphasized that the privilege statutes do not run to the original source, in this case, the licensee. Nor do the disciplinary statutes indicate the legislature intended the privilege to protect the credential holder (licensee). The court noted the closed session rights of the boards regarding disciplinary actions and immunity provided to boards, board members, and reporting persons or entities, all in an effort to promote the reporting of alleged wrongdoing in the interest of public protection. It held that the legislature did not intend to protect the credential holder (licensee) from discovery of the underlying facts supporting disciplinary proceedings after the attorney general has filed a petition. Finally, the court stated that to enforce the privilege under these circumstances would produce an absurd result as the patient has already waived her rights through the filing of the malpractice litigation.

In so recognizing the right of the patient to conduct further discovery, the court also held that the patient had the right to request and review the reports and other documentation in the possession of the DHHS and acquired in the investigation of the administrative proceedings. The court held that this issue was also disposed of through the privilege analysis noting that the licensee was not a party to the confidential matters, he was the subject of the investigation. Thus, the licensee was not entitled to claim the privilege.

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templates, the link to be spammed, and the e-mail addresses to spam. Spamtrackers.eu, an anti-spam research organization, describes the layers of fraudulent claims made on recent Canadian Pharmacy Web sites. New versions of these fraudulent Web sites display a logo for a non-existent agency, the American Drug Administration, that mimics the authentic logo for FDA, as well as a logo for the non-existent Canadian International Drug Association that mimics the legitimate Canadian International Pharmacy Association logo. In addition, sites displayed fake VeriSign Secured Seals and Secure Sockets Layer certificates, in an attempt to convince visitors that credit card transactions are secure.

As reported in an FTC press release, the recent case against the spammers who promoted the fraudulent “Canadian Healthcare” brand used similar spam tactics and volume. The ringleader running this expansive spam network, a New Zealand citizen residing in Australia, and his accomplice, a US citizen, recruited spammers from around the world to create messages directing users to Web sites run by the Affking affiliate program. According to FTC, the spammers deceptively marketed drugs under Affking’s Canadian Healthcare brand, when in fact the products ordered on associated Web sites were shipped from India, not Canada. The spam made unlawful claims about the drug products it marketed, and the Web sites promoted failed to secure buyers’ credit card information.

Similar domain and Web site names can make it difficult for computer users to discern which Web sites are legitimate and which are not. For example, the name of the now defunct I-SaveRx drug reimportation program has been adopted for deceptive use. From 2004 to 2009, the I-SaveRx program, created by the state of Illinois, operated online with the intent to save enrollees money by reimporting prescription drugs from Canada to the participating US citizens. The states of Illinois, Wisconsin, Missouri, Kansas, and Vermont participated in the program, which operated online at the domain name i-saverx.net. Though the program closed as of February 2009, the Web site isaverx.com now operates and advertises services similar to the former Illinois program. Isaverx.com is included in NABP’s Not Recommended list of Internet drug outlets as it appears to be out of compliance with US pharmacy laws and practice standards, but the similar domain name may confuse consumers into associating it with the former Illinois program.

Pharmacy patients should be aware that most Internet drug outlets claiming to be Canadian and selling prescription medications to US patients are not providing drug products approved for sale in Canada to Canadians. In fact, an FDA report released in August 2005 indicated that 85% of drugs promoted on the Internet as “Canadian” were actually manufactured in and shipped from 27 countries, including India, Costa Rica, and Vanuatu. When circumventing the closed and tightly regulated US supply chain and purchasing drugs from unapproved foreign sources, the risk of receiving counterfeit medication goes up.

Blackmarket B2B Exchange

Fueling such counterfeiting, business-to-business exchange Web sites include marketing for large quantities of unapproved active pharmaceutical ingredients.

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legle in his attempts to block the discovery of materials related to administrative proceedings.

Finally, the court addressed whether the information involving the disciplinary action (sexual misconduct from 2000 to 2008) was relevant to the malpractice action related to alleged misdiagnosis of spinal injuries in the emergency room. The patient argued that she would have asked additional and/or different questions of the licensee when conducting discovery had she known about the administrative action. The court held that the relevance of matters in discovery is broad, as opposed to the relevance of matters attempted to be introduced at trial. The standard for relevance in discovery includes information which “appears reasonably calculated to lead to the discovery of admissible evidence.” Agreeing with a Seventh Circuit case whereby a criminal defendant was permitted to impeach a witness (psychiatrist) with evidence that he was about to lose his license, the court held that parties generally have a right to discover information that might impeach a witness. Thus, the court held, while emphasizing that such ruling did not address admissibility at trial, that the patient was entitled to conduct the requested discovery.

As evident from this opinion, the administrative complaint and investigative file may, under certain circumstances, be discoverable in a subsequent civil case involving the licensee. Of course, while an administrative case is essential to the public protection mission of the regulatory board, civil cases may provide an element of deterrence and ultimate public protection as well.

Stetson v Silverman, 770 N.W. 2d 632 (NE 2009)
FPGEE Administered Successfully as Computerized Format in 2009; Applicants Have Access to Scores Online

Nearly 2,000 tests were administered in 2009 to foreign-educated pharmacists seeking licenses to practice in the United States. With roughly 900 applicants sitting for the April 14 Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and approximately 1,100 applicants sitting for the October 1 examination, these administrations marked completion of the first year of the return of the computerized FPGEE.

Like the paper-and-pencil examination, the computerized FPGEE was administered once in the spring and once in the fall; however, applicants were able to choose from more than 200 Pearson VUE testing sites located within the continental United States instead of only three.

Approximately 75% of, or 150, Pearson VUE testing sites were utilized by the 2,000 FPGEE applicants during the April and October 2009 administrations and each site held anywhere from one FPGEE applicant to 44 applicants. This number was a vast change from past years – when an average of 800 applicants were seated in one testing room.

With a smooth transition, the computerized FPGEE has received a positive response from applicants. NABP made one minor adjustment to the allotted testing break after administering the FPGEE in April to provide a more conducive testing experience for applicants. Usually lasting about six-and-a-half hours, the administration day can be long; however, applicants are now provided a 30-minute break between the morning and afternoon testing sessions. This break was increased by 15 minutes beginning with the October 2009 administration.

Examination Scores Available Online

In addition to taking a computerized examination, applicants now have the ability to download their examination scores from a secure Web page accessible from the NABP Web site, rather than waiting to receive them via mail. This benefit, which also became available in 2009, expedites the score retrieval process. With this new process, the scores are available within about six weeks of the examination. All applicants who sat for the FPGEE in October should now have access to their scores through the Web site.

Applicants are required to take the FPGEE as a component of the NABP Foreign Pharmacy Graduate Examination Committee™ (FPGECC®) certification process. The FPGECC Certificate serves as a means of documenting the educational equivalency of applicants’ foreign pharmacy education and their foreign licensure and/or registration status. In addition to passing the FPGEE, applicants are required to demonstrate English language proficiency by attaining the combination of the minimum passing Test of English as a Foreign Language™ (TOEFL®) and Test of Spoken English™ scores or the minimum passing TOEFL Internet-based Test score.

NABP encourages applicants preparing to sit for the FPGEE to take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP and designed to help familiarize applicants with the FPGEE. This Web-based practice examination exhibits the types of questions provided on the actual FPGEE and supplies applicants with a score estimate upon completion of the examination. The cost of the Pre-FPGEE is $50.

Additional information regarding the FPGEE, FPGECC, and Pre-FPGEE is available in the FPGECC Application Bulletin and in the Examination Programs section of the NABP Web site at www.nabp.net.

In 2009, the eastern third of the United States saw the largest number of FPGEE applicants, with approximately 58% testing in that region.
nabp newsletter

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gredients (APIs), which are often sold to produce the drugs distributed through Internet drug outlets, as revealed in Mark Monitor’s Summer 2009 Brandjacking Index. According to the report, listings on business-to-business exchange sites selling bulk powdered APIs have increased 80%, and such sites also sell unapproved branded pills. Further, listings from these suspicious sources include advertisements for unapproved generic versions of patent-protected drugs.

User and Consumer Protection

As McAfee and other security services warn, the best protection against cybercrimes is for computer users to avoid clicking on links in spam e-mails, regardless of where the message appears to originate.

Users should visit the legitimate Web sites of businesses where they have accounts, or contact companies directly before entering private data into an online form.

Boards of pharmacy and their licensees can assist by reminding patients and consumers that federal law prohibits the direct-to-consumer sale of drugs from other countries to patients in the US because they are not FDA-approved, and thus their safety and efficacy cannot be guaranteed.

Patients who do wish to purchase drug products through Internet pharmacies can be advised to consult the (VIPPS®) Verified Internet Practice Pharmacy Sites™ section of the NABP Web site, which also includes a list of Not Recommended Internet drug outlets.

NABP Actions

NABP has undertaken several initiatives to help educate and protect the public from cybercrimes related to the online sales of fraudulent pharmaceuticals.

• NABP distributes a bimonthly report to state and federal regulators, and other patient advocacy groups, providing updated data on Internet drug outlets as well as current information on related topics, such as cybercrime trends.

• NABP is also available to assist in educational presentations. For example, in December 2009, NABP staff delivered a presentation focused on the role that rogue Internet drug outlets play in the rise of prescription drug abuse in the US at a Prescription Drug Abuse Summit in Bismarck and Fargo, ND.

• NABP is developing educational materials to help pharmacists and other health care practitioners educate the public about the dangers of purchasing prescription medications online, as well as the associated risks of additional cybercrimes.

• NABP continues to reach out to the major search engines, encouraging them to more effectively filter rogue Internet drug outlets out of their paid advertising programs.

• The Internet Pharmacies section of the NABP Web site helps educate the public about the dangers of buying drugs online and provides links to related patient information.

State Actions

Several state boards of pharmacy – including Ohio, Idaho, Delaware, Kansas, Kentucky, New Mexico, Wyoming, and Vermont – help to educate their members and licensees about fraudulent Internet drug outlets and related activity through participation in the NABP state newsletter program. Many state boards of pharmacy continue to reach out to the major search engines, encouraging them to more effectively filter rogue Internet drug outlets out of their paid advertising programs.

Federal law guiding drug importation came under discussion again, as Senator Byron Dorgan proposed in December 2009 an amendment to allow personal prescription medication importation as part of the Patient Protection and Affordable Care Act. Proponents of the law believed it would provide patients with lower-cost, safe prescription medications. Opponents of the law, including the Health-care Distribution Management Association and Food and Drug Administration (FDA), argued that importation programs risk public health safety by allowing patients to receive drugs not approved by FDA and by increasing the risk that counterfeit and adulterated medications enter the domestic supply chain. FDA Commissioner Margaret Hamburg also emphasized the difficulty of implementing such an importation program and the vast resources that it would require.

Similar legislation has been introduced to Congress several times over the past decade.

• The Medicine Equity and Drug Safety Act of 2000 (MEDS Act) would have allowed pharmacists and wholesalers to reimport into the United States, FDA-approved prescription medications that had been manufactured domestically and then exported to foreign countries. The MEDS Act passed, but was not implemented by the US Department of Health and Human Services.

• The Pharmaceutical Market Access Act of 2003 would have allowed individuals to import certain drug products. In the summer of 2003, the act passed in the House, but died before it was passed by the Senate. As indicat-
also display on their Web sites a link to the Internet Pharmacies section of the NABP Web site. Kentucky and North Carolina require Internet drug dispensers in those states to be accredited by VIPPS. The Ohio, North Dakota, and New York state boards of pharmacy also forward information about Internet drug outlets to NABP; NABP investigates these sites and forwards this data to FDA. NABP encourages the boards of pharmacy to share any information or concerns they may have pertaining to Internet drug outlets.

Board of pharmacy hearings and investigations by states’ attorney general offices have helped to deter illegal dispensing and sales of prescription drugs through Internet drug outlets. The Ohio Board of Pharmacy led to the closing of an Internet drug outlet in March 2008, and the conviction of the pharmacist in May 2009 and the pharmacy owners in November 2009. In 2003, a disciplinary action taken by the Iowa Board of Pharmacy led to a six-year criminal prosecution in which federal authorities found evidence that Union Family Pharmacy had illegally dispensed more than a million prescription pain, diet, and psychiatric medications over a six-month period for two Florida-based Internet companies. The prosecution led to the convictions of 26 people in a US District Court.

Recent state legislation also helps to protect patients purchasing medications online. “Justin’s Law,” passed in Minnesota in 2008, requires prescriptions for commonly abused prescription medications to be based on a documented patient evaluation. North Dakota passed similar legislation which specifies that a face-to-face exam by the prescribing practitioner is required for patients wishing to purchase prescription medication through an Internet pharmacy.

Federal Actions

FDA, FTC, and CDC continue to take measures against the online marketing of fraudulent pharmaceuticals and related cybercrimes. For example, OnGuard Online is a government-sponsored program educating computer users about avoiding online identity theft and other cybercrimes. OnGuard Online, www.onguardonline.gov, provides free buttons and banners that link to its Web site. CDC also helps to alert the public about new Internet crimes and scams. On December 1, 2009, CDC issued a public alert regarding a phishing scam in which the fraudulent e-mail message claimed to be from CDC and informed recipients of the need to register for a statewide, CDC-sponsored H1N1 vaccination program. In reality, if a user clicked the link provided, malicious code was downloaded to the user’s computer.

Anti-spam research groups, NABP, and other organizations, have also partnered with these government agencies to work toward locating and foiling cybercriminals, including large networks of organized Internet criminals. However, since the methods of cybercriminals help keep them elusive, raising awareness and educating users about the risks of becoming a victim to pharmaceutical-related cybercrime remains one of the most effective ways to protect patients from this public health threat.
Pharmacists, Physicians, Scientists, and Policy Makers Share Viewpoints on Legalization of Medical Marijuana

More than 120 board of pharmacy members, practitioners, and other stakeholders in the practice of pharmacy gathered to discuss the issues surrounding the legalization of medical marijuana. With this issue as the focus of the first day of the NABP Symposium, held December 3-4, 2009, attendees heard about the pros and cons of medical marijuana from physicians, pharmacists, federal and state regulators, advocates, and other pharmacy professionals.

Kenneth Mackie, MD, Linda and Jack Gill Chair of Neuroscience and professor in the Department of Psychological and Brain Sciences at Indiana University Bloomington, began the day’s programming with an overview of the medical marijuana debate including a detailed explanation of the pharmacological attributes of the cannabis plant. Currently, he is working under grants from the National Institutes of Health and major pharmaceutical companies to isolate compounds from herbal cannabis in order to develop drugs. Mackie is especially focused on the endocannabinoid system and how it works in the body.

Mackie explained that cannabis is a complex mixture of compounds, including delta-9-tetrahydrocannabinol (THC), as well as other compounds. He stated that THC produces its effects by interacting with the endocannabinoid system, and that there are very real differences between oral THC and medical marijuana.

The Federal Status of Marijuana

Kevin Sabet, PhD, special advisor for policy and strategic planning for the Office of National Drug Control Policy (ONDCP), discussed the federal stance on medical marijuana stating that marijuana is, and will continue to be, a Schedule I controlled substance. Sabet told attendees that the decline of youth drug use that began in 1997 ended in 2009 and youths’ perceived risk of drug use is declining. Drugged driving has also become a problem, he said. A recent study showed that 16% of nighttime, weekend drivers tested positive for marijuana. He noted that 10% of people who use marijuana become dependant.

Sabet noted that some groups took the Department of Justice decision to no longer use its resources to pursue prosecution of legitimate users and distributors of medical marijuana in states that have legalized such activities as a sign that the Obama administration is softening its stance on marijuana as a Schedule I substance. Sabet stated that this interpretation is completely “off base,” and, in fact, ONDCP Director R. Gil Kerlikowski, President Barack Obama, and Vice President Joe Biden have all said that moving marijuana to Schedule II is a “non-starter.”

Should Marijuana be a Medical Option?

Barry D. Dickinson, PhD, the American Medical Association’s (AMA) director of science and biotechnology and the secretary of the AMA Council on Science and Public Health, discussed a recent AMA report on medical marijuana.

Based on AMA’s findings, the 2009 report concluded the following:

1. The AMA supports drug approval by federal scientific and regulatory review to establish safety and efficacy, and appropriate standards for identity, strength, quality, purity, packaging, and labeling, rather than by ballot initiative or state legislative action.
Public-Private Partnerships Offer Many Opportunities for Resource-Challenged Boards of Pharmacy

On the second day of the NABP Symposium, which was held December 3-4, 2009, attendees gathered to learn about public-private partnerships and how boards of pharmacy can benefit from such arrangements. Richard Norment, MA, executive director of the National Council for Public-Private Partnerships, began the day with an overview of what public-private partnerships are and gave some examples of partnerships on both the state and federal levels. Norment explained that public-private partnerships are “joint ventures” or “collaborative practices” as opposed to privatization, which gives all assets and control to the private company. He noted that public-private partnerships do not answer all problems, but they can leverage resources. Norment listed six keys to making a public-private partnership work.

1. **Statutory and Political Environment**: It is important to have someone with political power pushing for a public-private partnership contract. This is necessary because often there are no statutes in place to allow for public-private partnerships.

2. **Organized Structure**: This includes a dedicated unit with trained personnel to handle the project. This group must understand the actual cost of the project, not just the price, but rather the value. Sometimes a project might mean spending more up front, but the long-term value of the project should be worth more than the initial expenditure.

3. **Detailed Business Plan/Enforceable Contract**: Rather than specifying a design to the private sector, the public sector needs to provide performance expectations. If the project does not meet the agreed upon metrics then the public sector can withdraw from the agreement because the contract will be void.

4. **Guaranteed Revenue Stream**: The public sector must recognize that the private sector needs to be able to earn back the money spent up front.

5. **Stakeholder Support**: Communicating with stakeholders is critical; if the public does not understand why the partnership is being formed, there will be backlash.

6. **Pick Your Partner Carefully**: Public-private partnerships are long-term relationships; so, it is important to be sure that the private company selected is experienced and provides the best value – not just the lowest price. Also, it is important to remember each sector’s motivation. The private sector does not enter into public-private partnerships as a result of philanthropy; private companies will only take projects that are worth their while.

Norment concluded that while public-private partnerships are not always easy, they can be a valuable option. Such partnerships are often a means to cost-effective programs. Finally, he noted that public-private partnerships require a genuine partnership and open communication between the public and private sectors.

Janita Gordon, BS, senior advancement officer of the Arizona Community Foundation, shared her experiences with public-private partnerships including those of the Arizona Early Education Funds, the Affordable Housing Initiative, and education reform. The success of all of these programs, she said, hinged on leadership within the community, advocacy groups, buy-in from practitioners in the field, clear ownership, and strategic planning.

Next, Kim E. Light, PhD, professor at the University of Arkansas for Medical Sciences College of Pharmacy, and executive secretary of the Arkansas Pharmacy Support Group, described the public-private partnership (continued on page 38).
Medical Marijuana
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- The future of cannabinoid-based medicine lies in the rapidly evolving field of botanical drug substance development, as well as the design of molecules that target various aspects of the endocannabinoid system.

- To the extent that rescheduling marijuana out of Schedule I will benefit this effort, such a move can be supported.

- Physicians who comply with their ethical obligations to “first do no harm” and to “relieve pain and suffering” should be protected.

Dickinson noted that while AMA recommends reviewing marijuana’s status as a Schedule I drug, this recommendation is not an endorsement of state-based medical cannabis programs, but rather is intended to facilitate the development of cannabis-based drugs under the current drug review process.

Alice Mead, JD, director of United States professional relations at GW Pharmaceuticals, noted that the FDA process must not be forgotten when considering legalization of medical marijuana. Drug products that are approved through the FDA process are surrounded by a robust body of data to give a risk/benefit balance for the drug. Currently, she said, medical marijuana does not fit into the process.

To produce standardized starting materials that would meet FDA process criteria, medical marijuana would need to be an herbal material grown by clones under rigorous conditions, ideally computer-controlled greenhouses. Mead added that even if “cannabis” itself were moved to Schedule II, a specific cannabis or cannabis-based product would need FDA approval to be available by prescription. She concluded that development of an effective drug derived from cannabis takes time. Recently improved technology and research on the endocannabinoid receptor system means that we are only at the early stages of developing modern marijuana medications, and numerous preclinical studies, clinical trials, etc, are required.

Caren Woodson, MPP, director of government affairs at Americans for Safe Access, an organization promoting use and research of cannabis, stated that there is currently enough research to support the use of medical marijuana. She called for government agencies to work together to develop a solution to provide patients safe access to medical marijuana.

Are These Medical Miracles?

Sunil K. Aggarwal, PhD, MS-IV, a medical student and researcher at University of Washington School of Medicine, and Gregory T. Carter, MD, MS, professor of rehabilitation medicine at University of Washington School of Medicine, discussed the successes they have had with patients who were treated with medical marijuana. Carter noted that his patients do not smoke marijuana to obtain its benefits, but rather use a vaporizer or take the drug orally. Both Aggarwal and Carter stated that pharmacists play an important role in that pharmacists are the ones who can compound tinctures and capsules for patients in addition to providing counseling on proper use.

Donald I. Abrams, MD, professor of clinical medicine at the University of California, San Francisco, stated that through his research he has increasing evidence of medical marijuana’s antimalignant effects as well as its anti-inflammatory and antioxidant effects. However, he noted, it is difficult to study marijuana as a drug not only due to bureaucratic limitations, but also because it is difficult to find patients who are willing to participate in studies.

Speakers Share their Knowledge of Medical Marijuana

Speakers presented real-life examples of successful medical marijuana treatment during the late morning portion of the session Legalization of Drugs: Is the Time Right for Medical Marijuana? Pictured from left to right: Donald I. Abrams, MD, professor of clinical medicine, University of California, San Francisco; session moderator William T. Winsley, MS, RPh, NABP president-elect; Gregory T. Carter, MD, MS, professor of rehabilitation medicine, University of Washington School of Medicine; and Sunil K. Aggarwal, PhD, MS-IV, medical student/researcher, University of Washington School of Medicine.
A Regulatory Approach to Medical Marijuana

Paula Sahleen-Buckingham, associate analyst for the California Department of Public Health Medical Marijuana Program, and Jacob Appelsmith, JD, special assistant to the California Attorney General, discussed the current status of medical marijuana in California and the related programs.

Appelsmith stated that legalization of medical marijuana by a state is possible because each state has the right to criminalize or not criminalize whatever it chooses. California’s Proposition 215 is a constitutional provision that decriminalizes possession if the individual has an oral or written recommendation. Additionally, collectively cultivating marijuana for oneself is no longer considered criminal in that state.

Appelsmith admitted to shortcomings in the language of the proposition, which allows each local government within the state to develop its own rules and regulations. As such, in areas that lack well thought out rules and regulations there is widespread abuse of Proposition 215. For example, Los Angeles has 600 to 1,000 dispensaries, whereas a more appropriate number for the city would be less than 100 dispensaries. In areas with widespread abuse, California law enforcement focuses on those dispensaries that are profiteering or are involved in other activities such as illegal firearm possession or methamphetamine production.

This year, Californians will be voting on two ballot initiatives which would decriminalize marijuana (medical and non-medical), Appelsmith said. These ballot initiatives permit possession and sale for personal use of one ounce of marijuana, permit cultivation for personal use of up to 25 square feet, provide controls related to persons under age 21, and allow for local taxation and regulation of marijuana.

Lloyd K. Jessen, RPh, JD, executive director and drug control program administrator of the Iowa Board of Pharmacy, discussed the public hearings that are underway in Iowa. Due to an anomaly in the law, he explained, marijuana has a dual class in Iowa. While marijuana is classified as a Schedule I drug, it is also classified as a Schedule II drug for those patients qualified to use medical marijuana pursuant to Iowa Code Section 124.206(7)(a). However, there are currently no rules in place. Recently, the Board denied a petitioner request for the reclassification of marijuana. Through the appeals process, the board was directed by a judge to reconsider its ruling. As such, the Board has held public hearings and is researching the science behind medical marijuana. While most citizens they heard from are in favor of medical marijuana, Jessen stated that most pharmacists in Iowa are not in favor of legalization despite the support of the Iowa Pharmacy Association.

The Board plans to make a recommendation to the Iowa legislature at a special meeting on February 17, 2010. Jessen explained that in making this recommendation, the Board will consider many factors regarding marijuana including abuse potential, medical viability, and the risk to the public. Jessen added that Iowa Governor Chet Culver and the Iowa Office of Drug Control Policy do not support the legalization of medical marijuana.

Scott Galenbeck, JD, assistant attorney general in the Iowa Office of the Attorney General, stated that the legalization issue in front of the Board is not about medical marijuana, but rather is about legalization of all marijuana. Galenbeck gave an overview of the litigation (continued on page 45)
Public-Private Partnerships (continued from page 35)

partnership of the Arkansas Pharmacist Recovery Network (APRN). He explained that APRN receives funding from the Arkansas Board of Pharmacy, but that APRN handles all pharmacist recovery issues and contracts. Additionally, Executive Committee members on APRN have legislative immunity from prosecution.

Finally, Joshua M. Bolin, BA, field services senior manager at NABP, explained the public-private partnership that the Association has with the Maryland Board of Pharmacy. Like many boards of pharmacy, legislators are asking the Maryland Board of Pharmacy to do more with less resources. For example, in 2009 the Maryland Board was to begin enforcing a law that required out-of-state wholesale drug distributors to be inspected. To accomplish this, the Board would either have to have its own inspectors survey the wholesale drug distributors, get inspection information on the wholesale distributor from another board of pharmacy or regulating body, or the wholesale distributor would need to have an accreditation that was approved by the Board. None of these options appeared to be feasible, but language in the regulations allowed a fourth option for the Board. Specifically, the phrase “or its designee” allowed the Board to outsource the inspections to another party. The Maryland Board sought out NABP to perform this function.

The Maryland Board already recognizes VAWDCM (Verified-Accredited Wholesale DistributorsCM) accreditation but the Board wanted the ability to have NABP perform inspections only. Serving as the Board’s designee, NABP uses a Maryland inspection form, allowing the Maryland Board to have control. NABP surveyors record their observations of the facility, but the Board makes the ultimate decision as to if the wholesale distributor passes inspection.

During negotiations, NABP determined that it could provide its services for $850 per inspection. This includes surveyor fees, paper work, and travel expenses. This provides Maryland with subject matter experts at a cost savings, and frees up funds as well as Board investigators and staff for other projects.  

Presentation handouts can be found on the NABP Web site at www.nabp.net in the Meetings/Educational Sessions section.

Sponsorships Support Successful Symposium

NABP would like to thank the following companies and organizations for their generous sponsorships and grants that contributed to the success of the 2009 Symposium.

- Astellas Pharma US, Inc
- CVS Caremark Corporation
- Long Term Care Pharmacy Alliance
- Medco Health Solutions, Inc
- Omnicare, Inc
- Pfizer Inc
- ScriptPro LLC
- Walgreen Co
First Internet-Based MPJE State-Specific Review Provides Convenience and Flexibility; 113 Representatives Participate

NABP held its first Internet-based Multistate Pharmacy Jurisprudence Examination® (MPJE®) State-Specific Review October 5-19, 2009, as a means to increase involvement and development of the examination, as well as to offer a more convenient and flexible approach for state boards of pharmacy to participate.

In the past, the meetings were held as a three-and-a-half day event that took place in different locations throughout the United States, and boards were provided the opportunity each year to attend a session. As many of the boards experience shrinking staffs and budgets, the new Internet-based format has enabled boards with limited time and resources the opportunity to become involved in the review.

Many boards responded with positive feedback on the change to an Internet-based format. “It was a very interesting way to do the review and we appreciate all the work NABP went through to get this up and running. It was a wonderful way for us to review Wyoming’s statutes and rules,” says Mary Walker, executive director of the Wyoming State Board of Pharmacy.

Each participating state’s operational pool and new pretest questions are posted on a secure Web site for the boards to review; reviewers are able to see only the questions that are part of their state’s pool. Each participating board is provided with its own username and password and is able to designate multiple representatives to complete the work.

In addition, the Internet-based format is designed to be used by multiple users simultaneously. For Mary Inguanti, member of the Connecticut Commission of Pharmacy, this was a helpful way to encourage collaboration among board staff. “It was very helpful to permit multiple reviewers to log in simultaneously for successful completion of this very large scope of work,” says Inguanti.

While the time frame for boards to complete the MPJE is more flexible with the Internet-based format, boards do have a defined period of time to access their information. All MPJE participants had two full weeks to review items. When the participating state completes its review, NABP closes the board’s Web site access for examination and security purposes.

Although the MPJE State-Specific Review’s format has changed, the participants’ objectives have remained the same. The review still promotes the three primary responsibilities and goals as the boards review items specific to their own state:

1. review all the newly developed questions to determine which of them apply to their state;
2. review all questions currently approved for their state to ensure all the items are appropriate; and
3. ensure all questions accurately reflect contemporary pharmacy law as it applies to pharmacy practice.

Currently, 45 boards utilize the MPJE and are asked to participate in at least one MPJE State-Specific Review each year to determine the appropriateness of items in the MPJE for candidates seeking licensure. In 2010, two additional boards, South Dakota and Oklahoma, will be utilizing the MPJE. These boards will participate in the next scheduled MPJE State-Specific Review.

The MPJE consists of 90 multiple-choice test questions that are based on a nationally uniform blueprint of pharmacy jurisprudence competencies. The questions are approved by the state boards of pharmacy and address federal law as well as specific laws in each state.

The next MPJE State-Specific Review is tentatively scheduled for August 2-16, 2010.

For more information about the MPJE State-Specific Review, please contact custserv@nabp.net.

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Looking for breaking news and time-sensitive information relating to pharmacy legislation, regulations, and competency? Look no further! NABP brings you e-News, a free biweekly electronic newsletter delivered directly to your e-mail, providing up-to-date articles on policy issues and pharmacy practice standards.

To subscribe, send an e-mail to NABPnews@nabp.net with the word Subscribe written in both the subject line and body of the e-mail from the address you wish to subscribe. Questions? Contact custserv@nabp.net. Archives of e-News are available in the News section of the NABP Web site at www.nabp.net.
Meeting Program

May 22-25, 2010

**Hyatt Regency Orange County**

**Anaheim, CA**

**Saturday, May 22, 2010**

9 AM - 7 PM
Registration/Information Desk Open

2 - 4 PM
Pre-Meeting CPE

5 - 6 PM
Annual Meeting Orientation

7 - 10 PM
President’s Welcome Reception
Honoring NABP President
Gary A. Schnabel and his wife
Tammy
Dinner will be served
Dress: business casual

**Sunday, May 23, 2010**

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

7:30 - 8:30 AM
Fun Run/Walk

8 - 11:30 AM
Joint CPE

Educational Poster Session – Innovative Public Protection Projects

8 - 11:30 AM
Hospitality Brunch and Educational Table Top Display

**Monday, May 24, 2010**

**Noon - 4 PM**
First Business Session

12:30 - 1:30 PM
Keynote Address
Joe Flower, Health Care Economist

4 - 5 PM
Special Program

5 - 6 PM
NABP Executive Director Service Recognition Reception

**Tuesday, May 25, 2010**

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

8 - 9 AM
Continental Breakfast

9 - 10:30 AM
Executive Officer and Board Member CPE

9 - 10:30 AM
Compliance Officer CPE

10:45 AM - 12:15 PM
Joint CPE

12:15 - 1:30 PM
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 106th Annual Meeting schedule is subject to change.

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**NABP and the NABP Foundation is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. ACPE Provider Number: 205. Participants may earn ACPE-approved continuing pharmacy education credit from NABP. Participants in continuing pharmacy education programs will receive credit by completing a “Statement of Continuing Pharmacy Education Participation” and submitting it to NABP. A validated Statement of Continuing Pharmacy Education Credit will be sent as proof of participation within approximately six weeks. Full attendance and completion of a program evaluation form for each session are required to receive continuing pharmacy education credit and a Statement of Continuing Pharmacy Education Credit.**

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**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.
Health Care Economist Joe Flower to Provide Expertise on the Future of Health Care During Annual Meeting Keynote Address

Attendees will have the opportunity to hear from experienced Health Care Economist Joe Flower as he shares his views on the future of health care during the NABP 106th Annual Meeting, to be held May 22-25, 2010, at the Hyatt Regency Orange County in Anaheim, CA.

Flower, who will speak on “Health Care: Better, Faster, Cheaper,” has been writing, speaking, and consulting about change and the future for nearly two decades. He is principal author of, “Technological Advances and the Next 50 Years of Cardiology,” Journal of the American College of Cardiology (Vol. 35, No. 4, 2000). In addition, Flower has written frequently about genomics and the biotech revolution for, among others, Health Central.com and the American College of Cardiology.


In addition to authoring three major health care compendia and several hundred articles, Flower is a contributing editor at Health Forum Journal and Physician Executive. His recent clients include DNA.com, the Global Business Network, the World Health Organization, and the Department of Defense.

Flower is also a founding member of the International Health Futures Network. He holds a master’s degree from San Francisco State University, with postgraduate work in education at University of California, Berkeley.

Registration Now Available for 106th Annual Meeting

The NABP 106th Annual Meeting, Eureka! Partnering to Save Public Protection – Boards of Pharmacy and NABP, is fast approaching. Taking place May 22-25, 2010, the meeting will be held at the Hyatt Regency Orange County in Anaheim, CA. Attendees are encouraged to register now to ensure they receive the early registration rates.

In order to receive these rates, attendees must register on or before April 12, 2010.

Online registration may be accessed via the Meetings section of the NABP Web site at www.nabp.net. A printable registration form is also available for download.

Both types of registration offer attendees three payment options:
1. Mailing in the payment
2. Using a credit card (American Express, MasterCard, or Visa)
3. Paying in Anaheim

For more information about the 106th Annual Meeting, visit the Meetings section of the NABP Web site at www.nabp.net.

Around the Association

Board Member Appointments

- Mark Conradi, RPh, JD, has been appointed a member of the Alabama State Board of Pharmacy. Conradi’s appointment will expire on December 31, 2014.
- Joli Martini, PharmD, has been appointed a member of the Delaware State Board of Pharmacy. Martini’s appointment will expire on September 1, 2012.
- Ronald Wallace has been appointed a public member of the Georgia State Board of Pharmacy. Wallace’s appointment will expire on July 6, 2013.
- Jason Kizer, PharmD, has been appointed a member of the Tennessee Board of Pharmacy. Kizer’s appointment will expire on January 1, 2015.
NABP Seeking Poster Session Participants for 106th Annual Meeting

NABP is currently seeking poster session participants for its Annual Educational Poster Session. This year the poster session will focus on “Innovative Public Protection Projects,” and will be held during the NABP 106th Annual Meeting, May 22-25, 2010, in Anaheim, CA.

The Poster Session will be held Sunday, May 23, from 8 - 11:30 AM, and 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 innovative public protection projects, with other pharmacy professionals.

State boards of pharmacy members and staff, as well as schools and colleges of pharmacy, are invited to participate.

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

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 representative, such as a registered pharmacist, during display times. Posters must coincide with the Poster Session theme, “Innovative Public Protection Projects.” Assembly time will be available on Sunday, May 23, 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 Monday, March 1, 2010.

Travel Grant Available to Qualified Voting Delegates for 106th Annual Meeting

NABP is accepting travel grant applications for the 106th Annual Meeting held May 22-25, 2010, at the Hyatt Regency Orange County in Anaheim, CA.

State board of pharmacy qualified voting delegates will have the opportunity to receive up to $1,500 in grant monies to assist with Annual Meeting travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. The grant does not include Annual Meeting registration fees.

Grant applications may be obtained from NABP upon the direct requests of executive officers of the state boards of pharmacy. NABP requests that applications be submitted to NABP Headquarters prior to the Annual Meeting. All applicants will be informed of whether or not they have qualified for the grant.

For more information on the Annual Meeting Travel Grant, contact the NABP Executive Office at exec-office@nabp.net.

Tips for Submitting a Poster

For those interested in participating, the following is a list of suggestions on preparing a poster:

• Poster topics must adhere to the theme “Innovative Public Protection Projects.”

• Keep the poster title short, highlighting the topic.

• Make the font size at least 14 point and double-space paragraph lines to ensure readability from a distance of two to four feet.

• Enlist the help of students and/or interns on rotation in your office to prepare the poster.

• Prepare handouts to provide an overview of the poster and/or additional information including contact names, should attendees have questions.

• The display should be manned by a qualified representative, such as a registered pharmacist, throughout the duration of the session.
NABP explains rogue Internet drug outlets’ role in diversion and abuse during prescription drug abuse summit

NABP recently participated in a Prescription Drug Abuse Summit for health care professionals, hosted by North Dakota Attorney General Wayne Stenehjem. The one-day summit, taking place on December 8 in Bismarck, ND, and again on December 9 in Fargo, ND, was convened to create awareness of the rampant abuse and diversion of dangerous and addictive prescription medications. Addressing more than 600 health care professionals in all, NABP revealed that most Web sites selling prescription drugs operate illegally, reviewed the criteria for legitimately operating Internet pharmacies, and illustrated how rogue Internet drug outlets contribute to the problem of prescription drug abuse.

There is a common misconception that prescription medications purchased from any Internet drug outlet are safe. The perception that prescription drugs are safer than street drugs contributes to the popularity of their abuse. What many patients fail to realize, however, is that when purchasing medications from unknown sources online, the quality and safety of those medications is also unknown. Patients have grown to trust prescription medications in the United States because the manufacturing and supply systems are tightly regulated to ensure safety. Outside that circle of protection, however, those safeguards vanish, and the odds of getting counterfeit or substandard medication rise substantially.

Since NABP launched its Internet Drug Outlet Identification program in May 2008, staff has reviewed more than 5,000 Web sites selling prescription medications. Of those, 96% appear to be operating out of compliance with basic pharmacy laws and practice standards. Those sites found to be noncompliant are listed as Not Recommended on the NABP Web site. Internet pharmacies accredited by the (VIPPS®) Verified Internet Pharmacy Practice Sites™ or Vet-VIPPS™ programs are listed as Recommended. These Internet pharmacies have successfully completed NABP’s rigorous 19-point criteria evaluation and on-site inspection to ensure they adhere to the highest standards for quality assurance and patient safety.

Patients would be well-advised to consider who is on the other end of an Internet-based transaction involving the sale of prescription medications. Virtually anyone with a computer and a bank account can sign on to become an affiliate of a rogue Internet drug outlet network, establish a Web presence using a template, and start selling drugs online. Bearing in mind that these affiliate network programs are behind thousands of Web sites selling prescription drugs, it follows that the operators of most Internet drug outlets have no knowledge of, or concern for, patient safety.

Drug Enforcement Administration (DEA) links the dramatic increase in prescription drug abuse in recent years to ease of access and has named the Internet as one of the biggest culprits. Hydrocodone is the most commonly diverted and abused pharmaceutical in the US, and Internet drug outlets sell an inordinate volume of hydrocodone, among other controlled substance painkillers.

DEA tracked 34 known or suspected rogue Internet drug outlets and found that these sites dispensed 98.6 million dosage units of hydrocodone combination products in 2006. Controlled substances account for approximately 11% of prescriptions dispensed by legitimate brick-and-mortar pharmacies. By contrast, controlled substances accounted for 95% of prescriptions dispensed by these rogue sites. NABP research confirms that controlled substances are readily available online without a prescription.

Knowledge is key to protecting the public from these high-tech drug dealers. NABP continues to research Web sites selling prescription drugs and report its findings to the state boards of pharmacy, federal regulators, and interested stakeholders, as well as to the public through the Internet Pharmacies section of its Web site. The Association engages in and continues to seek partnership opportunities with other entities to educate health care professionals and the public on the dangers of buying prescription drugs online, thereby empowering patients to make informed choices.

Also at the summit, North Dakota State Board of Pharmacy Executive Director Howard C. Anderson, Jr, moderated a panel discussion detailing the functionality and successes of the state’s prescription drug management program. Other presentations provided insight on appropriate pain management, explained law enforcement efforts, and described the tragic results of the misuse of prescription narcotics. These presentations are available on the North Dakota Office of Attorney General Web site, at www.ag.state.nd.us.

More information on the Internet Drug Outlet Identification program is available in the Internet Pharmacies section of the NABP Web site at www.nabp.net.
DEG Poisonings Prompt Reminder to Consult Guidance Document

Due to recent reports on diethylene glycol (DEG) poisonings associated with contaminated glycerin in pharmaceutical syrups, Food and Drug Administration (FDA) advises practitioners to consult the 2007 “Guidance for Industry Testing of Glycerin for Diethylene Glycol.” The guidance recommends certain precautions should be taken to prevent use of glycerin, or other excipients, such as propylene glycol, contaminated with DEG. FDA has no reason to believe that the United States supply of glycerin is contaminated with DEG, but a number of deaths resulting from DEG-contaminated glycerin have been reported in other countries. FDA advises that pharmacy compounders using glycerin to prepare drug products either test for DEG content or ensure that testing was properly done by the supplier. Information on excipients at risk for DEG contamination can be found in a US Pharmacopeia bulletin available at www.usp.org/hottopics/propyleneGlycolSorbitolInformation.html.


FDA Warns to Avoid Use of Plavix with Prilosec/Prilosec OTC

FDA warns that patients should avoid using Prilosec®/Prilosec OTC™ (omeprazole) with Plavix® (clopidogrel). When used properly, both drugs provide significant benefit; however, when taken together, Plavix’s ability to block platelet aggregation may be reduced by about half. Prilosec blocks the liver enzyme CYP2C19, preventing Plavix from metabolizing into its active form, thereby reducing the effectiveness of Plavix. The Plavix label has been updated with warnings regarding treatment with Prilosec and other drugs that may inhibit the CYP2C19 enzyme. More information can be found in the November press release on FDA’s Web site at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm191169.htm.

FDA Launches Safe Use Initiative

On November 4, 2009, FDA announced the launch of the Safe Use Initiative, a program designed to reduce the likelihood of preventable harm from medication use. Through the program, FDA aims to collaborate with health care professionals and other stakeholders to identify drugs and drug classes that are linked to preventable harm, and to develop, implement, and evaluate cross-sector interventions to reduce harm. To further advance the Safe Use Initiative, FDA intends to hold a series of public meetings to gather feedback and will open a public docket to receive comments on the report and proposed candidate cases. The report, “FDA’s Safe Use Initiative – Collaborating to Reduce Preventable Harm from Medications,” describes the program in detail and is available for download at www.fda.gov/downloads/Drugs/DrugSafety/UCM188961.pdf.

FDA Guidance for Compounding Multiple Prescriptions of Tamiflu Oral Suspension

To assist pharmacists in meeting demand during shortages of commercially manufactured Tamiflu® oral suspension, FDA released “Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions.” This publication provides instructions for compounding the suspension in advance of receiving prescriptions when demand is high, a practice FDA considers acceptable if the amount compounded is commensurate with the number of valid prescriptions reasonably anticipated by the pharmacy within 24 hours. The update also includes instructions for storing, dispensing, and counseling patients regarding the medication. The guidance document is available at www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm188629.htm.

EUA for Investigational IV Antiviral Peramivir to Treat 2009 H1N1 Influenza

On October 23, 2009, FDA announced that it has issued an emergency use authorization (EUA) for the investigational antiviral drug peramivir intravenous (IV) in certain adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection who are admitted to a hospital. Peramivir may only be used for hospitalized adult and pediatric patients, based on one or more of the following reasons:

- The patient is not responding to either oral or inhaled antiviral therapy.
- When drug delivery by a route other than an IV route – eg, enteral (absorbed by the intestines) or inhaled – is not expected to be dependable or feasible.
- For adults only, when the clinician judges IV therapy is appropriate due to other circumstances.

The EUA was issued in response to a request from the Centers for Disease Control and Prevention, and will expire when the declaration of emergency is terminated or the authorization is revoked by the agency. FDA emphasizes that peramivir is the only intravenously administered influenza treatment currently authorized for use under the EUA for 2009 H1N1 infections. More information is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm187813.htm.
Medical Marijuana
(continued from page 37)

history pertaining to the current medical marijuana legalization case noting that the plaintiff has a history as a marijuana advocate. He added that the individual seeking the legalization of medical marijuana gave no statutory basis for change. Galenbeck also noted that public opinion on the issue is shifting, citing a November 23, 2009 Washington Post article that stated 44% of people in the United States are for full legalization – a 13% increase in nine years.

What has Canada Done?
Carole Bouchard, BPharm, MAP, executive director of the National Association of Pharmacy Regulatory Authorities, discussed Canada’s recent legalization of medical marijuana. Currently, 4,000 patients are approved to use medical marijuana and 2,000 doctors are trained to make recommendations for patients.

Current operational issues include the fact that the product is home grown and is not approved at a federal level with standard quality regulations. Additionally, there is no documentation for doctors on what the appropriate dosage is for patients relative to the patients illness or physical make-up. Bouchard stated that Canada’s current medical marijuana system is a quick fix and the future of the program is being considered.

Legalizing Medical Marijuana – Creating a Slippery Slope?
Andrea Barthwell, MD, FASAM, founder and chief executive officer of EMGlobal LLC, and former deputy director for demand reduction in the ONDCP, voiced her opposition to the use of medical marijuana. She stated that the focus should be on scientific development of properties from the plants into effective drugs, noting that breakthroughs are pending. Other issues she cited include:

• creating a pathway for similar legalization arguments for other drugs like cocaine and heroin;
• lack of accountability in the manufacturing and distribution process;
• unsafe delivery systems;
• black market profit potential if medical marijuana is taxed; and
• the potential for abuse.

Eric E. Sterling, JD, president of the Criminal Justice Policy Foundation, took the opposite view as Barthwell, stating that the federal government has been rejecting legalization legislation due to politics, despite scientific proof of the efficacy of marijuana. He stated that the argument that allowing medical marijuana will lead to abuse of the drug is not a rational argument. Sterling went on to say that opponents are against legalization because if Americans see others using medical marijuana they will decide that marijuana is not dangerous as a recreational drug and that any behavioral aspects can be managed.

Attendees Discuss Two Scenarios
After hearing the presentations on both sides of the argument, attendees had the opportunity to participate in roundtable discussions. For Case 1, participants were asked to discuss what actions boards of pharmacy would take if medical marijuana was rescheduled as a Schedule II drug. For Case 2, participants were to consider what actions boards of pharmacy need to take with medical marijuana remaining a Schedule I drug.

Those discussing Case 1 noted that it would be fairly easy to follow Schedule II laws if medical marijuana became a Schedule II drug; however, the difficulty lies in the fact that currently there are no products for pharmacists to purchase and dispense. In light of this, a United States Pharmacopeial (USP) Convention monograph would be needed to help with guidelines for growers, suppliers, and...
Alarming Trend in Ohio’s ‘Accidental’ Drug Poisonings

The Ohio Department of Health (ODH) recently noticed an alarming trend. In 2008, deaths from “accidental” drug overdoses exceeded the number of traffic fatalities in Ohio. While traffic fatalities have remained fairly consistent from year to year, drug overdose deaths have risen at an alarming rate. A large majority of those overdoses involve prescription opiates, often combined with other drugs or alcohol; however, opiates are appearing as a major cause in most of these deaths. In response to this trend, ODH has started holding local planning meetings around the state.

The Ohio State Board of Pharmacy reminds pharmacists that they can, and must, play a role in addressing this epidemic. According to Board rule 4729-5-20 OAC, pharmacists must perform prospective drug utilization review on every prescription filled, including detecting and resolving issues relating to overuse of medications. When a pharmacist determines that a patient is receiving opiates from multiple prescribers, the pharmacist should take steps to make sure the treatment is legitimate before dispensing the prescription. Often, a patient who is seeing multiple prescribers is doing so just to obtain the drugs. This is defined in law as deception (doctor shopping) and it is a felony in Ohio. However, a patient who is being treated at a major cancer center clinic may really see multiple prescribers due to the clinical rotations of the hospital’s house staff physicians. In other words, a pharmacist should not automatically assume that a patient is doctor shopping until they do some checking.

The Board encourages pharmacists to use the Ohio Automated Rx Reporting System (OARRS) report to verify the legitimacy of a patient (particularly a new patient) who presents a prescription for a controlled substance. The OARRS report is a valuable tool that gives information (names, addresses, etc) on the prescribers and pharmacies used by that patient. If the patient is receiving controlled substances from one prescriber (or one clinic) only, then a pharmacist’s comfort level with the prescription should be better than it would be if they found the patient had visited 10 prescribers and eight emergency rooms in the last six months.

In addition, the Board reminds pharmacists that they need to know the prescribers and the patients. If the patient lives a long distance away from the pharmacy, it would be prudent to question why the prescription is being presented there. Furthermore, if the prescriber’s office is also located a long distance from the pharmacy as well as the patient, the question to ask is why does the patient need to drive there to fill the prescription.

Often pharmacists are the first to detect a physician who begins to stray from patient care into drug trafficking. The Board often receives complaints from pharmacists when physicians begin to prescribe unusual quantities and unusual combinations of drugs. The Board encourages pharmacists to monitor this issue and contact the Board when they have such concerns.

Some indicators that there may be a problem with a physician who treats “pain” include patients that all get the same drug(s) in the same quantities (pain is not like an infection where one dose fits all); when most of the patients receive prescriptions for the highest strengths available (most patients do well on hydrocodone/APAP 5/325); when the doctor’s parking lot is full of cars from out of state or from several counties away; when you find that the doctor only takes cash; when the patients always pay you cash for their prescriptions (or they pay cash for the second prescription after Medicaid or another insurer paid for the first); or when the patients appear in van loads rather than individually.

The Board notes that the workload in most pharmacies is high and difficult to deal with on a daily basis, but reminds pharmacists that they must use good judgment when filling prescriptions. Pharmacists have a duty to the patients and to society to ensure that the drug therapy is appropriate and reasonable.

South Carolina Board Approves Updates to OTC Compounding

During its September 2009 meeting, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy approved the reinstatement of Policy and Procedure No. 133 regarding over-the-counter (OTC) compounding. The following is a list of minimum guidelines:

1. Component products used in OTC compounding should be available to the public.
2. Compounded product should be made on a patient-specific need and kept behind the pharmacy counter under supervision of the pharmacist.
3. Compounded product labels should include active ingredients, strength, dosage, directions for use, expiration date, and one of the following:
   a. lot number;
   b. batch number;
   c. control number; or
   d. identification number, as well as appropriate auxiliary labels.
4. Patients should receive detailed written or verbal information and counseling with all compounded products.
5. Records of products provided to patients must be maintained in a readily retrievable manner.
Volunteers Sought for Committee and Task Force Positions

NABP is seeking volunteers from its active member boards of pharmacy to serve on the Association’s 2010-2011 committees and task forces. Each executive officer and board member interested in serving on a committee or task force is encouraged to submit a letter of interest and a current resume or curriculum vitae. In addition, NABP encourages interested board staff to volunteer for NABP task forces.

All submissions must be sent to NABP Executive Director/Secretary Carmen A. Catizone by Friday, June 4, 2010. Letters should outline the volunteer’s applicable experiences and accomplishments, along with the reasons he or she wishes to be considered for appointment to a committee or task force. All materials will be forwarded to NABP President-elect William T. Winsley, MS, RPh, who will make the appointments when he becomes NABP president following the Association’s 106th Annual Meeting. For more information on volunteering for a committee or task force, contact the NABP Executive Office at exec-office@nabp.net.

Medical Marijuana (continued from page 45)

control and distribution of the drugs. One group pointed out that some states allow for compounding of botanicals through a monograph, but that states would need to change their laws to include medical marijuana. Furthermore, it was discussed that medical marijuana only be distributed through pharmacies with special permits and accreditation. One group said that although boards of pharmacy do not regulate pharmaceutical companies, in the case of medical marijuana the boards should promulgate rules on the production of medical marijuana.

Those discussing Case 2, in which medical marijuana remained a Schedule I drug, stated that if pharmacists were to get involved in the movement to allow medical marijuana, boards would need to work with law enforcement and the US Department of Justice Bureau of Alcohol, Tobacco, Firearms and Explosives. All agreed that pharmacists should be involved if marijuana is used for medical purposes and that pharmacists would need to be educated on its use and interactions with other drugs. Finally, one group stated that it is not the place of the boards of pharmacy to petition for drug reclassification and that as state regulators they do not want to tell federal regulators how to regulate.

NABP has no position on medical marijuana.

Newly Accredited DMEPOS Facilities

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

90th Street Pharmacy
New York, NY

Central-Clearing Drugs, Inc
Chicago, IL

Drum’s Pharmacy, Inc
Enfield, NC

Health First Pharmacy
Greensburg, KY

Illini Clinic Pharmacy
Silvis, IL

IV & Home Health Services
of Texas
Houston, TX

Lane Drugs
Brooklyn, NY

Luna Park Pharmacy, Inc
Brooklyn, NY

Marcia Pharmacy
New York, NY

MDS Pharmacy Inc
Skokie, IL

Mid Concourse Pharmacy Inc
Bronx, NY

New Horizon Pharmacy Corp
Sunnyside, NY

Norm’s Pharmacy
Tarzana, CA

North Scott Pharmacy, Inc
Eldridge, IA

Oatts Drug Company, Inc
Dublin, GA

Osborne Pharmacy and Health Care
Lynn, MA

Pharmacy Express
Glasgow, KY

Porter Pharmacy & Gifts, Inc
Van Buren, AR

Primacare Plus Pharmacy Inc
Flushing, NY

Summit Medical Pharmacy Inc
Summit, IL

The Heights Community Pharmacy Inc
New York, NY

Total Pharmacy Care
Pikeville, KY

Wall Drugs of Johnsonville, Inc
Johnsonville, SC

Weirick & Patterson Pharmacy Inc
Colfax, IA

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.
NABP 106th Annual Meeting
May 22-25, 2010
See pages 40-42 for details.
Quick and easy registration is available in the Meetings section of the NABP Web site, www.nabp.net, under 106th Annual Meeting.