Prescription Medication Counterfeiters Continue to Exploit Internet, Expand Globally

Counterfeit medications remain a serious threat to human health, both in the developed world and particularly in developing countries. Since the NABP Newsletter ran its last update on the issue of counterfeit medications in the August 2005 issue, the focus in the United States has shifted somewhat from loopholes in the wholesale market to “rogue” Internet drug outlets operating in conflict with pharmacy laws and regulations.

On the world stage, meanwhile, awareness of the counterfeit drug problem appears to have risen overall, as evidenced by efforts of such international organizations as the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD).

WHO defines counterfeit medications as those that have been “deliberately and fraudulently mislabeled with respect to identity or source.” In its fact sheet on counterfeit medicines, WHO notes that “[c]ounterfeit medicines range from random mixtures of harmful toxic substances to inactive, useless preparations. Occasionally, “high quality” fakes do contain the declared active ingredient. In all cases, however, contents of counterfeits are unreliable because their source is unknown or vague and always illegal. Additionally, fake drugs can cause harm to patients. The regular use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance. In some cases, it can lead to death.

A recent OECD report notes, “[c]riminal networks and organized crime are playing a significant role in counterfeiting and piracy . . . The groups involved in counterfeiting and piracy include mafias in Europe and the Americas and Asian ‘tris’,” which are also involved in heroin trafficking, prostitution, gambling, extortion, money laundering and human trafficking.” Moreover, the Internet, as the report discusses, offers an ideal means for these criminals; it offers them anonymity, flexibility to put up and take down sites, a huge

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Counterfeiters Exploit Internet
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potential market, a way to reach that market at low cost around the clock, and technology that allows easy deception.

In the United States
WHO has estimated that in the US and other developed countries, counterfeit medications account for probably less than 1% of pharmaceutical sales each year. This percentage still translates to more than 30 million prescriptions that might be filled with counterfeit medications each year – a significant threat to the public health and safety. Moreover, increasing sophistication on the part of counterfeiters, helped by improvements in technology, means that fakes are increasingly difficult to spot without a chemical analysis; they mimic often with startling accuracy the appearance of the original medication and packaging, even down to holograms.

Earlier this decade, the focus in the US was on the secondary drug wholesale market. States began to pass legislation requiring more stringent pedigrees – electronic or paper trails that track medications from manufacturer to pharmacy, preventing diversion or adulteration along the way – and certifying wholesalers, making it more difficult for illegitimate wholesalers to set up shop. As part of this latter effort, NABP launched its Verified-Accredited Wholesale Distributors® (VAWD®) program to help the state boards of pharmacy identify the legitimate wholesalers enabling boards to conserve all-too-scarce resources.

More recently, attention has shifted towards what may be becoming a greater threat: the Internet as a source of counterfeit medications. According to a report released last June by the European Alliance for Access to Safe Medicines, 62% of all medicines bought online were found to be fakes, and nearly 96% of the Internet pharmacies studied operated illegally.

The brand protection firm MarkMonitor reports in its summer 2008 Brandjacking Index™ that the number of patients buying medications from Internet drug outlets nearly tripled in the past year. This increased consumer traffic continues to fuel concerns that fake, diluted, stolen, or expired drugs are reaching patients from rogue Internet drug outlets. While many counterfeiters operate from foreign countries in Asia, eastern Europe, and elsewhere, many Web sites misrepresent themselves to gain consumer trust. MarkMonitor reports, “the wave of negative publicity around foreign pharmaceuticals in the past year has prompted many of these manufacturers to cloak their national origins.” In addition, the report notes that many Internet drug outlets are investing more in online marketing tools, while many neglect to invest in technologies such as encryption to protect patient data.

In a fact sheet on counterfeit pharmaceuticals, the US Immigration and Customs Enforcement (ICE) notes that, “in recent years, the Internet has become the primary tool for criminal organizations to advertise, communicate and conduct sales of counterfeit pharmaceuticals. The Internet has also become the primary mechanism for consumers to find, order, and pay for counterfeit pharmaceuticals.” According to ICE, criminal “trafficking organizations have created an illicit, unregulated supply chain of counterfeit, adulterated, misbranded, and unsafe drugs that are distributed directly to consumers in the United States and elsewhere,” rather than attempting to infiltrate the closely regulated legitimate US supply chain.

A number of entities, including the US Food and Drug Administration (FDA), NABP, professional associations, and media outlets have been seeking to educate consumers as to the dangers of rogue Internet drug outlets and the safest ways to purchase medications online, such as patronizing those sites that are Verified Internet Pharmacy Practice Sites™ (VIPPS®)-accredited. Besides the VIPPS-accredited pharmacies, which are listed as Recommended in the Internet Pharmacies section of the NABP Web site, the Association now also lists Reviewed pharmacies that
appear to comply with state and federal laws, and Not Recommended sites that appear to be out of compliance with federal and state laws or NABP patient safety and pharmacy practice standards.

In the last couple of years, a number of states have passed legislation regulating electronic prescribing and/or sale of medications on the Internet (see “State, Federal Regulatory Authorities Combat Rogue Internet Drug Distributors” in the April 2008 issue of the NABP Newsletter). Recent legislation in Virginia, for example, requires a nonresident pharmacy to be accredited by NABP through the VIPPS program, or certified by a substantially similar program approved by the Virginia Board of Pharmacy, if the pharmacy dispenses more than 50% of its total prescription volume pursuant to prescriptions received as a result of solicitation on the Internet, including solicitation by e-mail. The new law became effective July 1, 2008.

This year the US House and Senate passed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which would prohibit Internet pharmacies from providing controlled substances to consumers without a legitimate prescription (including an in-person medical examination) and would require certification of online pharmacies. At press time, the bill was awaiting the signature of the President. In addition, both state and federal law enforcement agencies have been moving against rogue Internet drug outlets. These efforts may be bearing some fruit. In its annual report examining controlled substance availability on the Internet, “You’ve Got Drugs! V: Prescription Drug Pushers on the Internet,” published in July 2008, the National Center on Addiction and Substance Abuse (CASA) at Columbia University found for the first time since 2004 a decline in the number of both portal and anchor sites identified during the study. Caveats include that the proportion of total sites offering the drugs for sale increased from 2007 to 2008, and, at 365, the number of sites advertising controlled substances and/or making them available for purchase remained high. While it is too soon to say if the decrease is significant or long-lasting, the report speculated that it might be due to increased law enforcement activity. In another encouraging sign, moreover, CASA noted that “[s]ome of the Web sites CASA identified this year list states where online sellers will NOT ship drugs” and speculated that “[t]hese practices may be in response to the emergence of state laws against online trafficking.”

NABP will provide an opportunity for state boards of pharmacy to share information and ideas on counterfeit medications with each other and other state and federal regulators, along with stakeholders in the pharmaceutical industry, at the Association’s 2008 Symposium, to be held December 4-5, 2008, at the JW Marriott Starr Pass Hotel in Tucson, AZ. More information and downloadable registration forms are available in the Meetings section of the NABP Web site, www.nabp.net, or by e-mailing custserv@nabp.net.

Worldwide

While some hints of progress may be discernable domestically, the worldwide situation remains dire. As much as 30% of the drugs available in some developing countries may be counterfeit, and disproportionately more so in rural or particularly impoverished areas. The US-headquartered Center for Medicine in the Public Interest has suggested that global counterfeit drug sales could expand to a $75 billion industry by 2010, and side effects of globalization have increased risks in the pharmaceutical supply chain worldwide. Free trade zones, areas specially designated by a number of countries to encourage trade, often waive tariffs and offer little regulatory oversight to the huge volume of goods that pass through them, making it easy for counterfeiters to hide or sanitize the (continued on page 162)
On occasion, judicial opinions of civil issues are relevant to the matters undertaken by boards of pharmacy and are helpful to informing board members on regulatory issues and legal interpretations. As readers know, medication errors, including wrongfully filling prescriptions, can have severe implications causing harm to patients. To protect the rights of harmed individuals, the parties have the right to pursue civil actions based upon various legal theories, usually involving allegations of negligence. In addition, boards of pharmacy may have the authority to initiate administrative action against the licensee(s) as provided under the pharmacy practice act and in the interest of protecting the public.

Time constraints are important to filing civil actions as certain causes of action are barred by law (under a statute of limitations) if filed after the expiration of a designated period of time. Many jurisdictions do not have a time bar to the initiation of administrative proceedings under the practice act, while others are controlled by a time period to conclude the administrative matter within a certain time frame. In civil matters, how particular causes of action are characterized may influence which statute of limitations applies. Consider the following:

On November 11, 2000, the husband of a patient took a prescription for Mirapex® to be refilled at the local pharmacy. The patient was taking Mirapex on her doctor’s orders for restless leg syndrome. At the pharmacy, an employee of the store, but not a pharmacist, mistakenly refilled the prescription with 1 mg tablets of Mirapex, thus each tablet contained eight times the prescribed dosage. The employee was working at the pharmacy, but was not under the supervision of the pharmacist at the time she refilled the prescription.

On November 13, 2000 and after taking one pill, the patient became dizzy, agitated and nauseated, and eventually lost consciousness. At the emergency room, hospital doctors determined that she suffered an adverse reaction to the excessive dosage of Mirapex. On October 7, 2003, the patient filed a negligence lawsuit against the pharmacy and the employee. The complaint contained numerous counts alleging a duty owed to the patient and a breach of such duty by:

a. Failing to dispense the appropriate medication dosage and refilling a prescription instead with eight times the prescribed dosage.

b. Failing to timely recognize the error made in dispensing medications.

c. Allowing persons other than a licensed pharmacist to refill prescriptions.

d. Failing to have a licensed pharmacist available on site to oversee, supervise and control the actions of persons not pharmacists who refilled prescription[s].

In addition, the patient alleged that the employee of the pharmacy was not a licensed pharmacist and owed a duty to the patient to not undertake dispensing medications as an unlicensed person. The patient also alleged that the employee engaged in negligent activities by:
a. Dispensing medication which she was not qualified to dispense as she was not a licensed pharmacist.

b. Failing to dispense the appropriate medication dosage and refilling a prescription instead with eight times the prescribed dosage.

c. Failing to timely recognize the error made in dispensing medications.

d. Failing to consult with a licensed pharmacist before dispensing medications.

The defendants moved for summary disposition of the litigation (arguing the case as set forth by the facts can be decided in favor of the pharmacy and its employee as a matter of law). In particular, the defendants argued that because the pharmacy is a “licensed health facility or agency,” the complaint sounded in medical malpractice, rather than ordinary negligence. The lower court denied the defendants motion without explanation.

The court of appeals affirmed the lower court denial of the defendants’ motion for summary disposition finding that a pharmacy is not a “licensed health facility or agency” subject to medical malpractice claims. However, the court of appeals also noted that pharmacists are licensed health care professionals subject to malpractice claims under applicable law. But, the employee in question was not a licensed pharmacist, nor was the pharmacy. The court concluded that, while the negligent acts of unlicensed agents or employees of licensed health facilities or agencies may be subject to medical malpractice claims, the finding that the pharmacy was not a licensed health facility or agency precluded the pursuit under a medical malpractice cause of action. Accordingly, the court of appeals held that the three-year statute of limitations applied and the defendants’ motion should be denied. The defendants appealed the case to the Michigan Supreme Court.

After identifying the standard of review, the Supreme Court turned its attention to the merits of the matter. In order for a claim to be subject to medical malpractice, certain requirements must be met. They include allegations that the actions: “(1) occurred within the professional relationship and (2) poses questions of medical judgment outside the realm of common knowledge and experience.”

A professional relationship exists if “a person or an entity capable of committing medical malpractice was subject to a contractual duty to render professional health-care services to the plaintiff.” While historically under common law, only physicians were potentially liable for malpractice, the Michigan legislature expanded the scope of those responsible under malpractice claims to include “a person or entity who is or who holds himself or herself out to be a licensed health care professional, licensed health facility or agency, or an employee or agent of a licensed health facility or agency. . . .”

The court noted that the primary issue in this matter is whether the employee and pharmacy are covered by the legislative expansion of persons subject to medical malpractice claims. (Interestingly, the Supreme Court referred to the employee as a “pharmacy technician” while the lower courts referred to her as an employee.)

In rejecting the arguments of the defendants (who were joined by the Michigan Pharmacists Association [referred to as MPA]), the court held that the relevant statutes (continued on page 162)
The French-based OECD also recently shone a spotlight on the counterfeit drug crisis with a report entitled "The Economic Impact of Counterfeiting and Piracy." While the report covers counterfeiting and piracy in general, it notes pharmaceuticals are particularly dangerous, since they can profoundly affect the public health and safety. The report recommends that governments strengthen civil and criminal remedies “to more effectively redress the harm caused to rights holders,” expand border measures, increase information disclosure, strengthen cooperation between industry and governments and among governments, and perform more regular assessments.

WHO, which launched a Rapid Alert System in 2005 to help spread the word about discoveries of counterfeit medications, in 2006 created a global partnership “to improve coordination and harmonization across and between countries so that eventually the production, trading, and selling of fake medicines will cease”: the International Medicinal Products Anti-Counterfeiting Taskforce, or IMPACT.

With collaborative international programs like these, governments may hope to arrest the progress of drug counterfeiters, if not eliminate the problem entirely. Despite the daunting odds against combating such crime, national efforts have shown that concerted and collaborative action involving legislators, regulators, and law enforcement, in addition to a good dose of consumer awareness and education, can have a positive impact.

In determining whether an entity is a licensed health facility or agency is the Public Health Code. Under the Public Health Code, definitions as to what is a health facility or agency are included and pharmacies are not enumerated as such. Because pharmacies are not included in the definitions, they cannot be liable for medical malpractice in that capacity. Nor can agents and employees be liable for medical malpractice “as agents or employees of a licensed health facility.” Thus, the Supreme Court affirmed the lower court that the employee and pharmacy cannot be held liable for medical malpractice.

Next, the defendants (and MPA) urged that the court find that a pharmacy is a licensed health care professional. The court rejected this argument citing the relevant sections of Michigan law and the fact that a pharmacy is not an individual. It held that a license to operate a pharmacy can be issued to a non-pharmacist. But the holder of a pharmacy license cannot open a pharmacy for business unless a licensed pharmacist is physically on site. These are important distinguishing factors in determining that while a pharmacist is a licensed health care professional, a pharmacy is not. Since the pharmacy is not a health care professional, it could not have a professional relationship with the patient.

The result of these conclusions is to determine that the applicable statute of limitations in this matter sounds in ordinary negligence (a three-year statute of limitations) rather than in medical malpractice (a two-year statute of limitations). Thus, the patient’s complaint was not time barred and the defendants’ motion to summarily dispose of the matter was denied. The court held that a pharmacy is neither a licensed health facility or agency nor a licensed health care professional and cannot be directly liable for medical malpractice. Thus, the patient’s claims of direct liability against the pharmacy and its employee and her claims for vicarious liability against the pharmacy as an employer sounded in ordinary negligence. Because the patient stated valid claims of ordinary negligence, the lower court properly applied the three-year statute of limitations and denied the defendants’ motion for summary disposition.

This case presents an interesting analysis of the legal significance of how the pharmacy and employee were classified for purposes of applying a statute of limitations. It is interesting to note that in previous “duty to warn” cases, pharmacists and professional associations have argued against recognition of licensees as professionals obligated to meaningfully participate in the physician-patient relationship and warn recipients of potential drug interactions. However in this matter, the pharmacy and MPA argued that the pharmacy was a health care professional or a licensed health facility for purposes of attempts to apply a shorter statute of limitations and, effectively preclude the litigation.

Kuznar v Raksha Corporation, 750 N.W. 2d 121 (MI 2008)
Working proactively to provide the tools to protect the public health, volunteers from state boards of pharmacy and other stakeholders come together to create positive change for patients. These dedicated members of the pharmacy profession, through their solid planning and decisive action taken during NABP committees and task forces, provide the impetus to evolve the practice of pharmacy.

Each year, the NABP Executive Committee reviews the resolutions passed by the membership at the last Annual Meeting, as well as recommendations from the Association president, to determine whether any task forces are needed to address current issues facing the boards. This year NABP will convene five single-issue task forces pertaining to:

1. the standardization of pharmacy technician education and training;
2. the Test of English as a Foreign Language® Internet-based Test (TOEFL® iBT) score requirement for Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification;
3. accreditation standards for community pharmacies;
4. medication collection programs; and
5. requirements for uniform prescription labeling.

Each task force is asked to research and discuss the issue and to make recommendations to the Executive Committee.

Standing committees are established by the NABP Constitution and Bylaws and remain in existence indefinitely to address Association issues on an ongoing basis.

As the NABP president does each year following the Annual Meeting, President Rich Palombo, RPh, has announced his appointments for the Association’s 2008-2009 committees and task forces.

Every effort has been made to accommodate individual requests to serve on a committee or task force and to ensure uniform representation from all regional districts.

Task Forces

The Task Force on Standardized Pharmacy Technician Education and Training met September 9-10, 2008, at NABP Headquarters in Mount Prospect, IL. (See “Task Force Examines Standard Requirements for Pharmacy Technicians” on page 167.) The task force resulted from a resolution, passed at the 104th Annual Meeting in May 2008, which notes that pharmacy technicians have become an integral component of pharmacy practice and that discussions among some state boards of pharmacy have resulted in the conclusion that there is the need for standardized education and training of pharmacy technicians. The charge of this task force was, after studying current state regulations regarding technician education and training, to assess the feasibility, in regard to the protection of the public health, of the states implementing standardized state requirements for technician education and/or training. The task force also recommended revisions to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) if necessary.

Chairperson of this task force was Susan Ksiazek, RPh, of the New York State Board of Pharmacy. Individuals appointed to serve as members are listed below with their state boards of pharmacy:

- Wendy Anderson, RPh, Colorado
- Lee Ann Bundrick, RPh, South Carolina
- Gay Dodson, RPh, Texas
- Jacqueline Hall, RPh, Louisiana
- Jeane Johnson, RPh, New Mexico
- Jerry Wiesenhahn, RPh, Ohio
- Ruth Conroy, PharmD, of California served as an alternate member, and the Executive Committee liaison was Gregory Braylock, Sr, RPh, member of the Executive Committee and of the Ohio State Board of Pharmacy.

The Task Force to Review TOEFL iBT Score Requirement...
Task Force Appointments
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pharmacy practice; and (3) the standards required by other, similar health programs are congruent with the NABP requirements. The task force will then recommend future steps for the Association.

Chairperson of this task force will be Lawrence H. Mokhiber, MS, RPh, of the New York State Board of Pharmacy. Individuals appointed to serve as members are listed below with their state boards of pharmacy:
- Thomas Bender, RPh, New Jersey
- Kevin Borcher, RPh, Nebraska
- W. Benjamin Fry, RPh, FIAACP, FACAP, Texas
- Kevin Mitchell, RPh, Ohio
- Anne Policastro, PharmD, MBA, Kentucky
- Jeanne Waggener, RPh, Texas
- Susan Martin, RPh, of Colorado was appointed as alternate member, and the Executive Committee liaison for this task force will be Cathryn J. Lew, RPh, member of the Executive Committee and of the Oregon State Board of Pharmacy.

The Task Force on Medication Collection Programs will also be held on December 6-7, 2008, at the JW Marriott Starr Pass Hotel in Tucson, AZ. Also a result of a resolution adopted at the 104th Annual Meeting in May 2008, the task force is charged with (1) evaluating current state and federal laws and regulations addressing prescription label format and content; (2) reviewing the results of the findings of both state and federal studies regarding prescription labeling; (3) studying the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information; and (4) recommending revisions, if necessary, to the NABP Model Act.

Chairperson of the task force will be Michael Romano, RPh, of Pennsylvania. Individuals appointed to serve as members are listed below with their state boards of pharmacy:
- Karen DiStefano, RPh, Rhode Island
- Leo Ross, RPh, Virginia
- Patricia Donato, RPh, New York
- William Prather, RPh, Georgia
- Barry Boudreaux, RPh, Nevada
- Virginia Herold, MS, California
- Ronald Huether, RPh, South Dakota

The Executive Committee liaison for this task force will be Karen M. Ryle, RPh, of Massachusetts, who
List for Not Recommended Internet Drug Outlets Grows to 1,007

In an effort to educate and protect patients from illegitimate drug outlets selling medications online, NABP continues to list Internet drug outlets on the NABP Web site that do not appear to meet state and federal laws and NABP patient and safety and pharmacy practice standards.

As of October 10, 2008, 1,007 sites were reported as Not Recommended. Of those:
- 942 sites do not require a valid prescription
- 615 sites offer foreign or non-FDA-approved drugs
- 517 sites are located outside the United States and selling drugs illegally to patients in the US
- 458 sites do not have a physical location
- 317 sites offer no patient-related information or support
- 213 sites do not have a valid return address
- 196 sites do not require a prescription
- 74 sites are located outside the United States and sell illegal drugs to patients in the US
- 66 sites do not have a valid telephone number
- 52 sites do not have a valid address
- 49 sites do not have a valid e-mail address
- 34 sites do not have a valid name or organization name
- 31 sites do not have a valid URL
- 22 sites do not have a valid telephone number
- 18 sites do not have a valid address
- 16 sites do not have a valid e-mail address
- 14 sites do not have a valid name or organization name
- 13 sites do not have a valid URL
- 12 sites do not have a valid telephone number
- 11 sites do not have a valid address
- 10 sites do not have a valid e-mail address
- 9 sites do not have a valid name or organization name
- 8 sites do not have a valid URL
- 7 sites do not have a valid telephone number
- 6 sites do not have a valid address
- 5 sites do not have a valid e-mail address
- 4 sites do not have a valid name or organization name
- 3 sites do not have a valid URL
- 2 sites do not have a valid telephone number
- 1 site does not have a valid address

According to MarkMonitor’s summer 2008 Brandjacking Index™, consumer traffic to Internet drug outlets has nearly tripled in the last year. In second quarter 2008, Internet drug outlets received 99,000 site visits per day, per site, compared to 32,000 site visits during the same period last year, according to the report. This increased traffic, in turn, has driven a threefold increase in revenues for these sites, from an estimated $4 billion in second quarter 2007 to $12 billion in the same period of 2008, the report notes.

Of the 2,386 Internet drug outlets MarkMonitor surveyed for the report, 64% of them had no protection measures to safeguard patient data. Additionally, the report cites a 36% growth in the availability of drugs in the online supply chain. The report is available on the MarkMonitor Web site, www.markmonitor.com.

A full listing of Recommended, Reviewed, and Not Recommended sites, along with the Internet Drug Outlet Identification™ program criteria and related patient information, is available in the Internet Pharmacies section of the NABP Web site at www.nabp.net.

Task Force Appointments
(continued from page 164)

is a member of the Executive Committee.

Standing Committees

The Committee on Law Enforcement/Legislation will meet in January 20-21, 2009, at NABP Headquarters. This committee develops or reviews language proposed by other NABP committees and task forces for incorporation into the Model Act. This committee is charged with the following tasks:
1. review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists;
2. develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association; and
3. recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Chairperson for the committee will be David Dryden, RPh, JD, of the Delaware State Board of Pharmacy. Individuals appointed to serve as members are listed below with their state boards of pharmacy:
- Jennifer Edwards, PharmD, Virginia
- Peter Orzali, RPh, Kentucky
- Dennis McAllister, RPh, Arizona
- David Potters, JD, West Virginia
- Debra Ringgenberg, RPh, Missouri

The Executive Committee liaison will be Lloyd K. Jessen, RPh, JD, member of the Executive Committee and executive director of the Iowa Board of Pharmacy.

The Committee on Constitution and Bylaws will meet on April 7, 2009. This committee reviews proposed amendments to the NABP Constitution and Bylaws, suggests changes where appropriate, and issues a recommendation for each proposed amendment.

Serving as chairperson of this committee will be Edward McGinley, RPh, of the New Jersey Board of Pharmacy. Individuals appointed to serve as members are listed with their state boards of pharmacy:
- Alice Mendoza, RPh, Texas
- Lydia Main, RPh, West Virginia
- Brenda Warren, DPh, Tennessee
- Vernon Benjamin, RPh, Iowa

The Executive Committee liaison is Hal Wand, MBA, RPh, member of the Executive Committee and executive director of the Arizona State Board of Pharmacy.

Following each committee or task force meeting, the group develops a report outlining its recommendations that will be forwarded to the Executive Committee for review and approval. The approved report is then distributed to all member boards and posted on the NABP Web site and NABP staff begins implementing the recommendations.
NABP Accepting 2009 Award Nominations for 105th Annual Meeting

Individuals who know an exemplary colleague or a board of pharmacy that represents the mission of NABP – protecting the public health – may nominate the eligible person or board for a 2009 NABP award to be presented at the 105th Annual Meeting, May 16-19, 2009, at the Hyatt Regency Miami in Florida.

Nominations are currently being accepted for the following awards:

2009 Lester E. Hosto Distinguished Service Award (DSA), 2009 John F. Atkinson Service Award, 2009 Fred T. Mahaffey Award, and the NABP 2009 Honorary President.

Lester E. Hosto DSA

This award is the highest honor bestowed by the Association. It was first simply known as the Distinguished Service Award, but was renamed by NABP to serve as a memorial to the 1990-1991 NABP President Lester E. Hosto, whose motivating presence in the practice of pharmacy was recognized by practitioners of his state, pharmacy leaders across the nation, and former United States President Bill Clinton.

The Lester E. Hosto DSA recognizes those individuals whose efforts to protect the public health greatly furthered the goals and objectives of NABP. Any individual who meets these criteria may be nominated for the DSA, regardless of his or her member affiliation with NABP.

2009 John F. Atkinson Service Award

Replacing the Lester E. Hosto Inspector DSA at the 105th Annual Meeting is the John F. Atkinson Service Award. This new award is named in honor of former NABP general counsel John F. Atkinson, who recently retired after serving as NABP legal counsel for more than 40 years. Recipients of this award are individuals who have provided NABP with exemplary service in protecting the public health and have shown significant involvement with the Association related to pharmacy law and compliance.

Any individual who meets the above criteria may be nominated for this award.

2009 Fred T. Mahaffey

Named after the late NABP Executive Director Emeritus Fred T. Mahaffey, who held the executive director position from 1962 to 1987, this award recognizes a member board of pharmacy that has made substantial contributions to the regulation of the practice of pharmacy over the past year.

Mahaffey, known as the “Father of the NABPLEX,” organized a process for constructing and administering the profession’s national licensure examination, which is now known as the North American Pharmacist Licensure Examination® (NAPLEX®). His leadership and contributions to NABP, state boards of pharmacy, and the protection of the public health were significant and established NABP as one of the leading pharmacy organizations.

Individuals considered for this award must have contributed to protecting the public health and welfare through the enforcement of state and federal laws and regulations, and to the advancement of NABP goals and objectives as specified in the Association’s Constitution and Bylaws.

Honorary President

NABP is also accepting nominations for the 2009 Honorary President. Nominees that will be considered for this award must meet the following criteria:

- exemplary services for, or on behalf of, NABP;
- strong commitment to NABP, the mission of the Association to protect the public health, and the practice of pharmacy; and
- affiliation (either current or past) as a board member or as an administrative officer of an active or associate member board.

NABP President-elect Gary A. Schnabel, RPh, RN, will present all awards during the 105th Annual Meeting.

Nominations for these awards must be received at NABP Headquarters no later than December 31, 2008. To submit a nomination, individuals may send a letter explaining why the nominee should be considered for the award, as well as a brief biography, current resume, or curriculum vitae of the nominee.

The NABP Executive Committee will review the nominations and select the Honorary President and award recipients. Please submit your nomination to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056. For more information, please contact Chris Siwik, professional affairs program analyst, via e-mail at csiwik@nabp.net.
Task Force Examines Standard Requirements for Pharmacy Technicians

In the last five years, the number of pharmacy technicians recognized by the state boards of pharmacy has more than doubled, from 139,560 reported by 27 states in 2003 to 284,421 reported by 36 states in 2008, according to census data provided in the Survey of Pharmacy Law. Currently, requirements for the training and licensing or registration of pharmacy technicians vary from state to state. An NABP task force met in September 2008 at NABP Headquarters to consider whether uniform standards would be in the best interest of patient health and safety.

The charge of the Task Force on Standardized Pharmacy Technician Education was to review and analyze the present state requirements for pharmacy technicians in regard to licensure, registration, and certification, and in regard to education and training; and to assess the feasibility, in regard to the protection of the public health, of the states implementing standardized requirements for technician education and training. In addition, based on these discussions, the task force recommended revisions to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) addressing this issue.

NABP Supports Technician Regulation

NABP first formally recognized pharmacy technicians in 1993 with amendments to the Model Act that called for state registration procedures, required site-specific training, and called for the establishment of a national technician competency examination and disciplinary clearinghouse. In 2000, NABP expanded its recognition of pharmacy technicians. Task forces and committees explored the issue and encouraged states to modify or eliminate ratios in pharmacy settings with quality assurance programs in place, and recognized two levels of pharmacy support personnel: pharmacy technicians and certified pharmacy technicians.

Certified pharmacy technicians were required to be registered with the state board of pharmacy, have completed a certification program approved by the board, and could, under the supervision of a pharmacist, perform certain activities, such as receive new prescription drug orders, handle prescription transfers, and perform drug compounding. Pharmacy technicians were also required to be registered with the state board of pharmacy, and could under the supervision of a pharmacist, perform certain activities such as assist in the dispensing process, process medical coverage claims, stock medications, or serve as cashier. They could not, however, participate in the receipt of new prescription drug orders or prescription transfers. Neither pharmacy technicians nor certified pharmacy technicians, according to regulations recommended in the Model Act, could participate in drug regimen reviews, clinical conflict resolution, prescriber contact concerning prescription drug order clarification or therapy modification, or patient counseling or dispensing process validation.

Also in 2000, in response to requests from member boards, NABP evaluated technician examinations and programs to ensure that they effectively assess technician competencies and to determine whether they could be used as one means for boards to determine eligibility of technicians to assist in the practice of pharmacy. This evaluation process resulted in an official partnership in January 2002 with the Pharmacy Technician Certification Board (PTCB). NABP assists in development and management of the PTCB examination and officially recognized the examination in the Model Act. As amended to reflect this change, the Model Act encourages use of the PTCB examination for technicians by the state boards.

The primary purpose of credentialing and licensure examinations is to assure the public that key professional standards have been met. Based on the trends of the last five years, it seems clear that the future of pharmacy practice includes increased and expanded use of technicians, further recognition of PTCB by states, and further recognition of technicians by the states.

State Regulations

According to the 2008 Survey of Pharmacy Law, 40 jurisdictions (38 states plus Guam and Puerto Rico) currently license, register, and/or certify pharmacy technicians, whereas 13 jurisdictions (12 states plus the District of Columbia), do not. Of the latter group, the boards of pharmacy in two jurisdictions (Kentucky and District of Columbia) are in the process of developing regulations, and Florida has adopted regulations that will take effect in 2010.

Twenty-nine jurisdictions have some form of technician training requirements, with variations ranging from on-the-job training by the pharmacist-in-charge appropriate to the technician’s duties, to successful completion of a board of pharmacy-approved certification program. Thirteen states specify continuing education requirements for technicians, ranging from three hours per year to 20 hours every two years. Fourteen states have technician examination requirements, and several of these states require certification by PTCB or other board-approved organization.

The boards of pharmacy in 39 jurisdictions have the authority to deny, revoke, suspend, or restrict technician registration.

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Standard Requirements for Pharmacy Technicians

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States Pass, Explore Legislation

Florida: On June 23, 2008, Florida Governor Charlie Crist signed into law Senate Bill (SB) 1360, which outlines new requirements for training, certification, and registration of pharmacy technicians. The new law requires the Florida Board of Pharmacy to adopt rules establishing the registration of the more than 40,000 pharmacy technicians currently working in the state by 2010. In 2011, Florida technicians will need to either complete a Board-approved training program with 1,500 hours of work as a technician under a Florida licensed pharmacist or become certified by a program accredited by the National Commission for Certifying Agencies, such as the PTCB program. Illinois: Beginning on January 1, 2010, within two years after being employed as a registered technician, a pharmacy technician must become certified by successfully passing the PTCB examination or another Board-approved pharmacy technician examination in order to continue to perform pharmacy technician’s duties. This requirement does not apply to pharmacy technicians hired prior to January 1, 2008.

Ohio: On May 29, 2008, the Ohio State Senate approved SB 203. The legislation requires pharmacy technicians to work only under the direct supervision of a pharmacist, to be 18 years of age or older, possess a high school diploma or GED, submit to a criminal records check that is submitted to the employer, have no felony convictions, and successfully pass competency examination approved in rule by the Ohio State Board of Pharmacy. Those employed as pharmacy technicians on the effective date of the bill will have one year from that date to pass Board-approved competency examination. New hires will have 210 days from the date of hire to pass Board-approved competency exams. Under the bill, only a pharmacist, a pharmacy intern, or a qualified pharmacy technician, as defined by the law, may engage in the compounding of any drugs, package or label any medication, or prepare or mix any intravenous medication to be injected into a human being.

Known as Emily’s Act, the legislation is named after 2-year-old Ohio girl Emily Jerry, who died on March 1, 2006, after a pharmacy technician mixed her IV solution incorrectly. The pharmacist on duty at the time lost his license and is currently facing felony charges of involuntary manslaughter and reckless homicide in Ohio. The technician was not charged criminally or sanctioned by the Ohio State Board of Pharmacy because Ohio has no statutes regarding pharmacy technicians. Emily’s Act has also been introduced federally (HR 5491) by Representative Steven LaTourette. (See Federal Legislation Proposed.)

Kentucky: On July 15, 2008, the Kentucky Board of Pharmacy has adopted draft legislation for the registration of pharmacy technicians. The legislation states that, effective April 1, 2009, pharmacy technicians in Kentucky must be registered with the Board.

South Carolina: South Carolina SB 1156 proposes to increase the pharmacy technician-to-pharmacist ratio from 3:1 (with two technicians being state certified) to 3:1 (with one technician being state certified) and 4:1 (with two technicians being state certified).

Washington: On May 29, 2008, the Washington State Board of Pharmacy adopted a rule that resulted in new requirements for certification as a pharmacy technician. Effective January 1, 2009, all technician applicants must pass a Board-approved national standardized examination and complete a Board-approved technician training program. Individuals who have obtained a pharmacy technician credential before January 1, 2009, will not be required to meet the new standards.

Task Force to Reconvene

The task force is recommending a second meeting to review existing state requirements for educational and training programs and national accrediting organizations’ core competencies to recommend a national standard for the educational and training requirements for pharmacy technician certification.

Federal Legislation Proposed

In February 2008, US Representatives Steven C. LaTourette of Ohio and Stephen F. Lynch of Massachusetts introduced federal legislation, HR 5491, that would assist in the implementation of training, education, registration, and certification requirements for pharmacy technicians nationwide. The Pharmacy Technician Training and Registration Act of 2008, or Emily’s Act, allows the Secretary of Health and Human Services to make grants to states to establish pharmacy technician registration programs that include passing the national PTCB examination, and subsequently complete mandatory continuing education and renewal every two years. The bill would also provide for states that accept grants to comply with the act and to report pharmacy technician errors to the Secretary annually.
NABP Program Review and Training Familiarizes Board Staff with Association Initiatives, Services

NABP hosted its Annual Program Review and Training session at Association headquarters for board of pharmacy staff, both new and those seeking a refresher course, on all NABP programs and services and the use of the Lotus Notes® software. Nineteen participants representing 15 state boards of pharmacy attended this interactive session on July 31, 2008, when they received an overview of the policies and procedures of NABP programs and services, as well as the opportunity to network with other board of pharmacy staff.

The day-long session offered hands-on training with Lotus Notes software and provided detailed information on the processes for accessing licensure transfer application status, viewing and printing North American Pharmacist Licensure Examination® (NAPLEX®)/Multistate Pharmacy Jurisprudence Examination® (MPJE®) score retrieval/score transfer reports, and confirming examination eligibility reports.

Christina Morris, assistant director from the Kansas State Board of Pharmacy, said the information provided during the training session was a valuable tool. “Having never used Lotus Notes before, a general overview of everything was great,” says Morris.

For Jazell Carter, licensing specialist from the Colorado State Board of Pharmacy, the range of information about all the Association’s programs and services was very useful. “I have a better understanding of NABP’s processes and role in the Department of Regulatory Agency’s mission to protect the public health for our state,” says Carter.

Additional topics covered during the Program Review and Training session included:
- Electronic Licensure Transfer Program® (ELTP®), license verification, e-mail, and data transfer functions;
- Healthcare Integrity and Protection Data Bank reporting and NABP Disciplinary Clearinghouse reporting;

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July Session Offers Interactive Training for Board Staff

Held at NABP Headquarters, the Annual Program Review and Training session provides board staff, both new and those seeking a refresher course, with information on the NABP programs and services as well as the use of Lotus Notes® software. Pictured from left to right are: Courtney Frank, licensing representative, establishments, Oregon State Board of Pharmacy; Cindy Parham, assistant to the executive director and director of operations, North Carolina Board of Pharmacy; and Kristin Moore, director of operations, North Carolina Board of Pharmacy.

Board Member Appointments

- Mary Kay Arceneaux, RPh, has been appointed a member of the Colorado State Board of Pharmacy. Arceneaux’s appointment will expire on July 1, 2012.
- David C. Hudson, RPh, has been appointed a member of the Mississippi Board of Pharmacy. Hudson’s appointment will expire on June 30, 2013.
- Jimmy L. White, RPh, has been appointed a member of the Mississippi Board of Pharmacy. White’s appointment will expire on June 30, 2013.
- Deborah A. Lange, RPh, has been appointed a member of the Ohio State Board of Pharmacy. Lange’s appointment will expire on June 30, 2012.
- Donald M. Casar, RPh, has been appointed a member of the Ohio State Board of Pharmacy. Casar’s appointment will expire on June 30, 2012.
- Barton G. Kaderly, has been appointed a public member of the Ohio State Board of Pharmacy. Kaderly’s appointment will expire on June 30, 2012.
The NABP 2008 Symposium will provide attendees with compelling continuing pharmacy education (CPE) sessions focused on exploring the challenges of combating counterfeit drugs and examining the logistics of establishing a behind-the-counter drug class. NABP encourages individuals to share this information with others in their organizations who may wish to attend. Full descriptions of the CPE sessions, additional Symposium information, and registration forms are available in the Meetings Section of the NABP Web site at www.nabp.net.

December 4-5, 2008

**JW Marriott Starr Pass Hotel**

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<th>Time</th>
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<tr>
<td>11:10 - 11:30 AM</td>
<td>Pedigrees: From Tomatoes to Jalapeños to Pharmaceuticals</td>
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<tr>
<td>11:30 - 11:45 AM</td>
<td>California Pedigree Law Update</td>
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<tr>
<td>11:45 AM - noon</td>
<td>Question and Answer Period</td>
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<tr>
<td>Noon - 1:15 PM</td>
<td>Luncheon</td>
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<tr>
<td>1:30 - 5 PM</td>
<td>Joint CPE</td>
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<tr>
<td>1:30 - 1:45 PM</td>
<td>What Are We Going to Do to Counter Counterfeiting?</td>
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<tr>
<td>1:45 - 2 PM</td>
<td>Collaborative Efforts for Tomorrow</td>
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<tr>
<td>2 - 2:10 PM</td>
<td>Question and Answer Period</td>
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<td>2:10 - 3 PM</td>
<td>Roundtable Discussion: The “Haves” and the “Have Nots” of Pedigrees</td>
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<tr>
<td>3:15 - 4:05 PM</td>
<td>Roundtable Discussion: Educating about Internet Drug Safety – Strategies for Informing and Educating Patients</td>
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<tr>
<td>4:10 - 5 PM</td>
<td>Roundtable Discussion: The Dream Team: A Strategy for Combating Counterfeit Drugs</td>
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**Tucson, AZ**

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<tr>
<td>6 - 6:30 PM</td>
<td>Meet and Greet…a networking opportunity</td>
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<td>6:30 - 8 PM</td>
<td>Dinner Under the Desert Sky</td>
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<td>Noon - 1:15 PM</td>
<td>Luncheon</td>
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<td>6:30 AM - 7:15 AM</td>
<td>Qigong Class</td>
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<td>7:15 AM - 8:30 AM</td>
<td>Continental Breakfast</td>
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<td>8:30 AM - 1 PM</td>
<td>Joint CPE</td>
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<td>8:30 - 9:15 AM</td>
<td>BTC Class in Canada</td>
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<tr>
<td>9:15 - 10:30 AM</td>
<td>BTC Issue Overview</td>
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<td>10:30 - 11:15 AM</td>
<td>Federal and State Law Issues</td>
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<tr>
<td>11:30 AM - 1 PM</td>
<td>BTC Point-Counterpoint</td>
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**Note:** The NABP 2008 Symposium 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. ACPE Provider Number: 205. Participants may earn up to 12 contact hours (1.2 CEUs) 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.

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.
Serving as the foundation for the establishment of the Association in 1904, licensure transfer has long been an integral component of NABP and its mission to support the state boards of pharmacy in protecting public health. Over the past year NABP has been focusing on this core service making several improvements to the Electronic Licensure Transfer Program® (ELTP®) system and identifying future enhancements, all of which will provide better service to the boards of pharmacy and the pharmacists transferring their licenses.

After operating licensure transfer for 93 years as a paper-based system, NABP launched ELTP in 1997, providing pharmacists with a quicker means for transferring their existing license from one state or jurisdiction to another through uniform licensure requirements recognized by all 50 United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. This new centralized electronic system allowed for verification of licensure via e-mail, thereby reducing the number of paper verification forms sent to and from the boards of pharmacy.

In late 2007, NABP upgraded ELTP to provide a more user-friendly and accelerated application process, enabling applicants to submit their applications online via an Internet-based form. With this improvement, ELTP application processing can take as little as 14 days, when in the past processing times were averaging between 30 to 60 days. In addition, the state boards of pharmacy experience a lower volume of inquiries regarding application status as applicants now have the ability to log on to their ELTP account and check the status of their applications on their own.

The licensure verification component, a crucial part of the ELTP process, has also been updated to enhance usability for the boards of pharmacy. With the updated process, the boards receive licensure verification requests from NABP via e-mail. These notification e-mails provide the boards with an active link to the licensure verification tool, which allows them to enter any comments or updated information regarding applicants directly into the database from their computers. This not only reduces the paper trail and board time spent faxing back verifications, but further expedites the ELTP process as a whole.

As an added benefit, NABP has restructured the Official Application for Transfer of Pharmacist Licensure (Official Application), providing the boards with concise, structured data that more clearly identifies information such as the applicant’s state of examination and license used as the basis for transfer. In addition, applicant examination scores and profiles are organized into charts, simplifying the appearance of the Official Application.

With the availability of the online ELTP application, the streamlined verification process, and improved layout of the Official Application, the boards of pharmacy can continue to expect expedited licensure transfer times and improved access to pharmacist information.

**Future Enhancements**

These improvements to ELTP are part of a series of enhancements to the current services provided to the boards. To further relieve board staff of resource- and time-intensive tasks, NABP is developing an online portal where boards will be able to access information relating to ELTP, licensure verification, score retrieval, and eligibility reports in one convenient location. In addition, the Association plans to offer a system that will allow the boards to manage licensure and disciplinary data via a secure Web portal. Creation of this system will assist the states and boards of pharmacy with emergency preparedness and response efforts by centralizing necessary resources and building a nationwide volunteer database of pharmacists who wish to volunteer their professional services during a disaster. Upon request, the boards of pharmacy will have access to the most current licensure status of a

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NABP Program Review and Training

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- NAPLEX and MPJE score replication and views, examination score replication, state/school rosters;
- Application, examination, and certification processes for the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification program;
- Verified Internet Pharmacy Practice Sites™ (VIPPS®), Verified-Accredited Wholesale Distributors® (VAWD®), and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation programs.
- Pharmacy Curriculum Outcomes Assessment™ (PCOA®) program; and
- Internet Drug Outlet Identification™ program.

Many of the board staff that attended the Program Review and Training session had positive feedback to share about their experience. “This has been one of the best trainings I’ve attended. It was very informative and helpful,” says Ma’ Lasha V. Norton, a regulatory specialist from the Florida Board of Pharmacy. “NABP staff was very welcoming, helpful, and courteous. I’m glad and honored to work with everyone here.”

This year’s Program Review and Training session was the second that Kelly Kendall, administrative assistant from the Arkansas State Board of Pharmacy, has attended, with the first being in 2007. “I think repeat visits are a good idea. I feel more connected to NABP this way,” she says.

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

ELTP

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specific individual or a full list of all volunteer pharmacists registered within the system.

NABP has been working with state boards to further determine what features will benefit the boards and provide results in the best interest of the patient. Based on this feedback, NABP is also establishing pilot programs to ensure that any system meets the requirements of the state boards of pharmacy. The demand for pharmacists to hold multiple pharmacy licenses continues to escalate each year as demonstrated in 2007 when the number of licensure transfer requests reached a record high of 8,257 requests, an increase of 9% from the number of requests in 2006. (See the article “Licensure Transfer Reaches Record Number of Requests for Ninth Consecutive Year” in the March 2008 issue of the NABP Newsletter.) As this demand rises, NABP is working to provide the boards of pharmacy with the tools to extend their access to pharmacist information beyond their state borders.

Currently, for licensure transfer to take place, applicants must first submit their Preliminary Application online through the NABP Web site with the appropriate fees. Upon receipt, NABP processes the applications. During this process, the Association verifies all licenses with the state boards of pharmacy electronically, and, when possible utilizes information from states’ Web sites for verification. Once the applications have been processed, applicants are issued the Official Application. The applicants then complete all necessary information in the Official Application, including any other specific information beyond their state borders.

Additional information on the ELTP process, state restrictions for transfer, and the online Preliminary Application is available in the Licensure Programs section of the NABP Web site at www.nabp.net.

Licensure Transfer Provides Foundation for Establishment of NABP in 1904

In 1903, during the American Pharmacists Association (APhA) annual meeting, Henry M. Whelpley, then dean of the St Louis College of Pharmacy, expressed the need for a national organization of state boards of pharmacy to develop a system for the exchange of licenses across state borders. In response to Whelpley’s presentation, as well as his earlier proposal in 1901 to create a conference of boards of pharmacy within the APhA section on education and legislation, APhA passed a resolution to hold the first NABP conference during its 1904 annual meeting, marking the beginning of the Association. More than 100 years later, NABP continues to provide its member boards of pharmacy with a means of reciprocating licensure.
District Court Ruling Overturned in Pharmacy Compounding Case

The US Court of Appeals, Fifth Circuit, on July 18, 2008, issued a decision in the case of Medical Center Pharmacy, et al, v Mukasey on the issue of pharmacy compounding. The case originated in the US District Court for the Western District of Texas, when 10 pharmacies specializing in compounding were sued by the US Food and Drug Administration (FDA) for failure to obtain the FDA approval required for “new drugs.” The pharmacies argued that they were engaged in compounding “an approved and legal practice” and that compounded drugs are not “new drugs” under the Federal Food, Drug, and Cosmetic Act. (See the September 8, 2006 NABP e-News under News/Press on the NABP Web site, www.nabp.net.) The appellate court clarified the extent to which the act permits FDA to regulate compounding. Concluding that the act, as amended, permits compounded drugs to avoid the new-drug approval process only in certain statutorily delimited circumstances, the appellate court overturned the judgment and returned the case to the district court for further proceedings as appropriate.

The court’s opinion is available at www.ca5.uscourts.gov/opinions/pub/06-06-5183-CV0.wpd.pdf.

Study Highlights Continued Prevalence of Rogue Internet Drug Outlets

A July 9, 2008 New York Times article, “Abuses Are Found in Online Sales of Medication,” highlights the continued prevalence of Internet drug outlets that operate in conflict with pharmacy practice laws. The article cites the recent report of the National Center on Addiction and Substance Abuse (CASA) at Columbia University, “‘You’ve Got Drugs!’ V: Prescription Drug Pushers on the Internet.” CASA reports that 85% of Web sites selling controlled substance medications do not require a valid prescription, and of those that do, half permit the prescription to be faxed, allowing significant opportunity for fraud. The New York Times article and related media coverage are available under “In the News” in the Internet Pharmacies section of the NABP Web site, www.nabp.net.

FDA Takes Action Against Companies Marketing Unapproved Injectable Colchicine

FDA is taking action against companies marketing injectable colchicine, which is an unapproved form of the drug. Colchicine tablets are not affected by FDA’s action at this time. The injectable form of colchicine is especially hazardous because the therapeutic index is very narrow. Adding to the problem, certain side effects that might alert the clinician that the dose is too high do not appear until the patient has already reached toxic levels. Because of its toxicity and the availability of safer therapies, injectable colchicine is rarely used to treat gout anymore, but some practitioners prescribe it to treat back pain. FDA states that the risks of this treatment outweigh the benefits. FDA also cautions pharmacies against compounding injectable colchicine products. Because of the drug’s toxicity and narrow therapeutic index, any errors that occur during compounding can have potentially fatal consequences.

NABP Seeking ACE Volunteers

NABP is currently accepting applications for volunteers to serve on its Advisory Committee on Examinations (ACE). ACE volunteers oversee the development and administration of all NABP examination and certification programs. ACE typically meets three to four times per year, and considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

ACE is composed of representatives from boards of pharmacy as well as faculty and staff of schools and colleges of pharmacy who exemplify the diversity in pharmacy practice. Pharmacists chosen to serve on ACE must hold an active, unrestricted license in any state or territory of the United States.

Each ACE appointment is for a three-year term beginning June 1, 2009. Current board of pharmacy members, past board of pharmacy members, and actively practicing pharmacists are encouraged to apply.

Interested individuals must submit a written statement of interest and a current resume or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056 or exec-office@nabp.net no later than December 31, 2008.

Please contact the NABP Competency Assessment Department at custserv@nabp.net with any questions regarding ACE.
Nevada Board Now Reciprocates with All Other States

Effective July 1, 2008, the Nevada State Board of Pharmacy now allows reciprocation of pharmacists licensed in all states, including California and Florida. Previous regulatory restrictions prohibited the Nevada Board from accepting reciprocation with California and Florida.

The Board states that for pharmacists to reciprocate a license from California, they must have been issued a license by taking and passing the North American Pharmacist Licensure Examination® (NAPLEX®); therefore, only California pharmacists who were licensed after January 1, 2004, will be accepted.

There are no restrictions for pharmacists reciprocating from Florida. The Board is hoping that this change in regulation will encourage more pharmacists to seek employment in Nevada.

WA Board Adopts Pharmacy Technician Standardized Examination Requirement

At a public hearing held on May 29, 2008, the Washington State Board of Pharmacy adopted rule changes that result in new requirements for certification as a pharmacy technician. Effective January 1, 2009, all technician applicants must pass a national standardized examination. In addition, all applicants are still required to complete a Board-approved technician training program. The rule does not pertain to individuals who obtained a pharmacy technician credential before January 1, 2009; therefore, they are exempt from the new standards.

In the next few months, the Board will be developing the criteria for a Board-approved examination. The plan for applying the rule includes adopting examination standards and identifying which examination(s) are Board-approved. The rule changes also require updates to the basic standards for Board-approved training programs. Updates to the proposed rule will be posted on the Washington State Board of Pharmacy Web site at https://fortress.wa.gov/doh/hpsa1/hps4/Pharmacy/default.htm (WAC 246-901-030 & 060).

AZ CS Prescription Monitoring Program Forges Ahead

The Arizona State Board of Pharmacy announced that the Arizona Prescription Monitoring Program (PMP) has made significant progress over the last few months. The program has selected a vendor after a lengthy and rigorous procurement process. The vendor, Health Information Designs (HID) of Auburn, AL, began testing the system in late July 2008 with the cooperation of a few independent and chain pharmacies. If testing results are satisfactory, data will begin being collected from both resident and nonresident pharmacies for the week ending October 11, 2008. The pharmacies should report the data to HID by October 17, 2008. Pharmacies were sent a dispenser manual from HID in late July that contained instructions for formatting and uploading the data. Most, if not all chain pharmacies, will be able to batch upload from their corporate headquarters, so individual pharmacies will not be involved with the data uploads. Pharmacies have until October 31, 2008, to provide all Schedule II through Schedule IV prescription data for the six months retroactive from April 1, 2008, prior to PMP’s implementation.

LA Board Proposes New Chapter for Controlled Dangerous Substances Regulation

The Louisiana Board of Pharmacy recently proposed an entirely new chapter of rules for controlled substances. The new chapter contains the current rules applicable to pharmacies in addition to all the rules necessary for all other controlled dangerous substance licensees. The Board was granted responsibility for the issuance of all controlled dangerous substance licenses in the state when the 2006 Louisiana Legislature transferred the responsibility from the Department of Health and Hospitals. The proposed rule and the promulgation process is available on the Louisiana Board of Pharmacy Web site in the Meetings & Notices section at www.labp.com.

New Jersey Announces Online Registration Application for Out-of-State Pharmacies

The New Jersey Board of Pharmacy recently posted its application for the registration of out-of-state pharmacies on the Board Web site. According to NJAC 13:39-4.19(a), which was adopted on November 19, 2007, “Any pharmacy located in a state other than New Jersey (hereinafter ‘out-of-state pharmacy’) that ships, mails, distributes or delivers in any manner, legend drugs or devices or controlled dangerous substances pursuant to a prescription into the State, or which participates in a central prescription handling arrangement pursuant to N.J.A.C. 13:39-4.18, shall be registered with the Board pursuant to this section.” The application can be found at www.state.nj.us/oag/ca/medical/ pharmacy.htm.
NABP Chairman Peacock Receives Prestigious Harold W. Pratt Award from NACDS for ‘Collaborative Spirit,’ Leadership

Oren M. Peacock, Jr, RPh, chairperson of the NABP Executive Committee received the prestigious Harold W. Pratt Award from the National Association of Chain Drug Stores (NACDS) on August 26, 2008. Peacock was presented with the award, which is the association’s highest honor, at the 2008 NACDS Pharmacy & Technology Conference.

“As an association, the most fundamental thing we must do is work together, and Oren embodies the collaborative spirit of NACDS,” said NACDS President and Chief Executive Officer Steven C. Anderson, IOM, CAE. “Viewed as a mentor by many, Oren is known for his ability to bring people together to discuss critical issues in a professional, dignified manner. He is an outstanding leader, and his presence has been a valuable addition to numerous pharmacy-related groups.”

NABP experienced the leadership described by Anderson first hand through Peacock’s tenure on the NABP Executive Committee. He was first elected to the Executive Committee in 2003 as a member representing District 6. After his three-year term he was elected president-elect and subsequently assumed the position of president and now chairperson of the Executive Committee.

“Oren is very deserving of this award,” said NABP President Rich Palombo, RPh. “During his term as NABP president in 2007-2008, he took the initiative to assess the status of quality outcome and peer review regulations in the states and in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy among several other accomplishments that furthered the cause for protecting public health.”

A former member of the Texas State Board of Pharmacy, Peacock was first appointed to the Board in 1996 and then reappointed for an additional term in 1999. While on the Board he served as president from 1998 to 1999 and from 2004 to 2005.

Peacock has contributed his time and efforts to many NABP committees and task forces, including the Task Force on Centralized Prescription Filling, the Committee on Constitution and Bylaws, the Committee on Resolutions, and the Task Force on the Evaluation and Modification of the NABP Constitution and Bylaws. In addition he has served on the Task Force to Develop Recommendations to Best Reduce Medication Errors in Community Pharmacy Practice. Peacock is also a member of such professional associations as the Dallas County and Texas Pharmacy Associations, American Pharmacists Association, and the Texas Federation of Drug Stores. He currently serves on the University of Texas and Texas Tech College of Pharmacy dean’s advisory council.

Currently, Peacock is a consultant for CVS Caremark. Before the change in ownership, he steadily progressed through the ranks of the Eckerd Corporation to the position of vice president of pharmacy relations. He graduated from the University of Texas College of Pharmacy with a bachelor of science degree in pharmacy.

Harold W. Pratt Award Recognizes Leaders in Pharmacy

The annual Harold W. Pratt Award, established in 1985 by the NACDS Board of Directors, recognizes individuals whose activities have contributed to the promotion, recognition, and improvement of the practice of pharmacy within the chain drug industry. The award’s namesake, Harold Pratt, dedicated himself to many years of service at Walgreens, becoming the industry’s first director of professional services. Over the course of his 43 years of service to Walgreens, Pratt came to be recognized as the “dean” of pharmacy professional service directors. He worked tirelessly to grow and promote pharmacy operations, and he was asked by NACDS to organize and chair its first pharmacy conference.
ACE Continues Mission to Safeguard Integrity, Validity of NABP Examinations

Members of the Advisory Committee on Examinations (ACE) convened on August 13, 2008, to discuss NABP examination and certification programs. Pictured from left to right are: Betty J. Dong, PharmD, professor of clinical pharmacy, University of California, San Francisco; Richard "Dick" Morrison, RPh, pharmacy investigator, Washington State Board of Pharmacy; Karen M. Ryle, MS, RPh, NABP Executive Committee liaison; Michael Duteau, RPh, member, New York State Board of Pharmacy; Tom Houchens, RPh, FASCP, director of pharmacy services, Laurel Housing Inc; Kendall M. Lynch, DPh, vice president, Maxor Correctional Pharmacy Services; Richard K. “Mick” Markuson, RPh, former executive director, Idaho State Board of Pharmacy; Arthur I. Jacknowitz, MS, PharmD, professor and distinguished chair, West Virginia University School of Pharmacy; Kevin Rynn, PharmD, FCCP, clinical associate professor, Rutgers University; and David Todd Bess, PharmD, member, Tennessee Board of Pharmacy.