‘Pharmacists Without Borders’: Another Record Number of Licensure Transfers

Threats to the public health – such as Hurricane Katrina and pharmacist shortages in some areas – as well as economic and population trends, are necessitating greater mobility among pharmacists in some cases and presenting new opportunities in others. Concurrently, technological advances are allowing pharmacists to practice in more than one state – and gain that capability quickly.

A major factor that has increased the mobility of pharmacists to practice across state lines is the growth of Internet pharmacies; several states, such as Kentucky, have begun to require pharmacists at mail-order pharmacies from other states that do business in Kentucky to obtain licenses to practice pharmacy in Kentucky. The Kentucky Legislature passed Senate Bill 63 in July 2005, which amended Section 315.0351 to require “Every person located outside this Commonwealth which, other than on an incidental basis, physically or by means of the Internet, facsimile, phone, mail, or other means . . . shall hold a current pharmacy permit . . . issued by the Kentucky Board of Pharmacy.” In 2005, pharmacists made 365 NABP Electronic Licensure Transfer Program® (ELTP®) requests to practice in Kentucky compared with 115 in 2004.

Another indication of the impact of the Internet and mail order on pharmacist mobility is the fact that, of the 7,489 ELTP requests, 1,150, or about 15%, represented a request to practice pharmacy in two or more states besides the pharmacist’s home state.

For the seventh consecutive year, pharmacists working under the jurisdiction of NABP’s member boards of pharmacy have requested a record number of licensure transfers. In 2005, the total of 7,489 requests surpassed the record of 7,292 established in 2004 by 2.7%. The program first (continued on page 63)
NABP Accredits First Two Wholesale Distributors Through VAWD Program

NABP announced on February 8, 2006, that CVS/Pharmacy’s Distribution Center in Indianapolis, IN, and US Oncology, Inc’s Fort Worth, TX facility successfully completed NABP’s Verified-Accredited Wholesale Distributors™ (VAWD™) program’s comprehensive criteria and on-site inspection to earn distinction as the first two wholesale distributors accredited by NABP. The accreditation of CVS/Pharmacy’s distribution facility and US Oncology Specialty, LP, represent a concerted and cooperative effort between state boards of pharmacy and wholesale distributors to protect the public from counterfeit drugs and continue to secure the integrity of the United States medication distribution supply chain.

“VAWD accreditation assures stakeholders and the public that wholesale distributors are appropriately licensed, have undergone intense background checks, and employ security and due diligence practices for safely distributing prescription drugs,” says NABP President Dennis K. McAllister, RPh. “NABP’s VAWD program performs extensive evaluation of wholesale distributors’ licensure status, conducts disciplinary screening through NABP’s Clearinghouse, performs criminal and financial background checks, reviews policies and procedures, and completes on-site inspections of wholesale distributor facilities at no cost to the states and with the assurances of NABP that the wholesale distributor is operating legally and in conformance with state laws and regulations.”

The VAWD program is rapidly becoming the national standard for safeguarding of the wholesale drug distribution chain.

“As a senator and a pharmacist in the state of Indiana, I can say with great confidence that Indiana’s requirement to have wholesale drug distributors accredited by NABP’s VAWD program, will help protect the integrity of the drug supply chain in our great state,” says Indiana Senator Marvin Riegelhette, RPh (R-Goshen). “I am hopeful that other states will take similar steps to ensure the safety of patients all across the country. As pharmacists, we are the last line of defense before the patient receives their medication. Indiana’s law and the VAWD program give us the confidence to dispense that medication, knowing that the medication has passed through a secure drug supply chain.”

CVS/pharmacy is America’s largest retail pharmacy, operating more than 5,400 retail and specialty pharmacy stores in 37 states and the District of Columbia. CVS/Pharmacy’s Distribution Center in Indianapolis has operated since 1961, serving approximately 1,400 CVS/pharmacy locations in 12 states.

“We are pleased to be the first retail pharmacy in the nation to receive VAWD accreditation from the National Association of Boards of Pharmacy,” says Matt Leonard, senior vice president of pharmacy at CVS/pharmacy. “We view this accreditation as a reliable and practical means of preserving the safety and integrity of the pharmaceutical supply chain. We engaged in this process as a way to further our commitment toward safeguarding the health and safety of our patients. CVS/pharmacy is proud to receive the VAWD accreditation, and we appreciate NABP’s commitment to this important issue.”

US Oncology, Inc, is one of the nation’s largest health care service networks dedicated exclusively to cancer treatment and research. In 2005, US Oncology launched US Oncology Specialty, LP, a specialty pharmaceutical distribution business to facilitate the seamless flow of oncology
NABP Executive Committee December 2005 Meeting Actions

During its December 1, 2005 meeting, NABP’s Executive Committee discussed and took action on the following items.

Emergency Response Plan
The issue of whether or not NABP could develop a model plan for when a disaster strikes, in order to assist the member boards, was raised. It was agreed that general guidelines for boards to use in a disaster should be developed. The Committee also discussed components of a model disaster plan. A model disaster plan will be prepared for the Executive Committee at an upcoming meeting.

Henry Cade Memorial Award
The Executive Committee reviewed and approved the following revised criteria for the Henry Cade Memorial Award:

- Purpose
  - The Henry Cade Memorial Award is awarded to an individual(s) who has supported the goals and objectives of the Association and the state boards of pharmacy to protect the public health and advanced the need to maintain the safety and integrity of the distribution and dispensing of medications.

- The Executive Committee selects an individual(s) to receive the award, presented during the Annual Awards Dinner at the Annual Meeting.

NABP to Share Information at APhA Meeting

During the American Pharmacists Association’s Annual Meeting & Exposition, which will take place March 17-21, 2006, in San Francisco, CA, representatives from NABP will be in Booth 145 to display posters and multi-media presentations highlighting online registration for the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (NPJE®).

Call for Committee, Task Force Participants

NABP is seeking volunteers from its active member boards of pharmacy to serve on the Association’s 2006-2007 committees and task forces. Interested board of pharmacy executive officers, members, and staff are encouraged to submit a letter of interest and a current resume or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone by Friday, May 26, 2006.

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.

NABP President-elect Lawrence H. Mokhiber will make the appointments when he becomes NABP president following the 102nd Annual Meeting, to be held April 8-11, 2006, at the Westin St Francis in San Francisco, CA.

Executive Committee

Donna M. Horn
Chairperson, District I
One-year term

Dennis K. McAllister
President, District VIII
One-year term

Lawrence H. Mokhiber
President-elect, District II
One-year term

Charles R. Young
Treasurer, District I
One-year term

Charles Curtis “Curt” Barr
Member, District V
Serving second year of a three-year term

Reginald B. “Reggie” Dilliard
Member, District III
Serving first year of a three-year term

John R. Dorvee, Jr
Member, District I
Serving first year of a two-year term

Patricia F. Harris
Member, District VIII
Serving first year of a three-year term

Richard A. Palombo
Member, District II
Serving second year of a three-year term

Oren M. Peacock, Jr
Member, District VI
Serving third year of a three-year term

Gary A. Schnabel
Member, District VII
Serving third year of a three-year term

William T. Winsley
Member, District IV
Serving first year of a three-year term

NABP’s Executive Committee is elected each year at the Association’s Annual Meeting. The 102nd Annual Meeting is April 8-11, 2006, at the Westin St Francis in San Francisco, CA.
Legal Briefs

Impugned Immunity = Impunity

The authority of a board of pharmacy to regulate the profession to the extent that the activities of licensees impact only individuals located in a foreign country presents interesting legal issues related to jurisdiction and board powers. As technology allows and, indeed, promotes international commerce issues, the legal authority of regulatory boards to regulate global activities will continue to surface and be subjected to potential challenge. Intertwined in the legal challenges will be issues interpreting state and federal constitutions. Issues addressing the immunity of boards, board members, and executive directors and administrators usually accompany legal challenges requesting judicial opinions on these complex jurisdictional issues. Consider the following.

A licensed pharmacist (licensed in 1991), who also acted as the sole owner, president, and operator of a licensed wholesaler (licensed in 1995), began to export pharmaceuticals to foreign countries. The pharmacist, as sole owner, made all decisions regarding the shipment of such pharmaceuticals to foreign countries. The California State Board of Pharmacy (Board) brought an administrative action against the license of the pharmacist and permit of the wholesale distributor, seeking to revoke or suspend the license and/or permit based upon the exportation of drugs. The Board alleged that the licensee and permit holder dispensed drugs without a license as a pharmacy (as opposed to a wholesale permit); failed to obtain a Drug Enforcement Administration registration to dispense and export dangerous drugs; and transferred, sold, or delivered dangerous drugs outside the United States to persons unauthorized by local and international law to receive such drugs. Each of these acts is prohibited under the applicable portions of the California Business and Professional Code relating to the regulation of the practice of pharmacy.

After the initiation of the administrative action, the pharmacist and wholesaler (collectively referred to as plaintiff) brought suit in federal district court against the Board and its executive director, claiming that the administrative proceedings attempting to discipline his pharmacist license and wholesale permit were in violation of the Commerce Clause of the US Constitution. The plaintiff sought declaratory and injunctive relief challenging the constitutionality of the statute and seeking to enjoin its application to the plaintiff.

The plaintiff alleged that the attempted assertion of authority by the Board over the plaintiff's license and permit, respectively, violated the Constitution in that the action was based on conduct that took place entirely in foreign commerce and was, thus, an extraterritorial application of the laws of California and an attempt by California to regulate the conduct of foreign commerce. As rephrased by the court, the issue was whether or not the Commerce Clause of the US Constitution overrides
the disciplinary authority of the State of California with respect to conduct that has occurred solely in the foreign commerce of the US and that has no separate effects within that state.

The Board and its executive director filed motions to dismiss under applicable Federal Rules of Civil Procedure, claiming that the plaintiff failed to state a claim upon which relief could be granted and alleging that the court did not have jurisdiction over the subject of the plaintiff’s claims. Under procedural motions to dismiss, the court accepts as true the allegations of the plaintiff and will only dismiss a matter if it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim(s) that would entitle him to relief. Motions to dismiss are procedural and, thus, not based upon a determination(s) on the merits of the complaint.

The Board and its executive director argued that the case should be dismissed because:

- The state has sovereign immunity under the 11th Amendment of the US Constitution;
- The state is not a “person” as defined under §1983;
- The Board and its officers have absolute immunity from suit; and
- Various abstention doctrines apply precluding the federal courts from exercising jurisdiction over a matter before the state proceedings are completed.

Addressing the 11th Amendment, the court noted that such sovereign immunity extends to state agencies and other governmental entities that can be viewed as an “arm of the state.” A state and its “arms” are immune from suit in federal court under the 11th Amendment, driving certain legal disputes to state court. However, in the instant matter, the court noted that the Board neither provided any evidence “nor even made any argument as to why the Board is a State agency or arm of the State.” Because the Board is asserting the protections under the 11th Amendment, it bears the burden of showing that it is an arm of the state. Thus, the court held that because no evidence was presented to establish that the Board was an arm of the state, the 11th Amendment argument must fail.

As applied to the executive director, the court held that, while sovereign immunity may protect a Board as an arm of the state, it does not protect the executive director because the plaintiff does not seek any monetary damages. In the instant case, the plaintiff only sought declaratory and injunctive relief to enjoin actions alleged to violate federal law. Thus, the court held that the 11th Amendment sovereign immunity as applied to the executive director must also fail.

Section 1983 refers to a citation to federal law that authorizes claims against any “person” who, under color of state law, causes a US citizen to be deprived of any rights, privileges, or immunities secured by the US Constitution and federal laws. Regarding the allegations that the Board, as an arm of the state, is not a person under §1983, the court reiterated that the Board placed nothing of record showing that the Board is an arm of the state. Thus, the court quickly rejected the argument of the Board seeking dismissal of the action.

Turning its attention to the executive director, the court held that the plaintiff is not precluded from seeking injunctive and declaratory relief under §1983 against the executive director in
Nonetheless, change may be in the air, impelled by technological advances and federal decree. At some point, will the pharmacy profession move toward a more mobile licensure model – a more “national” licensure model? Not surprisingly, such a concept raises many questions and concerns for the state boards of pharmacy. Nonetheless, some feel that a change in the way licensure is handled may be a question of “when” rather than “if.” The issue is whether or not licenses can be more national in scope while preserving state pharmacy boards’ individual control.

The Case for Change

The past two decades have ushered in changes in the practice and regulation of pharmacy, blurring some traditional state boundaries. Technology, of course, is part of the reason. Telepharmacy and the Internet are increasing patient convenience and offer some promise for alleviating problems resulting from pharmacist shortages. “Now we move medications across state lines,” says Philip Burgess, national director of pharmacy affairs for Walgreen Co (and a member of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy, though he is not speaking for the Board in this case). “Technology is not limited by state boundaries.”

The federal government – largely by trying to grapple with the complexities and expenses of health care on the national level – has also raised more issues to a national level. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) impacts state boards in a number of ways, including a preemption of state regulations in the area of e-prescribing (see “Medicare Part D Impacts on State Boards,” NABP Newsletter, January 2006, page 1).

A cry from the public and Congress for uniformity of regulations has cropped up lately, usually focused on specific issues: pseudoephedrine or the aforementioned e-prescribing, for example. Licensing may now have entered that arena as well. National attention to the role of wholesale drug distributors in the counterfeit drug problem, and to the ability of some unscrupulous wholesalers to stay in business despite state licensing requirements, has caused some to consider national licensing requirements as a positive. Overall, the recent trend has been toward a preemption of state law by federal laws.

Because of these factors, “In the future, I see a turf battle between federal agencies and state agencies,” says Burgess. He feels the time is right to look at models for national licensure. At the
same time, he feels that the term “national licensure” is misleading and shuts down the debate before it starts. “The term ‘national licensure’ conjures up some federal agency in Washington controlling pharmacy in each state,” he says. “That is not what I see. The term ‘national licensure’ sends out warning signals that are not necessarily valid.”

What Burgess does see are the faint beginnings of a debate about what he prefers to call “multi-state licensure.” Burgess warns, “It is a very complex issue and would need a lot of thought and evaluation. But it is appropriate for the dialogue to start.”

Burgess himself does not propose any specific model for multi-state licensure. But he sketches out one possible scenario: A pharmacist graduates from pharmacy school and obtains his or her license in the state of his or her residency. Later, perhaps, the pharmacist would go through a second application process for a multi-state license. “The bottom line is patient care,” says Burgess. “How do we set up a system to maximize technology to serve patients’ needs?”

Roadblocks
Not everyone feels that any move toward national or multi-state licensure needs to happen. “I do not see that it is needed,” says Bryan H. Potter, executive director of the Oklahoma State Board of Pharmacy. “Pharmacists have the best reciprocity of any [health care] profession. It’s very streamlined.”

Even if an argument could be made that pharmacist licensure flexibility could be improved, a number of sticky problem areas remain. Richard K. “Mick” Markuson, executive director of the Idaho Board of Pharmacy, raises a few of them: “You cannot practice [in a particular state] until you know the state laws . . . Every state has a different law exam,” he points out. And under whose jurisdiction would discipline be handled? “If you took away [a pharmacist’s] license in one state, is it taken away in every state?” he asks.

One of the most complicated problem areas is an economic one. Loss of license revenues “would destroy the boards,” says Markuson – particularly those that act as independent agencies and rely on licensing fees for a large part of their budgets. In NABP’s 2005 Biennial Resources and Responsibilities Survey (see NABP Newsletter, October 2005, page 169), 14 of 43 participating boards did not receive legislative appropriation for their budgets; given the cash-strapped position of many state governments, the loss of licensing fees could severely curtail regulation and enforcement capabilities. “It is a very poor idea,” Markuson sums up.

Potter agrees. “National licensure would be a sad state of affairs for public health,” he says. Assuming a centralized licensing and enforcement model, Potter says, “Public health is better served by a state board of pharmacy than a federal board of pharmacy.” He cites criticisms that have been directed at Food and Drug Administration (FDA), noting that FDA has not been adequately funded for the enforcement activities it is expected to carry out. “That is what you would have with national licensure,” he says.

Any sort of federal management of pharmacist licensure, both Markuson and Potter point out, raises the red flag of federal infringement of states’ rights, something few state legislatures are likely to be enthusiastic about. “License and disciplining those licenses must remain with the states,” says Markuson.
State Boards, Associations Addressing Patient Safety Improvement and Medical Error Mitigation on Multiple Fronts

In the 1999 report To Err is Human, the Institute of Medicine reported that 98,000 deaths per year can be attributed to medical errors. Total national costs (lost income, lost household production, disability, and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated at $17 billion to $29 billion, of which health care costs represent over one-half, according to an article titled “Costs of Medical Injuries in Utah and Colorado” published by Inquiry the same year. Patient safety and medication errors are, and will continue to be, a major public health concern.

Amid this concern, state boards of pharmacy have a unique opportunity to promote and implement regulatory initiatives for improving patient safety and minimizing the incidence of medication errors. NABP’s mission is to assist the state boards of pharmacy by developing, implementing, and enforcing uniform standards for the purpose of protecting the public health under the direction of the state boards of pharmacy. NABP, under the direction of the Executive Committee, has been at the forefront in various initiatives concerning patient safety.

NABP has developed regulatory guidance for the state boards of pharmacy. In December 2002, NABP convened the Task Force on Transition of Pharmacy Regulation from the Dispensing Process to Outcomes. Task Force members assessed the status of NABP’s Regulating for Outcomes initiative and prepared recommendations for the NABP Executive Committee that would assist states in transitioning current regulations from focusing on dispensing to patient care outcomes. Recommendations from this task force included a stronger emphasis on the reporting of medication errors via continuous quality improvement (CQI) programs.

Subsequently, the Task Force to Develop Recommendations to Best Reduce Medication Errors in Community Pharmacy Practice (Medication Errors Task Force) met in December 2004. This Task Force developed a number of recommendations for the Executive Committee concerning error reporting programs, CQI programs, and the formal education of health care professionals in practice and in training.

Error Reporting Systems Urged

The Medication Errors Task Force recommended that the Executive Committee encourage the state boards to require pharmacies to document and report medication error incidents to national patient safety programs such as the Institute for Safe Medication Practices’ (ISMP) and United States Pharmacopeia’s (USP) jointly operated Medication Errors Reporting Program (MERP). Other voluntary error reporting programs include two operated by Food and Drug Administration (FDA): the Vaccine Adverse Event
Reporting System and MedWatch, which is used to report medication errors or adverse reactions occurring after the use of medications or devices.

At the federal level, in July 2005, President George W. Bush signed the Patient Safety and Quality Improvement Act mandating a non-punitive reporting system for medication error reporting. According to this bill, all reported information will be organized into a patient safety database that will be available to the public. This database will be analyzed for national and regional trends. Those contributing to this database may be protected from an employer seeking punitive actions against them. Although the specifics remain unclear regarding when the reporting system will be established and functional, it is hoped that the system will encourage health care professionals and organizations to willfully report medication errors to ultimately improve patient safety and health care quality in practice settings.

The Medication Errors Task Force also advised the Executive Committee to urge NABP to continue to work with the boards to assess, develop, and implement best practices/non-punitive regulations and enforcement actions that are aimed to promote patient safety and medication error reduction. Many state boards have mandated that pharmacies develop and implement CQI programs. As defined in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act), a CQI program is “a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use.” According to the 2006 Survey of Pharmacy Law, approximately 15 states mandate CQI programs in various pharmacy practice settings.

In addition to mandated CQI programs, state boards also serve as a great resource in educating the profession about reported medication errors. In fact, the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) recommends sharing medication error incidents with other health care professionals via newsletters, journals, or bulletins. For example, NABP partners with ISMP to convey specific medication error occurrences via the National Pharmacy Compliance News section of the state boards of pharmacy newsletters. ISMP prepares a column to alert pharmacists about medication errors and provide them with recommendations to avoid these errors. ISMP also publishes the ISMP Medication Safety Alert!, a monthly newsletter based on actual practitioner medication error reports and prevention recommendations reported to the ISMP-USP MERP.

**Education, Professional Development Emphasized**

The Medication Errors Task Force also discussed the educational component of patient safety and medication error prevention. State board-mandated continuing education (CE) on the topics of patient safety and medication errors may serve as one means to (continued on page 66)
States Working to Secure Drug Supply Chain

With the increased awareness of the proliferating threat of prescription drug counterfeiting, state legislators and boards of pharmacy are taking heed, as indicated by a great deal of recent legislative activity relating to the safeguarding of the United States wholesale drug distribution system.

NABP’s role in assisting states in protecting the drug distribution system increased greatly when, in 2003, Food and Drug Administration requested that NABP update its Model Rules for the Licensure of Wholesale Distributors (Model Rules). With the input of Boards of Pharmacy, pharmaceutical manufacturers, wholesale drug distributors, pharmacies, and other key industry stakeholders, NABP has made significant changes to the Model Rules.

The updated Model Rules bring about three tiers of change to many of the existing state statutes:

- The first tier of change increases the licensing requirements for wholesale drug distributors and provides authority for the state boards to recognize an accrediting body to help curb the fiscal and operational impact on the state boards. This tier fills many of the holes in the existing regulatory model;
- The second tier of change requires pedigrees, thus enhancing security and integrity in the drug supply chain; and
- The third and final tier increases criminal penalties for counterfeiting.

In addition to the updates to the Model Rules, NABP has been actively involved in efforts with groups at the national level to obtain a secure and transparent drug distribution system. At the state level, NABP has assisted state boards of pharmacy in Indiana, Iowa, Kansas, Maryland, Nebraska, New York, Oklahoma, Oregon, and Washington by providing either legislative testimony or feedback on language as they developed legislation. According to the state boards and members of state legislatures, this support, and the Model Rules and NABP’s Verified-Accredited Wholesale Distributors™ (VAWD™) program, have been invaluable resources in legislation development.

2005 Legislative Activity

Thanks to the early efforts to protect the drug supply of Florida, California, and Nevada, many states found similar legislative success in 2005. NABP is proud to report that many components of the Model Rules were incorporated into several state legislative efforts.

Major victories for the safeguarding of the wholesale drug supply at the state level were recorded in 2005. Below is a description, although not all-inclusive, that provides a summary of 2005 state legislative efforts.

In Arizona, House Bill (HB) 2193 requires pedigrees for drugs that leave the normal distribution channel. The law also requires each wholesaler to identify a designated representative and obtain a $100,000 surety bond.

Arizona’s law also authorizes the Arizona State Board of Pharmacy to conduct a criminal background check on the designated representative and sets standards for drug returns.

Indiana Governor Mitch Daniels signed into law HB 1098, which requires existing license holders to obtain VAWD accreditation prior to renewing their licenses on September 30, 2006, and requires new wholesaler applicants to obtain VAWD accreditation if their license was not issued prior to January 1, 2006. Indiana’s law requires pedigrees for legend drugs that move outside of the normal distribution chain of custody and establishes the authority for the Indiana Board of Pharmacy to
establish a track-and-trace electronic pedigree system. HB 1098 also establishes criminal penalties for counterfeiting drugs.

**Iowa** passed HB 882, which incorporates language from the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*. The law defines pedigree and gives the Board of Pharmacy rule promulgation authority to set pedigree requirement circumstances. Iowa’s law also sets prohibited acts and establishes criminal penalties for knowingly counterfeiting drugs and devices.

**New Jersey** Senate Bill (SB) 1753 establishes more stringent licensure requirements, including a surety bond, criminal history background checks, and a designated representative for each wholesale distributor. The New Jersey law requires pedigrees and sets criminal penalties for counterfeiting.

In **New Mexico**, SB 413 defines pedigree and requires the New Mexico Board of Pharmacy to promulgate rules regarding requirements for pedigrees.

In **Oklahoma**, Governor Brad Henry signed into law SB 640 and HB 1347. Oklahoma’s law recognizes the VAWD program and provides for a waiver of certain requirements for entities that obtain the accreditation. Like Indiana, Oklahoma also requires pedigrees for products that move outside of the normal distribution chain of custody.

In **Texas**, HB 164 requires wholesalers to complete a comprehensive application, a criminal history including fingerprints, and obtain a $100,000 surety bond. The law also requires pedigrees for drugs that do not go through the “normal chain of distribution.”

In **Virginia**, SB 1326 defines pedigree and requires the Virginia Board of Pharmacy to promulgate rules to establish a pedigree system.

**2006 Legislative Activity**

Following the flurry of legislative activity on this issue in 2005, NABP fully expects 2006 to be just as busy for the state boards of pharmacy. The following are some examples of early activity in which NABP has been involved so far in 2006.

NABP presented information to the **Maryland** Board of Pharmacy on counterfeiting, and how the Model Rules and the VAWD program provide the safeguards to protect the drug distribution system.

In **Nebraska**, Legislative Bill (LB) 318 was initially introduced in 2005 and, as of press time, is still pending before the Nebraska legislature. It would require wholesalers to obtain a license; provide pedigrees for all sales, trades, and transfers of prescription drugs outside of the normal distribution chain; provide criminal and business background information; and submit to a state examination, among other safeguards. NABP provided feedback to the Nebraska Board of Pharmacy on LB 318. The bill’s language was amended to require facility inspections, allowing for a “nationwide recognized accreditation program” to conduct the inspection. The amended bill also establishes licensing requirements and standards and required licensure of all nonresident wholesale distributors.

At the request of the **Washington** State Board of Pharmacy, NABP has provided information on the Model Rules and the VAWD program. Legislation being discussed includes language from NABP’s Model Rules and also authorizes the Board to use an outside accrediting agency, such as NABP, to accredit wholesalers. Washington’s legislation also requires the Board to set requirements for pedigrees for drugs that move outside of the normal distribution channel.

**Idaho Requires Inspections**

The Idaho Board of Pharmacy has found an alternative way to protect the supply chain, despite not having made legislative changes to the state’s wholesale distributor statutes.
her official capacity. A state official, when sued for injunctive relief, is a person as defined under §1983 according to the case law. Thus, the court denied the defense that the executive director is not a person as defined under §1983.

The Board and executive director next argued that the defense of absolute immunity, also phrased as prosecutorial immunity, precluded the lawsuit from proceeding. In addition, the Board and executive director argued that judicial immunity also acted as a bar to the litigation. Citing previous immunity cases, the court rejected these arguments. The court stated that the defense of immunity, whether absolute or judicial, does not apply to suits for injunctive relief under §1983. Thus, the court rejected the defense of immunity argued by the Board and executive director.

Finally, the court addressed the defense arguments that the federal court should abstain from hearing the matter and defer to the state court for initial adjudication. Under what is referred to as the Burford Abstention doctrine, federal courts decline to interfere with state court proceedings or orders of state administrative agencies:

- Where there are difficult questions of state law bearing on policy problems of substantial public import; or
- Where the exercise of federal review of the question in the case would be disruptive of state efforts to establish a coherent policy with respect to a matter of substantial public concern.

In rejecting the arguments of the Board that the regulation of pharmacy practice and the distribution of dangerous drugs are of substantial bearing on public concerns, the court concluded that the Burford Abstention doctrine did not apply to the current matter. The court stated that the question in the instant case is essentially a pure constitutional challenge that would not intrude on the state process. It held that federal constitutional issues are easily separable from complicated state issues. Thus, the Burford Abstention doctrine was rejected as a defense to the suit.

The court also addressed the Board defense that the Younger Abstention doctrine also precluded the litigation. Under Younger, federal courts examine whether or not the relief sought in the federal court would interfere in some manner with the state court litigation. Application of the Younger Abstention doctrine generally directs federal courts to refrain from granting injunctive relief that would interfere with pending state court proceedings. Abstention in favor of state court proceedings is required if:

- State proceedings are ongoing;
- State proceedings implicate important state interests; and
- State proceedings provide the plaintiff with an adequate opportunity to litigate the federal claims.

The parties agree that, by virtue of the administrative proceedings, there are state proceedings that are ongoing. Thus the court focused on the second and third prongs of the test.

After an analysis of the importance of regulating the profession and distribution of pharmaceuticals, the court determined that important state interests are implicated. However, the court held, regarding the third prong, that the plaintiff in the current matter would not be provided with an opportunity to litigate the federal claims because the Board was unable to hear and determine constitutional matters. With the potential for sanctions of revocation of the pharmacist license and wholesale permit at stake prior to the adjudication of any constitutional claims, the court held that the plaintiff did not have an adequate opportunity to litigate these issues in the state administrative proceedings. Thus, the court held that the third prong was not met and the defense by the Board of the Younger Abstention doctrine failed.

Based upon the failure of all defenses argued by the Board and executive director, the court denied the motion to dismiss and the matter is ripe for litigation on the merits.

This decision presents an illustration of many procedural matters related to litigation against a board of pharmacy and its executive director. The principles of immunity and contemporaneous proceedings in a state administrative tribunal and a federal court are discussed. In this case, the Board and executive director were unsuccessful in forcing the dismissal of the matter.  

Adibi v California State Board of Pharmacy, 393 F. Supp. 2d 999 (D.C. CA 2005)
NABP’s State Newsletter Program Provides Updates on Regulatory Issues, New Laws to Pharmacists

NABP’s State Newsletter Program, originally named the Bureau of Voluntary Compliance, has been a part of NABP’s programs since 1979. Currently, 34 states participate in the program with six of these states providing their newsletters exclusively in an electronic (e-newsletter) format on NABP’s Web site at www.nabp.net.

In 1979, Smith, Kline, and French Laboratories approached the NABP Executive Committee with a unique proposal: they offered NABP an unrestricted grant for a two-year period, but the funds were only to be used for “promoting voluntary compliance of pharmacy and drug law.” Thus, the Bureau of Voluntary Compliance was born with 16 states participating in the first year.

NABP recently interviewed three of the state boards of pharmacy that have participated in the program for 27 years — since the program’s inception. Following are some of their comments and advice for those boards that are thinking of joining the program.

According to Former North Carolina Board of Pharmacy Executive Director David R. Work, “The State Newsletter Program has been a big help to us [the Board]. We use the newsletter as a means of communicating regulatory issues [to] licensees.”

Approximately a year ago, North Carolina switched to the State E-newsletter Program and has had much success with this change. North Carolina uses its state newsletter in the same capacity as when it was a printed document – as a medium to convey state legislation and recent pharmacy rules.

The Oregon State Board of Pharmacy also uses the state newsletters as official notice of changes to state rules and laws; it is the Board’s official communications tool.

In addition, the Oregon Board of Pharmacy issues self-inspection forms to each pharmacy in the state on an annual basis and one of the requirements stated on this form is that a binder of three years’ worth of state newsletters be kept. The North Carolina and South Carolina boards also require that a binder of state newsletters be kept in the pharmacy.

As with the other state boards of pharmacy, South Carolina also sees the state newsletters as an educational tool.

“The newsletters are a compliance tool that affect pharmacies and pharmacists and are used as an opportunity to educate and update readers.”

Lee Ann Bundrick, South Carolina Board of Pharmacy Administrator

As a member benefit, all of the state boards of pharmacy receive copies of the state newsletters of other boards participating in the program and many of the participating boards have reprinted articles from other board newsletters or have been prompted to report about a certain subject because of an article that appeared in another state board’s newsletter.

Also, on page 2 and 3 of the newsletters, the National Compliance Pharmacy News, which has the latest news every quarter, contains updates on federal laws and rules that pharmacists may not be aware of or for which they need further explanation.

For more information on NABP’s State Newsletter Program, please contact the Communications Department.
“Adventure is a matter of attitude – not altitude,” is Dr Jeff Salz’s motto, and Annual Meeting attendees will have the opportunity to hear about why he has found this to be true during his keynote address at NABP’s 102nd Annual Meeting at the Westin St Francis in San Francisco, CA, on April 9, 2006.

Throughout a lifetime of adventure and exploration, Salz has transformed these journeys into motivational presentations. He takes his audiences on a lively exploration of adventure and promotes its use as a strategy for increasing effectiveness on the job and in daily life; he explains that in order to make it through adverse and unexpected circumstances, an adventurer must be creative, and all of us must have this ability. In unfamiliar territory, the leader is the person with the map, and Salz will present that map to participants through colorful slides and thought-provoking insights about the uses of adventure that have been gained from his worldwide expeditions.

During his presentation at the 102nd Annual Meeting, Salz will guide attendees through the uncertainties of a changing world, inspiring them to chart their own course, achieve their goals, and turn each day into a “peak experience.”

Salz will share his “Six Steps to the Top”:
1. Leap Before You Look – risk-taking/action
2. Keep on Your Bearing – compassion/empathy
3. Aim High – envisioning/setting goals
4. Give It All You Have Got – teamwork/generosity
5. Work Some Magic – imagination/innovation
6. Enjoy the View – reflection/gratitude

Some of Salz’s most famous adventures include:
- Living with the Turkestani Khazaks of Central Asia;
- Riding with the Gauchos of Argentina and nomads of Mongolia;
- Searching for Shangri-La among the lost valleys of the Himalayas;
- Traveling in disguise with the Khampa nomads of Tibet, while fleeing the Chinese army;
- Traversing the length of the Andes on horseback and foot;
- Sailing the circumference of Lago Titicaca in a traditional reed boat; and
- Leading numerous expeditions to South America and adding several first ascents and solo first ascents to his credit, from the southern Patagonian Ice Cap to the Cordillera of Peru.

Salz has appeared in or been the subject of, several television specials, including Quest for the Cloud People, which follows his traverse of the upper Amazon and Jesus in the Himalayas, which is an investigation into the ancient legends of Jesus in the Himalayas.

Salz holds a doctorate of philosophy in cultural anthropology from Ryokan College, a master’s of science in education from International College, and a Bachelor of Arts degree in education from Prescott College. For 10 years he taught at San Diego University where he was named Outstanding Professor.

“When you choose to effect change, life becomes an adventure. Your vision becomes a creative force that inspires everyone and everything around you,” Salz states.

To register for the 102nd Annual Meeting, please use the form inserted in this Newsletter, or visit www.nabp.net to register online.

VAWD
(continued from page 46)
pharmaceuticals directly from the pharmaceutical manufacturers to its network of over 1,000 oncologists nationwide.

“This accreditation is a testament to the time and effort we invested in the development of our state-of-the-art distribution system and additional security measures, such as product lot number tracking from the manufacturer to the delivery to the patient. Oncologists in our network can have confidence in the integrity of the drug delivered to their practices, as well as the opportunity to achieve greater efficiencies in the timely delivery of care to their patients. Becoming one of the first companies to earn this important distinction is an honor that we share with all of our employees and network practices who helped us build this new distribution capability,” says Rolando de Cardenas, US Oncology’s vice president of pharmaceutical distribution.

For more information about NABP or NABP’s VAWD program, visit NABP’s Web site at www.nabp.net.
Errata
In the January 2006 issue of the NABP Newsletter it was incorrectly reported that the special room rate for the Westin St Francis is $189. In addition, the deadline to guarantee this rate was incorrectly reported. NABP’s special meeting rate for single/double occupancy at the Westin St Francis is $195 plus applicable taxes. To guarantee the special rate, reservations must be made by March 3, 2006. NABP regrets the error and any confusion it may have caused.
National Licensure
(continued from page 51)

One Model: The Nurse Licensure Compact
One health care profession, nursing, has developed a "mutual recognition" model of a multi-state license within the past few years and, so far, results are promising.

The Nurse Licensure Compact allows a nurse in any of the participating states to maintain one license, in her or his state of residency, but also to practice physically or electronically in the other participating states, subject to each state’s practice laws and regulations. The Compact essentially follows the driver’s license model: A driver is licensed in the state of his or her residency but may drive anywhere else within the United States — with the responsibility of abiding by local driving laws.

Between 1999, when the first state implemented the program, and the end of 2005, 21 states had passed the legislation necessary to be part of the Compact. “We have good momentum,” says Kristin Hellquist, director of policy and government relations at the National Council of State Boards of Nursing (NCSBN), which created the Compact. Hellquist expects to see more states coming on board within the next year or two.

Hellquist describes the Compact as essentially a contract between states. While only the licensee’s state of residence may take disciplinary action against the licensee, any other participating state can take disciplinary action against the privilege of practicing in that state. Information is shared on the NCSBN’s Nursys® database system, which is similar to NABP’s Pharmacist and Pharmacy Achievement and Discipline® database. While every member state of NCSBN has access to information such as final disciplinary actions on Nursys, Compact participants may access more detailed and preliminary information, so other state boards may take appropriate actions in a timely manner, if necessary. “Our mantra is ‘Locally enforced — nationally recognized,’” says Hellquist.

The Nurse Licensure Compact was originally created in the late 1990s in response to some of the same forces the pharmacy profession has faced: emerging technology changing the face of health care and a worrisome manpower shortage. “We were looking to simplify the process and remove some government barriers,” says Hellquist. By making it easier for nurses to be mobile, either through technology or physically, Hellquist notes, it could help address the current nurse shortage and allow patients better access to the health care they need.

Some legislators and regulators voiced concerns that signing on to the Compact would take vital information away from the state board — that the nursing board would no longer know who was practicing in that state, says Hellquist.

In actual fact, she says, prior to signing onto the Compact, “They do not know. They just know who holds active licenses.” She argues that, with one unduplicated count of nurse licensees, the states actually have access to greater knowledge. One unexpected side benefit of the Compact, she says, is the data it can provide on nurse licensees, the states who hold active licenses.”

In order to join the Compact, state legislatures must enact the interstate compact into state law or regulation. Implementation regulations must also be developed simultaneously with this process; model rules are available to assist states in this process. A program administrator for each state — often the executive director of the nursing board — meets several times a year with other administrators to aid coordination, and to form operations and policy guidelines for the Compact.

Looking Ahead
How will pharmacist licensing evolve? Given the continuing pressures of technology and federal law, it seems unlikely to remain stagnant. Some directions, such as federalizing pharmacist licensure, seem unpalatable, if not unworkable, and therefore unlikely. Yet, as the Nurse Licensure Compact shows, more nuanced models for greater flexibility are possible.

“How will pharmacist licensing evolve? Given the continuing pressures of technology and federal law, it seems unlikely to remain stagnant. Some directions, such as federalizing pharmacist licensure, seem unpalatable, if not unworkable, and therefore unlikely. Yet, as the Nurse Licensure Compact shows, more nuanced models for greater flexibility are possible.

“Maybe we’ve set up a system that is more cumbersome than it needs to be,” says Walgreen’s Burgess. If change would ease pharmacist manpower shortages, facilitate disaster assistance, and generally improve patient care, he implies, it is worth discussing.

nabp newsletter
Fourth Annual Poster Session at Annual Meeting: an Information Sharing Opportunity

State boards of pharmacy members and staff and schools and colleges of pharmacy have a unique opportunity to share information about the latest legislative issues, technology, policy development, or disciplinary cases at the Fourth Annual Poster Session held during NABP’s 102nd Annual Meeting. The session will take place Saturday, April 8, 2006, from 1 to 5 PM and Sunday, April 9, 2006, from 8 AM to noon during the 102nd Annual Meeting.

Interested in participating, but not sure where to start? Listed below are some tips on preparing a poster:

- Make the font size at least 14 point and double-space paragraph lines to ensure readability from two to four feet.
- Lay out the sections of your poster in a logical order so that the poster is easy to follow. Rather than affixing your documents to one large piece of poster board, which can cause a strain on poster pins, break your materials into three or four sections. You should also be able to move them around on the board.
- Enlist the help of students and/or interns on rotation in your office to prepare the poster.

Each participating board or school/college of pharmacy will be provided with one four-foot by six-foot bulletin board, which should be manned by a board-appointed representative during display times. To participate, interested boards should notify the NABP Meetings Desk. Please provide the poster topic.

Last year’s poster session at the 101st Annual Meeting in New Orleans, LA, featured posters with such titles as “The California Health Communication Partnership,” “Indiana’s Passage of VAWD™: Issues and Obstacles,” “IPS Evolution,” “Nevada’s Innovations Regarding the Regulation of Drug Wholesalers,” “Expanded Pharmacist Practice in New Mexico,” and “Internet Prescribing: The Utah Board of Pharmacy Order for Public Safety and Protection.”

State boards of pharmacy as well as schools and colleges of pharmacy students and faculty are encouraged to participate in the Annual Meeting poster session. Encore presentations are accepted and encouraged; posters will not be judged.
ISMP Issues Alert to Prevent Errors with Neuromuscular Blocking Agents

In September 2005, the Institute for Safe Medication Practices (ISMP) issued an ISMP Medication Safety Alert titled “Paralyzed by Mistakes – Preventing Errors with Neuromuscular Blocking Agents” that warned about inadvertently administering neuromuscular blocking agents such as pancuronium to patients who are not receiving ventilator support, which can lead to respiratory arrest. Some patients have died or have sustained permanent injuries as a result of these errors.

According to ISMP, these errors are due to a number of factors:

- Giving the blocking agent after the patient is extubated;
- Administering the agent too soon, before the patient is intubated;
- Preparing syringes from a multiple-dose vial and neglecting to label them;
- Unsafe storage; or
- Not knowing enough about the drug’s action.

ISMP reminds health care practitioners that these neuromuscular blocking agents are high-alert drugs and should receive the highest attention. Here are some of the ways ISMP suggests to prevent these errors:

- Limit access to drugs, allowing floor stock only in the operating room, emergency department, and critical care units;
- Segregate storage, keeping boxes containing these agents separate in refrigerators and on shelves;
- Place warning labels on vials, syringes, infusion bags, and boxes that read “Warning: Paralyzing Agent, Causes Respiratory Arrest”;
- Before dispensing and administering these drugs, require an independent double check of the drug against the actual order; and
- After the patient has been extubated or the drug has been discontinued, promptly isolate vials, syringes, and infusion bags containing the drug in a sequestered bin for pharmacy pickup.

To read this safety alert, visit www.ismp.org/newsletters/acutecare/articles/20050922.asp.

Luer Lock Misconnections

Luer fittings, connectors, and locks are commonly used to connect many medical devices, components, and accessories—they are also small, inexpensive, and convenient. Due to these factors, health care personnel may mistakenly connect the wrong devices and then deliver the substance through the wrong route; these errors can cause serious injury or even death.

In a December 2005 Food and Drug Administration (FDA) Patient Safety News, FDA offers some precautions to help prevent these deadly mix-ups:

- Teach staff to carefully inspect and then follow the proper connector sequence when connecting tubing and device components;
- Read and follow the equipment manufacturer’s recommendations and precautions, especially about compatibility with other devices;
- Do not modify intravenous (I.V.) or feeding devices because doing so may compromise the safety features built into their design;
- Consider using devices that are specifically designed for safety, to reduce the risk of misconnections; and
- Lastly, tell patients and family members that they must ask clinical staff for assistance when they need to disconnect and reconnect equipment because they could easily connect the wrong devices.

The full text of this article is available at www.accessdata.fda.gov/psn/transcript.cfm?show=46#6.

ISMP Warns About I.V. Administration of Nimodipine

ISMP warns about inadvertently administering nimodipine, or Nimotop® in a November 2005 Medication Safety Alert; this has resulted in patient deaths and serious injuries. Nimodipine capsules are given by mouth, but for patients who cannot swallow, the contents of an oral capsule can be extracted into a syringe, and then injected into a nasogastric tube (NG). Once the nimodipine is extracted in a syringe, the potential for administration errors is increased. ISMP notes that several incidents have occurred when a patient has been mistakenly injected with the contents of the syringe containing nimodipine intended for NG administration, and then the patient suffered from hypotension, cardiac arrest, and even death.

ISMP suggests that pharmacists warn patient care personnel about the danger of I.V. administration each time nimodipine is dispensed. ISMP also explains that some pharmacies are preparing nimodipine in advance for patients who cannot swallow, rather than having it prepared in the patient care area, in order to prevent this problem. Some pharmacies are also packaging the drug in amber oral syringes and labeling them “for oral (NG) use only.”

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Licensure Transfers

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exceeded 6,000 requests in 2002 and then crossed the 7,000-request threshold in 2004.

In 2005, Texas saw the most requests for licensure transfer into the state with 437, while Arizona had the second most requests from pharmacists for transfer into the state for the second consecutive year, with 422. The state receiving the third most licensure transfer requests into the state was Illinois, with 407. Pennsylvania’s pharmacists had the most requests to practice in other states, with 331.

Pharmacists in Louisiana, which suffered extensive damage from Hurricane Katrina in the late summer of 2005, received 178 license transfers out of the state in 2005 compared with 82 in 2004, a strong indication of their need to serve patients who were displaced to other states in the aftermath of the disaster.

In March 2005, ELTP applications became available online in both Microsoft Word® and Adobe® PDF formats on the Licensure Transfer/Licensure Transfer Application section of NABP’s Web site, www.nabp.net, for convenient access. Previously, boards of pharmacy were provided printed applications and then mailed them to candidates. Since the applications became available online, boards may direct applicants to the Web site, where they can download the applications.

The accompanying chart and map provide an overview of the 2005 licensure transfer request totals.
NABP Appoints Moné to ACPE Board

NABP is pleased to announce that Michael A. Moné, RPh, JD, has been appointed by the Association to the Accreditation Council for Pharmacy Education (ACPE) Board of Directors for a six-year term ending in 2012. Moné, a former member of NABP’s Executive Committee, has been a member of NABP’s Multistate Pharmacy Jurisprudence Examination® Review Committee since 1998, has chaired the Committee on Constitution and Bylaws and the Committee on Law Enforcement/Legislation, and was also a member of the Task Force on Privacy and Confidentiality. His professional experience also includes serving as executive director of the Kentucky Board of Pharmacy, speaker of the American Pharmacists Association (APhA) House of Delegates, assistant attorney general for the state of Florida, and staff attorney for United States Pharmacopeia Inc. Moné is currently a consultant on matters related to pharmacy and law and resides in Versailles, KY.

Moné is replacing Paul G. Boisseau, RPh, ScD – who completed a two-year term as ACPE vice president at the end of 2005 – as a member of the ACPE Board of Directors appointed by NABP. Moné joins two other ACPE board members appointed by NABP: David E. Holmstrom, former executive director of the Minnesota Board of Pharmacy, whose term covers 2002-2008; and Donald H. Williams, RPh, FASHP, former executive director of the Washington State Board of Pharmacy, whose term covers 2004-2010. Moné is an appointment-designee until July 1, 2006, when he becomes a voting member of the board.

NABP, the American Association of Colleges of Pharmacy, and APhA each appoint three members to ACPE’s Board of Directors, while the American Council on Education appoints one member.

Register Now for the 102nd Annual Meeting

San Francisco, CA, will be the place for “Unifying Members, Candidates, and the Profession – A Journey to the Core of NABP,” during NABP’s 102nd Annual Meeting April 8-11, 2006, at the Westin St Francis. You will see this unification theme come to fruition through events that offer something for all attendees, including business sessions, continuing education programming, the Meet the Candidates session, the New Member Seminar, and the Annual Awards Dinner.

Registration is now available on NABP’s Web site at www.nabp.net or by returning the inserted registration form. When registering, please indicate if you plan to participate in the Fun Run/Walk and/or the Spouse/Guest Tour of Alcatraz Island.

Special air travel and rental car rates are available through NABP’s designated travel agency Options Travel at 1-800/544-8785. When calling Options Travel, identify yourself as a registrant of NABP’s 102nd Annual Meeting and mention our special code, NABP102.

Around the Association
Campbell Named New Executive Director of North Carolina Board
The North Carolina Board of Pharmacy selected Jack W. “Jay” Campbell IV, RPh, JD, as its new executive director on February 1, 2006, replacing Terry Webb Grinder, RPh, JD, who had served in that capacity for the past 30 years. Campbell was valedictorian of his class at both the University of North Carolina (1993) and the Vanderbilt University School of Law (1997). His professional experience includes practicing law with Jones Day, a large multi-national firm in Washington, DC, and Helms Mulliss & Wicker, a large Charlotte, NC firm.

Tennessee Board Names New Interim Executive Director
The Tennessee Board of Pharmacy has named Kendall M. Lynch, RPh, the new president and chief executive officer of Franklin, TN-based Secure Pharmacy Plus, a provider of pharmacy services to correctional facilities.
Abbott Issues Alert on Certain Diabetes Care Blood Glucose Meters

Abbott Diabetes Care has issued a warning concerning problems with some of the company’s blood glucose meters; these meters could accidentally be switched from one measurement unit to another, possibly causing the patient to misinterpret the glucose test results. The affected glucose meters include the FreeStyle®, FreeStyle Flash™, FreeStyle Tracker™, Precision Xtra™, MediSense® Sof-Tact™, and MediSense® Optium™. Abbott meters are also sold under private label brands such as ReliOn® Ultima, Rite Aid®, and Kroger®.

These meters were designed to allow patients to view their test results in units customarily used in their own country. To do this, the patient could switch between showing the results in two different measurement units: mg/dL, the standard used in the United States, and mmol/L, which is used in many other countries. The problem occurs if the measurement units switch without the patient realizing it; this can happen when the patient resets the date and time or changes the battery, or even if the meter is dropped or bumped. Then, if the patient just glanced at the numbers without noticing the different units or the decimal point, he or she could incorrectly assume that his or her blood glucose level is too high or too low.

To resolve this problem, all new Abbott meters now have the correct unit of measurement locked in place. Patients can continue to use their older units, but they should make sure that their meter displays the glucose test result in mg/dL. If patients do not know how to change the measurement units, or if the units cannot be changed, they can contact Abbott Diabetes Care at 1-800/553-4105.

FDA Warns About Risks Involved in Filling US Prescriptions Abroad

FDA is warning health care professionals and consumers about filling their prescriptions abroad, which may have adverse health consequences due to confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. A January 2006 FDA investigation has found that many foreign medications, although marketed under the same or similar sounding brand names as those in the US, contain different active ingredients than in the US. Taking a different active ingredient may often harm the user.

According to Dr Murray Lumpkin, deputy commissioner for international and special programs, “The name of a drug bought from another country may be identical or similar to the name of the US prescription, but the active ingredient in the medicine may be different and not provide the right treatment.”

The investigation shows this health risk inherent in filling US prescriptions abroad and highlights the lack of standardization of drug trade names internationally. For example, in the US, Flomax® is the brand name for tamsulosin, a treatment for an enlarged prostate, while in Italy, the active ingredient in the product named Flomax is morniflumate, an anti-inflammatory drug.

FDA has also found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For more information on this topic, please see the article titled “Purchasing Foreign Drugs Online – May be Less Expensive, but More Risks are Involved” on page 6 of the January 2006 NABP Newsletter.

Also, for more information on FDA’s report, see FDA’s Public Advisory at www.fda.gov/oc/opacom/reports/confusingnames.html.
Error Mitigation
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Exposing pharmacists to these issues. According to the 2006 Survey of Pharmacy Law, Florida and New York are the only states with this requirement. Florida requires at least two of the 30 mandatory biennial CE hours to be a Board-approved course on medication errors. For its triennial registration period, New York requires that every pharmacist complete three hours of CE in the area of strategies used to reduce medication errors. The Medication Errors Task Force recommended that more states consider such requirements.

In addition to CE mandates, pharmacists can also focus on continuing professional development (CPD) to reduce medical errors. CPD is a concept that NABP and other national pharmacy organizations are advancing to ensure the lifelong learning of pharmacists. The Pharmacist Self-Assessment Mechanism™ (PSAM™) is a self-assessment tool that can assist pharmacists in obtaining objective, non-punitive feedback on their knowledge of current practice therapies. The PSAM is based on patient profiles and simulates real-life practice situations and patient therapies; the pharmacist is provided with feedback, including the correct answer, a brief rationale for the correct answer, and a reference where more information about the answer or applicable treatment guidelines can be obtained. The Idaho, Tennessee, California, and Wyoming boards have approved PSAM for CE credit.

In the first half of 2006, ISMP, along with FDA, planned to launch an educational campaign aimed at reducing the medication errors that result from the use of ambiguous abbreviations and dose designations on prescriptions. This campaign targets health care professionals, medical writers, the pharmaceutical industry, and FDA staff. It highlights some of the abbreviations, symbols, and dose designations that are most often misinterpreted, and recommends that they never be used.

Similarly, during the 100th Annual Meeting in 2004, NABP passed Resolution 100-9-04, National Patient Safety Goals, Prohibited Abbreviations, in which NABP and the boards of pharmacy encourage the use of “do not use” lists of abbreviations, acronyms, and symbols among health care providers and educators. The resolution also encourages the efforts of groups such as ISMP to perpetuate the concepts of prohibited abbreviations, acronyms, and symbols in communication between health care providers and educators.

Patient safety and medication error prevention can also be addressed in the curriculums of health professional students. The Medication Errors Task Force called for NABP to work with groups such as the American Association of Colleges of Pharmacy, the American Association of Colleges of Nursing, and the Association of American Medical Colleges to incorporate patient safety and medication error prevention into the health profession curriculums of pharmacy, nursing, and medicine.

Pursuant to this recommendation, NABP accepted the invitation from the Accreditation Council for Pharmacy Education (ACPE) to comment on the Draft Revision of ACPE Standards 2000 and Proposed Guidelines. NABP commented that the draft revision should incorporate additions in two key areas: safety and error reduction, and communication skills.

Focus on Processes
To Err is Human conveyed that medication errors are most often due to faults within a system or process, not an individual; therefore, it is necessary to change the system or process to reduce the chance that errors will occur. Parts of the system that can be changed include working conditions and workflow processes. For example, system and process factors such as working conditions, workflow, staffing, and increasing
prescription volumes may set the stage for an increase in medication errors. Recognizing that public health and safety depends on pharmacists being alert and cognizant, the Arizona State Board of Pharmacy adopted a resolution in 2001 strongly encouraging a 30-minute break for pharmacists.

The Best Practice Recommendations adopted by the Massachusetts Board of Registration in Pharmacy in 2001 can be used in various pharmacy settings and adapted based on available resources and the needs of the community served. One of the recommendations directs pharmacy owners and managers to develop and implement a workflow plan that maximizes the effective use of space, equipment, and staff by providing an adequate work and privacy area for counseling. The Board also recommends that pharmacies consider the use of technology and automated devices to aid staff in production and inventory processes. Pharmacists-in-charge should ensure that pharmacy staff is properly trained for their duties and routinely survey customers for further improvement of pharmacy operations.

In 2000, the Washington State Department of Health, in consultation with the pharmacy boards and licensing board of providers with prescriptive authority, developed recommendations for reducing medication errors. It encouraged the use of electronic prescribing (e-prescribing) to increase prescription legibility and urged prescribers to use standard terminology (eg, units, abbreviations) to prevent interpretation errors. The Medication Errors Task Force agreed that NABP should continue efforts in working with the Centers for Medicare and Medicaid and the National Committee on Vital and Health Statistics (NCVHS) to develop regulations and standards that would incorporate standardized processes for e-prescribing.

NABP has provided expert testimony to NCVHS in the development of e-prescribing standards.

In addition to the state boards and NABP, many professional organizations, such as the American Society of Health-System Pharmacists (ASHP) and NCC MERP, have taken a major role in advocating patient safety. ASHP has released many recommendations, including guidelines on preventing medication errors in hospitals and with antineoplastic agents. Although written specifically for hospitals, the ASHP Guidelines on Preventing Medication Errors in Hospitals could be applied to various pharmacy practice settings. NCC MERP has released recommendations targeted to health care organizations and professionals aimed at reducing errors due to similar names and/or pronunciations, packaging, and labeling of drug products and related devices. NCC MERP advises pharmacy staff to use only properly labeled and stored drug products and read the label at least three times (before, during, and after use) to avoid mistakes. The use of additional signage to point out “high alert” items such as look-alike, sound-alike drugs (eg, Lamictal® and Lamisil®) should provoke the staff to double-check when retrieving these drugs off the shelves. These recommendations are in agreement with a recommendation of the Medication Errors Task Force, which encouraged NABP to urge FDA to prevent the use of any product nomenclature, packaging, and labeling that may significantly contribute to medication errors.

Nursing organizations have also addressed patient safety. The American Nurses Association (ANA) is one of the founding members of NCC MERP and the National Council on Patient Information and Education (NCPIE), a non-profit coalition of approximately 130 organizations representing health care professionals, consumers and patients, voluntary health agencies, the pharmaceutical industry, and managed care. ANA is one of two nursing organizations that have served on the board of directors since 1982. NCPIE annually hosts “Talk About Prescriptions” Month and sponsors the “Be MedWise” campaign promoting the prudent use of OTC medicines.

The efforts regarding patient safety and medication errors among these various groups is admirable, but an effective solution to this problem cannot focus on a single approach and no single recommendation should be considered the “magic bullet” answer. At any rate, the wheels have been set in motion irrevocably and patient safety improvement and medical error mitigation will continue to be a major priority in the years ahead. NABP will continue to assist the state boards in guiding health care organizations and providers in their efforts to protect the public health.
Signs of Tamiflu Counterfeiting Threat Become Apparent

United States Food and Drug Administration (FDA) and other governmental agencies have warned that the attractiveness of the antiviral flu treatment Tamiflu®, along with a scarcity of supply, makes it a prime target for counterfeiters.

Law enforcement officials in the US, Europe, and Asia have recently launched joint "sting" operations against illegal Tamiflu producers and traffickers. Two seizures of shipments of counterfeit Tamiflu in the past few months underscore the susceptibility of the drug to counterfeiting.

In January, the world’s biggest seizure of fake Tamiflu to date took place in London, where officers from the Medicines and Healthcare Products Regulatory Agency (MHRA) confiscated 5,000 illegally imported packages of the drug worth a total of more than $800,000 US, according to January 16, 2006 edition of The Sunday Times. The MHRA was also investigating a company in Greater Manchester that was marketing inexpensive antiviral drugs with a Tamiflu brand name at a 1,500% markup, and also discovered about 20 Web sites selling Tamiflu.

In November 2005, US customs agents seized more than 50 shipments of counterfeit Tamiflu at an airmail facility near San Francisco International Airport. According to the Associated Press, the seizure was the first involving Tamiflu within the borders of the US.

The agents seized 51 separate packages that each contained up to 50 capsules that were labeled as generic Tamiflu. Suspicions arose because Tamiflu has no generic equivalent. Upon inspection of the drugs, it was determined that none of the capsules contained any of Tamiflu’s active ingredients, although they did contain some Vitamin C, according to David Elder, director of FDA’s Office of Enforcement.

The packages’ labeling was written in Chinese, and Roxanne Hercules, a spokeswoman for US Customs and Border Protection, noted that the packages apparently were being mailed to individuals who had ordered the drugs via the Internet. However, none of the packages were en route to doctors or hospitals. These shipments appear to be from the same source in China as supplies seized and identified by Austrian and Dutch officials late last year.

Illegal importation of fake Tamiflu was not unforeseen. On November 1, 2005, Randall W. Lutter, PhD, acting associate commissioner for policy and planning at FDA, warned of the threat of counterfeit Tamiflu and other drugs while testifying at a House Subcommittee on Criminal Justice, Drug Policy, and Human Resources hearing (NABP Newsletter, February 2006, page 30). "As the threat of pandemic flu emerges as a public health threat, FDA anticipates an increase in the sale of counterfeit or fraudulent treatments," Lutter said.

San Francisco Fact Box

The California Gold Rush

Site of NABP’s 102nd Annual Meeting
April 8-11, 2006, Westin St Francis, San Francisco, CA

The California Gold Rush was an exciting chapter of American history that involved the discovery of gold in Northern California. On January 24, 1848, James Marshall discovered gold while working at Sutter’s Mill. It did not take long for word to spread about the discovery and on February 2, 1848, the first ship, filled with Chinese immigrants seeking fortune, arrived in San Francisco. On August 19, 1848, the New York Herald was the first newspaper on the East Coast to report the California Gold Rush.

Most people seeking fortune headed to California in 1849, hence the nickname 49ers. The journey across the country was a difficult one, with many making the trek on foot or by wagon; sometimes it would take up to nine months to get to California. Because of the influx of treasure seekers, San Francisco’s population grew from approximately 800 in 1848 to over 50,000 in 1849. The California Gold Rush ended in 1858, when the New Mexico Gold Rush began.

MPJE State-specific Review Meeting Draws High Attendance; Optional Day Allows More Networking

NABP’s Multistate Pharmacy Jurisprudence Examination® (MPJE®) State-specific Review Meeting, which took place at the Hilton San Diego/Del Mar, CA, January 19-22, 2006, was deemed a success by all who participated. Out of the 46 states that participate in the MPJE program, 43 states, 80 people total, attended the meeting. Over the course of this three-day meeting, an average of 1,600 operational items were reviewed.

Almost all of those who attended this year’s State-specific Review Meeting took advantage of the newly added optional day, which was added because, in addition to reviewing their operational item pool, the board representatives also had to review and approve about 950 new items for pretest in their pool. The participants noted that this extra day offered extra time and eased some of the pressure for the participants to accomplish the review process. Also, the extra time gave MPJE program members and NABP staff an opportunity to network and exchange ideas and issues.

The MPJE State-specific Review Meeting is extremely important to the program because it is during this meeting that the state boards of pharmacy decide on the appropriateness of current examination items for candidates seeking licensure in their state and review new items according to the changes in state and federal pharmacy law.

The boards that participate in the MPJE program have three primary responsibilities that help ensure the accuracy and timeliness of the examination:

- Develop approximately 30 new questions;
- Review the newly developed questions from all states, to determine which of them apply to their state, and
- Review all questions currently approved for their state to ensure all the items are appropriate.

NABP develops and administers the MPJE at no cost to the participating boards. The boards are required to attend one State-specific Review meeting per year and encouraged to participate in the item-writing workshop. Both meetings are hosted and funded by NABP. In addition to evaluating items, boards of pharmacy are responsible for approving candidate eligibility and providing candidates with score reports.

Wholesale

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Under current law, Idaho requires an inspection for in-state and out-of-state facilities. Typically, the Board would require an out-of-state wholesaler to submit an inspection report from the state in which they are located. Idaho has had to deny several wholesalers whose home states do not require an on-site facility inspection the ability to do business in Idaho. As an alternative, Idaho is now allowing wholesale drug distributors from those states to obtain NABP’s VAWD accreditation as a means to meeting the statutory inspection requirement.

NABP Gives Support

NABP remains committed to assisting its members to understand and utilize the Model Rules or tighten existing state laws in regard to the licensure and regulation of wholesale distributors. NABP staff is available to participate in board meetings and deliberations, conference calls, or other meetings to assist the states in this regard. For assistance, contact Carmen A. Catizone, NABP executive director/secretary. Information on any activities that may be occurring in your state in regard to legislation or rules for the regulation or licensure of wholesale distributors is also welcome and can be forwarded to Catizone or Eleni Z. Anagnostiadis, NABP Professional Affairs director.
Every year, dedicated volunteers convene to review NABP’s competency assessment programs and safeguard the integrity and validity of the Association’s examinations. NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements. Among these committees is NABP’s Advisory Committee on Examinations (ACE), which oversees the development and administration of all examination programs, considers policy matters, develops long-range planning strategies, and recommends action on specific issues to NABP’s Executive Committee.

The listed individuals currently serve on NABP’s examination committees. Members of the North American Pharmacist Licensure Examination™ (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), and Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) review committees start their terms at the beginning of the year, while members of ACE begin their terms in the summer.

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Nashville, TN

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Member ..................................................... Jerry Moore Indian Springs, AL

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US Food and Drug Administration,
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Reminder
Annual Meeting
Travel Grant Program applications may be obtained by contacting NABP Headquarters and must be received at NABP Headquarters prior to the 102nd Annual Meeting, to be held at the Westin St Francis in San Francisco from April 8-11, 2006.

Carol Potrawski, NABP information services coordinator (right), accepts a certificate and gift from NABP Associate Executive Director Mary A. Dickson during a celebration of Potrawski’s 25th year of service last January at the NABP Headquarters in Mount Prospect, IL.