Pharmacists’ Expertise in Patient Care Renders Practice of Pharmacy Ripe for BTC Drug Class

Over the past several decades, the practice of pharmacy in the United States has experienced a gradual, ongoing paradigm shift wherein pharmacists play an increasingly vital role in patient care. Practice-wide educational requirements and competency standards have evolved to provide assurances that entry-level pharmacists are capable of providing services such as patient counseling and medication therapy management. Professional expectations within the practice depict pharmacists not only as medication experts, but also as patient advocates and educators, integral to the optimization of patient care outcomes. For these reasons, among other shifts in the health care environment, NABP maintains that today’s pharmacists are well-positioned to usher in a behind-the-counter (BTC) class of drugs.

Pharmacists, academics, and other experts have long argued that implementing a BTC drug class – wherein designated medications would be dispensed without a prescription but only with the intervention of a pharmacist – would increase patient access to medications and promote public health. Such a system, proponents say, would enable many prescription drugs to be reclassified as non-prescription, thus reducing strain on a currently over-taxed health care system, while still ensuring that patients receive the information and assistance they need to use their medications safely and effectively.

NABP has been urging the adoption of this third class of drugs since 1995, when the Association passed a resolution at its 91st Annual Meeting calling for its creation. Since then, educational standards and professional expectations for pharmacists in the US have continued to rise. As a result, today’s pharmacists are prepared to provide the higher level of patient care required for the success of a BTC drug class.

US Pharmacist Care Standards on the Rise

The decision of the Accreditation Council for Pharmacy Education (ACPE) in 1997 to require the PharmD as the sole professional practice degree for pharmacy in the US marked a turning point in pharmacist care. The PharmD curriculum is designed to provide pharmacists with the knowledge and skills necessary to provide patient care in a variety of settings, including hospital, retail, and long-term care environments. This expanded role for pharmacists is consistent with the increasing responsibilities and expectations placed on pharmacists in today’s health care system. As a result, the need for a BTC drug class becomes even more pressing, as pharmacists are well-equipped to handle the responsibilities associated with dispensing medications without a prescription.
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BTC Drug Class
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provide pharmacy students with the classroom and experiential education they need to master pharmacy practice, as well as to serve as patient-care providers who have the expertise to safely and competently counsel patients on the proper use of their medications. In 2008, ACPE saw the first batch of all-PharmD graduates who have demonstrated the successful completion of this intensive expanded curriculum.

ACPE is not alone in raising the bar to enter the practice of pharmacy in the US. The American Association of Colleges of Pharmacy’s Center for the Advancement of Pharmaceutical Education (CAPE) identifies the ability to provide patient-centered care as a necessary competency for pharmacy graduates. CAPE’s 2004 Educational Outcomes report says that in providing patient-centered care a pharmacist should be prepared to perform the following tasks:

• develop, implement, and monitor patient-specific, evidence-based pharmaceutical care plans;
• communicate and collaborate with patients and their other health care providers; and
• stay abreast of emerging issues that may impact patient-specific therapeutic outcomes in order to provide relevant information to patients and their other care providers.

In assessing the competencies of entry-level pharmacists seeking licensure, the North American Pharmacist Licensure Examination® includes sections that test applicants’ abilities to provide the patient-centered care expected of pharmacists today. Changes implemented in the 2005 examination blueprint include an increased emphasis on the skills required to communicate effectively with patients and other health care providers in regard to both prescription and over-the-counter medications, as well as dietary supplements.

Practice Approaches JCPP Future Vision

Today’s pharmacy education standards establish the foundation of the Joint Commission of Pharmacy Practitioners’ (JCPP) Future Vision of Pharmacy Practice 2015. Released in 2005, and endorsed by each JCPP member organization and liaison member; including NABP, the vision statement says pharmacy curricula should “prepare pharmacists to provide patient-centered and population-based care that optimizes medication therapy; to manage health care system resources to improve therapeutic outcomes; and to promote health improvement, wellness, and disease prevention.” This vision statement, then still evolving, was influential in establishing the expectations for pharmacist

GAO Report: Benefits of Behind-the-Counter Drug Class Unclear

Whether a behind-the-counter (BTC) drug class would truly benefit patients in the United States remains a matter of debate for the US Government Accountability Office (GAO). In its February 2009 report, Considerations Regarding a Behind-the-Counter Drug Class, GAO indicates that the potential outcomes of implementing a BTC drug class are unclear.

Updating the findings presented in the 1995 GAO report, Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated, the 2009 report describes the results of a study to examine drug availability across countries. GAO studied five countries it had reported on in 1995 (Australia, Italy, the Netherlands, the United Kingdom, and the US) and determined how 86 drugs available in all five countries were classified in each country. Based on this study, GAO reports, “[a]ll five study countries have increased nonprescription drug availability since 1995; however, the impact of restricted nonprescription drug classes on availability is unclear.”

While providing abundant information on the classifications of these 86 drugs in the five countries studied, GAO concedes a lack of compelling insight. “The classification of drugs in other countries and the existence of other classes provide little insight into the likely effect of a BTC drug class on nonprescription drug availability in the United States,” GAO reports. “It is unclear whether establishing a

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NABP Awards First Vet-VIPPS Accreditation to VetRxDirect, Inc

NABP has awarded its first Veterinary-Verified Internet Pharmacy Practice Sites” (Vet-VIPPS”) accreditation to VetRxDirect, Inc. Online veterinary pharmacy practice sites that obtain Vet-VIPPS accreditation exhibit their willingness to operate legitimately, assuring animal care providers that they are purchasing drugs and devices from a facility that meets the licensing requirements of the state in which the facility is based and each state to which it dispenses pharmaceuticals.

“VetRxDirect’s accreditation is due to its dedication to complying with the Vet-VIPPS criteria and commitment to meeting the patient/client safety practice standards,” states NABP President Gary A. Schnabel, RN, RPh. “NABP is pleased to award this facility with the first Vet-VIPPS accreditation.”

VetRxDirect was incorporated in Iowa in 2007. NuCara Management Group (a pharmacy management group) created VetCara, LLC, and partnered with a local Iowa City veterinarian to provide legal online veterinary pharmacy services to the marketplace. Following completion of its Web site design, VetRxDirect launched operations in January 2008 honoring what it calls the foundation of the veterinary profession: the doctor/client/patient relationship. The facility offers only non-controlled veterinary prescriptions and over-the-counter products and is committed to providing its clients with a secure online shopping experience.

“VetRxDirect is honored to be accredited as a Vet-VIPPS pharmacy by NABP. We will take this accreditation seriously, and we will continue to foster a closer relationship between the veterinarian, patient, and pharmacy. The Vet-VIPPS accreditation is very important to us. It helps our customers understand that we are appropriately licensed and comply with all federal and state laws and regulations. It also helps in the trust-building process with veterinarians who provide the prescriptions for their clients’ pets,” says T.J. Johnsrud, president of VetCara, LLC.

Launched by NABP in January 2009, the Vet-VIPPS program provides a vehicle for evaluating and accrediting legitimately operating online veterinary pharmacy practice sites in an effort to protect companion animals as well as non-food producing animals. It is designed to assist the states in their efforts to maintain control over the Internet-based distribution of prescription drugs and devices for these animals.

Vet-VIPPS is an expansion of the NABP VIPPS® program, which was established in 1999 after a coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise to develop criteria for accredited Internet pharmacies to follow. This year, the VIPPS program celebrates its 10th anniversary.

Pharmacies displaying the Vet-VIPPS Seal on their Web sites have demonstrated to NABP their compliance with Vet-VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between clients and pharmacists. By clicking on the Seal, a visitor is linked to the NABP Vet-VIPPS verification Web page where verified information about the pharmacy is maintained by NABP. The public is also welcome to search for a Vet-VIPPS Internet pharmacy that matches their needs by visiting the Vet-VIPPS section of the NABP Web site.

More information about the Vet-VIPPS program criteria and applications for accreditation are available in the Accreditation Programs section of the NABP Web site at www.nabp.net.
105th Annual Meeting Report of Counsel
By Dale J. Atkinson, JD

The 2009 Report of Counsel will attempt to capitalize on recent headlines of various publications addressing matters relevant to the regulatory community and relate them to the legal challenges confronting NABP, boards of pharmacy, and other pharmacy related entities. In short, the legal principles that may apply to boards of pharmacy, as public agencies created and empowered by statute, are different from those that apply to NABP and other like entities, as private sector organizations. The differing legal principles that apply to public agencies and private sector entities can be significant. The extent to which public sector agencies choose to rely upon private sector programs and services further blurs these complex legal theories. Readers are encouraged to read each article for content as this report is not intended to provide an exhaustive analysis of each concept. These articles are great for raising issues of interest to NABP and state board constituents.

“Chains’ ties run deep on pharmacy boards”
(USA Today, December 30, 2008)

The above article questions whether the involvement of chain drug stores in actively promoting the appointment of representatives to the various state boards of pharmacy is healthy or appropriate for the duties and responsibilities of boards of pharmacy and their members, and the conflicts all board members may encounter when addressing chain, hospital, or independent pharmacies. Understanding and accepting these immense public protection responsibilities is essential and boards are encouraged to continually reinforce these principles and the legal obligations under which they operate.

Simply stated, the legal obligations of boards of pharmacy (and for that matter any regulatory board) are to undertake the enforcement of the enabling legislation by regulating the profession in the interest of public protection. Applicants and licensees are entitled to certain legal rights in the licensure process, generally characterized as “due process” rights. Applicants for licensure are entitled to at least some form of procedural due process that requires the board to adopt and follow procedures in a fair and consistent manner in determining eligibility for licensure.

Once licenses are issued, licensees maintain a property interest in such license and are entitled to procedural and substantive due process in proceedings that threaten an adverse action against such license. Due process under these circumstances involves notification of allegations, the process to be followed, and opportunities for the
licensee to be meaningfully heard and present evidence, all before a fair and impartial tribunal. The fair and impartial tribunal requirement implicates a conflict of interest question whereby a board member(s) must objectively and without bias determine a matter before the board. Failure to adhere to such impartiality may be grounds for reversal of board action.

Board members are encouraged to ask questions and understand the legal principles related to bias and board action, noting that conflict of interest issues may be raised on virtually any board action, not just disciplinary proceedings.

“Dental board bucks change”

(Topeka-Capital Journal, May 10, 2008)

The above article examines the Kansas Dental Board reversal of an earlier decision to require applicants for licensure to “obtain a 75 percent on the [regional licensure examination] rather than the 55 percent viewed as acceptable by [examination developers].” The new (75%) passing standard resulted in numerous failures by examinees when in the past “only a few UMKC [University of Missouri-Kansas City] dental students fail licensure examinations.” Under the new, revised standards, the state board will allow the third-party testing organization to define the passing grade.

NABP has used and uses its expertise in developing, administering, maintaining, and defending its examination programs (North American Pharmacist Licensure Examination® [NAPLEX®], Multistate Pharmacy Jurisprudence Examination® [MPJE®], and others). The boards of pharmacy choose to rely upon the NAPLEX as one criterion in the licensure process. The benefits to all are clear and obvious. At no cost, the boards are relieved of the financial and time consuming processes of developing, administering, maintaining, and defending legal challenges to the examination. The applicants are provided with a fair, defensible minimum competence determiner of knowledge, skills, and abilities offered on an ongoing and consistent basis at a reasonable price. And, the examination is validated on a North American platform for uniformity and intended for recognition “across state lines,” allowing for ease of mobility of practitioners through a licensure transfer process without the need for re-examination. Similar arguments exist for additional NABP programs, including the MPJE and other NABP programs and services.

Unless prepared to defend a decision from a legal and psychometric perspective, regulatory boards must be cautious about specifically identifying a numeric or percentage score as the “passing point” of a licensure examination. Further, specific reference to scores/percentages may impact the uniform nature of an examination result and impact licensure transfer issues and practitioner mobility. Finally, boards are encouraged to base minimum competence determinations through the use of an examination on the validity of a pass point, rather than the number of candidates who fail the test. Criterion referenced examinations are based upon knowledge of the candidates, not the curve of performance. The requirement that boards of pharmacy recognize and abide by the passing standard validated by NABP is set forth in the state letter of agreement.

This article illustrates the importance for boards of pharmacy to understand how to use and why they rely upon NABP for products and services related to the licensure process. NABP operates its programs and services in a manner to assist state boards of pharmacy in fulfilling their public protection mandates of regulating the profession. While relying upon NABP, boards must also understand the bases for their decisions to ensure compliance with their obligations.

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Legal Briefs

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The legal bases for board decisions are, under most circumstances, different from those legal principles applied to NABP. At times, NABP may need to make a determination to protect the integrity of one of its programs/services (ie, invalidate a NAPLEX score). While consultation with the board(s) will occur, issues may surface if the board disagrees with such decision. In the event of a legal challenge to both NABP and the impact board(s), the differing legal principles will be highlighted.

“Scope of practice dispute can proceed, Texas court rules”

(American Medical News, January 5, 2009)

This article notes a state appellate court ruling that allows physicians, via the Texas Medical Association, to challenge the ability of chiropractors to perform certain medical procedures adopted by the Board of Chiropractors through the rulemaking process. This short article is instructive on numerous issues, including the rulemaking authority granted to the regulatory boards and the limitations on the breadth of such rules.

The article also illustrates the scope of practice issues and the existence of “turf battles.” It is important for the boards to understand their role in addressing the legislature and where the authority begins and ends. The professional promotion role of the professional association may not always coincide with the public protection role of boards and associations of boards and will be illustrated if litigation is pursued. Of interest, the article notes that the Texas Medical Association filed the lawsuit “jointly with the Texas Medical Board.”

While such a “partnership” between the professional association and the regulatory board may be justified under certain circumstances, the joint approach to the referenced litigation illustrates the interesting legal and practical considerations that lead to this partnership. As the legal process continues, the potential for conflict of interest issues regarding the professional promotion mission of the professional association and the public protection mission of the board may be emphasized.

“State should open complaints on doctors, report urges”

(Florida Health News, February 9, 2009)

This article advocates that “records of complaint investigations against doctors, nurses, and other licensed health professionals should be available to the public the same way as those who have state licenses in other fields.” In these professions, only complaints that have been investigated and where a subcommittee of the board finds “probable cause” are subject to public disclosure. Where there is no finding of cause, complaints and their initial investigations are never made public.

The issues identified illustrate the importance that boards of pharmacy are aware of the existence of applicable laws aside from the enabling statutes (practice acts). Freedom of Information or Open Records laws certainly impact board operations and board members should be aware of the applicability and limitations of such laws on board policies and operations. Most open records and meetings laws call for all board records to be subject to public disclosure, except where there is a specified exemption. In order to protect the boards, which operate in the public interest, boards and board members are cloaked with immunity protections for acts committed within the scope of the board duties.

On the other hand, NABP is not subject to open records and meetings laws and operates as a private entity not subject to disclosure. Such a standing by NABP provides distinct advantages insofar as maintenance of confidentiality is concerned. NABP, as the owner of the NAPLEX and other examinations relied upon by boards, must maintain such examinations and statistical data in confidence to protect the integrity of its programs. For example, NABP is not subject to the open meetings laws and has the liberty to meet in executive session to ensure confidentiality, while at the same time keeping the boards informed about essential examinations and services related to board determinations and licensure eligibility criteria.

“Criminal past is no bar to nursing in California”

(Los Angeles Times, October 5, 2008)

This article examines situations whereby nurses who have been subject to various serious criminal convictions remain “fully licensed to practice in California for years before the state nursing board [acts against their licenses].” It cites criminal acts including sexual offenses and attempted murder committed by individuals who remained licensed until up to three criminal convictions with some remaining licensed until five convictions.

Boards of pharmacy are empowered and expected to enforce the practice acts, including disciplinary action, in a manner that protects the public. While every criminal conviction may not constitute grounds for licensure denial or renewal or disciplinary actions, boards are encouraged to ask for such background information on their applications and renewal forms. In addition, boards are encouraged to act upon such information when circumstances so dictate. Assuming licensees self report (or are turned in by other licensees), boards should address the particular circumstances and act accordingly. Assuming the legal authority exists, we recom-
Since 2006, the NABP Legal Affairs Department has managed a variety of legal matters on behalf of the Association, including program and vendor contracts, trademark and copyright registrations, and legal research on regulations impacting NABP. The department also coordinates litigation and other projects with outside legal counsel, Atkinson & Atkinson. To assist in handling the growing work in the department, NABP is pleased to say that a paralegal recently joined the Legal Affairs staff.

Staff works with member boards regarding contracts for NABP services such as the North American Pharmacist Licensure Examination® (NAPLEX®), the Multistate Pharmacy Jurisprudence Examination® (MPJE®), and the state newsletters. As a result of these efforts, all states in the United States, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands are currently under contract for the provision of the NAPLEX and, for those jurisdictions utilizing it, the MPJE law examination.

NABP continues to protect the Association’s intellectual property by registering trademarks and copyrighted material, including secure examinations such as the NAPLEX, MPJE, and Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). NABP protects its program trademarks through cease and desist letters and other legal means when an organization is identified as improperly utilizing such marks or copyrighted material. For example, the Association targeted organizations that are holding out their products or services as being affiliated with or endorsed by NABP, and successfully halted a number of websites claiming accreditation through the Association’s Verified Internet Pharmacy Practice Sites™ (VIPPS®) program.

**Litigation Matters**

NABP’s lawsuits against the Board of Regents of the University System of Georgia and affiliated individuals (Board), as well as two professors, continue in both state and federal court. The litigation was initiated because NABP maintains that the integrity of the NAPLEX and MPJE were compromised. NABP appealed an April 2008 decision of the United States District Court for the Middle District of Georgia, which dismissed the copyright infringement claims against the Board on the basis that the court lacked jurisdiction over the Board; oral argument has been scheduled in July 2009, and NABP anticipates that a decision on the appeal will be made before the end of 2009. NABP’s claims against the individual professors, who were not dismissed from the case, are on hold while the appeal is under consideration in the United States Court of Appeals for the 11th Circuit. Moreover, the injunction prohibiting the professors from engaging in copyright infringement remains in place. In May 2008, NABP filed suit in Georgia state court against the Board and one of the professors alleging that they breached a 1995 contract in which it was agreed that the Board and the professor would cease all infringing use of NABP copyrighted materials and examination questions. This lawsuit is in the discovery phase of litigation.

An examination candidate recently sued NABP alleging, among other things, that the Association engaged in defamatory conduct when it reported the invalidation of the candidate’s examination score to its member boards. NABP denies any wrongdoing, and is preparing a response to the lawsuit.

NABP examination programs are of key importance to the Association and are operated in support of and in conjunction with its member boards. NABP will continue to vigorously defend its examinations against legal challenges so that the boards remain confident in the strength of the Association’s examinations.

**Conclusion**

As NABP grows and services to members continue to expand, the Association faces a variety of forces that threaten the integrity of its educational and public health protection programs. By working in partnership with the boards of pharmacy, NABP is able to successfully maintain efforts to safeguard its programs and the public health.
**Web-Based Interface Streamlines NAPLEX and MPJE Eligibility Reporting**

NABP has designed a Web-based interface to provide the boards of pharmacy with a streamlined process for confirming candidate eligibility dates for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). With this new user-friendly and expedited system, the boards have increased management capabilities for open candidate files, allowing them added flexibility when assigning candidates their examination eligibility dates.

The new interface, which was implemented in April 2009, replaces a manual system and streamlines the process by allowing the boards of pharmacy to securely log on with a user name and password to confirm candidate eligibility via the Internet through a NABP database. With the “one-click” option, the boards are able to choose the current date as the date of eligibility or they may use the edit capability to specify another date of eligibility. As candidates register, they will appear on their respective state’s list and once a candidate’s eligibility is confirmed by the board, notification is automatically sent to the test vendor, Pearson VUE, so that the candidates may schedule a test date.

Along with simplifying the eligibility process, the interface offers the boards of pharmacy other valuable features, including the ability to sort open candidate registrations by name, date of registration, or affiliation with the Foreign Pharmacy Graduate Examination Committee™ or licensure transfer program. In addition, a history tab is available allowing the boards to easily view past eligibility confirmations.

More information on this new interface is available by contacting NABP at custserv@nabp.net or via phone at 847/391-4406.

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**NABP’s New Computerized FPGEE Administration Debuts; Spring 2009 Examination Scores Released**

After seven years as a paper-and-pencil examination the computerized Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) returned on Tuesday, April 14, 2009, with a total of 898 candidates sitting for the examination.

The FPGEE is the third computerized examination to be administered by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®).

Like the NAPLEX and MPJE, Pearson VUE is now the test vendor for the computerized FPGEE examination, providing a secure and consistent test center network. As a benefit to utilizing Pearson VUE as the test vendor, candidates are able to choose from more than 200 Pearson VUE testing sites rather than being limited to three sites, as was the case with the previous paper-and-pencil format.

Score reports from the April 14 administration may be accessed through a link in the Examination Programs section of the NABP Web site at www.nabp.net.

The next FPGEE will be administered on Thursday, October 1, 2009. The deadline to register for the October 2009 examination is Thursday, September 17, 2009. Candidates will be able to schedule their test sites electronically approximately two to three business days after registering with NABP to take the FPGEE. The deadline to schedule for the examination is Monday, September 28, 2009. As with the paper-and-pencil format, the FPGEE administration will continue to be held one day in the spring and one day in the fall.

NABP provides the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification program as a means of documenting the educational equivalency of a candidate’s foreign pharmacy education and foreign license and/or registration, which assists state boards of pharmacy in qualifying candidates.

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NABP Installs New District 6 Representative on Executive Committee, Re-elects District 7 Representative

Joseph L. “Joe” Adams, RPh, member of the Louisiana Board of Pharmacy, was elected to serve a three-year member term, representing District 6 on the Executive Committee, and Cathryn J. Lew, RPh, member of the Oregon State Board of Pharmacy, was re-elected to serve a three-year member term, representing District 7.

Elections were held during the Final Business Session of the NABP 105th Annual Meeting, held May 16-19, 2009, in Miami, FL.

The newly elected officers of the NABP Executive Committee are President-elect William T. Winsley, MS, RPh, executive director of the Ohio State Board of Pharmacy, and Treasurer Malcolm J. Broussard, RPh, executive director of the Louisiana Board of Pharmacy. Gary A. Schnabel, RN, RPh, executive director of the Oregon State Board of Pharmacy, assumed the office of NABP president, and Rich Palombo, RPh, member of the New Jersey Board of Pharmacy, assumed the position of chairperson at the conclusion of the Annual Meeting.

In addition, the following members are continuing to fulfill their terms on the 2009-2010 NABP Executive Committee: Karen M. Ryle, MS, RPh, of Massachusetts (District 1); Elizabeth Scott “Scotti” Russell, RPh, executive director of the Virginia Board of Pharmacy (District 2); Michael A. Burleson, RPh, executive director of the Kentucky Board of Pharmacy (District 3); Gregory Braylock, Sr, RPh, of Ohio (District 4); Lloyd K. Jessen, RPh, JD, executive director of the Iowa Board of Pharmacy (District 5); and Hal Wand, MBA, RPh, executive director of the Arizona State Board of Pharmacy (District 8).

Joseph L. “Joe” Adams, RPh

Joseph L. “Joe” Adams, RPh, has been a member of the Louisiana Board of Pharmacy since 2000. In addition, he is a pharmacy manager for Walgreen Co, where he is responsible for the entire operation of the pharmacy. Adams has been a Walgreen Co employee since 1977, when he began as a clerk. After completing an internship at a Walgreens pharmacy and receiving his pharmacy license, Adams moved up the ranks from staff pharmacist to his current position.

An active member of NABP and the Louisiana Board, Adams has served on the NABP Committee on Law Enforcement/Legislation and the NABP Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety. As a member of the Louisiana Board, Adams serves on several committees including chairman of the Reinstatement Committee and as a member of the Regulations Revision Committee and the Violations Committee.

Among his other activities, Adams currently serves as a member of the Louisiana Medicaid Pharmacy and Therapeutics Committee, the Louisiana Pharmacists Association, the Louisiana Pharmacy Congress, and the National Association of Chain Drug Stores. He also is a member of the Health Care Reform Region 9 Consortia, and he was a delegate of Governor Kathleen Blanco’s Health Care Summit held in 2004. Adams was named 2004 Chain Pharmacist of the Year by the Louisiana Pharmacist Association.

Adams earned his bachelor of science degree in pharmacy from Xavier University of Louisiana College of Pharmacy.

Cathryn J. Lew, RPh

A past member of the Oregon State Board of Pharmacy, Cathryn J. Lew, RPh, was first appointed to the Board in 2001 and was reappointed in 2004. During this time, she was elected by the Board to serve as president for two terms and three terms as vice president. Currently, Lew is a clinical staff pharmacist at Sacred Heart Home Infusion/Hospice, a position she has held since 1995. Previous positions she has held include serving as a pharmacist at the University of Oregon Student Health Center as well as staff pharmacist at Sacred Heart Medical Center, Salem Hospital – SHAPES, where she was involved in urgent care, pharmacokinetics, and drug therapy monitoring.

An active member of NABP, Lew was first elected to serve a two-year term on the Executive Committee (continued on page 135)
NABP Streamlines Accreditation through Automated Field Surveys

With Centers for Medicare and Medicaid Services’ October 2009 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation deadline fast approaching, the quantity of required field surveys that NABP must perform remains steady. To assist in meeting the demand for field surveys, NABP made the official switch from a manual reporting process to the SansWrite Form Inspection and Development Software in March 2009. This advanced software has assisted NABP in automating field surveys of those facilities seeking DMEPOS accreditation. In addition, the software promotes a standardized process for creating, managing, and accessing report data.

SansWrite expedites the field survey process by eliminating extra steps and unnecessary duplication. With this implementation, processes have been condensed significantly. In some instances, surveyors are also utilizing tablet PCs during surveys in addition to the SansWrite software. These paperless mobile inspection tools further expedite the survey process, allowing surveyors to immediately input inspection data while on site. The PCs accept the data through recognition technology and touch-screen options, as well as through use of the traditional keyboard.

NABP also plans to automate field surveys for the Verified-Accredited Wholesale Distributors® program during third quarter 2009.

Newly Accredited DMEPOS Facilities

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

- **63rd Drive Pharmacy Corp dba K.S. Pharmacy**
  - Covington, KY
  - Accredited March 24, 2009
- **Blank’s Pharmacy, Inc**
  - Covington, KY
  - Accredited March 24, 2009
- **Eagle Drugs Pharmacy**
  - Southgate, MI
  - Accredited March 20, 2009
- **Fox Drug of Torrance**
  - Torrance, CA
  - Accredited March 20, 2009
- **Gabecare DirectRx**
  - Troy, MI
  - Accredited April 20, 2009
- **Robert Jacobson Pharmacy**
  - Yonkers, NY
  - Accredited April 20, 2009
- **63rd Drive Pharmacy Corp dba K.S. Pharmacy**
  - Rego Park, NY
  - Accredited March 20, 2009
- **Albertsons LLC 246 Stores**
  - Boise, ID
  - Accredited April 20, 2009

A full listing of accredited DMEPOS facilities is available on the NABP Web site at www.nabp.net.

Computerized FPGEE Administration

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Computerized FPGEE Administration

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dates for licensure in the United States. The FPGEE is one component of this program. To qualify for the FPGEC certification program, candidates are required to submit proper documentation from educational or licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy.

In addition, candidates must also pass the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™, or the TOEFL Internet-based Test, which are administered by Educational Testing Service. The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States, Guam, and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that candidates take the Pre-FPGE®, the only FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGE® is available at www.nabp.net.
Second Annual PCOA Administration Held, Score Reports Expected to Provide Valuable Data to Participating Colleges

Approximately 1,630 students from 15 schools and colleges of pharmacy, both public and private, participated in the second annual Pharmacy Curriculum Outcomes Assessment® (PCOA®) administration. The PCOA was administered from March 9-20, 2009, with each school specifying one day within the two week-time period.

After undergoing psychometric analysis, the administration score reports were released in June. These reports allow participating schools across the United States to compare the results of their students in the same professional year. In addition, NABP is confident that the value of the data provided will increase exponentially over the years as the schools and colleges are able to analyze and interpret the data to assist with the education and preparation of pharmacy students.

First administered in April 2008, the PCOA is a comprehensive assessment tool developed by NABP and key stakeholders in response to the need expressed by the US schools and colleges for assistance with curriculum development and measurement of student performance and growth. The third annual PCOA will be held during the first quarter of 2010. Schools and colleges of pharmacy interested in participating are encouraged to contact the NABP Competency Assessment Department at 847/391-4406 or via e-mail at custserv@nabp.net.

Additional information regarding the PCOA is available in the Assessment Programs section of the NABP Web site at www.nabp.net.

Newly Accredited VAWD Facilities

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

Aurobindo Pharma USA, Inc
Cranbury, NJ
Accredited March 25, 2009

Butler Animal Health Supply, LLC
Albany, NY
Accredited February 20, 2009

Butler Animal Health Supply, LLC
Aurora, CO
Accredited March 25, 2009

Cardinal Health 200, Inc dba Cardinal Health
Dixon, CA
Accredited March 25, 2009

Cardinal Health 411, Inc dba Cardinal Health
Elk Grove, CA
Accredited March 25, 2009

Caremark Repack, LLC
Gurnee, IL
Accredited March 13, 2009

Centric Health Resources, Inc dba Centric Health Resources
Chesterfield, MO
Accredited February 20, 2009

CEVA Logistics US, Inc
Arlington, TX
Accredited May 11, 2009

Clinical Supplies Management, Inc
Fargo, ND
Accredited February 20, 2009

Eckerd Corporation dba Rite Aid Charlotte Distribution Center (#53)
Charlotte, NC
Accredited May 11, 2009

Fresenius USA Manufacturing, Inc dba Fresenius Medical Care North America
Ogden, UT
Accredited May 11, 2009

Global Pharmaceutical Sourcing
Rockville, MD
Accredited March 11, 2009

Graceway Pharmaceuticals, LLC
Piney Flats, TN
Accredited April 10, 2009

Howell Marketing Services, a division of F.M. Howell and Company
Elmira, NY
Accredited March 25, 2009

InSource, Inc
Bastian, VA
Accredited April 10, 2009

Integrated Commercialization Solutions, Inc
Kentucky
Accredited April 10, 2009

McKesson Corporation dba McKesson Drug Company
West Sacramento, CA
Accredited March 30, 2009

McKesson Corporation dba McKesson Drug Company
Girardeau, MO
Accredited April 10, 2009

McKesson Corporation dba McKesson Drug Company
Everett, WA
Accredited March 30, 2009

Patterson Logistics Services, Inc
Dinuba, CA
Accredited April 9, 2009

Q Logistics, Inc
Cedar Knolls, NJ
Florham Park, NJ
Accredited April 10, 2009

Safo Dental Supply Company
Buffalo Grove, IL
Accredited May 6, 2009

Top Rx, Inc
Bartlett, TN
Accredited March 25, 2009

UPS Supply Chain Solutions, Inc
Reno, NV
Accredited May 11, 2009

A full listing of more than 350 accredited VAWD facilities is available on the NABP Web site at www.nabp.net.
Legal Briefs
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mend criminal background checks be undertaken both at the initial licensure stage as well as during periodic renewal stages. These board decisions are subject to due process scrutiny if challenged. At times, NABP may be confronted with decisions regarding its programs and the impact of past behavior (ie, qualification for the Foreign Pharmacy Graduate Examination Committee™). If challenged, a differing legal standard will apply to NABP, in spite of the fact such NABP decision may impact a board decision as well.

“A quandary in Sweden: criminals in med school”
(The New York Times, March 24, 2009)

This article uncovers how one of Sweden’s most prestigious medical schools unknowingly admitted a convicted murderer and “struggled with ways to expel him.” Additional convicted criminals were also identified as currently enrolled students at various medical schools in Sweden.

The existence of a criminal history creates interesting legal questions as to the authority of certain entities to require and use criminal backgrounds to screen applicants. For instance, should United States pharmacy schools ask for or require criminal histories as part of the application process? Should a pharmacy school admit and allow a student to matriculate through the educational program if such student is otherwise ineligible (or potentially ineligible) for licensure in all or many states? Is this fair to the student and regulatory board? The legal restraints on educational schools (further complicated if the university is a “state” school) may be very different from those placed upon boards of pharmacy.

Similar questions may be asked of NABP should it explore limiting access to the NAPLEX of examinees based upon character issues (ie, if past examination breaches/cheating related to a candidate occurred). Again, as a private sector organization, the legal principles that apply to NABP would differ from those applied to the public sector boards of pharmacy.

“ACPE: Pharmacy school troubled for 6 years”

This article chronicles the history of issues confronting a college of pharmacy and its recent probation status determination made by the Accreditation Council for Pharmacy Education (ACPE). Importantly, it highlights the activities in ongoing litigation that illustrates the realities of legal disputes.

Like NABP, ACPE is a private entity that, among other things, creates and enforces standards to promote quality in pharmacy education. The legal protections afforded to programs that voluntarily seek accreditation status will be subjected to differing scrutiny than decisions by boards of pharmacy. Thus, the legal principles applied to a dispute between ACPE and one of its programs will generally involve theories related to the private sector.

To the extent that boards of pharmacy and/or legislation choose to rely upon ACPE, legal challenges will trigger a different and more intense scrutiny, as impacted programs may attempt to blur the line between the public sector board of pharmacy and the private sector ACPE.

“NAPLEX, Georgia MPJE exams suspended indefinitely”
(American Pharmacists Association News and Templates, August 29, 2007)

This article announces the suspension of the NAPLEX and Georgia MPJE by NABP in August 2007. As with the references above, the impact of NABP actions trigger an impending consequence to the boards of pharmacy. The legal principles pursued by NABP as a result of an alleged examination breach were tailored to address the fact that one party to the ongoing litigation is a state university, which is subject to certain rights and protections as a state entity. Other private sector entities and/or individuals were potentially legally culpable under differing theories. At the same time, it is likely that impacted applicants for licensure examined multiple legal theories involving potential actions against state entities (the board of pharmacy and the state university) private entities (NABP and examination vendors), and private individuals (individual parties that may have been involved).

On a regular basis, NABP is confronted with issues and decisions that affect its programs and/or services provided to boards of pharmacy. These decisions will likely impact individuals, as well as the relative board (or boards) of pharmacy. In the event of a legal dispute, the characterization of the actions taken (or not taken) by the entity will dictate the legal theory or basis for resolution.

The aforementioned articles are intended to illustrate and highlight the numerous responsibilities of the boards of pharmacy and merely identify how varying legal theories apply to circumstances, dependent upon the party or parties involved. The 2009 Report of Counsel is by no means attempting to specifically identify and describe the varying legal principles applicable to each circumstance. It is worthy to begin to recognize these differing roles and the legal bases for supporting relationships and decision-making. Boards of pharmacy are encouraged to understand what decisions ultimately lie with the public sector and to make such decisions on an informed basis. When necessary, NABP will justify and defend the decisions that ultimately impact the boards of pharmacy and their constituents.
NABP Announces One New and Four Reappointed Members to Serve on ACE

NABP has appointed one new member and reappointed four members to serve on the 2009-2010 Advisory Committee on Examinations (ACE). This standing committee, established by NABP in 1912, was created to safeguard the integrity and validity of NABP examinations.

ACE oversees the development and administration of all of the Association’s examination and certification programs. ACE also considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

ACE typically meets three to four times per year and consists of individuals who are affiliated members of NABP, including current active board of pharmacy members and administrative officers, individuals who have served within the last five years as a member or administrative officer of a board of pharmacy, and non-affiliated individuals who are practicing pharmacists or serving as pharmacy school faculty. Members serve three-year terms and ex officio members serve one-year terms.

As of June 1, 2009, the following individuals are serving terms on ACE and the Executive Committee liaison is Hal Wand, MBA, RPh. 

**2009-2010 ACE Members**

<table>
<thead>
<tr>
<th>Name</th>
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<td>Tom Houchens</td>
<td>London, KY</td>
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<td>(Chair)</td>
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<td>Sara St. Angelo*</td>
<td>Indianapolis, IN</td>
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<td>David Todd Bess</td>
<td>Cane Ridge, TN</td>
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<td>Michael Duteau**</td>
<td>Baldwinsville, NY</td>
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<td>Judy Gardner</td>
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<td>Arthur I. Jacknowitz</td>
<td>Morgantown, WV</td>
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<td>Kendall M. Lynch</td>
<td>Nashville, TN</td>
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<td>Betty J. Dong**</td>
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<td>(Ex Officio Member)</td>
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<td>Kevin O. Rynn**</td>
<td>Piscataway, NJ</td>
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<td>(Ex Officio Member)</td>
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<tr>
<td>Richard Morrison**</td>
<td>Bothell, WA</td>
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* Indicates new member  
** Indicates reappointed members

NABP Accepting Applications for ACPE Representative

The NABP Executive Committee is accepting letters of interest and curricula vitae (CV) until Tuesday, September 1, 2009, from individuals interested in serving a six-year term as one of the Association’s three representatives to the Board of Directors of the Accreditation Council for Pharmacy Education (ACPE).

Interested active board of pharmacy members, administrative officers, or individuals who have served within the last five years as members or administrative officers of an active board of pharmacy are encouraged to submit a current CV and a letter of interest to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056, by the September 1 deadline. Appointees must be available to attend two to three board meetings per year, three to four college or school of pharmacy on-site visits, an ACPE annual meeting, and an orientation program to be held in January 2010. The term will officially begin on July 1, 2010.

Letters of interest should be a short narrative, no longer than one page, highlighting the following:

- relevant experiences and talents that qualify the candidate for service,
- candidate’s views on educational and accreditation issues facing the ACPE Board of Directors,
- why the individual wishes to serve, and
- what the candidate would contribute as an appointee of NABP.

On June 30 of every even-numbered year, the six-year term of one NABP representative expires. A subcommittee of the Executive Committee will present a recommendation for the appointee to the full Executive Committee at its November 2009 meeting for final approval.

For more information please contact the Executive Office at exec-office@nabp.net.
BTC Drug Class
(continued from page 118)

competencies now embraced by US colleges and schools of pharmacy. According to the JCPP Future Vision, “[p]harmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes.” They will have the “authority and autonomy to manage medication therapy and will be accountable for patients’ therapeutic outcomes.”

Working cooperatively with practitioners of other disciplines to care for patients, pharmacists, as depicted in the JCPP vision statement, will be “the most trusted and accessible source of medications and related devices and supplies; the primary resource for unbiased information and advice regarding the safe, appropriate, and cost-effective use of medications; valued patient care providers whom health care systems and payers recognize as having responsibility for assuring the desired outcomes of medication use in collaboration with patients and their other care providers.”

Calling for the support of the boards of pharmacy, Gary A. Schnabel, RN, RPh, announced during the 105th Annual Meeting in Miami, FL, his initiative as NABP president to embrace and work to advance the JCPP vision in the context of patient care and protection of the public health. He asked that the boards of pharmacy assist in this effort by providing the regulatory environment necessary to foster this collective vision of practitioners and regulators. Schnabel noted the work of past presidents in the areas of patient safety, error reporting, and accreditation of pharmacies, stating that he would work to integrate relevant components of the JCPP Future Vision of Pharmacy Practice 2015 into NABP strategic planning to significantly revamp the regulation and practice of pharmacy in the best interest of the patient.

For several years now, this vision has been guiding the evolution of pharmacy education and practice standards. The establishment of a BTC drug class, NABP maintains, would build upon the foundations currently in place and advance the practice of pharmacy toward this future vision.

Collaborative Practice, MTM Set Precedents

The emphasis on working as members of an interprofessional team is supported by the majority of states’ enactment of collaborative health care practice legislation that includes an expanded patient-care role for pharmacists. Collaborative practice enables pharmacists to work together with physicians, contributing their specialized knowledge and skills to improve patient outcomes. Under a collaborative practice agree-

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Report Cites Issues Needing Resolution

If a BTC drug class were to be established in the US, GAO reports, several issues would first need to be resolved. Such questions pertain to the roles and responsibilities of pharmacists, such as defining their BTC dispensing responsibilities and training needs; infrastructure issues, such as establishing systems for the transfer of patient information and private consultation areas; and cost-related issues, such as the availability of third-party coverage for BTC drugs and counseling.

In regard to pharmacist responsibilities for dispensing BTC drugs, GAO cites the Food and Drug Administration’s suggestion that these duties could include, but not be limited to, reviewing or conducting an initial screening for clinical laboratory results, contraindications, or drug interactions; advising consumers on safe drug use; and monitoring for continued safe or effective use.

GAO points out that stakeholders would also have to determine whether a standard set of BTC dispensing requirements

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BTC Drug Class
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ment, qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for such activities as performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens. Thus, there is ample precedent for pharmacists to play an active role in patient care.

The suitability of pharmacists to provide integrated patient care is further supported by the Medicare Prescription Drug Improvement and Modernization Act of 2003, which establishes the need for medication therapy management (MTM) services to be provided by pharmacists for high-risk patients. The Centers for Medicare and Medicaid Services (CMS) requires pharmacies serving Medicare Part D beneficiaries to have established an MTM program that, among other things, “ensures optimum therapeutic outcomes for targeted beneficiaries through improved medication use; reduces the risk of adverse events”; and “is coordinated with any care management plan established for a targeted individual under a chronic care improvement program.”

Pharmacy Practice Adapts to Meet Societal Needs
These regulations and practice standards have been established over the years to fill a societal need in patient health care today. The Institute of Medicine describes this need in its 2006 report, Preventing Medication Errors, which calls for a “paradigm shift in the patient-provider relationship,” wherein pharmacists and other health care providers “must communicate more with patients at every step of the way and make that communication a two-way street, listening to the patients as well as talking to them. They should inform their patients fully about the risks, contraindications, and possible side effects of the medications they are taking and what to do if they experience a side effect.”

The report further asserts that “patients should be given opportunities to consult about their medications at various stages in their care,” including at the pharmacy. Proponents, including NABP, argue that a BTC drug class would provide the opportunity for pharmacists to provide this enhanced level of patient care.

Underlying this position is the ongoing mission of NABP and its member boards of pharmacy to protect the public health. Many sources call for enhanced patient care, particularly in light of today’s aging population and an ever-increasing array of medications available to treat a range of ailments. Pharmacy stakeholders have answered that call by raising the bar for new pharmacists to ensure their ability to provide patient care services, and providing resources to assist in the systemization of enhanced patient care. According to NABP and other proponents of a BTC drug class, these factors render the practice of pharmacy in the US ripe for a BTC drug class.

GAO Report
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would apply to all pharmacies and pharmacists across the country, and how to ensure that pharmacists meet their responsibilities for dispensing BTC drugs, including providing necessary counseling.

NABP has indicated that if a BTC drug class were created, the Association would work with the state boards of pharmacy to establish national standards for a number of issues, including the types of data systems, consumer interactions, documentation, and expertise required for a BTC practice. Recognizing that resource constraints present a challenge for many boards of pharmacy to oversee a BTC drug class, NABP has indicated its ability to inspect pharmacy facilities and provide documentation on behalf of the boards of pharmacy through its pharmacy accreditation program, currently in development.

Another consideration in the establishment of a BTC drug class, GAO notes, would be determining if additional training would be needed for pharmacists and pharmacy staff and assessing whether all pharmacists and pharmacy staff would need to undergo this training. In pharmacist education today, more emphasis is being placed on patient care and assessment than was the case in earlier years, GAO reports, noting that, to fulfill degree requirements, pharmacy students must now earn a doctor of pharmacy degree.

Proponents of a BTC drug class note that these more stringent educational requirements prepare pharmacists to provide the level of patient care needed to ensure the success of such a system. The GAO report does not address the educational standards or qualifications of pharmacists to provide these services in the countries studied.

Thus, whether Australia, Italy, the Netherlands, and the United Kingdom have undertaken similar measures to prepare pharmacists for their role in dispensing a BTC class of drugs is a matter that remains to be fully vetted. In the US, however, NABP is prepared to continue advocating for a BTC drug class and providing the boards of pharmacy with the support they need to ensure the success of this and other patient care initiatives.
**Around the Association Remembrance**

Debra C. Ringgenberg, RPh, executive director of the Missouri Board of Pharmacy from 2007 to 2008, passed away on June 2, 2009, after an extended illness. Ringgenberg was a distinguished pharmacist and exemplary executive director dedicated to advancing the practice of pharmacy through her governmental service. Prior to joining the Missouri Board, she served as an inspector, investigator, and compliance officer for the Iowa Board of Pharmacy from 2002 to 2007, where she was instrumental in handling Internet drug investigations and in helping the Board develop rules for sterile compounding.

**Executive Director Change**

James Queenan, RPh, MBA, has been appointed executive secretary/director of the New Hampshire Board of Pharmacy, effective March 30, 2009. Prior to this, Queenan was the pharmacy operations manager and pharmacy specialist for Hannaford Bros. He has more than 30 years experience in pharmacy operations and management, including multi-unit management, pharmacy openings, and quality/

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**NABP Revises VAWD Criteria Pursuant to Updated Model Rules**

NABP has updated the criteria for its Verified-Accredited Wholesale Distributors® (VAWD®) program pursuant to updates made to the Model Rules for the Licensure of Wholesale Distributors in 2008. The changes made to the Model Rules were implemented pursuant to the Executive Committee's approval of recommendations made by the 2007-2008 Task Force on Prescription Drug Diversion from Common Carriers. The purpose of the amendments to the Model Rules and the subsequent changes to the VAWD criteria was to further protect the public in the distribution of prescription drugs and improve quality and safety in patient care. The criteria can be found under the Accreditation Programs section of the NABP Web site.

**Doctor Found Guilty of Smuggling Foreign Cancer Drugs Into US**

On May 8, 2009, Vinod Chandrashekm Patwardhan was convicted in the US District Court for the Central District of California of conspiracy, two counts of introducing misbranded drugs into interstate commerce with intent to defraud or mislead, and three counts of smuggling. Patwardhan, an Upland, CA oncologist, was arrested in August 2008 by federal authorities after being charged with introducing foreign misbranded drugs into interstate commerce. A May 11, 2009 news release issued by the Court stated that evidence presented during a seven-day trial showed that Patwardhan regularly purchased unapproved cancer drugs from foreign countries including India, Honduras, Panama and the Philippines. From 2004 until his arrest last August, Patwardhan smuggled or caused to be smuggled more than $1.3 million worth of unapproved drugs from foreign countries. Patwardhan was scheduled to be sentenced on July 20 and faced a statutory maximum penalty of 71 years in federal prison.

**FDA Develops Q & A’s for Initiative Against Contaminated Weight Loss Products**

Food and Drug Administration (FDA) has developed questions and answers to help consumers, health care practitioners, and the general public understand FDA's actions regarding weight loss products contaminated with various prescription drugs and chemicals. Many of these products are marketed as dietary supplements. Unfortunately, FDA cannot test and identify all weight loss products on the market that have potentially harmful contaminants in order to ensure their safety. FDA laboratory tests have revealed the presence of sibutramine, fenproporex, fluoxetine, bumetanide, furosemide, phentoyin, rimonabant, cetilistat, and phenolphthalein in weight loss products being sold over-the-counter. Enforcement actions and consumer advisories for unapproved products only cover a small fraction of the potentially hazardous weight loss products marketed to consumers on the Internet and at some retail establishments.

More information is available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm136187.htm.

**DEA Issues Interim Final Rule on Internet Pharmacy Regulations**

Drug Enforcement Administration (DEA) has issued an interim final rule to implement the Ryan Haight Online Pharmacy Consumer Protection Act. Enacted in October 2008, the Ryan Haight Act amended the Controlled Substances Act and Controlled Substances Import and Export Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances over the Internet. Except for a few subsections, including the definition of telemedicine, this interim rule took effect on April 13, 2009. Among other requirements, the Ryan Haight Act requires online pharmacies to obtain modified DEA registration. DEA accepted comments on these interim regulations through June 5. More information is available in the April 6 Federal Register at www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf.
Arizona State Board of Pharmacy Reacts to Changing Economy

Recent Arizona State Board of Pharmacy newsletters have detailed the size of the current and projected Arizona State budget deficits and the negative impact on state agencies large and small. The Board of Pharmacy fund sweeps (in excess of $3 million so far) by the legislature in fiscal years 2008 and 2009 coupled with potential fund sweeps in fiscal year 2010 may still result in layoffs of compliance (investigative) and/or administrative staff resulting in a devastating impact on the Board’s mission of protecting the public health and safety.

The Board determined that simply cutting expenses is not enough and has endeavored to identify additional sources of revenue. Since many of the Board’s fees were lower than Arizona statutes allow and most had not been raised since 2002, a rule change was initiated that resulted in raising a majority of the fees charged by the Board for various licenses and permits that became effective May 7, 2009. Since most fees are prorated monthly, when fees are able to be evenly divisible by 12 (months), the fees were raised to that amount rather than the highest amount allowed in order that most prorated fees result in even dollar amounts. This will save expenses by reducing the time both in-house and contract employees spend collecting and reconciling change in the office before deposits are made with the treasurer’s office.

The economic impact statement accompanying the rule change, written by Dean Wright, estimates that the fee increases will raise approximately $228,000 in additional revenue annually. Using data from the NABP Survey of Pharmacy Law, the Board estimates that the increases will only result in fees in Arizona that are in the top third of the fees charged by the other US states and territories. The fees (both new and unchanged) are displayed on the Arizona State Board of Pharmacy Web site at www.azpharmacy.gov/pdfs/fee_chart.pdf.

New Jersey Board of Pharmacy Must Approve Technician Certification Programs

New Jersey Administrative Code (N.J.A.C.) 13:39-6.15(f)(2) lists the certification requirements for pharmacy technicians who are working when the registered pharmacist to pharmacy technician ratio exceeds 2:1. These certification requirements are:

(i) successfully passing the Pharmacy Technician Certification Board’s Pharmacy Technician Certification Examination and fulfilling the requirements to maintain this status, or;

(ii) passing a Board-approved certification program and fulfilling the requirements to maintain this status, or;

(iii) completing a specific pharmacy and/or corporation’s Board-approved program, which includes a testing component and

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Around the Association

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compliance assurance. Queenan was also appointed to serve as a retail pharmacy representative for the New Hampshire Privacy Task Force and the Medical Error Subcommittee. He earned his bachelor of science degree in pharmacy from Massachusetts College of Pharmacy and his master of business administration degree from Southern New Hampshire University.

Board Member Appointments

• Christopher Kim, RPh, has been appointed a member to the Alaska Board of Pharmacy. Kim’s appointment will expire on March 1, 2012.

• Joseph Bryant, PD, has been appointed a member of the Arkansas State Board of Pharmacy. Bryant’s appointment will expire on July 1, 2015.

• Larry Hadley, RPh, has been appointed a member of the Kentucky Board of Pharmacy. Hadley’s appointment will expire on January 1, 2013.

• Joel Thornbury, RPh, has been appointed a member of the Kentucky Board of Pharmacy. Thornbury’s appointment will expire on January 1, 2013.

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State Board News

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satisfies the criteria set forth in N.J.A.C. 13:39-6.15(g). Completion of a specific pharmacy and/or corporation’s Board-approved program qualifies the pharmacy technician to work only for that specific pharmacy and/or corporation. If the pharmacy technician becomes employed by another pharmacy and/or corporation, the pharmacy technician shall be required to complete the new employer’s training program.

The Board notes that completion of a certification program not approved by the New Jersey Board of Pharmacy will not satisfy the requirements of N.J.A.C. 13:39-6.15(f)2.

Minnesota Board Stresses Importance of Technician Registration

Despite repeated notifications published in the Minnesota Board of Pharmacy newsletters, Board inspectors continue to encounter individuals performing the duties of a pharmacy technician without being registered as such. In many cases, there is no indication that the pharmacist-in-charge (PIC) ever attempted to make sure that the individual working as a technician was registered. One case that recently came to the Board’s attention involved an individual who presented the PIC with a photocopy of a technician registration card that had been altered to indicate that the individual was currently registered. In reality, that technician’s registration had been suspended by the Board.

Minnesota Rule 6800.3850 states in part: “Pharmacy technicians may be used in performing pharmacy tasks not specifically reserved in this chapter to a licensed pharmacist only when the technician is properly registered with the board.” Minnesota Rule 6800.2400 states, in part, that it is “the pharmacist-in-charge’s duty and responsibility . . . to ensure that all persons working as pharmacy technicians are registered with the Board, in accordance with part 6800.3850.” The Minnesota Board of Pharmacy Web site has a feature that allows for verification of licensure or registration. This feature can be accessed at www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx. Verification can also be accomplished by calling the Board’s office at 651/201-2825. Individuals must be registered before they can work in a pharmacy as technicians.

The Board has the authority to take disciplinary action against the license of the pharmacy. It is likely that the Board will begin exercising this authority given the continuing problem of having unregistered individuals performing the duties of a pharmacy technician.

Montana Board of Pharmacy v Canadian Connection

On January 15, 2009, the Montana Board of Pharmacy appeared in State District Court in Helena, MT, to ask the court to find Thomas Kennedy, of Billings, MT, in contempt of court for ignoring a preliminary order of injunction. The Board was represented by Michael Fanning, Board counsel, and Anjeanette Lindle, Board attorney.

Kennedy operated Canadian Connection, a business that put people in touch with a pharmacy in Calgary, Alberta, which then sent drugs directly to patients in Montana and elsewhere in the United States. For his efforts, Kennedy received a 16% commission, and court documents estimated he earned about $7,000 per year.

On October 4, 2004, the court issued a preliminary injunction that stated in part: “While Kennedy is not a pharmacist and Canadian Connection is not a pharmacy, Kennedy is assisting Canadian mail service pharmacies, which are not registered with the Board, in providing prescription medication to
Montana residents. This is a violation of Section 37-7-301, MCA.” The order of preliminary injunction provides that: “Thomas E. Kennedy, dba Canadian Connection, including his employees and agents, if any, is enjoined from engaging in any activity which causes or facilitates the importation or assists in the importation of prescription drugs from any place outside of the United States. This order shall remain in effect until further order of the court.”

Testifying on behalf of the Board of Pharmacy, Rebecca Deschamps, RPh, stated she visited Kennedy’s business in 2005, posing as a potential customer, and that Kennedy dispensed pharmaceutical advice she considered potentially dangerous. Among other things, Kennedy told her she could get a better deal on medications by purchasing double strength pills and then splitting them in half. Deschamps told the court such splitting could result in irregular doses that could be harmful.

At the January 15 hearing the court found overwhelming evidence, including Kennedy’s own admissions, that he had disobeyed the Order of Preliminary Injunction, and for over four years continued to engage in the activity that was specifically enjoined by the court.

Kennedy was fined $4,000, and in order to avoid incarceration and an additional fine, ordered to immediately comply with the Order of Preliminary Injunction issued October 4, 2004.

Following the hearing, Kennedy stated he would close his business.

Washington State Requires New Background Checks

On January 1, 2009, the Washington State Department of Health began a pilot project to use federal fingerprint-based background checks for certain applicants for health profession licenses. The pilot focuses on applicants from out of state and some with a criminal history in Washington. Out-of-state applicants are a focus because they are unlikely to have criminal history information in the Washington State Patrol database.

Applicants must pay $49.25 to have their fingerprints checked against the federal database. They are also responsible for the arrangements and the cost of taking the fingerprints. Fingerprints must be taken on the fingerprint card provided by the department. Fingerprint services may be obtained at local law enforcement offices. The department will notify applicants who need to undergo this background check. Failure to submit fingerprints will delay processing of their applications. Applicants need to plan for an additional five to 10 working days for the credentialing process. Anyone hiring out-of-state pharmacy personnel should consider this process in their planning.

NABP Installs New Representatives

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Active Committee in 2007. She has also served on the Committee on Law Enforcement/Legislation. Among her other activities, Lew is a member of the Oregon State Pharmacy Association, Oregon Society of Health-System Pharmacists, served as a member of the Pharmacy Technician Certification Board Stakeholder Policy Council in 2005 and 2006, and has served on the Oregon Society of Health Care Pharmacists Board. In addition, she was the Oregon delegate for the Northwest Pharmaceutical Care Conference in 1994. Lew was a recipient of the Oregon Society of Health-System Pharmacists Outstanding Sponsored Activity Award.

A graduate of Oregon State University, Lew earned a bachelor of science degree in pharmacy and was a member of the Rho Chi Honor Society.
Save the Date!

NABP invites board of pharmacy executive officers, members, and compliance officers, as well as state and federal regulators and other stakeholders to unite December 3-4, 2009, for the NABP 2009 Symposium. The fast-paced, one-and-a-half-day workshop will offer attendees the opportunity to discuss current issues in pharmacy as well as earn continuing pharmacy education credit. More information will follow in future issues of the NABP Newsletter and on the NABP Web site at www.nabp.net.