NABP Releases Updated NAPLEX Blueprint

NABP regularly conducts practice analysis surveys to update and validate the North American Pharmacist Licensure Examination™ (NAPLEX®) competency statements that define the examination blueprint. These surveys ensure that the competencies accurately reflect the current knowledge, judgment, and abilities required of entry-level pharmacists seeking licensure. The results of the surveys are also used by NABP to determine the distribution of questions in each of the three major content areas of the NAPLEX blueprint.

As a result of the survey performed in June 2003, substantive revisions were made to update the NAPLEX blueprint. The updated blueprint is available for viewing on NABP’s Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning in spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers into each competency area instead of a single competency area as with the current NAPLEX blueprint. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

As a result of the updated blueprint and competency statements, a new passing score study was conducted. The NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate’s ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX.

The new passing standard will go into effect along with the updated blueprint in the spring of 2005.
The NABP Newsletter (ISSN 8756-4483) is published ten times a year by the National Association of Boards of Pharmacy (NABP) to educate, to inform, and to communicate the objectives and programs of the Association and its 66 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $35 per year.

Executive Committee

Donna S. Wall
Chairperson, District IV
Donna M. Horn
President, District I
Dennis K. McAllister
President-elect, District VIII
Lawrence H. Mokhiber
Treasurer, District II
Charles Curtis Barr
Member, District V
Michael A. Moné
Member, District III
Richard A. Palombo
Member, District II
Oren M. Peacock, Jr
Member, District VI
Gary A. Schnabel
Member, District VII
Charles R. Young
Member, District I

Feature News

Boards of Pharmacy, Attorneys General Convene for Importation Enforcement Workshop and Task Force

Two resolutions passed at NABP's 100th Annual Meeting, held April 24-27, 2004, in Chicago, IL, prompted the creation of the Importation Enforcement Workshop and Task Force: Resolution No 100-1-04, Illegal Importation – Federal and State Enforcement of Reimportation Laws and Resolution No 100-17-04, Prosecution of Entities Aiding and Abetting in the Illegal Importation of Prescription Medications.

NABP invited member boards of pharmacy, attorneys general offices, and other interested stakeholders to discuss importation enforcement guidelines and strategies at its Importation Enforcement Workshop and Task Force, June 22-23, 2004, in Arlington, VA. The Association welcomed representatives from 16 states and the District of Columbia, as well as the Food and Drug Administration, Drug Enforcement Administration, and pharmaceutical industry to the meeting.

The NABP Task Force was commissioned by the Executive Committee in response to the continued interest and involvement of the state boards of pharmacy and state attorneys general in the importation of drugs. NABP President Donna M. Horn appointed the following individuals to serve on the Task Force: Donald H. Williams, chairperson, former executive director of the Washington State Board of Pharmacy; Howard C. Anderson, Jr, member, executive director of the North Dakota State Board of Pharmacy; Bill Veniot, member, New Brunswick Pharmaceutical Society; and William T. Winsley, member, executive director of the Ohio State Board of Pharmacy. Also invited to participate as ex-officio members were Patricia Good, chief, Liaison and Policy Section, Office of Diversion Control Drug Enforcement Administration (DEA) and Elizabeth A. Willis, chief of Drug Operations Unit, Office of Diversion Control, DEA. Richard A. Palombo, New Jersey Board of Pharmacy, was the NABP Executive Committee liaison.

The objective of the Workshop was twofold: to compile an Enforcement Guideline Document that state boards of pharmacy and their legal counsel could utilize as they consider prosecuting entities involved in the illegal importation of drugs, and develop a Strategic Plan to assist the boards in managing the changing regulatory environment surrounding importation.

The Strategic Plan will address how state boards of pharmacy respond when the illegal importation of drugs is encouraged and sanctioned in their states, what the boards must do to repair a regulatory process that has been damaged by a complete disregard of state and federal laws, and what regulatory and legislative initiatives will need to be enacted and implemented if importation is legalized and approved for implementation by the Department of Health and Human Services.
Importation Enforcement Workshop

During the Workshop, which included presentations and discussions with regulators and legal experts who have combated entities illegally assisting in the importation of prescription drugs, Task Force members gathered information for the Enforcement Guideline Document. The Document is particularly useful for boards of pharmacy that have not yet taken legal action against entities—especially storefront pharmacies—that assist in importing prescription drugs in violation of state and federal law. State boards of pharmacy and attorneys general submitted examples of warning letters, cease and desist orders, petitions, pleadings, appellate documents such as memoranda of law, and other documentation that states have issued or filed to halt illegal importation activities so that NABP could compile the documentation into a reference guide that supplements the Enforcement Guidelines. In July, NABP distributed the Enforcement Guideline and legal documents via CD-ROM to all member boards of pharmacy, board counsel, and Workshop participants.

Those invited to speak at the Workshop shared their experiences in halting the operations of entities that assisted in, or were directly engaged in, the illegal importation of prescription drugs; commented on public safety issue; and analyzed the legal strategies for confronting importation as a public policy issue. Speakers included Jack Atkins, board counsel, Montana Board of Pharmacy; Grant Moak, assistant attorney general, Oklahoma State Board of Pharmacy; Jerry Moore, executive director, Alabama State Board of Pharmacy; Carson Carmichael, board counsel, North Carolina Board of Pharmacy; Tom McGinnis, director of Pharmacy Affairs, Office of Policy, Food and Drug Administration (FDA); Moira Gibbons, Electronic Licensure Transfer Program®/Verified Internet Pharmacy Practice Sites™ manager, NABP; and Susan C. Winckler, vice president for policy and communications and staff counsel for the American Pharmacists Association (APhA).

Atkins, who initiated legal actions to halt the operations of Rx Depot, a storefront operating in his state of Montana, noted that storefront operations can easily be established with nominal equipment to receive and, subsequently, transfer the prescription information. Necessary equipment merely includes a telephone, fax machines, scanners, and credit card processors, all of which can be readily operated from anywhere—even the proprietor’s home. Atkins also stated that boards sometimes must use creative approaches to prosecute storefronts that often boast that the law does not apply to them. “What we did and how we did it is not necessarily something you will find in a law school textbook,” he said.

Moak explained how he began prosecuting storefront pharmacies in 2002 when he began working with the Oklahoma State Board of Pharmacy. “It has been a fascinating journey since I’ve been assigned to the Oklahoma Board,” he said. “Until my assignment, I led a relatively peaceful existence as an assistant state attorney general.”

Since that time, Moak successfully prosecuted numerous licensees and violative activities including Rx Depot’s business operations in Oklahoma, against which Moak won a court-imposed injunction. “Use public health and safety as the basis of your case,” he advised Workshop attendees.

For Moore, one victory against a storefront pharmacy quickly increased to five as he sought and won temporary restraining orders against several storefronts that operated in Alabama. “All five judges we stood before granted temporary restraining orders, without notice, in favor (continued on page 145)
Bottom of the Fifth

By Dale J. Atkinson

Under circumstances where administrative and criminal proceedings may be concurrently pursued (or for that matter where criminal behavior may be implicated), various complex legal issues related to evidentiary matters may arise. In particular, the Fifth Amendment of the United States Constitution (and similar state constitutional principles) may impact the prosecution and defense strategies of the parties. The Fifth Amendment provides, in part, that no person shall be compelled in any criminal case to be a witness against himself. As is evident from the language of the Amendment, self-incrimination prohibitions are triggered by the criminal prosecution of an individual. This begs the question of the impact of an individual subject to an administrative proceeding invoking the Fifth Amendment and how such a refusal will be treated by the administrative tribunal.

The following case addresses several important questions regarding the Fifth Amendment and its application to an administrative proceeding. Please note that the court appears to equate “civil” matters with administrative matters for purposes of the application of privilege principles. Equally important, the case addresses several procedural issues that provide insight to the mechanisms accessible to boards pursuing administrative prosecutions of individuals.

Nursing home administrators are licensed by the State of Missouri and are responsible for the general administration, management, and supervisory capacities of the operations of the particular nursing home, whether or not in ownership. As with other licensed professions, the enabling legislation creates and empowers a board to license qualified individuals and discipline those who fail to follow the legislative mandates. Based upon four deaths of elderly residents of a nursing home related to heat issues within a two-day period, the home’s administrator was administratively charged with multiple violations of the practice act.

Using grounds related to competence, misconduct, negligence, and violations of the Missouri Board of Nursing Home Administrators’ regulations, the Board initiated complaints with the Administrative Hearing Commission (AHC) against the licensee. The licensee filed a general denial to the complaints. Thereafter, the Board filed requests for admissions and the production of documents. In response to this procedural maneuver by the Board, the licensee refused to answer the requests (other than providing her name, address, and attorney) by invoking her rights under the Fifth Amendment of the US Constitution and Article I Section 19 of the Missouri Constitution.

Thereafter, the Board filed a motion for summary judgment, a procedural avenue that provides for the administrative tribunal to rule on the legal issues only because there are no issues of material fact.
in dispute. The Board attached supporting exhibits, attachments, reports, affidavits, and other documentary materials to its motion for summary judgment. The licensee, through her counsel, stated that she had no objections to the Board’s motion and that she would not be filing a response thereto as she planned to continue invoking her privilege against self incrimination as advised by her independently obtained criminal counsel. Based upon the record before it, the AHC granted the Board’s motion for summary judgment.

The Board held a hearing on the level of sanctions to be administered to the licensee and ultimately revoked the license. The licensee appealed the matter to the circuit court, which affirmed the order of the Board. The licensee appealed the matter to the court of appeals.

After addressing the standard of review to be undertaken by the appellate court on a summary judgment case, the court turned its attention to the arguments of the licensee. First, the licensee argued that her constitutional privilege against self incrimination had been violated in that the Board drew an adverse inference from her invocation of the Fifth Amendment in response to the discovery requests. The court disagreed.

After determining that the Fifth Amendment may be invoked relative to discovery requests, the court addressed the impact of the self-incrimination privilege in administrative and civil proceedings. It noted that while invoking the Fifth Amendment in a criminal proceeding does not allow for a negative inference, “the courts have never held that a Fifth Amendment claimant in a civil proceeding must be shielded from all possible negative consequences that may attend to his invocation of the privilege. . . . Deciding whether to take the Fifth is a matter of personal choice, to be exercised in view of the facts of a particular case.”

Therefore, a party to a civil/administrative proceeding who asserts the privilege against self incrimination must bear the consequence of lack of evidence. Quoting the US Supreme Court, the appellate court stated “[T]he prevailing rule is that the Fifth Amendment does forbid adverse inferences against parties to civil actions when they refuse to testify in response to probative evidence against them. . . . Moreover, this adverse inference may be drawn by the fact finder at either the summary judgment stage or at trial.”

The court also recognized the limits to the extent to which a negative inference may be indulged by a civil fact finder. In short, judgment may not be based alone on the silence of the claimant, but must be supported by affirmative evidence of the board establishing a prima facie case. A party seeking to benefit from a negative inference in a civil/administrative case must make an affirmative showing to support its right to judgment and cannot rely exclusively upon the other party’s refusal to testify. Once the board establishes a prima facie case and the licensee remains silent in the face of such facts, the tribunal may infer that she is unable to deny the board’s assertions.

In the instant case, the Board presented substantial evidence supporting the allegations of the administrative complaint. The licensee chose to remain silent and did so at her own peril. Several additional arguments by the licensee, relating to whether the evidence supported the findings (continued on page 146)
Explore the Future State of Regulation at NABP’s Fall Educational Conference, Earn Up To 10 CE Hours

The role of regulatory agencies has been forever changed by both illegal importation and globalization. To assist the boards of pharmacy in responding to those factors, NABP is offering continuing education (CE) sessions at the Fall Educational Conference (FEC), November 11-14, 2004, at the Renaissance Vinoy Resort and Golf Club in St Petersburg, FL, where representatives from the boards and state attorneys general offices can study proposed and pending legislation focused on importation, review federal and state regulatory and legislative actions, gain an overview of state and federal initiatives to ensure the safety and quality of compounded products, and examine the new Medicare regulations of the Medication Therapy Management (MTM) Services, among other relevant issues.

Friday, November 12
The FEC’s programming lineup will commence with a session co-hosted with the American Society for Pharmacy Law (ASPL). “Federal/State Regulatory and Legislative Actions in 2004,” from 8:15 to 9:45 AM, will highlight recent federal and state legislative and regulatory activity focusing on importation, pharmacy compounding, patient safety, and medication anti-counterfeiting measures.

A follow-up to NABP’s Importation Enforcement Workshop, held June 22-23, 2004, in Arlington, VA, “The Changing Landscape of Importation: Patient Safety and Accessibility” from 10 AM to noon, will discuss proposed and pending federal legislation regarding importation such as the Safe Import Act of 2004 (S2493) and Pharmaceutical Market Access Act of 2003 (HR 2427) with particular attention to provisions relating to personal importation, Internet pharmacies, anticounterfeiting measures, and the role of pharmacies and wholesalers. An update on various state government-administered importation programs will be covered along with other efforts to address the rising cost of prescription medications. At the conclusion of the presentations, attendees may participate in a discussion concerning the opportunities and challenges in regulating importation.

Saturday, November 13
The World Health Organization, one of the first entities to document the prevalence of medication counterfeiting, estimates that 5-7% of the total international medication supply may be counterfeit. Given the incidence of counterfeiting and diversion, boards of pharmacy are faced with stark challenges to license, inspect, and regulate medication distribution entities. “The Inspection and Accreditation of Wholesale Distributors: Regulating with Limited Resources,” from 8:30 to 10 AM, will provide an overview of the NABP Model Rules for the Licensure of Wholesale Distributors and the accompanying NABP Verified-Accredited Wholesale Distributors Program, aimed to assist states in the inspection and licensure of wholesale distributors.

Pharmacy compounding continues to challenge boards of pharmacy, Food and Drug Administration, and pharmacists to differentiate compounding from manufacturing. Unfortunate transgressions such as the Robert Courtney case, in which a pharmacist was convicted and sentenced to prison for intentionally diluting chemotherapy compounded products that inevitably resulted in death and serious harm to a number of cancer patients, continue to impact and confound this issue and call to question what is safe and legal compounding. During “Recent Efforts to Address the Regulation of Pharmacy Compounding,” from 10:15 AM to 12:15 PM, participants will be provided with an overview of various state and federal initiatives to ensure the safety and quality of pharmacy compounded products and updated on the recent activities of the Pharmacy Compounding Accreditation Board.

Sunday, November 14
In order to decrease the diversion of controlled substances, many states have developed and implemented unique programs designed to detect crimes such as “doctor shopping.” During “State Efforts to Combat the Diversion of Controlled Substances,” from 8 to 9:30 AM, participants will learn the structure and operation of prescription monitoring programs; explain challenges and opportunities in implementing such a program; and discuss patient confidentiality, reporting, and data accessibility issues. In addition, other programs and initiatives targeted to halt controlled substance fraud and diversion such as the use of tamper resistant and counterfeit proof prescription blanks will be discussed.

As the prescription medication demands and the need for patient care services continue to increase among the elderly population, it is anticipated that the recent passage of the Medicare Part D (continued on page 147)
Fall Educational Conference Program
Special Sessions co-hosted with the American Society for Pharmacy Law (ASPL)

November 11-14, 2004  The Renaissance Vinoy Resort and Golf Club  St Petersburg, FL

Thursday, November 11
2 - 6 PM  Registration/Information Desk Open
6 - 8 PM  Welcome Reception  Co-hosted with ASPL  (Buffet dinner will be served.)

Friday, November 12
7 AM - noon  Registration/Information Desk Open
7 - 8 AM  Continental Breakfast
8 - 8:15 AM  Welcome Remarks
8:15 - 9:45 AM  Federal/State Regulatory and Legislative Actions in 2004  Co-hosted with ASPL  Program #205-999-04-006-L03  (0.15 CEUs or 1.5 Contact Hours)
9:45 - 10 AM  Refreshment Break
10 AM - noon  The Changing Landscape of Importation: Patient Safety and Accessibility  Program #205-000-04-007-L03  (0.20 CEUs or 2.0 Contact Hours)
Noon - 1:15 PM  Luncheon  Co-hosted with ASPL
Afternoon/Evening Free

Saturday, November 13
7:30 AM - noon  Registration/Information Desk Open
7:30 - 8:30 AM  Continental Breakfast

Sunday, November 14
7 - 10 AM  Registration/Information Desk Open
7 - 8 AM  Continental Breakfast
8 - 9:30 AM  State Efforts to Combat the Diversion of Controlled Substances  Program #205-000-04-010-L04  (0.15 CEUs or 1.5 Contact Hours)
9:30 - 9:45 AM  Refreshment Break
9:45 - 11:15 AM  Medicare Prescription Drug, Improvement, and Modernization Act of 2003: New Opportunities in Medication Therapy Management and Electronic Prescribing  Program #205-000-04-011-L03  (0.15 CEUs or 1.5 Contact Hours)
11:15-11:30 AM  Closing Remarks

NABP and the NABP Foundation are approved by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmaceutical education. ACPE Provider Number: 205. Participants may earn up to 10 hours of ACPE-approved continuing education credit from NABP. Participants in continuing pharmaceutical education programs will receive credit by completing a “Statement of Continuing Pharmaceutical Education Participation” and submitting it to the NABP office. A validated Statement will be sent as proof of participation within approximately six weeks. Full attendance and completion of a program evaluation form for each session are required to receive continuing pharmaceutical education credit and a Statement of Participation.
NABP Provides Electronic Prescribing Testimony to NCVHS

The Medicare Modernization Act (MMA) that was signed into law in December 2003 includes provisions related to electronic prescribing. Under the new Medicare law, the Center for Medicare & Medicaid Services is required to develop national standards for electronic prescription drug programs with input from the National Committee on Vital Health Statistics (NCVHS). By September 2005, the secretary of the United States Department of Health and Human Services will adopt initial electronic prescribing standards to meet MMA requirements.

On July 28, 2004, NABP testified before the NCVHS Subcommittee on Standards and Security. NABP believes that electronic transmission of prescriptions offers a significant opportunity to enhance the quality and safety of patient care by reducing prescription medication errors.

NABP has been involved in defining and monitoring electronic transmission activities since 1996. Model regulations developed by NABP and state laws and regulations adopted by the states in the late 1990s outlined the parameter for transmitting prescriptions via facsimile while providing the vision and latitude to accommodate emerging technologies such as computer-to-computer transmission.

Electronic Transmission Survey to the Boards

The significant increase in the past year of regulatory activity regarding electronic transmission is closely associated with anticipated changes in the Medicare requirements and the expected initiative of the federal government to encourage its adaptation. In order to determine the extent of regulatory activity and the similarities and variations among the states, NABP recently conducted a survey of the state boards to determine which states allow for electronic transmission of prescriptions in the current practice context and what challenges and/or barriers the states face in implementing regulations to allow for electronic transmission of prescriptions.

NABP’s survey found that nearly every state allows for the electronic transmission of prescriptions. Security of the prescription, evolving technology, and the absence of Drug Enforcement Administration regulations regarding the electronic transmission of controlled substances were the primary barriers addressed in the survey. NABP thanks the 36 states that responded to the survey.

MMA Pre-emption of State Laws and Regulations

NABP is reviewing the new MMA standards and the pre-emption of state laws that will result. Although NABP recognizes that there is a limited need to provide for pre-emption and foster the development of national standards that facilitate implementation and allow for uninhibited practice across state lines, the pre-emption should not totally eviscerate safeguards the states have in place to protect patients.

NABP recommends that the following principles be incorporated into the national standards addressing the electronic transmission of prescriptions. The principles are designed to assure that electronic transmission standards safeguard patient health, safety, and welfare.

- Ensure Against Unauthorized Access
- Authenticity and Security of Prescription
- Patient Confidentiality
- Privacy of Individually Identifiable Health Information
- Prescriber-Pharmacist Collaboration
- Patient Choice

While many arguments can be made to support the rapid adoption of electronic prescribing by the health care profession, the primary considerations should be patient safety, public protection, and high quality health care delivery during the development of national standards. NABP will provide regular updates in future NABP Newsletters regarding the status and development of the MMA national electronic prescribing standards.
Importation Enforcement

(continued from page 139)

of the Board – and that is almost unprecedented,” he explained. “In each case, we brought one of our own inspectors and the judges designated him as a special process server of the restraining orders.” Moore added that one of the judges was strongly persuaded that a storefront needed to be shut down after the North Carolina Board informed the judge that patients were required to relinquish their rights to sue the pharmacy.

Cease and desist orders are powerful tools when combating storefront pharmacies, according to Carmichael, counsel to the North Carolina Board of Pharmacy. He explained that this method worked for the North Carolina Board because most of the storefront operations in the state have been relatively small operations. Carmichael added that three major legal grounds have been used to proceed against storefront operations in North Carolina:

- Violating the federal Food, Drug, and Cosmetic Act;
- Using a pharmacy or pharmacy-like term to indicate the site is offering to sell prescription drugs to the public; and
- Causing unlicensed persons to dispense prescription drugs.

FDAs McGinnis assured attendees that those boards that require assistance to investigate and take action against entities involved in the illegal importation of drugs may contact FDA and the agency will provide any assistance it can.

McGinnis listed the many safety concerns associated with imported prescription drugs that FDA discovered during its investigations over the past few years. FDA’s July and August 2003 US Customs import blitz examinations of prescription drugs uncovered serious safety concerns, McGinnis said. Drugs coming into the country included improperly labeled drugs, controlled substances, drugs requiring risk management and/or restricted distribution programs, drugs not licensed by FDA, and investigational products. FDA’s tests showed that some of these drugs were subpotent and even superpotent. Adding to safety concerns, FDA’s investigations found that some drugs that were thought to be ordered from Canada actually originated from other locations such as Belize.

There are many bills pending that would legalize importation, but, Winckler, vice president for policy and communications and staff counsel for APhA, emphasized, “Most federal bills do not address states’ rights.” She added that the proposed bills call for federal regulation of imported drugs, but few mention a role for the states.

Of the numerous bills currently pending, Winckler said the broadest bill, House of Representatives Bill (HR) 2427, which passed in the House in July 2003, allows prescription drug importation from all over the world including Australia, Canada, the European Union, Japan, Liechtenstein, and South Africa. It also allows for the importation of the greatest number of drugs of all the pending bills; drug exceptions specifically stated in the bill include only controlled substances, a limited number of biologic drugs, and intravenous drugs.

Another pending bill that Winckler believes has much momentum to be passed is Senate Bill (SB) 2328. This bill legalizes personal and commercial prescription drug importation of many medications with a few more limitations than HR 2427. Winckler noted that although SB 2328 attempts to limit importation of FDA-approved drugs, it would also permit importation of drugs that are like FDA-approved drugs, ie, drugs that have the same active ingredient or salt or ester of the active ingredient.

Strategic Plan for Importation Regulation

The second charge of the Task Force was to develop a Strategic Plan to aid state boards of pharmacy in analyzing their present regulatory base and identifying strategies that will enable boards of pharmacy to remain effective in the new practice environment created by importation policies which ignore state and federal laws or allow importation. The Task Force discussed the aforementioned issues and developed a preliminary draft of the Strategic Plan. This Strategic Plan will be further developed at NABP’s Fall Educational Conference, November 11-14, 2004, at the Renaissance Vinoy Resort and Golf Club, St Petersburg, FL.

To obtain a copy of the Enforcement Guideline Document CD-ROM, or for more information on NABP’s activities concerning illegal drug importation, please call 847/698-6227 or e-mail custserv@nabp.net.
Apply Today for NABP’s Annual Meeting Travel Grant

NABP is pleased to offer voting delegates the opportunity to apply for the Association’s Annual Meeting Travel Grant for the 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel in New Orleans, LA. The program will reimburse the board of pharmacy’s official delegate up to $750 in travel expenses including transportation, hotel accommodations, and meals. Boards of pharmacy that are not reimbursed for travel expenses by the state are eligible to receive a travel grant.

Those interested boards must have their official delegate complete an application, which can be downloaded from NABP’s Web site at www.nabp.net or obtained through NABP’s Customer Service Department by calling 847/698-6227. Applicants must submit documentation that their state will not provide reimbursement for Annual Meeting attendance. This documentation can be in the form of a per diem or travel policy, or a letter stating that the state will not reimburse the board of pharmacy for expenses incurred by attending NABP’s Annual Meeting. Grant monies cannot be applied to Annual Meeting registration fees. All applications and supporting documents must be received at NABP Headquarters no later than December 31, 2004. Applicants will begin receiving notification in February 2005, stating whether or not they have qualified for a grant.

For more information, contact Customer Service via e-mail custserv@nabp.net. Materials should be sent to the NABP Foundation, Attn: Annual Meeting Travel Grant Program, 700 Busse Hwy, Park Ridge, IL 60068.

NABP’s travel grant program is available for the boards to utilize through a grant courtesy of Pfizer US Pharmaceuticals.

Legal Briefs

(continued from page 141)

and whether inadmissible hearsay was allowed into the record, were rejected by the court. Accordingly, the sanction against the licensee was upheld by the court of appeals.

Of additional interest, the court, in response to the licensee’s continued denial of responsibility for the tragic events, reviewed the public policy mandates illustrated within the practice act. It stated that the responsibilities of nursing home administrators are set forth in the statute and that the licensee’s continued attempts to blame the deaths on “pre-existing institutional failures” makes it evident to the court that the licensee “does not fully comprehend the extensive responsibility Missouri law places on nursing home administrators.” Perhaps the courts may also extrapolate such an analysis to the extensive role individual pharmacists play relative to employer/facility permit holders who may impose workload issues or other conditions that inhibit safe pharmaceutical care.

This case analyzes the impact of the Fifth Amendment privilege on administrative proceedings. Under circumstances whereby the board presents its prima facie case, adverse inferences may be drawn from the silence of the licensee. Boards of pharmacy should be aware of the application of self-incrimination privilege in their respective jurisdictions.

FDA Test Results of Prescription Medications Purchased from Bogus Canadian Web Site Show Products Substandard

An assay conducted by the United States Food and Drug Administration (FDA) of three commonly prescribed drugs the agency purchased from a Web site advertised as Canadian showed the medications were fake, substandard, and potentially dangerous. This finding prompted FDA to reiterate its warning that purchasing medications from unknown sources is dangerous. FDA further advises consumers to look for online pharmacies that participate in NABP’s Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation program.

FDA investigators purchased generic versions of Viagra®, Lipitor®, and Ambien® – none of which has an FDA-approved generic version – from a Web site advertising “Canadian Generics” that has been sending spam e-mails promoting its products. The assay results showed that the Ambien (a Schedule IV controlled substance) received was superpotent, putting patients at risk for central nervous system depression, especially in elderly or debilitated patients. The Lipitor, which was subpotent, failed standard dissolution tests at only 57% of the active ingredient claimed on the label. It also failed FDA’s purity testing. The so-called “generic” Viagra also contained too little of the active ingredient. It also failed the dissolution test, and had an unacceptable level of impurities.

“The test results of our analyses offer proof positive that buying prescription drugs online from unknown foreign sources can be a risky business. As was the case here, even where a Web site looks legitimate, FDA has clear evidence that the Web site is dispensing misbranded drugs that are not the same quality as those approved by the FDA for sale in the United States. Consumers who believe they are getting equivalent products from reputable sources are being misled and putting their health at risk,” said FDA Acting Commissioner Dr Lester M. Crawford. FDA continues to advise consumers to look for the VIPPS Seal as one method to help minimize the risks of getting bad quality medications from disreputable sources. The VIPPS Seal assures consumers that the online pharmacy is appropriately licensed, is legitimately operating via the Internet, and has successfully completed a rigorous criteria review and inspection.

For more information on FDA’s test results, visit www.fda.gov/importeddrugs/chart071304.html. For more information on NABP’s VIPPS program, visit www.nabp.net or contact NABP’s Customer Service Department at 847/698-6227 or via e-mail at custserv@nabp.net.

Fall Educational Conference CE

(continued from page 142)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003: New Opportunities in Medication Therapy Management and Electronic Prescribing,” from 9:45 to 11:15 AM, will provide participants with an opportunity to examine and understand the new Medicare regulations of the MTM provision and the ability to describe recent collaboration efforts of government-appointed committees with practitioners, industry stakeholders, and regulators to encourage the implementation of electronic prescribing technology.

Registration Information

Attendees may earn up to 10 CE credit hours. Individuals registering on or before October 15, 2004, will receive a discounted early registration fee. Registration remains open after October 15 and on site at the Vinoy but at the full registration rate. To register, please complete the form inserted in this Newsletter, or visit NABP’s Web site at www.nabp.net for registration forms.

To obtain additional information about the 2004 FEC with special sessions co-hosted with ASPL, contact NABP’s Meetings Desk at 847/698-6227, e-mail custserv@nabp.net, or visit the Association’s Web site.
Reminder

NABP is pleased to announce three convenient ways to register for the 2004 Fall Educational Conference to be held November 11-14, 2004:

- Online at www.nabp.net,
- Submitting the pre-printed registration form in this Newsletter to NABP, and
- On site in St. Petersburg, FL.

Members of the North American Pharmacist Licensure Examination™ Review Committee conduct an item review at a July 23-25, 2004 meeting in Chicago, IL.