NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

newsletter

AID TO GOVERNMENT – THE PROFESSION – THE PUBLIC – 1904 TO 2002

NABP Discovers Security Breach, Halts FPGEE

NABP's Examination Security Group recently discovered a security breach in the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) perpertrated by a group of FPGEE candidates. As a result of the breach, administration of the FPGEE was halted effective November 19, 2002, until a full investigation is conducted and a secure examination established. The Association anticipates the introduction of a new examination in mid-2003 and reinstatement of the program.

Although all facets of the security breach have not been definitively established, NABP is working to determine which scores have been compromised by the breach. Accordingly, NABP has taken the following steps to protect the public health and welfare and ensure the integrity of the FPGEE testing program:

1. FPGEE scores affected by the compromise will be invalidated. Affected candidates will be allowed to retake the FPGEE once the new examination has been established.
2. Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certificates awarded to candidates who passed the exam affected by the compromise will be invalidated. Affected candidates will also be allowed to retake the

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NABP Comments on FDA's Compounding Compliance Policy

NABP recently provided comments to US Food and Drug Administration (FDA) on its *Compliance Policy Guides Manual Section 460.200 "Pharmacy Compounding"* (CPG) that provides guidance to drug compounders and FDA staff on how FDA intends to address pharmacy compounding of human drugs. FDA released the CPG on the heels of the April 29, 2002 Supreme Court decision *Thompson v Western States Medical Center* that invalidated §503A of the Federal Food, Drug, and Cosmetic Act.

The compliance policy guide outlines that while FDA will defer to state authorities regarding less significant violations of the Act related to pharmacy compounding, it will consider enforcement action when the scope and nature of a pharmacy's activities raise the types of concerns associated with a drug manufacturer and result in significant violations of the new drug adulteration or misbranding provisions of the Act.

"NABP clearly recognizes and supports the authority of FDA to regulate the manufacturers

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FPGEE once the new examination has been established.

3. All existing FPGEE testing appointments have been cancelled at the testing centers.
4. Candidates with an Authorization to Test (ATT) will not be allowed to schedule an examination appointment at the FPGEE testing centers. The period of time during which qualified candidates are eligible to take the FPGEE will be extended. New ATTs will be issued.

"Upon learning of this serious breach of security, NABP, in keeping with its responsibility of aiding the state boards in the protection of public safety and welfare, initiated a large-scale investigation and will pursue all workable remedies to the fullest extent as permitted by law," states NABP President John A. Fiacco. "We deeply regret having to take such serious actions, but feel that it needs to be made clear to candidates that NABP does not tolerate such security breaches. We are also creating additional security measures to protect against possible future breaches and will keep boards updated on an ongoing basis."

This incident is isolated to the FPGEE and does not affect NABP's North American Pharmacist Licensure Examination™ (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), or Disease State Management (DSM) examinations.

For updated information, please visit NABP's Web site at www.nabp.net or e-mail the Customer Service Department at custserv@nabp.net. Customer Service may also be reached at 847/698-6227. NABP

Frequently Asked Questions About FPGEE Administration

Why did NABP stop administering the FPGEE?

NABP detected a security breach in the FPGEE. In the interest of protecting public safety and maintaining the integrity of the FPGEC Certification Program, NABP was forced to temporarily halt the administration of the FPGEE.

How did NABP find out there was a problem?

NABP employs a wide variety of methods to ensure the security of its examinations. Due to the confidential nature of these processes, no further information can be released.

Are any candidates that are FPGEC certified and licensed by our state board affected by this compromise?

As our investigation continues, NABP will invalidate certificates awarded to candidates who passed the examination affected by the compromise. NABP will contact affected state boards.

Can foreign graduates still apply to the FPGEC program while the exam is halted?

Yes. NABP will continue to accept FPGEC applications even though the exam itself has been temporarily halted.

What happens to candidates that have already scheduled an appointment to take the FPGEE?

All FPGEE appointments have been cancelled. There is no need to contact NABP or the testing center to cancel an appointment. Candidates scheduled to take the NAPLEX, MPJE, or any DSM examinations are not affected.

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NABP Comments on FDA's Compounding Compliance *(continued from page 125)*

and the manufacturing of prescription drugs," states Carmen A. Catizone, NABP executive director/secretary, in the October 28, 2002 response letter to FDA Dockets Management Branch. "Similarly, NABP maintains that the regulation of pharmacy compounding is the constitutional purview of the state boards of pharmacy and an activity that must continue in order for patients' needs to be best served."

For NABP, one of the most important declarations within the CGP notes that "the focus of the CPG will be establishments with retail pharmacy licenses . . . engaged in manufacturing and distributing of unapproved new drugs for human use and not pharmacists and pharmacies engaged in the traditional practice of compounding human drugs . . . upon the receipt of a valid prescription for an individually identified patient from a licensed practitioner."

NABP strongly maintains that this focus and recognition should be reflective in the individual components of the CPG and that the primary purpose of the CPG should be to help regulators and practitioners definitively distinguish between compounding and manufacturing.

With that premise in mind, NABP points out that repeated references on how FDA intends to regulate pharmacy compounding confuses this focus and appears to suggest that FDA is disregarding the authority of the states and indicating its intent to regulate pharmacy compounding. In that regard, the Association requests that FDA remove all such references or clarify its recognition of state authority over pharmacy compounding.

NABP also sets forth that while some of the factors FDA intends to use to determine whether or not to initiate enforcement action are valid in determining whether or not an entity is acting as a manufacturer and, if not licensed as such, is violating the Food, Drug, and Cosmetic Act, others are not. For example:

- The CPG must recognize and allow for the compounding of products withdrawn from the market for safety reasons for individual patients pursuant to a bonafide prescriber-patient-pharmacist relationship.
- NABP requests consideration to allow for the compounding medications from bulk active ingredients that are not components of FDA-approved drugs without an FDA-sanctioned investigational new drug application (IND) for individual patients pursuant to a bonafide prescriber-patient-pharmacist relationship.
- NABP asks FDA to define in greater detail the phrase "commercial scale equipment." While the Association agrees that the presence of commercial scale equipment is often an indicator that the pharmacist/pharmacy is engaged in the manufacturing of products and not the compounding of medications, currently, two state boards of pharmacy specifically allow the use of commercial scale manufacturing or testing equipment in compounding pharmacies.
- NABP agrees that selling compounded drugs at wholesale would indicate a compounding pharmacy is likely acting as a manufacturer. However, NABP is aware of the accepted practice whereby pharmacies that compound drugs sell them to prescribing practitioners who then administer them to individual patients. NABP asks that FDA clarify whether or not this practice is exempt.
- NABP believes that the act of failing to operate in conformance with applicable state law regulating the practice of pharmacy may contradict FDA's recognition of state authority to regulate the practice of pharmacy. NABP asks that it be removed or rephrased to recognize the separation of authority and cooperative enforcement actions of the states and FDA.

For more information about the compounding legislation and the acts FDA will consider when determining when to initiate enforcement action, please see "Supreme Court Strikes Down FDAMA Compounding Legislation" on the cover of the May/June 2002 *NABP Newsletter*. NABP

Legal *Briefs*

Uncostitutional?

By Dale J. Atkinson, JD

An important tool in the enforcement and public protection responsibilities of a regulatory board includes the authority to assess reasonable costs upon a disciplined individual. Such board authority, of course, derives from the empowering statute of the regulatory entity. Without statutory authority, it is likely that a board cannot impose costs upon individuals. Cost recovery is important to the financial stability of the board and can provide persuasive negotiation in resolving matters short of an expensive and time-consuming formal hearing.

A chiropractor accused and found guilty of professional misconduct had his license revoked, but the revocation was suspended with a 60-day suspension and he was placed on five years' probation, and he was assessed pre-hearing investigation and prosecution costs of $17,500. The chiropractor appealed the board action to the trial court, which upheld the board order. Thereafter, the chiropractor appealed the matter to the appellate court.

The appellate court held that the record was supported by substantial evidence and upheld the findings of misconduct. However, the appellate court held that the board order mandating the payment of the costs assessed violated the due process rights of the chiropractor and directed the lower court to modify the order relative to the assessment of costs. The matter was appealed to the Supreme Court of California.

> *"…the board was granted the statutory authority to promulgate rules and regulations as the board may deem proper and necessary for the performance if its work, the effective enforcement and administration [of the Act], … and the protection of the public."*

In its analysis, the Supreme Court addressed the historical perspective of the State Board of Chiropractic Examiners and the legislation enacted to regulate the practice and protect the public. The Court also reviewed the applicability of the Administrative Procedures Act and the regulations adopted by the board. Specifically, the board was granted the statutory authority to "promulgate rules and regulations as the board may deem proper and necessary for the performance if its work, the effective enforcement and administration [of the Act], . . . and the protection of the public."

Based upon this grant of authority, the board adopted regulation 317.5, the subject of the challenge by the chiropractor. Regulation 317.5 empowers the board to request the Administrative Law Judge to assess reasonable costs of investigation and prosecution of an administrative proceeding, including the charges imposed by the Attorney General. Under the regulation, the board may reduce or eliminate the award.

The chiropractor claims the regulation is facially unconstitutional as it violates his due process rights by discouraging him (and others) from requesting hearings on administrative matters undertaken by the board. As observed by the court, a facial challenge to the constitutionality of the legislation is measured on the applicability of the particular circumstances at issue and not some hypothetical situation that may arise in the future.

In upholding the regulatory scheme, the court distinguished the current case from previous decisions cited by the chiropractor in support of his position. The court noted that the regulation at issue authorized the imposition of pre-hearing costs, which merits a finding of constitutionality of the regulation. The pervious opinion was distinguished from the current matter in that the

statute found to be unconstitutional allowed for the imposition of the costs of the hearing and for the hearing officer as part of an award against a licensee.

The court also held that the regulation was not adopted to discourage hearing requests but was intended to reduce the operating costs of the board to better assist it in achieving the public protection mission mandated by the enabling legislation. Thus, the regulation serves a "proper legislative goal" and has a "real and substantial relation to the object to be attained."

The Supreme Court also assessed the regulation under the test articulated in 1976 by the United States Supreme Court in *Mathews v Eldridge*. The test requires due process challenges to be assessed under the following three criteria:

1. The private interest that will be impacted by the official action;
2. The risk of an erroneous deprivation of such interest through the procedures used and the probable value, if any, of additional or substitute safeguards; and
3. The government's interest, including the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Identifying the private interest at stake, the court emphasized the legal significance of a professional license and the property interests attached thereto. However, the court also emphasized the intent of the regulation to assess costs of investigation and prosecution **before** the formal hearing and the fact that the board may reduce or eliminate the assessment of costs, thereby making their imposition upon a disciplined individual to be discretionary. Accordingly, the risk of erroneous deprivation of a property interest through the imposition of costs did not, according to the court, justify recognition of the arguments of the chiropractor.

Addressing the third prong, the court recognized the fiscal issues relative to cost recovery, as well as the fact that cost recovery was available to most regulatory boards in California. The court stated that although board financial aspects are not the sole measurement, the "Government's interest, and hence that of the public, in conserving scarce fiscal and administrative resources is a factor that must be weighed."

Finally, the court rejected the arguments of the chiropractor that the authority to impose costs was not reciprocal in that the board did not have to pay the costs incurred by a licensee whom the board unsuccessfully prosecutes in an administrative matter. The court quickly rejected this argument stating that the due process requirements do not mandate the imposition of reciprocal rules. The court also, again, noted the fiscal issues potentially imposed upon a board under such an argument.

It is interesting to note that the issue of whether or not the board, in adopting the regulation, acted outside its scope of legislative authority was not perfected on appeal to the Supreme Court. Accordingly, the Court did not address whether or not the board was empowered by statute to adopt a regulation authorizing the imposition of costs upon a disciplined individual.

The California Supreme Court reversed the findings of the Court of Appeals and upheld the regulation as constitutional. Thus, the California State Board of Chiropractic Examiners is able to assess pre-hearing costs upon a disciplined individual. Boards of Pharmacy are encouraged to examine their practice acts and regulations to determine the applicability of cost-assessment authority over pharmacists and pharmacies. This authority is an important element in enforcing the pharmacy practice acts.

Zuckerman v State Board of Chiropractic Examiners, 124 Cal. Rptr. 2d 701 (CA 2002) NABP

Attorney Dale J. Atkinson is a partner in the law firm of Atkinson & Atkinson, counsel for NABP.

Professional Affairs *Update*

FDA Approves Subutex, Suboxone to Treat Opiate Dependence

US Food and Drug Administration (FDA) announced on October 8, 2002, the approval of Subutex® and Suboxone® tablets for the treatment of opiate dependence. Both medications treat opiate addiction by preventing symptoms of withdrawal from heroin and other opiates. Based on the potential for abuse of the drugs, FDA and the Department of Health and Human Services recommended that Drug Enforcement Administration (DEA) place the active ingredient, buprenorphine, in Schedule III under the Controlled Substances Act (CSA).

These products represent two new formulations of buprenorphine and are supplied in 2 mg and 8 mg tablets that are placed under the tongue and must be allowed to dissolve. The first of these formulations, Subutex, contains only buprenorphine, and is intended for use at the beginning of treatment for drug abuse. The other, Suboxone, contains both buprenorphine and the opiate antagonist naloxone, and is intended to be the formulation used in maintenance treatment of opiate addiction. Naloxone guards against intravenous abuse of buprenorphine by individuals physically dependent on opiates.

Subutex and Suboxone are the first narcotic drugs available for the treatment of opiate dependence that can be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000. Under this new law, medications for the treatment of opiate dependence that are subject to less restrictive controls than those of Schedule II can be prescribed in a doctor's office by specially trained physicians.

The sponsor, Reckitt Benckiser Pharmaceuticals, in collaboration with FDA and with input from other Health and Human Services agencies, has developed a comprehensive risk-management program designed to deter abuse and diversion from its legitimate use in patients and educate physicians regarding proper use of these drugs, close monitoring of drug distribution channels, and child-resistant packaging.

The risk-management program also provides for active and passive surveillance to identify if and when the drugs are being abused. The surveillance will include interviews with substance abusers, monitoring local drug markets, data collection, and the monitoring of adverse event reports. Reports of the results of these surveillance efforts will enable FDA to identify untoward effects from the availability of buprenorphine and, if indicated, to take appropriate actions to protect the public health.

In addition, the provisions of the DATA include limits on the number of patients individual physicians are allowed to treat and a special DEA registration for the use of this drug, thus providing additional safeguards as this drug enters the office-based treatment setting.

USP-NF Proposes General Chapter Supporting Unit-of-use Packaging

The United States Pharmacopeia (USP) proposed a new General Chapter <1136> to the United States Pharmacopeia 27 and the National Formulary 22 (USP 27-NF 22, 2004 annual edition) that encourages pharmacists to dispense medications in the original manufacturer's containers.

According to the USP, dispensing prescriptions in the manufacturer's original unit-of-use packaging offers several key advantages for the pharmacy practice community:

- Pharmacists save time by no longer having to count and repackage dosage units;
- Human error in filling prescriptions may be reduced;

- Labels can be affixed directly to the medication's container; and
- Pharmacies can use the manufacturer's expiration date as the beyond-use date or one year, whichever date is earlier.

The proposed new General Chapter provides guidance on unit-of-use packaging practices and includes detailed information on materials of construction, package closure types, repackaging and reprocessing, and labeling and dispenser responsibility.

Comments on the proposed new chapter should be addressed to Dr Claudia C. Okeke at USP, 12601 Twinbrook Pkwy, Rockville, MD20852. Additional questions pertaining to unit-of-use packaging can be e-mailed to mediarelations@usp.org.

Accutane Medication Guide Changes

The updated version of the Accutane Medication Guide (MedGuide), distributed to pharmacists in early September 2002, is now printed on **tan** paper and replaces all other versions of the MedGuide. Pharmacists should discard **all** MedGuides printed on white, yellow, or green paper, and distribute only those printed on the tan paper. This Medication Guide for Accutane summarizes, in simple language, the professional package insert, including the approved indication for Accutane and major adverse events reported in the package insert. The revision to the MedGuide was developed in conjunction with US Food and Drug Administration (FDA) and replaces the MedGuide released in July 2002. NABP

FAQs About FPGEE Administration *(continued from page 126)*

What is the status of current applications?

Review of applications and supporting documentation will not be affected by the halting of the FPGEE. The FPGEC will continue to review all current and future applications and supporting documentation and will contact applicants if there are deficiencies in the application.

Will NABP refund candidate examination fees?

NABP will not issue any refunds for the FPGEC Certification Program or FPGEE unless the candidate wishes to withdraw his or her application as per the instructions in the *FPGEC Certification Program Application/Registration Bulletin*. NABP regrets any inconvenience this may cause candidates.

When will the examination be restarted?

NABP is developing a plan to begin administration of the examination in mid - 2003. After the details for the examination have been established, a formal announcement will be made and affected candidates will be notified via mail in early 2003.

Will candidates have to reapply to the FPGEC once the replacement exam is offered?

No. NABP will continue to process FPGEC applications and offer the replacement exam to eligible candidates when it is available. Therefore, there will be no need for current candidates to reapply to the FPGEC Certification Program. However, candidates who failed the FPGEE prior to the halt will be required to submit a new application per the instructions in the *FPGEC Certification Program Application/Registration Bulletin*.

What happens to candidates with current ATTs?

The ATT is no longer valid. Additional information will be provided in early 2003.

What will happen to the people responsible for the problem?

NABP and all applicable enforcement agencies will seek the maximum allowable civil and criminal punishment for anyone convicted in this incident. NABP

Pharmacy Personnel Needed for Bioterrorism Response Teams

The events of September 11 and the days that followed prompted the Joint Commission of Pharmacy Practitioners (JCPP) Working Group on Emergency Preparedness and Response to collaborate with the US Department of Health and Human Services in the establishment of the National Pharmacists Response Team (NPRT). Deployments, if called to serve, last approximately two weeks and will be comprised of 10 regionally based teams of 200 pharmacists, pharmacy students, and pharmacy technicians who could be called upon to assist in a mass vaccination or chemoprophylaxis campaign. NPRT members will have to complete an online continuing education course; additional education and training will follow once members are assigned to teams.

According to the *American Journal of Health-System Pharmacy*, teams will represent the 10 US Public Health Service (PHS) regions, which are based in the following cities: Boston (Region I), New York (II), Philadelphia (III), Atlanta (IV), Chicago (V), Dallas (VI), Kansas City, MO (VII), Denver (VIII), San Francisco (IX), and Seattle (X).

When members are activated, they will:

- Be paid as a federal employee on the civil service scale;
- Be reimbursed for travel, housing, and per diem costs;
- Be protected via the Federal Tort Claims Act for liability under the normal scope of practice;
- Have recognition of license in the state where they are deployed;
- Have access to training modules (American Continuing Pharmaceutical Education credit); and
- Be deployed no longer than two weeks. Employers will treat these team members like military reserve and national guard members.

PHS is also offering alternate ways for pharmacists to participate in emergency preparedness:

1. Commissioned Corps Readiness Force (CCRF): A cadre of PHS officers that directs, enhances, and supports federal agencies' responses to disasters and other public health emergencies.
2. Disaster Medical Assistance Team (DMAT): A group of professional and paraprofessional medical personnel that provides emergency medical care during a disaster or other event anywhere in the country. For more information on DMAT and CCRF, visit http://oep-ndms.dhhs.gov.
3. Planning committee of a Metropolitan Medical Response Team. One hundred and twenty-two cities have a federal contract to plan for their metropolitan area's response to biological and chemical terrorism. For more information on this program, visit www.mmrs.hhs.gov.

According to the American Nurses Association (ANA), ANA, along with HHS and PHS, is also establishing a National Nurses Response Team (NNRT). The NNRT will be a large cadre of nurses who would function under the auspices of HHS and could be quickly deployed in response to a major national event. The NNRT will be dedicated to responding to a Presidentially declared disaster to provide mass immunization or chemoprophylaxis to a population at risk. As the NNRT sponsor, the ANA would serve as the conduit to recruit registered nurses, relying on its capacity to reach thousands of nurses through its organizational relationships with its 54 constituent member associations and more than 100 specialty nursing organizations.

Pharmacists interested in the NPRT can visit www.aphanet.org for more information. NABP

CDC Upgrades National Pharmaceutical Stockpile for Emergencies

Learning from the terrorist attacks last fall when the National Pharmaceutical Stockpile's medications were deployed in bulk containers of thousands of tablets, the Centers for Disease Control and Prevention (CDC) upgraded the stockpile to include unit-of-use bottles of antiinfectives, new packaging equipment, and four more 12-hour push packages, raising the total to 12. This upgrade, made possible by an increase in the stockpile's budget, will help to decrease the potential problems that could arise when trying to dispense drugs in an emergency.

Each push package, intended as an immediate response to a disaster, contains 50 tons of antiinfectives, chemical antidotes, antitoxins, life-support medications, intravenous administration and airway maintenance supplies, surgical items, and other medical supplies that can be shipped by ground or air transport within 12 hours of a federal decision to release the supplies. About 10 of the 130 cargo containers in each 50-ton push package contain prescription drug products, according to a CDC pharmacist.

With this upgrade, each push package also contains two high-speed industrial repackaging machines that can produce 5,000 unit-of-use sealed bags of medications per hour. State and local emergency management workers and health care volunteers do not need special training on the use of the packaging equipment as a five-member program staff, known as the CDC Technical Advisory Response Unit, will assist emergency workers and operate the machines if necessary. This differs from the system involved in the previous stockpile, which was used after the September 11 events and last fall's anthrax attacks, in that nearly all of the antiinfectives were supplied to emergency workers in bulk form and had to be repackaged onsite for patients.

The stockpile's formulary of drug products is subject to change when the CDC receives new information about potential threats. A CDC spokesperson said the agency relied on the advice of several experts, including pharmacists, and feedback from emergency workers to determine what the CDC needed to do to make the stockpile user-friendly.

The CDC is responsible for managing the stockpile and coordinating deployment to disaster locations. The agency has contracted vendors to package 50% of the stockpile's antiinfective supply, including doxycycline, ciprofloxacin, and amoxicillin, into 10- or 25-day supply unit-of-use bottles that are replicas of the larger manufacturer-made containers. NABP

Constitutional Amendment Deadline Set

All proposed amendments to NABP's Constitution and Bylaws must be submitted in writing to the Office of the Executive Director/Secretary between February 3, 2003, and March 20, 2003, to be considered during NABP's 99th Annual Meeting, May 3-7, 2003, at the Philadelphia Marriott in Philadelphia, PA. Submission dates are established by NABP's Constitution, which specifies that proposed amendments may be accepted no earlier than 90 days and no later than 45 days before the Annual Meeting's First Business Section. For more information about the amendment procedure, contact NABP Executive Director/Secretary Carmen A. Catizone at ceo@nabp.net. NABP

Florida Board Proposes Internet Pharmacy Rule

The Florida Board of Pharmacy proposed a new rule in June 2002 that would place Florida-based pharmacies and pharmacists on notice regarding the invalidity of prescriptions generated through questionable methods. The questionable methods engaged by these online pharmacies usually consist of physicians filling prescriptions for patients who have not had physical examinations by the doctors and, thus, have no established physician-patient relationship.

According to John D. Taylor, executive director of the Florida Board of Pharmacy, the rule was proposed in response to the proliferation of complaints received by the Board concerning Florida-based online pharmacies and the increasing alarm that potentially dangerous drugs like hydrocodone and phentermine have become available from these online pharmacies. Edwin Bayo, senior assistant attorney general and counsel to the Board of Pharmacy, reiterates, "The [B]oard maintains that prescriptions written by doctors who have not established a valid physician-patient relationship are not valid prescriptions. The Florida Board is not alone in its position that a physician-patient relationship must be present. Bayo, who also serves as counsel to the Florida Board of Osteopathic Medicine as well as the Florida Board of Medicine, has also taken the position that prescribing medications based solely on answers to an electronic medical questionnaire is not acceptable.

Violating the rule could result in a $1,000 fine per prescription and probation, with possible revocation of a Florida pharmacy's or pharmacist's license, say prosecutors from the State Department of Health.

Recent Challenges

The Board of Pharmacy rule was approved by the Board in concept; however, it cannot be enacted until challenges and any court appeals have been resolved. There have been appeals by online pharmacies; one of whom is United Mail Pharmacy Services in Broward County. According to The Council for Responsible Telemedicine (CRT), a District of Columbia-based nonprofit organization dedicated to educating and enlightening consumers, state regulatory agencies, and governing bodies about the ethical practice of telemedicine, member company United Mail Pharmacy Services challenged the rule, with CRT arguing that the rule could invalidate patient-physician relationships established through the Internet and prevent quality online patient care. CRT spokesperson Robert Smoley explains that the "rule puts pharmacists in the impossible position of determining whether a physical examination was conducted prior to filling a prescription and undermines the time-tested prescription process." According to Smoley, the rule could circumvent federal law by putting an undue burden on pharmacists to check the validity of each prescription written by a licensed physician.

After the October 8, 2002 hearing, the Florida Board revised the text of the proposed rule and modified the language to better suit the appeals of the online pharmacies. Taylor explains that, "The language of the rule had been modified, but the concept remains the same." The new text, revised and approved by the Board as of October 8, 2002, reads:

> 64B16-27.832 Standards of Practice for Filling Prescriptions Generated Through the Internet
>
> It has come to the attention of the Board that Florida licensed pharmacies and pharmacists are dispensing prescription medications which have been authorized by prescribers licensed in Florida and elsewhere based solely upon the answers to an electronic medical questionnaire. For the purpose of dispensing by a Florida licensed pharmacist or pharmacy, a prescription issued by a practitioner to a patient with whom the practitioner has not established a valid physician-patient relationship is not a valid prescription. A pharmacy or pharmacist that dispenses a prescrip-

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Around the *Association*

South Carolina Board Welcomes New Pharmacy Investigator

Edward "Eddie" Durant, RPh, joined the South Carolina Board of Pharmacy as a part-time inspector. A graduate of the University of South Carolina, Durant has 25 years of experience in the practice of pharmacy, most recently working for the Department of Health and Environmental Control (DHEC) – Bureau of Drug Control as a controlled substance inspector and investigator.

2002 Bowl of Hygeia Award Recipients

The following individuals were among those named Wyeth Pharmaceutical's 2002 Bowl of Hygeia Award recipients.

- **Stan W. Grigg, RPh,** Colorado State Board of Pharmacy
- **James Powers, RPh,** Florida Board of Pharmacy
- **Richard P. Zarek, RPh,** Nebraska Board of Pharmacy
- **Edith Micale, RP,** New Jersey State Board of Pharmacy
- **James R. Bradham, RPh,** South Carolina Board of Pharmacy
- **Betty Hong Yamashita, RPh,** Utah Board of Pharmacy
- **Lydia Main, RPh,** West Virginia Board of Pharmacy

New Pharmacy Coordinator for Illinois Board

Judy Cullen replaces **Kim Scott** as pharmacy coordinator for the Illinois Department of Professional Regulation – State Board of Pharmacy.

New Board Members

NABP Welcomes the following new board of pharmacy members.

- **Rita Fischbach**, consumer member, Illinois Department of Professional Regulation – State Board of Pharmacy
- **Sheila L. Mitchell, PharmD, FASHP**, member, Tennessee Board of Pharmacy NABP

Florida Board Proposes Internet Pharmacy Rule *(continued on page 126)*

tion that the pharmacist or pharmacy knows or reasonably should know has been issued in a manner that is not in compliance with applicable State and Federal regulations governing the prescriber's authority and standard of practice is dispensing outside the course of the professional practice of pharmacy.

Specific Authority: 465.005, 465.0155 FS.

Law Implemented: 465.003(14), 465.015(2)(c), 465.0155, 465.016, 465.026 FS.

History – New.

Taylor says that the Board hopes the rule will go into effect by the end of 2002. NABP

Season's Greetings from Your Friends at NABP

Applications/IT/Database: *Back row, Mike Mazurkiewicz, Sara Castle, Andrew Duda, Mary Lou Grien, Jim Weiss. Middle row, Nick Camcam, Marilyn Lavin, Penny Piper, Pat Limper, Dinah Gaudiano. Front row, Hazel Contreras, Pat Metz, Brenda Eduku. Not pictured: Theresa Kmieciak, Carol Lechowski, Frankie O'Malley.*

Communications and Customer Service: *Back row, Lara Jackson, Sue Shellito, Courtney Karzen, Rene Renganathan, Mark Harbeke. Front row, Christie Nielsen, Brian Smith, Kim Collett, Mike Egan.*

The Executive Office and Accounting: *Back row, Mary Dickson, Melissa Madigan, Chris Siwik, Sally Stein, Karen Oster. Front row, Larry Strass, Linda Forman, Carmen Catizone, Madge Motyka. Not pictured: Anne Pugliese.*

Human Resources and Office Services: *Gus Howard, Patricia Milazzo, Nick Milott. Not pictured: Rita Chodor.*

Electronic Licensure Transfer Program™, Foreign Pharmacy Graduate Examination Committee Certification™ Program, and Testing: *Back row, Matt Lee, Jolene Schuetter, Lisa Pugliese, Doug Bernius, Diane Signatur, Avery Spunt, Lori Schumacher. Front row, Lawana Lyons, Chandra Loyd, Carol Potrawski, Moira Gibbons. Not pictured: Gene Johannes.*

Massachusetts Department of Public Health Announces Policy on Distribution of Potassium Iodide (KI) in Radiological Emergencies

As a result of the discussion over the past few years on the issue of potassium iodide (KI) for the public in an event of an incident at commercial nuclear power plants along with recent concerns over terrorism threats, the Massachusetts Department of Public Health (MDPH), the Massachusetts Emergency Management Agency (MEMA), and the Massachusetts Board of Registration in Pharmacy have put into place plans for the distribution of KI to the public.

Potassium iodide, a chemical compound taken before or shortly after exposure to radioactive iodine (radioiodine), can be used to protect the thyroid gland from possible radiation injury. The uptake of radioiodine increases the risk of thyroid cancer, especially in children. Taking KI saturates the thyroid gland with stable (non-radioactive) iodine. This prevents or reduces the amount of radioiodine that will be taken up by the thyroid.

The risks of stable iodine administration include sialadenitis (inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions, and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should persons with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity.

Accessibility of KI for Children and Infants

US Food and Drug Administration (FDA) determined that the benefits of KI treatment to reduce the risk of thyroid cancer outweigh the risks of such treatment in neonates. Regarding the dosage of KI for children, the only currently available, FDA-approved over-the-counter formulation is a 130 mg tablet. This is the recommended dose for adults and for adolescents approaching adult size (less or equal to 70 kg), and was the dose recommended until recently for all persons one year of age or older. However, in December 2001 FDA made revised recommendations regarding the lowest effect dose, namely 16 mg under age 1 month, 32 mg for age 1 month to 3 years, and 65 mg for age 3 years to 18 years. Until the 65 mg tablet is available in an FDA-approved formulation, MDPH, and the Massachusetts Board of Registration in Pharmacy, along with FDA, support the administration of the 130 mg tablet for children in settings such as schools or child care centers in the event of emergencies.

The Distribution Plan

The Nuclear Regulatory Commission (NRC) has made KI available for distribution to individuals living in Massachusetts towns within the 10-mile Emergency Planning Zones (EPZs) of the Pilgrim, Seabrook, and Vermont Yankee Nuclear Power Stations. This supply allows for two pills per person in these areas.

As of June 2002, the pre-distribution plan consisted of pre-distributing one KI tablet to each eligible individual when living or working within the 10-mile EPZ of the three nuclear power plants (Seabrook, Pilgrim, Vermont Yankee). The remaining KI would have been stockpiled at locations outside of the 10-mile EPZ for use after evacuations. A stockpile of KI was also pre-distributed to public and private schools and daycare facilities within the 10-mile EPZs.

- For the Massachusetts towns around the Seabrook and Pilgrim nuclear power stations, the KI was distributed through local pharmacies for residences, and from MDPH/Radiation Control Program (RCP) for businesses and schools/daycare centers. For towns in the Vermont Yankee station area, plans for distribution were through the town clerk's offices.
- MDPH prepared press releases and public information notices detailing information about KI, the distribution plan, how eligible individuals can receive KI, how pharmacies, schools, and townships are working with MDPH in the distribution plan, as well as information specifically for pharmacists and physicians, all of which is available on the RCP Web site, www.state.ma.us/dph/rcp or the MDPH Web site,

www.state.ma.us/dph/dphhome.htm.

- For pre-distribution for household residents, the pharmacies were sent an appropriate supply of the IOSAT tablets, the Ambex insert, and the MDPH envelope, as well as receipt forms for the individuals to sign. As of July 10, 2002, Massachusetts received envelopes printed with the latest FDA guidance along with reprints of the Ambex package insert that will be enclosed with each pill. The envelopes were filled with the pills and boxed up into quantities of 1,000 tablets for each pharmacy and town hall. Delivery was in late July. Evidence of residence in the EPZ (for example, driver's license, tax bill, etc) was required for individuals who picked up the tablets. Residents also had to sign a receipt form.
- For pre-distribution for the schools, letters were sent out to the superintendents explaining the details of the program, and asking for voluntary participation, along with all the background information that is available on the Web sites.
- For businesses located within the 10-mile EPZs, the owners of the businesses were advised to ascertain the number of employees wishing to have KI and make a request for the KI directly to the RCP. The receipt forms from the pharmacies and towns were, directly returned to the RCP for record-keeping purposes.
- Stockpiles of the remainder of KI are maintained at the National Pharmaceutical Stockpile/Metropolitan Medical Response System locations in Massachusetts.

The pre-distribution process through the pharmacies extended through September 30. After September 30, individuals can obtain KI through the mail upon request through the Radiation Control Program Web site, telephone contact, or written request to the Program. KI is also available for purchase at some pharmacies.

Charles R. Young, executive director of the Massachusetts Board of Registration in Pharmacy, explains that, "The potassium iodide distribution plan in Massachusetts is the first

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NABP, FSMB, CSAT to Sponsor Workshops for State Medical, Pharmacy Boards

NABP, the Federation of State Medical Boards (FSMB), and the Center for Substance Abuse Treatment (CSAT) will sponsor a workshop on two dates entitled, "State Regulatory Policy: Responding to Changes in the Oversight of Opioid Addiction Treatment," for state medical and pharmacy boards covering provisions of the Drug Addiction Treatment Act of 2000 (DATA); the buprenorphine clinical practice guidelines; the Federation's *Model Guidelines for Opioid Addiction Treatment in the Medical Office;* and the application of federal drug and alcohol confidentiality law, 42 CFR, Part 2, to office-based treatment.

On October 8, 2002, US Food and Drug Administration (FDA) approved buprenorphine and buprenorphine/naloxone for treatment of opioid addiction by individual physicians in office settings. This new treatment modality, authorized under the DATA, allows qualified physicians to prescribe and pharmacists to dispense FDA-approved Schedule III-V narcotics for addiction treatment.

The first workshop will be offered January 10, 2003, at the Crystal Gateway Marriott in Arlington, VA, and the second on February 21, 2003, at the Hyatt Regency DFW (inside the Dallas/ Fort Worth International Airport) in Dallas, TX. The sessions offered at both workshops include "Drug Addiction Treatment Act of 2000 (DATA)," "Drugs Approved for Office-Based Opioid Addiction Treatment," "Model Policy Guidelines for Opioid Addiction Treatment in the Medical

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State Boards of Pharmacy Interact with NABP Staff at Board Training, Program Training Sessions

Seventeen participants from 14 state boards of pharmacy engaged in board training and program review sessions held at NABP headquarters in Park Ridge, IL on three dates in late August and mid-September. Staff from Arkansas, South Carolina, Virginia, Alaska, Delaware, Indiana, Kentucky, Michigan, Oregon, Utah, Maryland, Mississippi, Nebraska, and Texas participated in the sessions, which focused on reviewing the license transfer and testing programs; the Verified Internet Pharmacy Practice Sites™ (VIPPS™) program; and the Clearinghouse and Healthcare Integrity Protection Data Bank (HIPDB). NABP staff also provided instruction on procedures and various documents the boards process on a regular basis.

Each session allotted time for board staff to discuss any problems or issues concerning procedures, processes, and computer software.

Staff encouraged the boards to utilize the direct-processing service NABP offers, wherein NABP handles both fee and registration form processing for the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®), alleviating the boards of this task. Once a candidate's fees and form are received, NABP compiles a list of each state's applicants and provides it to the appropriate board. In turn, the states notify NABP as to which applicants are eligible to sit for the exams. Currently, 29 states utilize NABP's direct-processing service, while more have expressed interest.

Each session included a pop quiz covering the areas in which the participants received instruction. Participants and NABP staff benefited from the quiz because participants put their knowledge to practical use and staff could determine the success of their teaching methods.

NABP Surveys Boards

NABP surveyed each participant to solicit feedback about the sessions. Questions ranged from the least to most enjoyable portion of the sessions, to recommendations for future meeting topics. As in past years, the ability to meet and interact with different boards' staff and NABP staff was the most enjoyable aspect of the training sessions as well as sharing common issues. Extremely beneficial to the boards was instructing board staff on NABP programs, services, and applications, which allows for individual problems to be addressed hands-on and questions to be more fully answered. The participants suggested that more time, more hands-on work, and break-out sessions for participants to discuss specific questions with NABP staff should be incorporated in following sessions. Other topics that should be included in future sessions relate to how NABP processes eligibility lists, more information on HIPDB, comparison of the requirements/differences for each state, information that must be saved other than score data, responding to VIPPS verification, one-on-one training with NABP and board staff, and utilizing Lotus Notes more effectively.

NABP is evaluating different scheduling opportunities for 2003 training sessions that will allow additional staff to attend.

NABP President John A. Fiacco states, "NABP continually strives to assist its members by hosting annual training sessions for board staff. These seminars facilitate a dialog and interaction among the boards and NABP, and ultimately benefit applicants by improving the processes utilized by NABP and the boards."

NABP provided all state boards with *User Manuals* from the training programs to ensure that they will have an understanding of NABP's programs and computer systems. NABP

NABP Plans for NAPLEX Practice Analysis

During the North American Pharmacist Licensure Examination™ (NAPLEX®) Review Committee's Annual Meeting in April 2002, the NAPLEX Review Committee (NRC) performed a preliminary review of the NAPLEX's competency statements that pointed to a need for re-examination of the test blueprint. The NRC concluded during this meeting that a practice analysis may be necessary to determine the area(s) of the blueprint that may require changes to reflect current aspects of entry-level pharmacy practice.

Among the reasons to take into consideration when determining if a practice analysis is warranted are:

- To document when changes in practice are seen or documented, or if shifts in emphasis in certain activities may affect the relative importance of blueprint competencies;
- Good testing practice requires that a practice analysis be conducted to establish and/or confirm a validity evidence for the examination; and
- To identify the important tasks, knowledge, and skills necessary to safeguard public health, safety, and welfare.

To initiate the practice analysis study, several documents related to pharmacist practice were recommended by the NRC for review to confirm that important elements of entry-level practice are addressed in the blueprint, and to identify any of the elements that may be missing. The entire study, including a survey of the profession, will likely take four to six months with additional time involved to implement changes to the examination that may result from the practice analysis study. The critical incident will be used as a building block to support results of the NRC blueprint review.

At a NRC subcommittee meeting in October 2002, members began formulating critical incidences related to the NAPLEX subcompetency statements. A critical incident identifies possible actions taken by a successful, competent, entry-level pharmacist as well as possible actions that are not related to successful management of an event that could possibly lead to life-threatening outcomes.

Blueprint Revision

The current NAPLEX blueprint was implemented in 1997 for the computer-adaptive examination. The 1997 blueprint resulted from an extensive practice analysis that incorporated the results of the 1994 Scope of Pharmacy Practice Study. Outcomes of the upcoming practice analysis may result in the shifting of areas and the weight of certain competencies.

Plans are underway to validate the results of the blueprint revisions in a Web-based survey made available to a selected sample of pharmacists. The survey will collect information dealing with pharmacist demographics as well as on practice activities. Pharmacists will be asked to rate practice activities according to the frequency of performance and the criticality of the activity. The survey may also include a comments section.

Testing Standards

According to *Standards of Educational and Psychological Testing* (American Educational Research Association, American Psychological Association, and National Council on Measurement in Education; 1999), "Tests [such as the NAPLEX] used in [licensing] are intended to provide the public, including employers and government agencies, with a dependable mechanism for identifying practitioners who have met particular standards." The standards continue to explain that these credentialing tests are devised to establish whether or not the crucial knowledge and skills of a certain domain have been mastered by the candidate.

The NAPLEX competency statements offer important information about the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. NABP

Frequently Asked Questions Regarding NAPLEX, MPJE Fee Increase

NABP initially reported to boards and US schools and colleges of pharmacy in September 2002 that effective January 1, 2003, North American Pharmacist Licensure Examination™ (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®) candidates will pay increased fees for both examinations. Since that time, the Association has received the following frequently asked questions (FAQs).

Why did NABP increase the Fees?

The increase comes after NABP learned that Chauncey Group International, Ltd, intends to increase vendor administration fees, or sitting fees, over the next several years. At this time, NABP decided to increase the examination base fees to offset the increased cost of examination development.

Will the fee to transfer a NAPLEX score change?

The fee to transfer NAPLEX scores to participating states will remain at $75.

When will the fee increase take effect?

Any registration form sent to NABP postmarked on or after January 1, 2003, will be subject to the new fees. Candidates will be notified if the proper fee was not included and applications will not be processed until all fees are received.

How much will the fees increase?

The NAPLEX base fee will increase from $250 to $300 and the vendor administrative fee will increase from $110 to $130. The total NAPLEX registration fee will increase from $360 to $430. The MPJE base fee will increase from $85 to $110 and the vendor administrative fee will increase from $45 to $60. The total MPJE registration fee will increase from $130 to $170.

Why are fees being increased again so soon?

The base fees for the NAPLEX have not been increased since 1997 and the base fees for the MPJE have not been increased since 1999. The vendor administration fee, or sitting fee, was last increased in 2001 to reflect the cost being charged to NABP. New contracts were signed in 2002 with Chauncey Group International, NABP's exam administrator. These contracts increased the fee being charged to NABP, and consequently raised the fee being charged to candidates.

What is the difference between the base fee and the vendor administrative fee?

The base fee that is managed by NABP refers to the costs used to offset exam development and applications, and NABP member services such as meetings and publications. The vendor administration fee, or sitting fee, relates to the exam delivery and includes the use of a testing facility as well as other on-site activities. These costs are determined by Chauncey Group International and, therefore, may be adjusted annually according to the needs of the testing vendor.

How long until the next fee increase?

It is anticipated that these fees will remain in effect through December 2004.

This isn't much notice. Didn't NABP know it would need to raise fees earlier in the year?

The new contracts for exam administration were not finalized until the middle of 2002. Upon determination of the new fee structure, NABP made every effort to disseminate the fee increase information as quickly as possible.

For more information on the NAPLEX and MPJE fee increases, please contact custserv@nabp.net. NABP

Massachusetts Department of Public Health

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to use pharmacies for the point of distribution, and while this is a terrific opportunity for the 'most reachable of the health professions', it also carries with it some challenges, particularly the need to distribute information regarding dosing of KI in a health-literacy focused manner, so that when a young mother opens the package and reads that the dose for an infant is 16 mg and the tablet provided is 130 mg, she will understand what to do, especially if there is an emergency.

Pharmacists should dispense the KI personally with verbal counseling instructions to the recipients instructing them to read the directions right away and to call back and make an appointment to discuss any information not completely understood.

Otherwise, I consider that [p]harmacists/pharmacies are the most appropriate points of distribution for this important project." NABP

NAPLEX Pool to Include Items on Dietary Supplements

Beginning in April 2003, items on dietary supplements will be incorporated into the North American Pharmacist Licensure Examination® (NAPLEX®). The NAPLEX Review Committee (NRC) recommended the inclusion of such items in an effort to maintain an exam that coincides with the requirements of entry-level practices of pharmacy practice.

- Herbals and nutraceuticals will be referred to as dietary supplements as defined by the Dietary Supplements Health and Education Act of 1994 (DSHEA);
- Questions will be limited to efficacies, adverse effects, toxicities, and drug interactions.
- The United States Pharmacopeia and the National Formulary, along with professional journals will be used for clinically significant efficacies, adverse effects, toxicities, and drug interactions.

In January 2000, NABP surveyed 81 schools and colleges of pharmacies concerning curriculum requirements for herbals and nutraceuticals. Of the 58 schools that responded, ". . . 41 [schools] include the teaching of herbal products as either part of another course [ie, over-the-counters and therapeutics] or as a required course solely dedicated to herbal products and/or nutraceuticals."

Courses on herbal and nutraceutical products cover a broad range of topics including the role of US Food and Drug Administration (FDA) in regulating drugs and dietary supplements, clinical efficacy studies for herbals, product standardization issues, and documented drug interactions. In addition, many courses cover the top 10-20 herbal products offered on the market.

Results demonstrated that nearly 40% of the schools that responded [to the survey] have required herbal or nutraceutical courses; 31% have both elective and required courses, and only 28% of these schools solely offer only elective courses. Of those schools that responded, less than 2% offer no type of herbal or nutraceutical course.

Please see "Survey Finds Nutraceuticals Being Added to Pharmacy Curriculum" in the October/November 2000 *NABP Newsletter* to obtain additional information about the 2000 study. NABP

FSMB, NABP, CSAT to Sponsor Workshops *(continued from page 139)*

Office," and "Confidentiality Requirements."

Recognized experts in their fields include Donald H. Williams, executive director of the Washington State Board of Pharmacy, and Executive Director of the Virginia Board of Medicine William L. Harp, MD, who will present a discussion on the Model Policy Guidelines; and Medical Officer with the National Institute on Drug Abuse Alan Trachtenberg, MD, MPH, and Patricia M. Good, chief Liaison and Policy Section, FDA, who will speak about DATA. Efforts are underway to qualify the workshop curriculum for continuing medical education credit. The curriculum has been approved for continuing pharmaceutical education credit.

State medical and pharmacy boards may designate one board member and one senior staff member to attend the workshop of their choice. Registration forms for medical board attendees must be signed by the medical board president/chair, while registration forms for pharmacy board attendees must be signed by the pharmacy board executive officer. For those attending the January 10, 2003 workshop, registration forms must have been received by the Federation **no later than December 2, 2002**, and **no later than January 13, 2003,** for those attending the February 21, 2003 workshop.

NABP mailed a memo to the boards of pharmacy containing this information as well as the registration form in October 2002. Interested individuals can also obtain this information, the registration form, as well as details about travel, hotel reservations, and the workshops by contacting FSMB through their Web site at www.fsmb.org, phone at 817/868-4007, or by e-mailing the Education Department at edu@fsmb.org. NABP

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NABP Meeting Dates

Thursday-Friday, January 23-24, 2003
Committee on Law Enforcement/Legislation
Hyatt Rosemont, Rosemont, IL

Thursday-Friday, March 20-21, 2003
Committee on Constitution and Bylaws
Hyatt Rosemont, Rosemont, IL

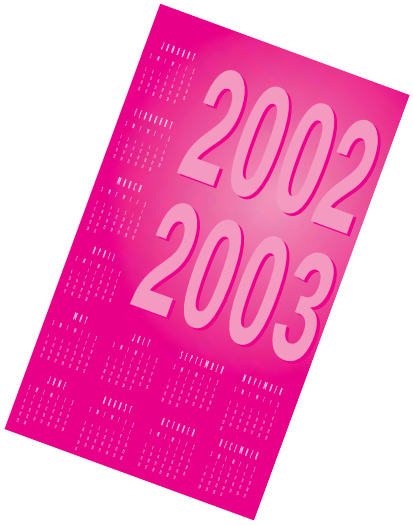
Friday, May 2, 2003
Pre-Convention Executive Committee Meeting
Philadelphia Marriott, Philadelphia, PA

Saturday-Wednesday, May 3-7, 2003
NABP's 99th Annual Meeting
Philadelphia Marriott, Philadelphia, PA

Wednesday, May 7, 2003
Post-Convention Executive Committee Meeting
Philadelphia Marriott, Philadelphia, PA

Sunday-Tuesday, September 14-16, 2003
Fall Legislative Conference
Mayflower Hotel, Washington, DC

Saturday-Wednesday, April 24-28, 2004
NABP's Centennial Annual Meeting and Celebration
Fairmont Hotel, Chicago, IL



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