

# newsletter

AID TO GOVERNMENT - THE PROFESSION - THE PUBLIC - 1904 TO 2001

## NABP/FSMB Ask for HHS Assistance

On October 25, 2001, NABP and the Federation of State Medical Boards (FSMB) combined forces to present a letter to US Department of Health and Human Services (HHS) Secretary Tommy Thompson seeking assistance from HHS in controlling the illegitimate and illegal pharmacy Web sites that are engaging in prescribing and distribution of medicines approved for the treatment of anthrax infection to the public. The letter explains to HHS the research undertaken by both NABP and FSMB that indicates the distribution of these medications and the panic these Web sites are causing is an "immediate and significant threat to the health and security of the United States." The letter goes on to explain that the Web sites are engaging in illegitimate and poor medical practice as patients receive no physical face-to-face examinations by physicians and instead face health risks like "adverse drug reactions/interactions,

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## NABP Works to Halt Illegitimate Web Sites' Sale of Anthrax Medications

This fall's anthrax attacks targeting members of Congress and the media, as well as the US Postal Service, presented new opportunities for those operating illegal and often unlicensed Web sites selling prescription-only Cipro® and other antibiotics used to treat anthrax.

By offering the antibiotic to anyone with the cash to pay for it, these Web sites play into the public's mistaken fears and attempt to make a profit from those fears.

Ironically, patients seeking medications to protect them from the biological threat of anthrax may be opening the door to a different and possibly more dangerous threat. Cipro, should only be dispensed to those individuals who have been exposed to the bacteria, not to those who want use it for prophylaxis.

Patients risk receiving counterfeit products, illegal generic products (ciprofloxacin), and products that have not been properly stored and handled. Further, patients are often not provided with important information such as directions for use and side effects.

Since the earliest days of the anthrax scare, NABP has received numerous e-mails and phone calls from the public and members of state boards reporting Web sites that were selling medications to treat anthrax and, often times, spreading false and misleading information. Many of these sources note that they did not receive the ordered medication after paying for it online or that they received damaged or distorted medication via the mail.

NABP investigates these Web sites to determine whether they

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Suspicious Anthrax Treatment Web Sites Reported to NABP



## NABP Works to Halt Illegitimate Sales *(continued from page 153)*

are licensed and legitimately providing online medications for patients and reports adverse findings to the state boards and the Food and Drug Administration (FDA). In some cases NABP purchased or attempted to purchase Cipro from some of these sites.

In one such instance, NABP staff went online to purchase Cipro. NABP was denied the prescription by one site, possibly due to NABP using its company credit card and office e-mail address. But when a personal credit card was used, the request for the medication was approved and the drug shipped to NABP headquarters. The packaging and labeling of the drug seemed to be legitimate. The Cipro arrived in an amber vial, with the necessary information on the label including patient's name, doctor and pharmacy name and location, drug name, strength, and quantity. Although the pharmacy involved is licensed, it still offers online prescriptions with only online medical consultations between the patient and physician. According to the Federation of State Medical Boards, the Federal Trade Commission Web site, and the American Medical Association this kind of practice is considered substandard medical care.

Another site from which NABP successfully purchased Cipro, is a Costa Rican-based site that prescribes and dispenses the generic version of Cipro. The site implied that both the brand and generic versions are

equivalent. NABP received the generic version when it made the purchase. In this case, the packaging and labeling were unidentifiable, consisting of 10 tablets in a brown envelope with handwritten information.



At this time the Centers for Disease Control and Prevention (CDC) and FDA are cautioning patients to avoid foreign Web sites too because there is a higher risk of being cheated and the US government has little control over these sites.

As a result of these investigations, NABP is cautioning the public to buy prescription pharmaceuticals from pharmacies they know and trust. If patients want to make purchases online, NABP stresses to do so only from online pharmacies properly licensed with the appropriate state boards of pharmacy. Patients should look for the Verified Internet Pharmacy Practice Sites™ (VIPPS™) seal, which certifies that the pharmacy is licensed and compliant with the relevant state board of pharmacy and has met a rigorous criteria review that considers patient confidentiality, authenticity and validity of prescriptions, a quality-assurance program, and patient-pharmacist consultation. VIPPS-certified sites may be identified by the

VIPPS seal of approval on the pharmacies' Web sites. Patients may also access the VIPPS database directly via NABP's Web site at [www.nabp.net](http://www.nabp.net).

*One Web site mailed the medication in the standard amber vial with the labeled prescription; there was refill option information and details about the doctor and pharmacist who approved the prescription.*

NABP President Richard K. "Mick" Markuson explains that NABP has "found a number of sites that are exploiting people's fears and concerns." Markuson goes on to say that NABP is "tracking them down and turning them over to the



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states and the Food and Drug Administration for prosecution.”

Of course, the lack of a VIPPS logo does not necessarily mean that an online pharmacy is practicing pharmacy illegally. Patients should look for the following characteristics of a legitimate online pharmacy:

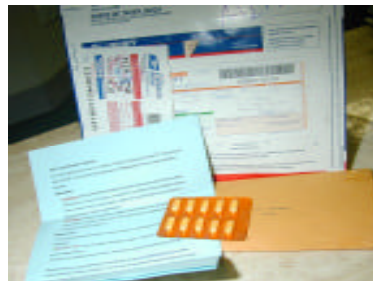
- The pharmacy site is licensed in the state(s) in which the site is doing business (or shipping to).
- There is detailed information about the licensure of the pharmacist or pharmacists practicing at the site.
- There is information about where the product was manufactured.
- There is contact information, beyond a toll-free customer service number; even better, there is a physical address.
- There is detailed information about the products.
- There is more than just an online medical form that

the patient is asked to fill out. Online medical consultation is not equivalent to a physical examination and evaluation to establish a

doctor/patient relationship. Online forms rely on the consumer's knowledge of

his/her medical status; a potentially dangerous situation since the patient may not know enough about his/her own health, may not know about potential allergies, and may not know if there is a better alternative treatment available.

- A feature known as “Ask the Pharmacist” is a sought-after feature on licensed and legitimate sites.



*Another site sent the tablets in a handwritten brown envelope. It included a letter briefly describing how and when to take the tablets.*

NABP is answering patients' questions about what to do if a Web site is suspected of being an illegal source for the sale of Cipro and other prescription

medications.

Patients are advised to immediately contact their state board of pharmacy to report their suspicions. It is crucial that all records of communications between the patient, the board,

and the site be retained as evidence. If there are payment issues involved, the Attorney General's office should be contacted to report credit card fraud.

NABP will continue to follow up on reports of illegal prescribing sites in order to protect the public health while assuring the continued availability of such medications from legitimate sources. **NABP**

## NABP, Illinois Cook County State's Attorney's Office Collaborate

NABP recently provided information and advice that enabled the Illinois State's Attorney's Office to bring charges in Illinois against three pharmacy Web sites. NABP gave details on how these illegal sites operate and why. One of these sites and the owner was charged with violating the Illinois Pharmacy Practice Act and the Illinois Consumer Fraud and Deceptive Business Practices Act. The pharmacy was engaging in sales of Cipro® to the public without

proper medical examination and consultation. The charge went through in early November and is currently awaiting a hearing that may result in an injunction to halt the site's operation.

In November, in an effort to keep the state boards informed of other illegitimate Web sites, NABP provided them with a list of Web sites that were selling Cipro to the public. Going forward, a similar list will be

provided on a monthly basis. NABP staff gathers the information from phone calls and e-mail messages sent by patients and members of the state boards. After the sites have been thoroughly researched, they are placed on this list of suspicious sites.

For a listing of the illegitimate Web sites selling Cipro, see “Suspicious Anthrax Treated Web Sites Reported to NABP” on page 166 of this *Newsletter*. **NABP**

## But I Didn't Inhale

By Dale Atkinson, JD



It is essential for regulatory boards to understand the “Grounds for Discipline” section of the enabling statute in order to effectively carry out their public protection mission.

Practice Acts contain some ambiguities by design in order to provide the board with the flexibility to enforce a stagnant statutory scheme in spite of changing times. Reliance upon violations of criminal statutes as grounds for administrative disciplinary actions can be especially complex. Consider the following.

A nurse submitted an application for employment to a particular nursing center. As part of a pre-employment screening, the nurse submitted to various drug screens. The nurse’s urine drug screen tested positive for the presence of marijuana and cocaine.

Based upon these positive test results, the regulatory board filed a complaint with the Administrative Hearing Commission (AHC). (The judicial opinion does not reveal how the regulatory board received information about the positive test results.) Thereafter, the board submitted Requests for Admissions, which included statements that the nurse had consumed marijuana and cocaine on or about March 1996, and that she had sub-

mitted to a pre-employment urine drug screening. Based upon the procedural processes within the state, Requests for Admissions are allowed in administrative proceedings and recipients of such requests have 30 days to respond. Failure to respond within 30 days results in an admission on the part of the individual upon which these requests were propounded. The nurse failed to answer within 30 days and such questions were deemed admitted and submitted into evidence at the hearing.

Among other grounds cited, the board accused the nurse of “violating the drug laws or rules and regulations of [Missouri] or any other state or the federal government.” In referencing the drug law statute alleged to have been violated, the board cited a particular section of the Missouri Criminal Code that required proof of the conscious and intentional possession of a contraband drug. Accordingly, the conscious and intentional possession of a contraband drug provided the basis for a disciplinary license proceeding by the Board of Nursing.

After an evidentiary hearing, the AHC held that the board did not establish the necessary elements to sustain disciplinary actions against the nurse. The board appealed the matter.

First, the Court of Appeals addressed the issue of the appropriate burden of proof.

Because the board relied upon an allegation of a violation of the drug laws of Missouri as one basis for the charge, it was necessary to identify the criminal statute. An issue was identified as to whether the criminal burden of proof (beyond a reasonable doubt) or the administrative burden of proof (preponderance of the evidence) was applicable. In resolving this matter, the Appellate Court held that the life or liberty of the licensee was not at jeopardy and, thus, a preponderance of the evidence standard was applicable in the administrative proceeding.

Also, the Court of Appeals held that to prove a breach of the particular section of the Practice Act, which relied upon the violation of the criminal statutes, the board was compelled to prove that the nurse knowingly and intentionally possessed marijuana or cocaine. In upholding a decision of the AHC, the court held that whether knowledge and intent can be inferred from a positive drug test and/or consumption had not yet been decided by the courts in Missouri. Evidence of the nurse’s positive drug test and her consumption of marijuana and cocaine was not sufficient to establish, even under the preponderance of the evidence standard, that the nurse knowingly and intentionally possessed marijuana and cocaine as described by the

criminal statute. The court held that additional proof of intentional or knowing possession was required and, in the absence of such, the board failed to establish the requisite mental state element required by the particular criminal statute. Accordingly, the exoneration of the nurse for violating the particular sections of the Practice Act was upheld by the Court of Appeals. Boards of Pharmacy must be keenly aware of criminal

elements that may be necessary to establish wrongdoing based upon possession, use, and/or distribution of drugs. The “intent” issues necessary in criminal proceedings is a difficult element for regulatory boards to address in administrative proceedings. A simple question or request to admit querying individuals as to whether they “intentionally and knowingly” possessed or used drugs may answer some of these questions. However,

individuals may refuse to answer these questions citing their rights under the Fifth Amendment of the United States Constitution. The Fifth Amendment will be the topic of the next *Newsletter* article. **NABP**

*State Board of Nursing v. Berry* 32 S.W.3d 638 (MO App.Ct. 2000)

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## **NABP/FSMB Ask for HHS Assistance** *(continued from page 153)*

misdiagnosis, and failure to identify complicating conditions.” The illegal distribution of the medicines could further endanger patients as they may develop resistant strains of anthrax. In addition, these sites’ sales could place a strain on the supply of the medications should a large-scale outbreak occur. Finally, the sites themselves could be housing other biological threats and dangerous substances. NABP and FSMB seek to have “nationwide actions” to assist the present efforts of the states and halt the operation of these sites by urgently recommending that:

1. these sites’ activities are an immediate and serious threat to public health and national security and that the

prescriptions issued from such sites do not meet the legal requirements of Section 503 (b)(1) of the

*... research undertaken by both NABP and FSMB that indicates the distribution of these medications and the panic these Web sites are causing is an “immediate and significant threat to the health and security of the United States.”*

Federal Food, Drug, & Cosmetic Act;

2. the Food and Drug Administration (FDA) and other appropriate agencies be granted the authority to impose a nationwide injunction or enforce compliance of these sites;
3. the US Customs authority and other agencies be expanded to enforce the prohibitions on the importation of medications;
4. the US State Department seek the cooperation of foreign governments to shut down the operations of illegitimate foreign Web sites.

See “Committee Members from Government Reform and Energy and Commerce Support NABP/FSMB’s Initiative” on page 160 of this *Newsletter* for more information. **NABP**

# Professional Affairs *Update*

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## DEA Proposes New Central Fill Regulations

The US Drug Enforcement Administration (DEA) published a proposed rule in the September 6, 2001 *Federal Register* that would amend its regulations to provide for the use of central fill pharmacies, also known as refill pharmacies, fulfillment centers, or call centers, in the dispensing of controlled substances. Current DEA regulations do not permit the use of such pharmacies for the dispensing of controlled substances.

Central fill pharmacies provide services to retail pharmacies by preparing and packaging prescriptions for retail pharmacies to dispense to patients. Prescription information is transmitted from a retail pharmacy to a central fill pharmacy where the prescription is filled or refilled. The filled prescription is delivered to the retail pharmacy for pickup by the patient.

The proposed rule would allow central fill pharmacies to register as practitioners under 21 CFR 1301.13(e)(1)(iii) and would expand the definition of "dispense" to include the activities of central fill pharmacies. Both the pharmacist employed by the central fill pharmacy and the pharmacist dispensing the prescription to the patient would be responsible for ensuring that the prescription was issued for a legitimate medical purpose.

The full text of the proposed rule can be viewed on the DEA's

Web site at [www.deadiversion.usdoj.gov/fed\\_regs/rules/2001/fr09062.htm](http://www.deadiversion.usdoj.gov/fed_regs/rules/2001/fr09062.htm). For further information, contact Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, DEA, Washington, DC 20537, phone: 202/307-7297.

## DEA Forms Available on Web Site

The US Drug Enforcement Administration (DEA) recently announced the availability of selected reports and applications required by the federal Controlled Substances Act on the DEA Web site at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov). These DEA form numbers, with their descriptions following, are currently available:

- 41: Registrants' Inventory of Drugs Surrendered
- 106: Report of Theft or Loss of Controlled Substance
- 161: Application for Permit to Export Controlled Substances
- 189: Application for Individual Manufacturing Quota
- 224A: Renewal Application for Registration – Retail
- 225: New Application for Registration – Wholesale
- 225A: Renewal Application for Registration – Wholesale
- 236: Controlled Substances Import/Export Declaration
- 250: Application for Procurement Quota for Controlled Substances
- 357: Application for Permit to Import Controlled Substances

363: New Application for Registration – Narcotic Treatment Program

363A: Renewal Application for Registration – Narcotic Treatment Program

486: Import/Export Declaration – Chemical

510: New Application for Registration – Chemical

510A: Renewal Application for Registration – Chemical

The forms are available in PDF format, so it will be necessary to have Adobe Acrobat or Adobe Acrobat Reader installed on your computer. Two versions of each form will be available 1) an interactive version, which will allow the user to complete the form online and print it on his or her printer for signature and mailing; and 2) a blank form, which can be printed and completed manually. The DEA recommends completing the form online to reduce errors.

## FDA Announces Changes to Accutane Pregnancy Risk Management Program

The Food and Drug Administration (FDA) recently announced significant changes to the Accutane® risk management program for pregnancy prevention. The new program, called S.M.A.R.T.™ (System to Manage Accutane® Related Teratogenicity), was developed in consultation with the FDA by Accutane's manufacturer, Hoffmann-La Roche, Inc. The program is designed to enhance the safe and appropriate use of Accutane.

Detailed information about the program will be mailed to physicians and pharmacists on January 2, 2002, and physicians, pharmacists, and patients must be in compliance with the program by April 10, 2002.

The S.M.A.R.T. program partners Accutane prescribers, patients, and pharmacists in an effort to prevent fetal exposure. Specifically, the program requires the following:

- Prescribers must read the S.M.A.R.T. "Guide to Best Practices" provided by Roche; then sign and return to Roche the Letter of Understanding documenting their knowledge of the measures to minimize fetal exposures to Accutane. The manufacturer has also developed educational materials for prescribers and nurses. Prescribers will then receive from Roche special yellow self-adhesive Accutane Qualification Stickers. All prescriptions for Accutane should have the special yellow sticker attached to the prescriber's regular prescription form. This sticker will indicate to the pharmacist that the patient is "qualified" according to the new package insert, which means that the female patient has had negative pregnancy tests as indicated below, as well as education and counseling about pregnancy prevention. The pregnancy test will be repeated every month throughout the Accutane


treatment course, and no prescriptions for more than a one-month supply of Accutane should be given at a time.

- All female patients must have two negative urine or serum pregnancy tests before the initial Accutane prescription is written, and for each month of therapy they must have a negative pregnancy test result before receiving their next prescription, regardless of whether they are sexually active. All female patients must select and use two forms of effective contraception simultaneously for at least one month prior to initiation of Accutane therapy, during therapy, and for one month following discontinuation of therapy unless they have had a hysterectomy or commit to absolute abstinence. They must sign a Patient Information/Consent Form about Accutane and birth defects. Finally, female patients must be given the opportunity to enroll in the Accutane Survey. This confidential survey, which has been ongoing for many years, collects data to help Roche and FDA decide if S.M.A.R.T. is helping to prevent exposure of unborn babies to Accutane. Patients who agree to participate in the Survey will be making a major contribution to the public health.
- Pharmacists will dispense Accutane only upon presen-

tation of a prescription with the special yellow Accutane Qualification Sticker.

Pharmacists will dispense a maximum one-month supply of Accutane, fill prescriptions within seven days from the date of "qualification," and provide a Medication Guide to patients with each Accutane prescription. Requests for refills (ie more Accutane without a new prescription) or computerized or phoned-in prescriptions will not be filled.

To measure the effectiveness of the S.M.A.R.T. program, Roche will use several independent outcome assessment approaches. These include the Accutane Survey, conducted by the Slone Epidemiology Unit of Boston University School of Public Health, and an independent audit of pharmacies to assess the use of Accutane Qualification Stickers by prescribers. Prescribers, patients, and pharmacists must all participate fully in these critically important measures to ensure that fetal exposure to this potent teratogen does not occur.

Exposure of an unborn baby to Accutane is a serious adverse event and should be reported to Roche or directly to the FDA MedWatch Program. The contacts are as follows: Roche Medical Services 1-800/526-6367 or FDA MedWatch program 1-800/FDA-1088. MedWatch can also be accessed via the Internet at [www.fda.gov/medwatch/index.html](http://www.fda.gov/medwatch/index.html). 

## Committee Members from Government Reform and Energy and Commerce Support NABP/FSMB's Initiative

On November 26, 2001, Ranking Minority Member Henry A. Waxman, from the Committee on Government Reform and Ranking Minority Member John D. Dingell, from the Committee on Energy and Commerce stood behind NABP and the Federation of State Medical Boards (FSMB)'s joint request for assistance from the Department of Health and Human Services (HHS) and Secretary Tommy G. Thompson in taking action to prevent the "inappropriate sales of Cipro® and other antibiotics over the Internet."

The letter to HHS explained the recent events of Web sites offering Cipro and other antibiotics for anthrax infection to "an alarmed public without a doctor's prescription." Waxman and Dingell stressed that the "Antibiotic sales by these businesses can cost as much as [10] times more than the government pays and lead to unnecessary adverse reactions and antibiotic resistance." The letter states that although the Food and Drug Administration (FDA) has "moved to stop [W]eb sites from selling foreign drugs in the United States," the "agency has not taken a clear position on sites that offer domestic antibiotics illegitimately."

The committee members explain that many state boards of medicine and pharmacy have worked with state attorneys

general and have tried to "take action against suspect [W]eb sites and participating physicians and pharmacists." Unfortunately, as the letter goes on, "state laws often are vague and can require that prosecutors revisit the question of whether prescribing drugs over the Internet is appropriate in each case." Waxman and Dingell say another issue is that "states are wary of starting an investigation of a [W]eb site that may lead to doctors and pharmacists in another state's jurisdiction."

The letter goes on to say that many state pharmacy organizations are now turning to FDA for leadership and support, requesting "urgent assistance" to halt the threat of these illegal Internet sales of antibiotics. The letter reaffirms the potential hazards that are caused by these Web sites in their unscrupulous and illegitimate sale of antibiotics. Among Waxman and Dingell's points is how, in some instances,

the sites may mail out Cipro without any prescription at all. In others, physicians who have never met, interviewed, or examined purchasers may churn out dozens of prescriptions a day. Such lax rules essentially guarantee that some patients will suffer needless adverse reactions because allergies or compli-

cating medical conditions will not be identified. Moreover, should someone start taking Cipro for actual anthrax symptoms, the lack of a doctors' exam might prevent him or her from receiving more intensive and potentially life-saving treatment.

Waxman and Dingell quote NABP, FSMB, and the Centers for Disease Control and Prevention (CDC), explaining that the distribution and use of these medications by Internet sites could further risk the lives of Americans through the development of resistant strains of anthrax and other biological terrorist agents.

Waxman and Dingell urge HHS and Thompson to make a decisive move in support of this initiative by prompting FDA to use its legal authority in clarifying that "a valid prescription excludes internet sales on the basis of a questionnaire without any real doctor-patient relationship." The letter stresses that with this essential move against these Web sites, FDA will then enable the state agencies, "to enforce federal law in this area" and "to shut down these dangerous businesses," in the end halting the potential danger to the American public's health and safety. **NABP**

# Recognizing and Responding to Illnesses Caused by Biological Agents

Pharmacists, physicians, and other health care providers must be alert to illness patterns and diagnostic clues that might indicate an unusual infectious disease outbreak associated with the intentional release of a biological agent. Indications of such suspicious symptoms should be immediately reported to local or state health departments. Indications of intentional release of a biological agent include:

- Groups of people in the same location or area with symptoms that suggest an infectious disease outbreak, such as an unexplained febrile illness associated with sepsis, pneumonia, respiratory failure, or rash, or a botulism-like syndrome with flaccid muscle paralysis.
- Groups of individuals who are not within the age group normally associated with common diseases.
- Numerous cases of acute flaccid paralysis with prominent bulbar palsies that would suggest a release of *botulinum* toxin.

NABP and its member boards of pharmacy are committed to the belief that it is critical for the public to get timely and accurate information so they may better protect themselves and their families. During these dangerous times, consumers will be looking to their physicians, pharmacists, and other health care professionals for current and accurate information about the diseases caused by these biological agents, the medications that

can treat and stop them, and the side effects of such drugs.

State health departments should implement plans for educating and reminding health care providers about how to recognize unusual illnesses that might indicate intentional release of a biological agent. Strategies for responding to potential bioterrorism include:

1. providing information to health care providers and laboratories about how and when to report events to appropriate authorities;
2. implementing a 24-hour-a-day, seven-day-a-week plan to receive and act on any legitimate reports suggesting intentional release of a biological agent;
3. investigating any report that suggests an intentional release of a biological agent;
4. implementing a procedure to collect and transport specimens for storage and laboratory analysis;
5. reporting immediately to the Centers for Disease Control and Prevention (CDC) if the results of an investigation suggest release of a biological agent.

## Biological/Chemical Threats

While the media has been concentrating on the anthrax situation, there are, unfortunately, other diseases with greater potential to harm the

public. The CDC lists anthrax, smallpox, and pneumonic plague as diseases that pose “the biggest” biological threats. Other agents of concern include *Clostridium botulinum* toxin (botulism), *Francisella tularensis* (tularemia), and the Hemorrhagic fevers.

### Smallpox

Smallpox is caused by variola virus. Initial symptoms include high fever, fatigue, and head-and-backaches, followed by a rash. The majority of patients recover, but death occurs in up to 30% of the cases. Smallpox is spread from one person to another through face-to-face contact. Although routine vaccination against smallpox ended in 1972, the level of immunity, if any, among persons vaccinated before 1972 is uncertain; therefore, these persons are assumed to be susceptible. At the present time, vaccination against smallpox is not recommended to prevent the disease in the general public and, therefore, is not available.

### Botulism

Botulism is a muscle-paralyzing disease caused by a toxin made by the bacterium *Clostridium botulinum*. Foodborne botulism, which occurs when a person ingests a pre-formed toxin that leads to illness within a few hours to days, is a public health emergency because the contaminated food may still be available to other people. The two other forms of this illness are infant botulism, which occurs in a

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## Recognizing Illnesses Caused by Biological Agents (continued from page 161)

small number of susceptible infants who have *C. botulinum* in their intestinal tract, and wound botulism, which occurs when wounds are infected with *C. botulinum* that secretes the toxin.

With foodborne botulism, symptoms begin within six hours to two weeks after eating the contaminated food. Symptoms include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness that leads to paralysis of the breathing muscles. Botulism is not spread from one person to another. There is an antitoxin that is effective in reducing the severity of symptoms if administered early in the course of the disease.

### Pneumonic Plague

Pneumonic plague occurs when *Y. pestis* infects the lungs. The first signs of illness in pneumonic plague are fever, headache, weakness, and cough with bloody or watery sputum. The pneumonic plague progresses over two to four days and may cause septic shock and, without early treatment, death. Person-to-person transmission of pneumonic plague occurs through face-to-face contact with the affected individual. Early treatment is essential and several antibiotics are effective, including streptomycin, tetracycline, and chloramphenicol. There is no vaccine against plague.

### Anthrax

The main points to remember about anthrax are that it

cannot be passed from person to person. If exposed, infection can be prevented with antibiotics such as penicillin, doxycycline, and fluoroquinolones. Only people who are exposed to the disease need to take the antibiotics. Treatment of close contacts is not necessary, unless those contacts were also exposed to the same source of the infection. Intravenous ciprofloxacin and intravenous doxycycline can be used to act against anthrax. Adverse side effects of ciprofloxacin, which is indicated for use in reducing the progression of inhalation anthrax in patients who are 18 years and over, include vomiting, diarrhea, headaches, dizziness, sun sensitivity, and rash. Side effects of doxycycline range from nausea, vomiting, or diarrhea, to more severe reactions like swelling of the face, difficulty breathing, severe headaches, vision changes, liver damage, severe fatigue, and blood problems.

During the past few months, prescription orders of Cipro<sup>®</sup> have been increasing, with concerned individuals trying to “stock up” on the antibiotic to protect themselves and their families from the threat of anthrax. However, because Cipro should only be used by individuals who are exposed to the disease and because storage conditions and validation of expiration dates cannot be assured, the general public should not ask physicians to write prescriptions for the drug. There is also the risk that individuals could become immune to other antibiotics if

taken unnecessarily. NABP, the CDC, and other federal agencies stress that the government will provide the appropriate antibiotics from its stockpile when necessary.

The serious forms of human anthrax are:

- Cutaneous anthrax, where the skin surface is exposed and skin lesions develop.
- Gastrointestinal anthrax, in which the particles are indigested.
- Inhalation anthrax, which is most often fatal, occurs when the particles are inhaled.

Initial symptoms of inhalation anthrax may resemble a common cold. After a few days, the symptoms progress to severe respiratory problems and shock. The intestinal disease form of anthrax is characterized by an acute inflammation of the intestinal tract. Initial signs of nausea, loss of appetite, vomiting, and fever are followed by abdominal pain, vomiting of blood, and severe diarrhea. Cutaneous anthrax appears as a swelling on the skin, usually on the arms or hands, which then develops into a central area of ulceration or a depression, and then a dark, blackish-brown scab forms over the area. It can be painless and may be accompanied by a fever.

### Inhalation Tularemia

Inhalation of *Francisella tularensis* causes an abrupt onset of an acute, nonspecific febrile illness beginning three to five days after exposure, with

*(continued on page 166)*

## The National Pharmaceutical Stockpile Program

The mission of the Centers for Disease Control and Prevention's (CDC) National Pharmaceutical Stockpile (NPS) Program is to ensure the availability of life-saving pharmaceuticals, antibiotics, and chemical antidotes, as well as medical, surgical, and patient support supplies for prompt delivery to the site of a biological or chemical terrorist event in the United States or its territories. The NPS is used to supplement the initial response to an incident of biological or chemical terrorism. That response will come

from local and state emergency, medical, and public health personnel. The primary purpose of the NPS is to provide critical drugs and medical material.


The contents of the stockpile include antibiotics for anthrax, pneumonic plague, and tularemia.

The NPS has two basic components:

- The first consists of eight 12-hour Push Packages consisting of a pre-assembled set of supplies, pharmaceuticals, and medical equipment positioned in environmen-

tally controlled and secured warehouses. The location of the secured warehouses can not be disclosed as it is confidential information.

- The second component is comprised of Vendor Managed Inventory (VMI) material. VMI packages are at hand in case more supplies are needed and can be tailored to a specific threat agent.

For more information about the CDC and the NPS, visit their Web sites at [www.cdc.gov](http://www.cdc.gov) and [www.cdc.gov/nceh/nps/default.htm](http://www.cdc.gov/nceh/nps/default.htm). 

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## NABP, APhA Will Launch [pharmacist.com](http://pharmacist.com)

[Pharmacist.com](http://Pharmacist.com), the Web portal developed by NABP and the American Pharmaceutical Association (APhA), will soon be launched, providing the pharmacy community with a one-stop portal offering breaking pharmacy news, a complete suite of continuing education services, online practice exams from NABP, and other services.

"[Pharmacist.com](http://Pharmacist.com) will be an accessible and helpful tool for pharmacists concerning all of the aspects of the practice of pharmacy," states NABP President Richard K. "Mick" Markuson.


The Web site, divided into six different sections: licensure, drugs and diseases, education,

careers, resources, and a store will be monitored and updated by both Associations. NABP will initially contribute information to the licensure, education, and career sections, while APhA will contribute data for all six sections of the portal and be the sole contributor of the drugs and diseases section.

In the licensure section, NABP will provide site users with current and useful information, as well as practice exams for NABP-produced competency assessment mechanisms and access to the Renewal and Application Process (RAP). (See

the "Renewal and Application Process Update" article on page 93 of the July 2001 *NABP*

*Newsletter* for more information about RAP.)  
Breaking

news about pharmacy practice, as well as other promotions will be an integral part of [pharmacist.com](http://pharmacist.com)'s career section. Such news and information may include excerpts from the *NABP Newsletter* or other NABP publications. There will also be links between [pharmacist.com](http://pharmacist.com) and the individual NABP and APhA Web sites. 



## *Season's Greetings from Your Friends at NABP*



*The Executive Office, Human Resources, and Information Technology*



*Applications/Database, Foreign Pharmacy Graduate Examination Committee Certification® Program*



*Competency Assessment and Electronic Licensure Transfer Program™*



*Communications and Customer Service*

## Recognizing Illnesses Caused by Biological Agents (continued from page 162)

pleuropneumonitis developing in a substantial proportion of cases during subsequent days.

### Hemorrhagic Fever

Illness is usually characterized by abrupt onset of fever, myalgia, and headache. Other signs include nausea and vomiting, abdominal pain, diarrhea, chest pain, cough, and pharyngitis. Bleeding manifestations will occur as the disease progresses.

More information about these and other disease topics can be obtained by visiting the CDC Web site at [www.cdc.gov](http://www.cdc.gov).

### Common Sense, not Paranoia

The US government is both capable and ready to deal with any threat to the people and

the nation. The White House has been stressing that the best thing for people to do to protect themselves from any kind of attack is to maintain a constant and attentive awareness of their surroundings, noting anything out of the ordinary, while at the same time not being overly paranoid. The CDC, which continues to hear stories about people purchasing gas masks and hoarding food and medicine in case of an attack, emphasizes this is not necessary. US Department of Health and Human Services Secretary Tommy Thompson states that "People should not be scared into thinking they need a gas mask. In the event of a public health emergency, local and state health depart-

ments will inform the public about the actions individuals need to take."

President George W. Bush stresses that Americans should go on with their daily routine, and not change their lives in drastic measures. According to NABP President Richard K. "Mick" Markuson, NABP is also "taking necessary precautions it needs to maintain a safe working environment for its employees while at the same time not acting on fear and paranoia." Having access to the right information, whether from trusted sources online or between individuals and organizations, is the best way to arm the public and prepare citizens everywhere on how to protect their health and safety.

**NABP**

## Suspicious Anthrax Treatment Web Sites Reported to NABP

[www.99-viagra-vaniga-online-pharmacy.com](http://www.99-viagra-vaniga-online-pharmacy.com)

[www.ultrameds.com](http://www.ultrameds.com)

<http://3561607395/candy7>

[www.rxusaonline.com](http://www.rxusaonline.com)

[www.planetpills.com](http://www.planetpills.com)

[www.pillsonthenet.com](http://www.pillsonthenet.com)

[www.net-dr.com](http://www.net-dr.com)

[www.myfastrx.com](http://www.myfastrx.com)

[www.MexicoDrugstore.com](http://www.MexicoDrugstore.com)

[www.medalife.com](http://www.medalife.com)

[www.iquestinfo.com](http://www.iquestinfo.com)

[www.goodpills.com](http://www.goodpills.com)

[www.e-secure-health.net](http://www.e-secure-health.net)

[www.drugsonthenet.com](http://www.drugsonthenet.com)

[www.cipropharmacy.com](http://www.cipropharmacy.com)

[www.ciproclinic.com](http://www.ciproclinic.com)

[www.cipro.info](http://www.cipro.info)

[www.cipro-for-less.com](http://www.cipro-for-less.com)

[www.antibiotic-cipro.com](http://www.antibiotic-cipro.com)

[www.buy-phentermine-online.com](http://www.buy-phentermine-online.com)

[www.bioterrorism.com](http://www.bioterrorism.com)

[aprescribe.com](http://aprescribe.com)

[www.anthrax-treatment-cipro-antibiotic-medication.com](http://www.anthrax-treatment-cipro-antibiotic-medication.com)

[www.anthraxdrugstore.com](http://www.anthraxdrugstore.com)

<http://2-buy-cipro.com>

[www.usamedicine.com](http://www.usamedicine.com)

[www.IwantCipro.com](http://www.IwantCipro.com)

[www.medications.com](http://www.medications.com)

[www.anthrax-antibiotics.com](http://www.anthrax-antibiotics.com)

[www.1drugstore-online.com](http://www.1drugstore-online.com)

[www.1onlinepharmacy.com](http://www.1onlinepharmacy.com)

<http://64.80.217.12/tophost/th002>

[www.500mg-cipro-4-anthrax-exposure-and-treatment.com](http://www.500mg-cipro-4-anthrax-exposure-and-treatment.com)

**NABP**

# Expanded Computer Training Session Offers New Forum for Feedback

The extensive, computer training and program review sessions held at NABP headquarters in Park Ridge, Ill, in late August and early September this year provided board of pharmacy staff with training on NABP programs using Lotus® Notes software and a forum for discussion with program staff at NABP.

NABP President Richard K. “Mick” Markuson discussed the changes to this year’s program. “The previous training sessions focused specifically on how NABP programs worked with Lotus Notes,” he noted. “However, this year’s training expanded to include an interactive discussion of NABP programs, processes, and documentation procedures, as well as feedback between the state boards and NABP staff.”

The training session served as a refresher course for some. They focused primarily on the processes and procedures that keep the relationship between NABP and the boards organized, coherent, and accurately documented, especially for the staff who use Lotus Notes in their communications with NABP’s testing, Clearinghouse, and licensure transfer programs. The following topics were emphasized.

- Verification of licensure data for the ELTP;
- Importance of reporting disciplinary information to NABP, including information pertaining to applicants whose licensure

applications have been denied; and

- How Lotus Notes is used to report roster and exam score information for

*“... this year’s training expanded to include an interactive discussion of NABP programs, processes, and documentation procedures, as well as feedback between the state boards and NABP staff.”*

*– NABP President Richard K. “Mick” Markuson*

candidates taking the pharmacist licensure examinations.

Participants also reviewed NABP’s programs and software and shared information on the Clearinghouse and the Healthcare Integrity Protection Data Bank (HIPDB). Board staff suggested ways for NABP to continue to help the boards in their processes and what specific areas needed improvement.

This communication effort was furthered by a follow-up survey designed to provide NABP with suggestions for future training sessions. According to the

survey results, participants found this meeting with NABP staff, the interaction between the various boards, and the open discussion valuable. In the future, board staff would like additional “hands-on” training and in-depth discussions about other states’ administration procedures for handling licensure matters. They would also like to see:

- Details on the proper process for handling correspondence sent to NABP;
- Information about the history and future of NABP;
- Additional information about NABP’s programs.

Everyone involved agreed the training session facilitated the exchange of information, improved staff’s understanding and comfort level with the Lotus Notes software, and enhanced the interpersonal relationships between board and NABP staff members.

While 19 of the state boards sent staff members to this year’s training, NABP provided all state boards with User Manuals of the Lotus Notes programs to ensure that all the boards will have a knowledgeable understanding of the software. The training session was a joint effort by NABP’s ELTP, Information Technology, Application/Database, and Testing Departments. For additional information, please contact NABP at 847/698-6227 or e-mail [comm@nabp.net](mailto:comm@nabp.net).



## Missouri QA: Teach, Don't Punish

The Missouri Board of Pharmacy's Quality Assurance (QA) Program addresses prescription discrepancies through a nonpunitive and cooperative effort that, according to Missouri's November 2001 *Newsletter*, "seems to work well, based on the results that the Board has seen from the . . . program initiated in those pharmacies needing improvement."

Missouri Board of Pharmacy Executive Director Kevin Kinkade says that, "while the program has its limits, it has been successful in recognizing and decreasing error rates."

Developed mainly in response to complaints from consumers, the QA program was developed to assist the Board in determining what discrepancies are the most prevalent in the practice setting and whether certain pharmacies need assistance in changing some practices in order to reduce discrepancies within the dispensing processes.

The Board is reviewing prescriptions for possible discrepancies during its routine inspections. According to the *Newsletter*, "if a record discrepancy is noted, the inspector will complete a quality assurance form and discuss each completed form with the pharmacist-in-charge (PIC) or attending pharmacist to consider possible follow-up reviews of the prescription in

question and then report any findings to the Board office."

Even if there is no further review by the PIC, the form is returned to the Board, where it is used to build a database regarding the number and types of discrepancies that are observed in pharmacies and with individual pharmacists.

To date, the Board has gathered the following statistics:

- 64% of discrepancies involve labeling directions;
- 18% relate to the wrong strength of a drug;
- 10% of discrepancies are the wrong drug provided; and
- 8% include all other discrepancies.

Working with these statistics, the Board has started to formulate solutions for pharmacists and develop educational efforts through the *Newsletter* and presentations geared toward reducing the number of discrepancies. Kinkade noted that during a state association meeting, a continuing education (CE) course on decreasing discrepancy rates was offered. These CE classes, which are offered throughout Missouri for continuing education credit, cover such topics as statistics, variances, and how pharmacists may evaluate dispensing techniques.

In some instances where a high error rate is detected at a pharmacy, quality assurance plans have been developed. When it is determined that a quality assurance plan is

needed, the PIC and the board inspector meet to discuss and develop a written plan which is monitored by the Board to make sure it runs smoothly.

". . . [A]ll of the pharmacies that we have executed a plan with have had dramatic drops in error rates as observed by inspectors when later reviews take place. In only one case was there an exception to this," Kinkade reports.

## Missouri's Nonpunitive Approach

Kinkade emphasizes that this is a nonpunitive approach.

"Even though we have limits (number of prescriptions to review, etc), there has been much improvement," Kinkade explains. "This is a team effort with a goal to reduce pharmacists' apprehensions within the process. Of course there is always a small percentage of incompetent or negligent pharmacists, but most of the discrepancies are system-related."

According to Kinkade, Missouri is considering future peer review legislation. This legislation would be similar to the peer review process already implemented in some states. "With legislation," he notes, "we will probably run into the problem of protection of records with the trial attorneys,"

In the meantime, the Missouri Board believes this cooperative and voluntary compliance program has shown early measurable success. **NABP**

## NABP Releases Survey of Pharmacy Law, NABPLAW, and Model Act

NABP released the 2001-2002 edition of the *Survey of Pharmacy Law*, the fall 2001 update to the NABPLAW® pharmacy law database, and the 2001 update of the *Model State Pharmacy Act and Model Rules (Model Act)*.

Updated annually, the *Survey* is a compilation of the major state laws and regulations that govern the pharmacy profession. The information is displayed in a chart format with clarifying footnotes for easy reference. Each state board of pharmacy reviews and updates its information yearly to reflect changes in the state's laws and regulations. An educational grant from Wyeth-Ayerst Pharmaceuticals enables NABP to provide complimentary copies of the *Survey* to the nation's schools and colleges of pharmacy for distribution to all final-year pharmacy students. The purchase price of the *Survey* is \$20.

NABPLAW 3.3 contains all the changes and amendments to

state pharmacy laws and board of pharmacy regulations as of September 1, 2001. Updated in the fall and spring, the database's powerful search capability allows users to search for a given topic across one, several, or all 50 states as well as the District of Columbia and Guam. A one-year subscription, which includes two updates, is available for \$995 for single-site users. Multiple-site licenses are also available. Contact NABP for information about special rates for educational institutions and boards of pharmacy. NABPLAW is available in a CD-ROM format.

The *Model Act*, which is updated each fall, contains model language that may be used when developing state laws or board rules, along with the most recent commentary. This year's most recent update incorporates model language developed by NABP's Task Force on Centralized Prescription Filling, Task Force on Ex-

panded Use of the Internet in Pharmacy Practice and Regulation, Task Force on Model Guidelines for Formulary Development, Task Force on Drug Diversion through Institutional Outlets, and Committee on Law Enforcement/Legislation.

The *Model Act* is available for \$30 as a Microsoft® Word 97 document on a 3½-inch, IBM-compatible, computer disk. To purchase the *Survey* or the *Model Act*, send a request with an accompanying check or money order made payable to NABP to the NABP Publications Desk, 700 Busse Highway, Park Ridge, IL 60068. To purchase NABPLAW, please make a check or money order payable to the NABP Foundation and send the request to the same address. Refunds are not available for publication orders. **NABP**

*Mitsuru Uchiyama (left), Chairman of the Board of the Japan Pharmacists Education Center, a nonprofit foundation focusing on continuing education of pharmacists in Japan, visited NABP and met with Associate Executive Director Mary Dickson and Executive Director/Secretary Carmen A. Catizone. Mr Uchiyama was in the US researching the licensure examination system and procedures. **NABP***



# Around the Association

## NABP Mourns Deaths of Duncan and Limbaugh

Alfred J. Duncan, NABP's past president from 1966 to 1967 and former secretary of the Arizona State Board of Pharmacy from 1962 to 1980, died October 26, 2001. Duncan, a native of Missouri, was active in Board activities since 1941. Sympathy cards can be sent to his grandson, Jim Carey, at 12718 N 72nd Ave, Peoria, AZ 85381.

Carl L. Limbaugh, a drug inspector with the Alabama State Board of Pharmacy for 25 years, died at the age of 81 on September 29, 2001. Limbaugh was the first recipient of the "Distinguished Service Award for Board Inspectors," presented by NABP, and was recognized by the Alabama state senate for his outstanding achievements.

In addition to his work as a drug inspector, Limbaugh served as a lieutenant in the Birmingham Police Department for 27 years. His last two years with the city were on assignment with the Federal Government Drug Task Force, United Narcotic Drug Operations.

## Progar Receives NACDS Pratt Award

Ralph E. Progar, RPh, NABP past president, received the 2001 Harold W.

Pratt Award, presented by the National Association of Chain Drug Stores (NACDS). Progar was honored for contributing to the promotion, recognition, and improvement of the chain pharmacy industry during the association's 44<sup>th</sup> annual pharmacy and technology conference in September. Currently, he serves as vice president of pharmacy relations for the Eckerd Corporation.

Progar has furthered the practice of pharmacy through his long relationship with NABP. In 1996, he was elected president of NABP. In a personal letter to Progar, Carmen A. Catizone, NABP's executive director/secretary, writes, "Your leadership and service in the chain drug industry is a testament to past and future recipients of this prestigious award. The Eckerd Corporation and the pharmacy profession are fortunate to have such a distinguished leader."

## Lee Named Utah Pharmacy Technician of the Year by USHP

Ryan C. Lee, chairman of the Utah Board of Pharmacy, received the Utah Society of Health-System Pharmacists' (USHP) annual "Pharmacy Technician of the Year Award" for 2001. Ryan served on NABP's "Standardization of Technicians' Roles and Competencies" Task Force in December 1999. USHP selected Lee

from a group of technicians nominated by their peers.

## Bowl of Hygeia Award Recipients

Each year, Wyeth-Ayerst recognizes pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, the following board of pharmacy members received the "Bowl of Hygeia" Award for 2001.

Current members:

D. Frank Landrum, president, Georgia State Board of Pharmacy

Donna S. Wall, president, Indiana Board of Pharmacy and NABP Treasurer

William L. "Buck" Stevens, executive director, Mississippi State Board of Pharmacy


Joseph J. Bova, New York Board of Pharmacy

Past members:

Paul J. Gionet, Alaska Board of Pharmacy

Richard L. Ross, retired executive director, Kentucky Board of Pharmacy

Carol V. Batemen, South Carolina Board of Pharmacy

Donna M. Bovell, District of Columbia Board of Pharmacy 

## California Transition to NAPLEX

As reported in the August 2001 *NABP Newsletter*, the California State Board of Pharmacy voted to use the North American Pharmacist Licensure Examination™ (NAPLEX®) to satisfy the state's requirements for the professional licensing of pharmacists. Candidates must also pass a state-specific jurisprudence examination as a condition of licensure in California. Before individuals in the state may sit for the NAPLEX, however, the state legislature must enact legislation and the California jurisprudence examination component must be in place. With the California Legislature slated to convene in January 2002, the earliest the state could transition to the NAPLEX is January 1, 2003.

According to the California State Board of Pharmacy Web site, the Board is not currently sponsoring legislation to shift to the NAPLEX but would support legislation containing the following elements:

1. Amends Business and Professions Code Section 4200 to accept as passing a written and practical exam, the use of:
  - the North American Pharmacist Licensure Examination on or after January 1, 2003; and
  - the Multistate Pharmacy Jurisprudence Examination™ (MPJE®) for California on or after January 1, 2003.

2. Creates a new section to the Business and Professions Code allowing those who have passed the NAPLEX exam after January 1, 1999, to become licensed in California if the individual has also:

- been licensed in an other state for three years;
- passed the MPJE for California on or after January 1, 2003;
- is licensed in good standing and has completed 30 hours of Continuous Education in the last two years.

**NABP**

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## 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 18, 2002, and April 4, 2002, to be considered during NABP's 98<sup>th</sup> Annual Meeting, May 18-22, 2002, at

the Pointe Hilton Tapatio Cliffs Resort in Phoenix, Ariz.

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 Busi-

ness Session. The First Business Session is scheduled for Sunday, May 19. For more information about the amendment procedure, contact NABP Executive Director/Secretary Carmen A. Catizone at 847/698-6227. **NABP**

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## Correction

The October 2001 *NABP Newsletter* contained some misinformation regarding the Advisory Committee on Examinations (ACE).

NABP is seeking volunteers to fill two open positions on ACE, the standing committee that oversees the development and administration of all NABP examination programs.

Please advise any individuals who wish to be considered as a candidate for an open position to submit a written statement of interest and a current resume or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone at NABP headquarters no later than December 28, 2001.

Lawrence H. Mokhiber, executive secretary of the New York Board of Pharmacy, was recently appointed ACE chair succeeding Harold B. Sparr, president of the Massachusetts Board of Registration in Pharmacy. Past Chair Donald H. Williams, executive director of the Washington State Board of Pharmacy, is a member. **NABP**

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## NABP Meeting Dates

Thursday-Friday, January 24-25, 2002  
Committee on Law Enforcement/  
Legislation, Marriott Suites  
O'Hare, Rosemont, Ill

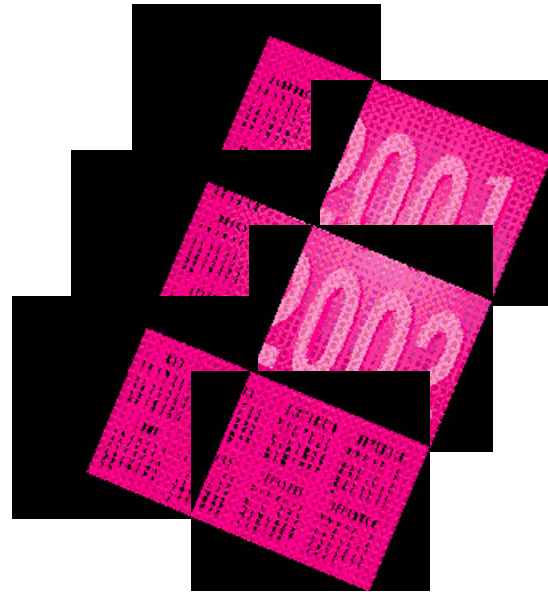
Friday-Saturday, February 8-9, 2002  
Executive Committee Meeting, Mirage Hotel,  
Las Vegas, Nev

Friday, April 5, 2002  
Committee on Constitution and Bylaws Meeting  
NABP Headquarters, Park Ridge, Ill

Friday, May 17, 2002  
Pre-Convention Executive Committee Meeting,  
Pointe Hilton Tapatio Cliffs Resort,  
Phoenix, Ariz

Saturday-Wednesday, May 18-22, 2002  
NABP's 98<sup>th</sup> Annual Meeting,  
Pointe Hilton Tapatio Cliffs Resort,  
Phoenix, Ariz

Wednesday, May 22, 2002  
Post-Convention Executive Committee Meeting  
Pointe Hilton Tapatio Cliffs Resort,  
Phoenix, Ariz



## newsletter

National Association of Boards of Pharmacy  
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Park Ridge, Illinois 60068

