newsletter

National Association of Boards of Pharmacy®

February 2005 / Volume 34 Number 2

aid to government
the profession
the public
1904 to 2005

This Month on www.nabp.net:

Special Items
Template for Enforcement Guidelines Regarding the Administrative Prosecution of Entities Importing Prescription Drugs into the United States

Download NABP's Updated National Specified List of Susceptible Products

Headlines
NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

Examinations
2005 *NAPLEX/MPJE Registration Bulletin*

Upcoming Meetings

Saturday-Tuesday, May 21-24, 2005
NABP's 101st Annual Meeting
Sheraton New Orleans Hotel
New Orleans, LA

Sunday-Tuesday, August 7-9, 2005
NABP/AACP District III Meeting
Marriott Hotel
Knoxville, TN

Thursday-Saturday, August 11-13, 2005
NABP/AACP District V Meeting
Minneapolis, MN

Thursday-Saturday, September 29-October 1, 2005
NABP/AACP District I Meeting
Location TBD

NABP Executive Committee Finalizes Criteria for National Specified List of Susceptible Products, One Drug Added to List

The National Drug Advisory Coalition (NDAC), which was created by the NABP Executive Committee in response to a recommendation from the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, assembled on September 9, 2004, and convened via conference call on October 4, 2004, to review and revise NABP's "National Specified List of Susceptible Products" (the List) as well as draft and recommend criteria that detail standards and guidance for the List revision process. Based upon the recommendations of the Coalition, the Executive Committee was able to finalize the criteria for NABP's List this past November. Also, in accordance with the Coalition's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on the List.

The NDAC is a standing committee whose members are appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. In February 2004, the Model Rules were updated by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

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In This Issue. . .

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

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List Criteria

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The List, which NABP released in February 2004, was created to help states reduce redundancy as they update and adopt regulation, and represented a starting point for states that had an imminent need for such direction. By adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists. NABP adapted its original List from the Florida Statewide Pharmaceutical Services and Drug Wholesaler Advisory Council (Florida Department of Health) until the NDAC was appointed in mid-2004. The Coalition consisted of 14 members (including ex-officio members) with representation from NABP, the state boards of pharmacy, the American Medical Association, the American Society of Health-System Pharmacists, the Healthcare Distribution Management Association, the National Association of Chain Drug Stores, the Pharmaceutical Research and Manufacturers of America, and the United States Pharmacopeia. Ex-officio members, who served as resources to the Coalition and were non-voting members, included representatives from Food and Drug Administration (FDA), Lew Kontnik Associates, Cardinal Health, and Pfizer, Inc.

Section 1 Criteria

Section 1 of the criteria specifies that the Coalition may recommend that a product be placed on the List if FDA or a state or federal law enforcement agency issues an official notice that a prescription drug has been adulterated, counterfeited, or diverted. In addition, the product under consideration must meet at least one of the sub-criteria as listed in Section 1 (shown below).

Sub-criteria

(I) The Coalition receives notice from a law enforcement agency that a significant shipment of a prescription drug has been stolen or missing;

(II) The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer of the prescription drug because of concerns for counterfeiting or diversion;

(III) The Coalition receives notice from a manufacturer, a wholesale distributor, or a law enforcement or government agency responsible for regulating the sale or distribution of prescription drugs, that a falsified pedigree (or other similar documentation) was passed or a legitimate pedigree was not passed by or to a wholesale distributor or pharmacy;

(IV) The prescription drug is used extensively for serious and/or life-threatening conditions, where drug non-responsiveness would not be considered to be medically unusual;

(V) The prescription drug is a single source injectable drug or immune globulin;

(VI) The prescription drug is commonly prescribed and available for normal prescription use in dosages or strengths that have a substantial wholesale cost or appears among the IMS top 50 single source revenue-generating prescription drugs that may encourage counterfeiting or diversion;

(VII) The prescription drug is in limited supply due to a national shortage and the shortage is characterized by a time period of no less than nine months; or

(VIII) The prescription

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HHS Task Force Report Finds 'Significant Risk' in Drug Importation

The United States Department of Health and Human Services (HHS) Task Force on Drug Importation released its Report on Prescription Drug Importation on December 21, 2004, stating that ". . . American consumers currently purchasing drugs from overseas are generally doing so at significant risk." In addition, the HHS Task Force determined that ". . . a commercial importation program could be feasible but would require new legal authorities, substantial additional resources and significant restrictions on the type of drugs that could be imported, which could increase the costs of imported drugs."

In response to the recently released report, NABP President Donna M. Horn adds, "The Association appreciates the efforts of HHS to study the issue of prescription drug importation. The HHS Task Force report corroborates NABP's long-held stance that illegal prescription drug importation is an unsafe practice that would put patients at risk for adulterated or counterfeit drugs."

Over the past few years, NABP has consistently voiced its concern regarding illegal importation and the safety of American patients. During the Stakeholder Meeting hosted by the HHS Task Force on May 14, 2004, NABP Executive Director/Secretary Carmen A. Catizone presented NABP's stance on importation, as approved by the Association membership at NABP's 100th Annual Meeting and Centennial Celebration in April 2004. Catizone explained that NABP's member boards of pharmacy passed a resolution resolving that NABP will continue to oppose illegal importation of medications, express to Food and Drug Administration (FDA) the concerns of member states, and strongly urge FDA or the appropriate legal authority to pursue actions against state and local governments for endorsing, promoting, or engaging in the illegal importation of medication.

> "The HHS Task Force report corroborates NABP's long-held stance that illegal prescription drug importation is an unsafe practice. . . ."
>
> NABP President Donna M. Horn

"NABP has learned that medications shipped from locations purported to be in Canada have originated in Slovenia, Pakistan, and Vietnam," Catizone told the HHS Task Force. "Each progression to extend the distribution source to unknown borders further away from the FDA drug approval process and the state regulation of pharmacy practice makes the situation more dangerous. The extension of importation to countries lacking effective drug approval processes, regulatory systems, or practice standards furthers the erosion and destruction of the entire regulatory system for the practice of pharmacy."

Catizone noted that NABP recognizes patients' concerns about the affordability of medications, and cautioned that a solution resolving the conflict of cost versus safety must be developed to "address the needs of US patients and prevent irreparable damage to, if not the elimination of, the regulatory systems in the US."

Task Force Conclusions

The HHS Task Force was created to answer key questions posed by Congress as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. As such, it was charged with exploring whether or not processes for drug importation that assure patient safety can be established. In addition, it studied the potential impact of drug importation on the health of American patients, medical costs, and the development of new medicines.

The past several years have seen state and local government officials pushing for, and sometimes implementing, prescription importation programs despite the dangers and illegality associated with these activities. And as officials have pushed their cause, there has been a rise in the number of individuals crossing the border to buy prescription drugs – be it a physical trip or via the Internet. According to the HHS report, in 2003 nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately $700 million, entered the US from Canada alone. The report further states that an equivalent amount of drugs arrived from the rest of the world from both developed and emerging countries – and FDA has not approved the majority of these drugs.

The HHS Task Force specifically noted the dangers of ordering prescription drugs over the

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Can't Catch Me, I'm a Licensee

By Dale J. Atkinson

The applicability of the criminal statutes and their interaction with the relevant practice acts, which regulate a particular profession, can create interesting legal issues that illustrate the importance of meticulous legislative drafting of laws. Criminal codes and practice acts each play distinct roles, while at the same time they also share the common goal of public protection.

In the case of *Commonwealth of Pennsylvania v Gordon,* 515 A. 2d 558 (PA 1986), a licensed pharmacist was criminally convicted of selling one bottle of Dilaudid® containing 100 pills to a criminal informant. The consideration for the exchange included $800, a prostitute, and a paid hotel room. The informant arranged to purchase two bottles, which the pharmacist brought to the motel, but told the pharmacist he could only "scrounge up the cash" for one bottle. The parties arranged for a second sale when the informant could raise the additional $800. The informant did not have a prescription for the Dilaudid and was wearing a "wire," an electronic surveillance device, that recorded the entire transaction. The pharmacist never requested that the informant produce a prescription.

The pharmacist was immediately arrested and charged with violating applicable sections of the Pennsylvania criminal code. Specifically, the pharmacist was charged with violating laws that prohibit one from:

> Knowingly or intentionally possessing a controlled or counterfeit substance *by a person not registered under this act or a practitioner not registered or licensed by the appropriate state board* [emphasis added], unless the substance was obtained directly from, or pursuant to, a valid prescription. . . .
>
> Except as authorized by this act, the manufacture, delivery, or possession with intent to manufacture or deliver, a controlled substance by a *person not registered under this act, or a practitioner not registered or licensed by the appropriate state board* [emphasis added], or knowingly creating, delivering, or possessing . . . a controlled substance.

After a bench trial (without a jury), the pharmacist moved for a directed verdict in his favor alleging that he could not be convicted of violating the statutes because, by their very terms, they do not apply to individuals licensed by the Commonwealth. The pharmacist's motions were denied and he was convicted and sentenced to 11 to 23 months in jail and fined and assessed costs of $2,500. The pharmacist appealed to the Superior Court of Pennsylvania.

On appeal, the pharmacist again argued that the statutes cannot form the basis of a criminal conviction because they do not apply to licensed persons. The Superior Court agreed with the pharmacist and reversed the convictions. The Commonwealth appealed the reversal to the Pennsylvania Supreme Court and asked that the Supreme Court address the issue of whether or not pharmacists licensed to distribute drugs in the course of their professional conduct are exempt from criminal prosecution under

the applicable Pennsylvania statutes for selling drugs without a prescription and in exchange for cash and sexual favors.

In rejecting the arguments of the pharmacist and agreeing with the Commonwealth, the Supreme Court stated that the pharmacist was not acting in the course of his professional practice and that his status as a licensed practitioner was not enough to exempt him from criminal prosecution. The court held that to fall within the definition of a practitioner, in this case a pharmacist, the party claiming the exemption must act within the "course of professional practice." Status of a licensee is only the beginning of an analysis of the application of exemption under the statute.

In *Commonwealth of Pennsylvania v Fremd,* 2004 WL 2051164 (Superior Ct PA 2004), the Superior Court of Pennsylvania was recently confronted with the issue of the applicability of the criminal statute (and its exemption from prosecution) related to a physician. In *Fremd*, a licensed physician was criminally convicted of, among other counts, three counts of prescribing and/or delivering controlled substances outside the scope of treatment principles. The licensee was sentenced to 18 to 36 months imprisonment and 10 years probation.

On appeal, the licensee argued that he was exempt from prosecution under the applicable sections of the criminal statutes by virtue of his status as a licensed physician. Similar to *Gordon*, the licensee argued that he cannot be convicted of violating the Pennsylvania law because he is licensed and the law is specifically drafted to address conduct by individuals not registered or licensed under the act.

In rejecting these arguments, the Superior Court cited the *Gordon* case and agreed that the mere fact that the individual is a licensed physician does not preclude prosecution under the statute. In *Fremd*, the evidence established that the licensed physician treated the live-in girlfriend of a relative for neck, lower back, and shoulder issues. The patient was having financial difficulties and the physician suggested that she could sell Dilaudid for $20 per pill, keep $10, and provide $10 back to the physician. The physician gave the patient three prescriptions, but the patient never carried out any "sales," nor did the physician receive any monies. (Several additional counts related to insurance fraud, solicitation of sexual favors as payment for drugs, and prescribing and dispensing without a medical purpose or without medical exams further substantiated the convictions and sentence.)

In upholding the inapplicability of the exemption language of the statute, the Superior Court found that the evidence supported the fact that the actions of the physician were unrelated to a treatment plan and, therefore, not within the course of his professional practice. As such, the criminal conviction was upheld and the rationale espoused in *Gordon* was followed.

The interplay between criminal prosecutions, statutes imposing criminal sanctions, and administrative matters can create interesting legal issues. In these cases, the courts were required to interpret the statutes to understand the legislative intent and whether or not licensed individuals were "exempt" from criminal prosecutions under the particular sections of the act. Of course, there are other sections of the criminal code and practice acts that may have provided an additional mechanism for criminal prosecutions. Drafting legislation and determining under what sections of the code to prosecute persons can be difficult, but are in need of precision.

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

Electronic Prescribing Takes Off

The utilization of electronic prescribing is gaining momentum, especially with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requiring national standards for e-prescribing by 2009. Of course, e-prescribing has been an option for some time now, but it was not until about 2001 that it began to gain widespread implementation by the pharmacy profession. In recent years, state boards of pharmacy have been revising and interpreting their regulations and educating pharmacists, often through board of pharmacy newsletters.

E-prescribing can be as simple as a computer or other device printing out a prescription for the patient to carry to a pharmacy, or the facsimile transmission of prescriptions. But, while 10 years ago these strategies were revolutionary, more complex systems have begun to redefine e-prescribing. Fred Gebhart summarized this brave new world in the September 13, 2004 issue of *Drug Topics*: "Complete e-prescribing gives the prescriber medical history, formulary, prior authorization requirements, treatment guidelines, cost comparisons, and utilization review. The completed prescription moves electronically to the patient's chosen pharmacy."

How close are we to the near-universal adoption of such prescribing methods? Close. According to Simon P. Cohn, chairperson of the Subcommittee on Standards and Security of the National Committee on Vital and Health Statistics (NCVHS), an advisory board appointed by outgoing United States Department of Health and Human Services (HHS) Secretary Tommy G. Thompson, about 75% of US pharmacies are currently equipped to accept electronic prescriptions. The NCVHS Subcommittee on Standards and Security, which has been charged with providing recommendations for national e-prescribing standards, has estimated that between 2% and 18% of physicians prescribe electronically. At an educational forum organized by the National Council for Prescription Drug Programs (NCPDP) last August, Cohn predicted that most remaining pharmacies and physicians will have jumped on the e-prescribing bandwagon by the beginning of 2006.

Most of the attention lately, however, has focused on the development of national standards, and on bringing more practitioners into the e-prescribing fold. Lost in the shuffle at times are the regulatory issues and requirements, which boards of pharmacy deal with on a day-to-day basis, that coincide with leaps in technological advancement.

The Case for E-Prescribing

Just about everyone in or connected to the health care industry is enthusiastic about e-prescribing and its potential benefits. As summarized in a formal report issued by the eHealth Initiative in April 2004, electronic prescribing in an ambulatory care setting has the potential to "improve safety, quality, efficiency, and cost. Studies suggest that the national savings from universal adoption could be as high as $27 billion." The report suggests that about $2 billion of this

would result from reduced hospital and doctor visits caused by medication errors.

For its part, the NCVHS subcommittee's first letter of recommendations to (outgoing) HHS Secretary Thompson, written in September 2004, emphasized patient safety. "Many reports have identified that the current prescribing system is prone to errors," the subcommittee wrote. "Analysis shows that e-prescribing systems can avoid more than 2 million ADEs [adverse drug events] annually, of which 130,000 are life-threatening."

NABP also strongly supports electronic prescribing, primarily because of the tremendous positive impact it may have on patient safety. "[E]lectronic transmission offers a significant opportunity to enhance the quality and safety of patient care by reducing prescription medication errors," said Carmen A. Catizone, executive director/secretary of NABP, as part of his July 2004 testimony before the NCVHS Subcommittee on Standards and Security. (See "NABP Provides Electronic Prescribing Testimony to NCVHS" in the September 2004 *NABP Newsletter* for a fuller description of the Association's testimony.)

A resolution on electronic transmission of prescriptions passed by NABP's membership during the Association's 100th Annual Meeting and Centennial Celebration in April 2004 further demonstrates NABP's commitment to e-prescribing. Specifically, the resolution charges "that NABP work with interested stakeholders involved in the electronic transmission of medication orders and replacement of handwritten medication orders with computer printed or electronic prescriptions to develop national standards which establish and encourage the use of a standardized template for the configuration of prescriptions that are computer printed or electronically transmitted. . . ." The resolution also mandates a review of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* for possible revisions to its electronic transmission of prescriptions section as well as consideration of the evolving practices of telepharmacy, the central processing of prescriptions, and remote dispensing.

Physicians themselves have been perhaps the group slowest to enthusiastically utilize e-prescribing. The eHealth Initiative report points to several of the main barriers to e-prescribing including high start-up costs, lack of specified reimbursement, and concerns about reduced office efficiency, particularly during initial adoption of the technology.

On a cautionary note, the state boards of pharmacy have reminded their pharmacists that, while electronic transmission of prescriptions may cut down on prescribing errors, they do not eliminate them. A physician might enter a prescription for the wrong patient, for example, or accidentally choose the wrong medication from a list. It must be considered that human error is inevitable and cannot be completely eliminated. Boards, therefore, have continued to emphasize that pharmacists must continue to counsel patients and use their professional judgment in filling prescriptions.

But What of Regulation?

Almost all states permit some sort of electronic prescribing, either by specific regulation or by default, and have done so for several years. Recently, however, more states have added regulatory language specific to electronic prescribing. For example, last winter Massachusetts rolled out

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Electronic Prescribing

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to great fanfare a new law addressing e-prescriptions. In other states, modifications have occurred more quietly, as numerous boards urge state legislatures to pass requisite laws.

According to a survey NABP sent to the state boards of pharmacy in mid-2004, primary factors that can slow the regulation-writing process include fraud and privacy concerns, and continually evolving technology. Regulations allowing prescriptions for controlled substances – particularly Schedule II medications – have frequently been put on hold even in states that have otherwise explicitly addressed electronic prescribing, pending official guidance from Drug Enforcement Administration.

Variations in the regulations between different states have long been identified as a barrier to the swift, universal adoption of e-prescribing. The eHealth Initiative makes a recommendation, in its report, to "Strongly encourage unification of varying state regulations concerning the proper format of a prescription." The report notes that many of these regulations "are directed toward the same objectives, but differ because of separate development. . . ." NABP's 2001 Task Force on Electronic Transmission of Prescriptions made a similar observation at that time, noting that "Members wanted to urge states to eliminate restrictive requirements . . . so that uniform electronic prescription systems can be used in all states." Four years later, however, numerous variations still remain.

The NCVHS subcommittee has reportedly considered a recommendation to resolve this issue by utilizing federal pre-emption of state rules and regulations as provided in the Medicare Modernization Act of 2003. Catizone, in his testimony before the subcommittee, urged some caution: "Although NABP recognizes that there is a limited need to provide for pre-emption and foster the development of national standards that facilitate implementation and allow for uninhibited practice across state lines, the pre-emption should not totally eviscerate safeguards the states have in place protecting the patient."

While state regulatory activity and the national standards currently under study provide the grease for any transition to electronic prescribing to keep progressing, the moving gears themselves lie primarily in the private sector. (The boards of pharmacy do not completely disappear during this process, of course. Ohio, for example, must individually approve e-prescribing systems to ensure compliance with such factors as privacy and fraud protections before pharmacies may utilize the technology.) Electronic prescription programs aim to facilitate electronic prescribing and provide education and support to health care providers entering the e-prescribing world. More common than individual physicians or small offices purchasing software and equipment, networks encourage greater numbers of physicians to make the leap to e-prescribing, in the hope that the whole system will pay off in the long run. For example, a management company used by a large circle of physicians might, with some backing from a benefits provider, sign up with an e-health program provider and then offer the services to the member physicians, helping to subsidize the high start-up costs, facilitate training, and ease office transition difficulties.

As the move toward more universal electronic prescribing practices continues to speed ahead, NABP will persist with participating in the process to help state boards of pharmacy ensure that the process leads where everyone intends: to a better health care system characterized by increased patient safety.

What Would You Like to Read About in the *NABP Newsletter*?

Do you have an interesting idea for an article that relates to the boards of pharmacy and/or the practice of pharmacy? Send an e-mail to the attention of the editorial manager at custserv@nabp.net, and inform the Communications Department of your idea for an article. Or do you want to know about a timely issue that is affecting the pharmacy profession? E-mail us and mention what topic you would like further discussed or broadened. Questions and/or comments? Send them our way; we'd be more than happy to hear them!

List Criteria

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drug exhibits a similar mechanism of pharmacologic action and/or possesses a similar chemical structure of another prescription drug that is already included on the List.

Section 2

Section 2 outlines when a product can be considered for placement on the List: if official notice has not been issued from FDA or a state or federal agency regarding the adulteration, counterfeiting, or diversion of a product. If a product meets any three of the eight criteria listed in Section 1, then the product may be considered. This provides the Coalition with an alternate mechanism by placing a product on this List that may not have been identified by the industry or regulatory agencies as a product that had been counterfeited, adulterated, or diverted.

The remaining sections (Section 3-6) of the criteria address how changes are made to NABP's List and how additions to and deletions from NABP's List will be communicated to state and federal agencies, the industry, and professional associations; and provide a mechanism for the Coalition to place a product on the List via an emergency vote. All recommendations of the Coalition must be adopted by a majority vote before such recommendations are submitted to the Executive Committee. If approved, the Executive Committee will notify all state boards of pharmacy, FDA, the product's manufacturer, and various national health professional and industry associations of the drug's inclusion on the List. Deletion of a drug from the List will also be communicated to those entities. Any addition to the List shall become effective 90 days after the Executive Committee officially releases such information to allow for dissemination of the information.

In the case of an urgent public health threat, the criteria allow for an emergency vote so that the Coalition may reconvene.

In addition to recommending placement of products to NABP's List, the Coalition is also responsible for recommending when products should be removed from the List. In considering whether or not to remove a product from the List, the Coalition shall evaluate the original factors regarding the product's addition to the list, the availability of generic forms of the drug, and pricing changes.

Addition to List

The recent numerous incidences of Viagra® counterfeiting and diversion led the Coalition to formally recommend that this product be placed on NABP's List. Viagra satisfied the criteria guidelines and, therefore, was presented to the Executive Committee for inclusion on the List; this recommendation was approved at the November 2004 Executive Committee meeting.

To view the full criteria as well as an overview of the NDAC, please visit NABP's Web site at www.nabp.net.

National Specified List of Susceptible Products

1. Combivir® (lamivudine/zidovudine)
2. Crixivan® (indinavir)
3. Diflucan® (fluconazole)
4. Epivir® (lamivudine)
5. Epogen® (epoetin alfa)
6. Gamimune® (globulin, immune)
7. Gammagard® (globulin, immune)
8. Immune globulin
9. Lamisil® (terbinafine)
10. Lipitor® (atorvastatin)
11. Lupron® (leuprolide)
12. Neupogen® (filgrastim)
13. Nutropin AQ® (somatropin, E-coli derived)
14. Panglobulin® (globulin, immune)
15. Procrit® (epoetin alfa)
16. Retrovir® (zidovudine)
17. Risperdal® (risperidone)
18. Rocephin® (ceftriaxone)
19. Serostim® (somatropin, mannalian derived)
20. Sustiva® (efavirenz)
21. Trizivir® (abacavir/lamivudine/zidovudine)
22. Venoglobulin® (globulin, immune)
23. Viagra® (sildenafil)
24. Videx® (didanosine)
25. Viracept® (nelfinavir)
26. Viramune® (nevirapine)
27. Zerit® (stavudine)
28. Ziagen® (abacavir)
29. Zocor® (simvastatin)
30. Zofran® (ondansetron)
31. Zoladex® (goserelin)
32. Zyprexa® (olanzapine)

NABP's Examinations and ELTP Display Growth Over the Past Five Years

NABP's statistical analysis of its programs and services over the past five years shows that these programs and services have steadily grown over this time period. In addition, the Pre-NAPLEX® and the Pre-FPGEE® were developed to assist candidates who are planning to sit for the North American Pharmacist Licensure Examination™ (NAPLEX®) and the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), respectively.

Contributing Factors

Several factors contributed to the increase in applications to NABP's examinations and licensure transfer program.

Electronic Licensure Transfer Program

- The current US pharmacist shortage.
- Florida's acceptance of the transfer of pharmacists since 2001.
- Requirements from some states to have licensed pharmacists-in-charge.

NAPLEX

- An increase in the number of pharmacy schools and colleges.
- The California law, which went into effect January 1, 2004, requiring passing the NAPLEX as a condition of licensure.

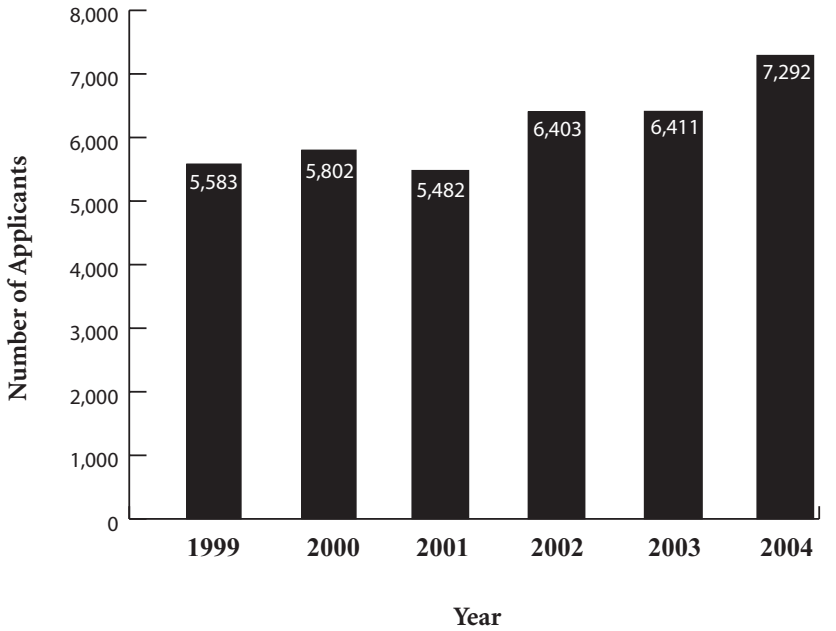
MPJE

- The Multistate Pharmacy Jurisprudence Examination® (MPJE®) was launched in November 1998 with 33 states contracted to participate in the program.
- There are now 45 jurisdictions that require the MPJE for licensure.

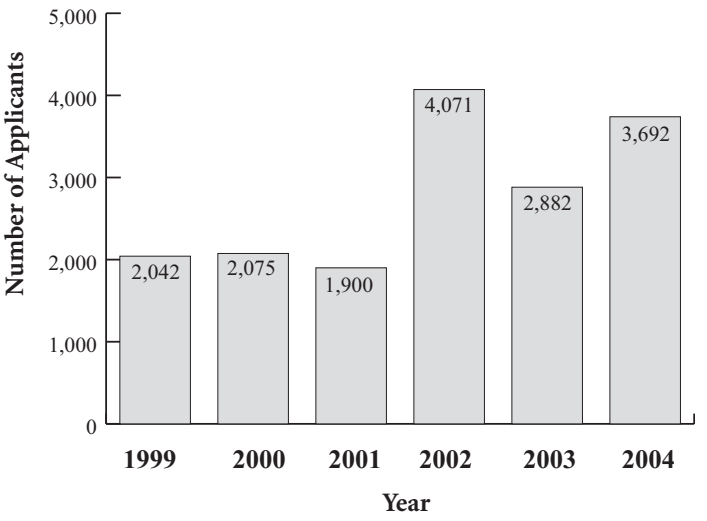
FPGEE

- The recruitment of pharmacists from overseas.
- The current US pharmacist shortage.
- The 2002 spike in applicants was a result of heightened requirements for foreign-educated pharmacists that went into effect on January 1, 2003.

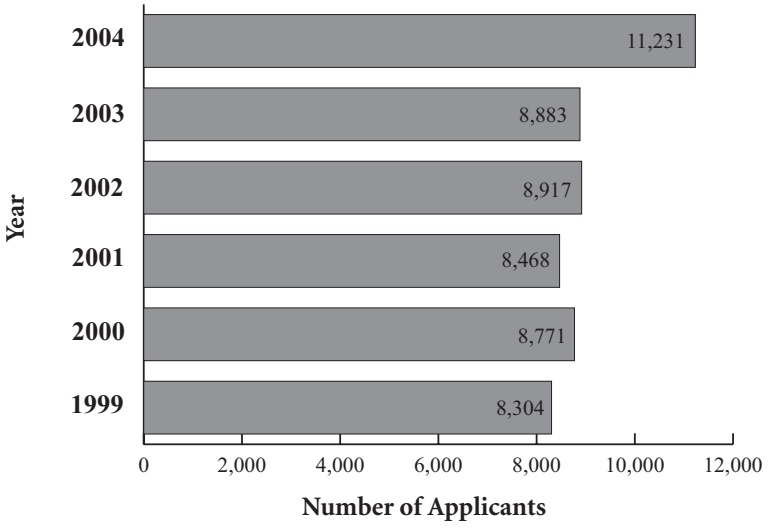
ELTP® Applicant Growth Over the Past Five Years



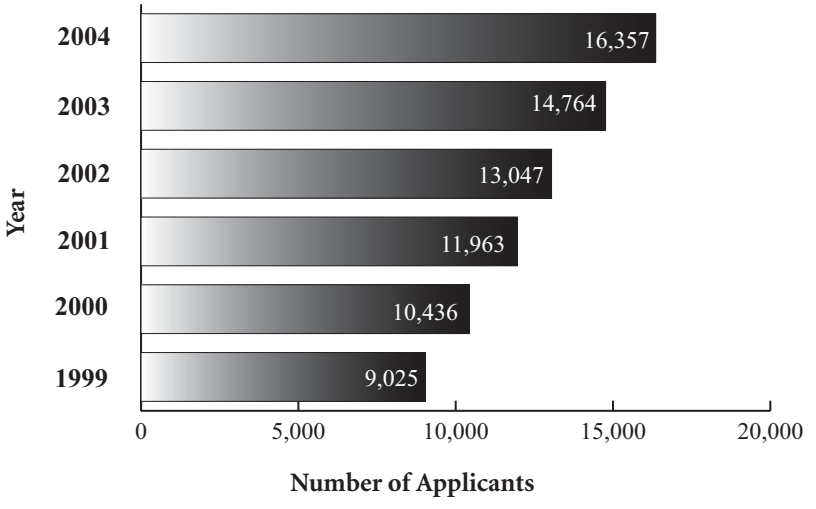
FPGEE Applicant Growth Over the Past Five Years



NAPLEX Applicant Growth Over the Past Five Years



MPJE Applicant Growth Over the Past Five Years



Network with Annual Meeting Attendees While Exploring New Orleans During Optional Events, Programming

NABP's 101st Annual Meeting optional events and programming provide participants with the opportunity to network with fellow attendees. The Annual Meeting programming lineup will once again include the ever-popular Optional Spouse/Guest Tour, Fun Run/Walk, and the New Member Seminar during the Association's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel in New Orleans, LA.

Experience the Barataria Swamps

Take a step back in time in ancient, pristine swamps where it is no surprise to see large expanses of floating freshwater marshes, bald cypress trees, egrets, ibis, a wide variety of amphibians, and, of course, alligators during the Optional Spouse/Guest Louisiana Swamp Tour on Saturday, May 21, 2005, from 1 to 4:45 PM. During the two-and-a-half-hour Swamp Tour, participants will cruise past a sacred Native American mound, a local Cajun cemetery, and Cajun fishing boats along the bayou as they travel into the "Treasure Island Swamps of Barataria," home of the pirate Jean Lafitte and his men, where, legend has it, Spanish gold bullion and other treasure are buried to this day.

Tour participants will get a firsthand look at the geology and ecology of this part of the United States, sometimes being so close that they can reach out and touch the Spanish moss hanging from the trees.

Participants of the 101st Annual Meeting Spouse/Guest tour will not only experience the Swamps of Barataria's fragile ecosystem, but they will drift past many historical sites on the two-and-one-half-hour "Treasure Island Swamps of Barataria" tour including a 2,000 year-old Indian Burial Mound, a Cajun Cemetery, the Fleming Plantation home, and the Trading Post of Barataria. Photo provided courtesy of Louisiana Swamp Tours.

Attendees will board NABP's privately chartered 60-passenger Louisiana Swamp Tour Boat – this luxury boat is larger and more comfortable than other swamp cruise boats, offering cushioned seats, restroom facilities, a roof, and windows that can be raised or lowered during inclement weather. Also, there is plenty of standing and walking room, all with great views. The boats are US Coast Guard inspected. There is also a gift and snack shop available at the start of the tour. Shuttle bus transportation is included in the cost of the tour, which is $34 per person. Those interested in the Louisiana Swamp Tour must register by May 6, 2005, as space is limited.

Fun Run/Walk

For the seventh consecutive year, the Association will once again offer its Fun Run/Walk providing an excellent opportunity for meeting attendees to jump-start their day. This 3.1 mile excursion kicks off from the Sheraton at 6:30 AM on Sunday, May 22, 2005, and leads participants past such sites as the Aquarium of the Americas and the Mississippi River Moonwalk. Led by guides, participants have the option of running or walking the course. Bottled water, power drinks, and granola power bars will be provided to each runner or walker. Participants must register (for no charge) by May 6, 2005.

New Member Seminar

Recently appointed board of pharmacy members or those members attending their first NABP Annual Meeting are encouraged to attend the New Member Seminar, to be held on Saturday, May 21, from 2:45 to 5 PM. Led by members of NABP's Executive Committee, parliamentarian, and legal counsel, the seminar focuses on the Association's many program and service offerings as well as parliamentary procedures followed during the Annual Meeting Business Sessions and potential situations new board members may experience.

For more information about the 101st Annual Meeting, please call NABP at 847/391-4406 or e-mail custserv@nabp.net. Information and registration forms may also be found on NABP's Web site at www.nabp.net.

May 21-24, 2005 Sheraton New Orleans Hotel New Orleans, LA

Please note that the 101st Annual Meeting Program is subject to change.

Saturday, May 21, 2005

9 AM - 6 PM
Registration Desk Open

1 - 5 PM
Educational Presentation Area Open/Poster Session

1 - 5 PM
Hospitality Suite in Presentation Area
Hosted by the Louisiana Board of Pharmacy

1 - 4:45 PM
Optional Spouse/Guest Tour
Louisiana Swamp Tour

1 - 2:30 PM
District Nominating Procedures Review

2:45 - 5 PM
New Member Seminar

7 - 10 PM
President's Welcome Reception
Honoring NABP President Donna M. Horn
Buffet Dinner will be served. Dress: business casual attire

Sunday, May 22, 2005

6:30 - 7:30 AM
Fun Run/Walk

7:30 AM - 4:30 PM
Registration Desk Open

8 - 9 AM
Continental Breakfast
(*in Presentation Area*)

8 AM - noon
Educational Presentation Area Open/Poster Session

8:30 AM - noon
Meeting of the Committee on Resolutions

1 - 1:15 PM
Welcome Remarks
Carmen A. Catizone, NABP Executive Director/Secretary

1:15 - 2 PM
Keynote Address

2 - 2:15 PM
Refreshment Break

2:15 - 4:45 PM
First Business Session

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

Monday, May 23, 2005

7 AM - 4 PM
Registration Desk Open

7 - 8 AM
NABP/USP Breakfast
Sponsored by the United States Pharmacopeia, Inc

8 - 11 AM
Meeting of the Committee on Resolutions

8:15 - 10:15 AM
CE Programming

10:15 - 10:30 AM
Refreshment Break

10:30 AM - noon
CE Programming

12:15 - 12:30 PM
Second Business Session

12:30 - 12:45 PM
Refreshment Break

12:45 - 2:45 PM
Meet the Candidates Session
(Lunch provided.)

2:45 - 3 PM
Break

3 - 4:15 PM
Third Business Session

4:15 -5:30 PM
ACPE Open Hearing on PharmD Standards Revision

Tuesday, May 24, 2005

7:30 AM - 4 PM
Registration Desk Open

8 - 9 AM
Continental Breakfast

8 - 9 AM
Past Presidents' Breakfast
(By invitation only.)

9 - 10:30 AM
CE Programming

10:45 - 11:45 AM
Open Mike Session

11:45 AM - 1 PM
Lunch Break
(on your own)

1 - 4 PM
Final Business Session

2:30 - 2:45 PM
Refreshment Break

7 - 10:30 PM
Annual Awards Dinner
Dress: semiformal attire

NABP Executive Committee Nomination, Election Procedures Reviewed

With NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel in New Orleans, LA, three short months away, NABP's delegates will soon be charged with one of their most important responsibilities – the election of officers and members to the NABP Executive Committee. In accordance with the amendments to the NABP Constitution and Bylaws adopted at the 100th Annual Meeting and Centennial Celebration in Chicago, IL, in April 2004, nominations for open member positions took place at District meetings in 2004, while nominations for officer positions will be announced at the upcoming 101st Annual Meeting.

Officer Nominations

As outlined in NABP's Constitution and Bylaws, individuals who wish to run for an open officer position on NABP's Executive Committee must submit to the NABP executive director/secretary a letter of intent and a resume or curriculum vitae at least 60 days prior to the Annual Meeting (by March 22). Those individuals who have been determined by NABP to meet all qualifications for office will be placed on the ballot. Additional nominations will be taken from the floor of the Annual Meeting, but only those members who have notified the executive director/secretary in writing at least 30 days prior to the Annual Meeting (by April 22) of their intention to seek office and who are deemed qualified by NABP will be eligible. Those individuals who are nominated from the floor shall be placed on the ballot at the Annual Meeting.

Open 2005-2006 officer positions include president-elect and treasurer. The treasurer serves a one-year term while the individual elected president-elect makes a three-year commitment to the Association. Following one year as president-elect, he or she serves one year as NABP's president before assuming the responsibilities of chairperson of the Executive Committee for a final year.

Member Nominations

District nominations for each open member position (representing Districts I, III, IV, and VIII) were completed at the 2004 District meetings; however, nominations for open member positions may still be taken from the floor. To be nominated from the floor, individuals must submit notice of their intent at least 30 days prior to the Annual Meeting to the NABP executive director/secretary in accordance with Article IV, Section 3(c)(ii) of the NABP Constitution and Bylaws.

The current nominees for open Executive Committee member positions include:

District I

- Susan DelMonico, Rhode Island Board of Pharmacy
- John R. Dorvee, Jr, Vermont Board of Pharmacy
  (The term length for the District I position will be a two-year term.)

District III

- Reginald B. "Reggie" Dilliard, Tennessee Board of Pharmacy

District IV

- William T. Winsley, Ohio State Board of Pharmacy

District VIII

- Patricia F. Harris, California State Board of Pharmacy

- Kathryn H. "Katie" Craven, Nevada State Board of Pharmacy

Nominations from the Floor, Election

During the First Business Session on Sunday, May 22, NABP President Donna M. Horn will announce the open Executive Committee officer and member positions. At this time, those candidates who are on the ballot have the opportunity to have up to two Association members speak on their behalf. The president will also accept nominations from the floor from those candidates who have submitted (by April 22) a letter of intent to run for office and have been qualified by NABP. Each candidate may have up to two seconding speeches, each of which may last no longer than two minutes.

President Horn will announce the final ballot during the Second Business Session on Monday, May 23. A "Meet the Candidates Session" will follow that announcement to allow NABP members the opportunity to discuss issues and platforms with the contenders for office.

Voting will take place during the Final Business Session on Tuesday, May 24. The election will be conducted by written ballot and counted by three tellers appointed by the president. Candidates, whether opposed or unopposed, must receive a majority of the delegate votes present in order to be elected to office. If more than two candidates are slated for office and no candidate receives the required majority, the candidate(s) receiving the fewest votes will be eliminated from subsequent ballots under procedures described in the NABP Constitution and Bylaws. The results of the election will be announced immediately and an installation ceremony will be conducted for the new officers and members of the 2005-2006 Executive Committee. Members assume their terms immediately following the Annual Meeting.

Current Committee

The following individuals will hold office in 2005-2006 without election:

- Chairperson: Donna M. Horn, Massachusetts, District I
- President: Dennis K. McAllister, Arizona State Board of Pharmacy, District VIII
- Member: Richard A. Palombo, New Jersey Board of Pharmacy, District II (second year of his first term)
- Member: Charles Curtis Barr, Nebraska Board of Pharmacy, District V (second year of his first term)
- Member: Oren M. Peacock, Jr, Texas State Board of Pharmacy, District VI (third and final year of his first term)
- Member: Gary A. Schnabel, Oregon State Board of Pharmacy, District VII (third and final year of his first term)

For More Information

NABP encourages members and executive officers of state boards of pharmacy to run for office under the terms specified in the Constitution. Candidates should forward to the office of the executive director/secretary a statement (of reasonable length) explaining why they are interested in serving on the Executive Committee and a current resume or curriculum vitae. They should be willing and able to devote the time necessary to serve as an officer or member of the Executive Committee.

Correspondance should be mailed to NABP Executive Director/Secretary Carmen A. Catizone, 1600 Feehanville Drive, Mount Prospect, IL 60056. For more information regarding the nominating process, election procedures, and responsibilities of an Executive Committee officer or member, e-mail exec-office@nabp.net or call NABP Headquarters at 847/391-4406.

Around the Association

New Board Members

David Todd Bess, RPh, was named member of the Tennessee Board of Pharmacy by Governor Phil Bredesen. His term expires July 15, 2010. He replaces M. Forrest Parmley.

Medelyne Dimaria, RPh, was appointed member of the New York Board of Pharmacy by Governor George E. Pataki. Her term expires on July 31, 2009. She replaces John A. Fiacco.

Albert Garcia, RPh, was named member of the Florida Board of Pharmacy by Governor Jeb Bush. His term expires on October 31, 2005. He replaces Helen Fong.

Melissa Graham, RPh, was named member of the Missouri Board of Pharmacy by Governor Matt Blunt. Her term expires March 11, 2009. She replaces Barbara Dunning.

John Mudri was named consumer member of the Florida Board of Pharmacy by Governor Jeb Bush. His term expires on October 31, 2005. He replaces Patricia Krestan.

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NABP Task Force on Active/Associate Membership Convenes

NABP's Task Force on Active/Associate Membership convened on November 18-19, 2004, in Northbrook, IL, to review the NABP Constitution and Bylaws' differentiation of Active and Associate member states. After meeting, the Task Force presented recommendations to the NABP Executive Committee on how Active and Associate membership should be defined in the Constitution and Bylaws in the present context of NABP and state governments. The final recommendation, with the Executive Committee's approval, will be available on NABP's Web site, www.nabp.net, at the end of the first quarter in 2005.

The organization of NABP's membership into Active and Associate status is an important component of the checks and balances system. This system has successfully preserved the interstate transfer of pharmacist licensure through the NABP Clearinghouse Program, in accordance with uniform standards developed by and agreed upon by the individual states. The distinction between Active and Associate membership is that Active membership affords participation in NABP's various committees and voting processes. Currently, the core requirement for Active membership status is acceptance of uniform licensure transfer requirements and participation in NABP's Licensure Transfer Clearinghouse and competence-based licensure programs.

In 2004, California and Florida were granted Active membership status. While evaluating these states' qualifications for Active membership, the Executive Committee recognized that strict adherence to the specific requirements of the NABP Constitution and Bylaws varies among the states depending upon legislative mandates in the individual states. In addition, the Executive Committee noted that changes in the practices and mandates of the states and provinces and modernization of the NABP Licensure Transfer Clearinghouse Program signal an opportunity for NABP to examine how the founding and binding constructs of NABP membership can be more clearly defined.

The Task Force members include Patricia F. Donato, member, New York Board of Pharmacy (chairperson); William T. Douglass, Jr, executive director, West Virginia Board of Pharmacy; Dennis M. Jones, executive secretary, South Dakota State Board of Pharmacy; Kendall M. Lynch, director, Tennessee Board of Pharmacy; Sheila Mitchell, member, Tennessee Board of Pharmacy; Richard J. Oubre, member, Louisiana Board of Pharmacy; and Sara St Angelo, member, Indiana Board of Pharmacy.

Following are the Task Force's recommendations.

The Task Force recommended several changes to Article II of NABP's Bylaws. These suggestions include necessitating that Active members utilize NABP's Clearinghouse to process requests for score and licensure transfer. As such, participation requirements in conjunction with using the Clearinghouse include:

1. ensuring that applicants have graduated from an accredited pharmacy degree program approved by the board;
2. ensuring that applicants have passed a competence assessment examination approved by the board. If applicants were examined after June 1, 1979, that they passed the National Association of Boards of Pharmacy Licensure Examination or the North American Pharmacist Licensure Examination™; and
3. ensuring that applicants' licenses are in good standing from the member board.

For more information about NABP's Task Force on Active/Associate Membership, please e-mail custserv@nabp.net.

Progress on Patient Safety Five Years After IOM Report

Five years after the Institute of Medicine's (IOM) 1999 report, *To Err Is Human: Building a Safer Health System*, patients do not feel safer – despite many promising efforts made by the health care industry and the United States government, according to a recent report published in the *New England Journal of Medicine*.[1] The key to increasing patient confidence, as stated in the report entitled "Improving Patient Safety – Five Years after the IOM Report," is to expand and accelerate current efforts as well as come to a consensus among policymakers, health care professionals, and the public concerning "which events should be publicly reported and what systemwide steps are needed to prevent avoidable harm."

Since the IOM report, much work has been done to improve patient safety. Federal agencies began developing programs regarding patient safety following President Bill Clinton's December 7, 1999 executive order requiring federal agencies and departments to determine activities needed to improve patient safety. Health care purchasers, industry trade organizations, and accrediting and standards-setting bodies also created new programs. One such program called for computerized order entry, evidence-based hospital referrals, and physician staffing in intensive care units; the report's authors cite evidence that facilities are adopting these recommendations with survey results that show a 12% increase in staffing of intensivists in intensive care units between 2001 and 2003. Additionally, computerized physician order entry grew from 2% to 5% in that time period. On a Congressional level, the House of Representatives and the Senate both passed bills to increase the reporting of medical errors and problems with patient safety in 2003 and August 2004, respectively.

Despite these activities, in a 2004 national survey conducted by the authors, one-third of respondents reported personal or family experience with medical errors. Those surveyed do not feel safer, and 55% said they are dissatisfied with the quality of health care in the US. Only 17% of those surveyed think health care is better than it was five years ago, and 40% believe it has "gotten worse."

In order to improve patients' confidence in the health care system, the authors believe that there must be a consensus regarding which events should be publicly reported and how best to report these events. Challenges to obtaining this consensus, according to the authors, include the "gap between the steps identified as important to patient-safety experts and the view of [health care] providers." In addition, the authors say, physicians strongly oppose public reporting of medical errors, despite the fact that 71% of the public believes in the effectiveness of public reporting of medical errors by government agencies. The authors noted that, as stated in the 2003 IOM report *Patient Safety: Achieving a New Standard of Care*, the key to improving patient safety and confidence is "a culture that encourages the sharing rather than the hiding of errors and near misses."

[1] Altman DE, Clancy C, Blendon RJ. Improving Patient Safety – Five Years after the IOM Report. *N Engl J Med*. 2004; 351:2041-2043.

Pharmacy Compounding Accreditation Program Update

The voluntary compounding accreditation program under development by NABP for the Pharmacy Compounding Accreditation Board (PCAB) has garnered much attention with 25 pharmacies expressing interest in becoming accredited. In addition, progress has been made in several areas of the program, which is on target to be fully operational by the end of the first quarter of 2005.

Currently, the PCAB Board of Directors is finalizing documents and processes for the surveying of compounding pharmacies. Once finalized, pharmacies seeking accreditation will receive an information packet that will outline survey criteria and focus areas. The application package of information also assists compounding pharmacies in organizing documents and compiling a self-assessment.

The selection of surveyors is also moving forward as NABP prepares the first list of volunteer surveyors for the PCAB Board of Directors' approval. PCAB will continue to accept applications from individuals who wish to become surveyors. Individuals interested in applying should possess experience in pharmaceutical compounding and may contact NABP at 847/391-4406 or custserv@nabp.net for more information.

For more detailed information on PCAB, please see the article "Compounding Pharmacy Accreditation Program Development Under Way" on page 162 of the October 2004 *NABP Newsletter*.

HHS Task Force

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Internet from international sources. "Imported drugs include those that pose special concerns, such as drugs that require special handling, drugs with high abuse potential, drugs that should be sterile, counterfeit drugs, improperly packaged drugs shipped loose in sandwich bags and envelopes, and drugs from countries that have differing and sometimes more limited regulatory authority to assure the safety of pharmaceuticals manufactured and exported from those countries," the report states.

Regulatory Issues

Since the adoption of the federal Food, Drug, and Cosmetic Act in 1938, the US has had in place strict guidelines to ensure safe and effective marketing of new drugs. Since that time, the country has employed a closed system that involves manufacturers, wholesale distributors, and pharmacies that move drug products from the point of manufacture to the end user. To ensure the safety of American patients, a similar framework would need to be established for imported prescription drugs. Implementing such a system would be no easy task – nor would it be inexpensive – according to the HHS Task Force.

"This report determines that it would be extraordinarily difficult to ensure that drugs personally imported by individual consumers could meet the necessary standards for a certification of safety to be made. . . ." The report further states that ". . . a commercial importation program could be feasible but would require new legal authorities, substantial additional resources and significant restrictions on the type of drugs that could be imported. . . ."

Currently, FDA has about 3,800 employees assigned to inspections of the nation's food, drug, biologic, medical device, and veterinary drug supply. Only 450 of those are involved in import activities, and a limited number of FDA inspectors are available to staff the US's 14 international mail facilities. According to the report, FDA managers have repeatedly noted that the number of personal drug shipments arriving at these facilities is already overwhelming to staff. Likewise, the HHS Task Force found that legalizing commercial prescription drug importation would require significant investment in new information technology and personnel as well as appropriate standards to ensure adequate inspection of commercial quantities of drug products.

Task Force Key Findings

The US Department of Health and Human Services Task Force on Drug Importation summarized its December 21, 2004 Report on Prescription Drug Importation with eight Key Findings:

1. The current system of drug regulation in the US has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to ensure continued high standards of safety and effectiveness of the US drug supply.
2. There are significant risks associated with the way individuals are currently importing drugs.
3. It would be extraordinarily difficult and costly for "personal" importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.
4. Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.
5. The public expectation that most imported drugs are less expensive than American drugs is not generally true.
6. Legalized importation will likely adversely affect the future development of new drugs for American consumers.
7. The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.
8. Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

Foreign Health Agencies

In a December 21, 2004 letter to House Speaker J. Dennis Hastert (R-IL) regarding the Task Force's report, outgoing HHS Secretary Tommy G. Thompson asserted that ". . . any plan to permit importation must be limited to commercial importation of a discrete number of high-volume, high-cost prescription drugs from **a country with equivalent drug safety protections**" [emphasis added]. The report expanded on Thompson's

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Iowa Board Investigates Internet Pharmacies

For nearly a year and a half, the Iowa Board of Pharmacy Examiners has been heavily involved in several investigations involving suspicious Internet pharmacies. These investigations included both brick-and-mortar pharmacies that offered their services via the Internet and Internet-only pharmacies, and led to an addition to one of the Board's administrative rules.

Following is the December 2004 Iowa Board of Pharmacy Examiners Newsletter *article on this investigation, which has been reprinted with the Iowa Board's permission.*

Internet Drug Distribution – Alert!

The Board is aware that various companies have made contacts with Iowa pharmacies for the purpose of acquiring "fulfillment partners." It is an attempt to recruit legitimate pharmacies to fill illegitimate Internet-based prescriptions that are generated by various Web sites.

For example, in one case that came to the Board's attention this summer, a Delaware-based limited liability company sent recruitment letters to many Iowa pharmacies. The letter was titled "Looking to Expand – Interviewing Fulfillment Partners Now!" The letter began this way:

> [Name of company] is the Internet's Leading Online Pharmacy. Over the course of the last three years, we have experienced tremendous growth in selling and delivering [Food and Drug Administration]-approved medications to the online community thru [sic] our existing network of fulfillment partners. However, with continued explosive growth for this year in the United States, we are currently interviewing possible fulfillment partners. This is an excellent opportunity for established pharmacies like yours to generate a substantial additional income stream that would be complimentary to your existing operations. Paying you a fee of $6 per order filled generates this complimentary revenue stream. There is no need to be concerned with shipping payments to carriers, as all shipping is handled by third party billing with our National Carrier, United Parcel Service. All you need to do is take the prescription and efficiently and accurately dispense the medication. Payment for cost of goods sold and all fulfillment fees earned is made weekly.

It is an attempt to recruit legitimate pharmacies to fill illegitimate Internet-based prescriptions that are generated by various Web sites.

The company called itself "the Internet's Leading Online Pharmacy." When we investigated, however, we found that the company was not licensed as a pharmacy in any state including Iowa. Nor was it Verified Internet Pharmacy Practice Sites™ certified by NABP.

We conducted a domain search for the Web site address and learned that it was domiciled in Moldova (formerly part of the Union of Soviet Socialist Republics). The Web site's registrant was identified as a corporation located in Tortola, British Virgin Islands.

We telephoned a marketing representative for the company and anonymously requested additional information about the program. We were told that the company was approximately three years old and was currently processing about 1,500 prescriptions per day.

We were told that Iowa pharmacies who would agree to become "fulfillment partners" would be paid for the cost of the medication plus a $6 flat fee. The company provided drug prices on its Web site and collected credit card and shipping information. The partner pharmacy would be directed to go online and retrieve "batches" of prescriptions that were waiting to be "fulfilled." The company would arrange for automatic pick-up of the filled prescriptions from the partner pharmacy via one of the common commercial carriers.

Furthermore, the marketing representative explained to us that customers go online and order whatever medications they are seeking. An online questionnaire is completed by the customer and forwarded to a "physician" who is employed by the company. The customer has no contact with the physician and has no legitimate doctor-patient relationship with him or her, except by way of the online questionnaire. It appears that in many instances there is no real "physician" involvement whatsoever.

This company is similar to another Web-based company that the Board and other agencies investigated last year. In that case, the

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Around the Association

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Peter Orzali, Jr, RPh, was appointed a member of the Kentucky Board of Pharmacy by Governor Ernie Fletcher. His term expires on January 1, 2009. He replaces Tim Armstrong.

Ann C. Peterson was appointed a consumer member of the Nevada State Board of Pharmacy by Governor Kenny C. Guinn. Her term expires October 31, 2007. She replaces Robert Wood.

J. David Wuest, RPh, was appointed a member of the Nevada State Board of Pharmacy by Governor Kenny C. Guinn. His term expires October 31, 2007. He replaces Larry Pinson.

Board Reappointments

Bob Parrado, RPh, and **Rebecca Poston, RPh**, were reappointed to the Florida Board of Pharmacy by Governor Jeb Bush. Their terms expire on October 31, 2008.

Patricia Thornbury, RPh, was reappointed to the Kentucky Board of Pharmacy by Governor Ernie Fletcher. Her new expiration date is January 1, 2009.

Pre-NAPLEX Forms Revised

NABP revised its Pre-NAPLEX® forms to reflect the updated North American Pharmacist Licensure Examination™ (NAPLEX®) blueprint. The three new forms will provide candidates with the best representation of the NAPLEX while aiding them in assessing their ability, knowledge, and judgment expected of entry-level pharmacists. The Pre-NAPLEX remains the only NAPLEX practice examination written and developed by NABP.

Conveniently located on NABP's Web site, www.nabp.net, and at www.pre-naplex.com, students can sit for the pre-examination 24 hours a day, seven days a week from any location with Internet access, such as home, school, work, or even a public library. The Pre-NAPLEX consists of 50 questions and three different forms are available. At the conclusion of each practice examination, candidates will receive a scoring estimate of how they may perform on the NAPLEX. The fee to sit for the Pre-NAPLEX is $50 per attempt.

Promissor, Inc, an expert in computer-based assessment exams with offices in Philadelphia, Chicago, and London, hosts the Pre-NAPLEX. Providing knowledge measurement services to clients around the world, Promissor designs assessment solutions, provides test development services and delivery via multiple testing options, and offers comprehensive client support services.

For more information, please visit the NABP or the pre-NAPLEX Web sites or contact NABP's Customer Service Department at 847/391-4406 or custserv@nabp.net.

Reserve Your Space for NABP's Annual Meeting Poster Session

There is no time like the present to reserve your space for the Third Annual Poster Session at NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel in New Orleans, LA. Located in the Educational Presentation Area and open for viewing on Saturday, May 21, from 1 to 5 PM and Sunday, May 22, from 8 AM to noon, the Poster Session provides a forum for boards of pharmacy to share information about their latest legislative issues, technology, "hot topics," policy development, or disciplinary cases on a four-foot by six-foot bulletin board.

Schools or colleges of pharmacy are also encouraged to participate in the poster session. Those interested can notify the NABP Meetings Desk via phone at 847/391-4406 or via e-mail at custserv@nabp.net by **Monday, April 4, 2005**. Please provide the poster topic. If your board or school is interested in displaying on only one day, please inform the NABP Meetings Desk.

For presentation tips and other information, see page 22 of the January 2005 *NABP Newsletter*, or contact the NABP Meetings Desk.

Errata

In the January 2005 *NABP Newsletter*, an incorrectly worded sentence appeared in the article "NAPLEX/MPJE Vendor Contract Renewed." The sentence should have read, "Vendor fees relate to the use of the test center and the on-site activities relating to the examination **experience**." NABP apologizes for any confusion caused by this error.

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Compliance News

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company partnered with an Iowa-licensed pharmacy that "fulfilled" Internet-based orders for prescription drugs, which resulted from online questionnaires completed by customers. The Board brought disciplinary action against that Iowa pharmacy and the pharmacists and a technician who worked there. All Iowa pharmacies need to be aware of and fully informed of the dangers associated with forming partnerships with Web-based companies that attempt to legitimize prescriptions by way of online questionnaires or similar efforts.

In response to the growing problem of illegal Internet drug distribution, the Board has adopted the following addition to administrative rule 8.19(4) effective December 15, 2004 (the new language is underlined):

657 Iowa Administrative Code (I.A.C.) – 8.19(4) – Legitimate purpose. The pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-practitioner relationship.

New Orleans Facts

Site of NABP's
101st Annual Meeting
Sheraton New Orleans Hotel
May 21-24, 2005

New Orleans' French Quarter has something to entice any visitor – superb architecture, history, fancy shops, jazz clubs, and, of course, Bourbon Street. Located on the bend of the Mississippi River, the French Quarter consists of 120 blocks.

With more than 35,000 buildings listed on the National Register of Historic Places, New Orleans has the most historic buildings of any other United States city – and several of these buildings are located in the French Quarter. While in New Orleans, Annual Meeting attendees can view many of these historic buildings including:

- Le Petit Theatre du Vieux Carre – the oldest continuously running community theatre in the US.

Photo courtesy of New Orleans Metropolitan Convention and Visitors Bureau, Inc.

- Avart-Peretti House – Tennessee Williams lived in this brick house while writing *A Streetcar Named Desire*
- The Cabildo – the site of the signing of the Louisiana Purchase.

(Source: www.neworleansonline.com/neworleans/fq/fqwelcome.html)

HHS Task Force

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point that other countries may not abide by the same stringent drug safety laws, noting the difficulties involved in obtaining support from foreign governments concerning the safety of exported drugs, in particular those drugs that are transshipped or not intended for import.

Despite the HHS Task Force's direct inquiries, few governments submitted comments with specific strategies or steps to collaborate with the US government on safely importing drugs. In addition, no foreign governments expressed interest or willingness to cooperate in any expansion of legal US importation – nor were they motivated to provide assurance of the safety and effectiveness of drugs exported from their countries.

Furthermore, the HHS Task Force found that there would likely be an increased risk of litigation exposure for manufacturers, distributors, doctors, and pharmacists if importation were made legal. The report noted that the largest source of additional liability would be an increase in the number of injuries and poor disease outcomes "if imported drugs are, as a class, less safe and effective."

The full HHS Task Force report comprises a year's worth of research and includes opinions from diverse groups as well as empirical data. To view the report in its entirety, visit www.hhs.gov/importtaskforce/.

A record 84 participants attended NABP's Multistate Pharmacy Jurisprudence Examination® State-Specific Item Review Meeting, which was held January 21-23, 2005 in Scottsdale, AZ. The 84 participants came from 43 states and attended the meeting to complete and review their state-specific item pool. Pictured from left to right are Joseph DeMino, member, Maryland Board of Pharmacy; Melvin Rubin, president, Maryland Board of Pharmacy; and Christina Harvin, legislative and regulations manager of the Maryland Board of Pharmacy.

Reminder

NABP's new Headquarters is located at 1600 Feehanville Drive, Mount Prospect, IL 60056. The main phone number is 847/391-4406 and the fax number is 847/391-4502.

nabp newsletter

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