newsletter

National Association of Boards of Pharmacy®

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aid to government
the profession
the public
1904 to 2006

This Month on www.nabp.net:

Special Items
Register Now for NABP's 102nd Annual Meeting in San Francisco, CA

2005 Fall Educational Conference CE Summaries

Special News for Pharmacists/Technicians/ Pharmacies/Wholesalers Affected by Hurricane Katrina

Headlines
Author Provides Insight into *Dangerous Doses* at Fall Educational Conference

Upcoming Meetings

Thursday-Friday
January 26-27, 2006
Committee on Law Enforcement/Legislation Meeting
NABP Headquarters
Mount Prospect, IL

Thursday-Friday
February 23-24, 2006
Committee on Constitution and Bylaws Meeting
NABP Headquarters
Mount Prospect, IL

Saturday-Tuesday,
April 8-11, 2006
NABP 102nd Annual Meeting
Westin St Francis,
San Francisco, CA

Medicare Part D Impacts on State Boards

Effective January 1, 2006, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) offers senior citizens and individuals with disabilities a prescription drug benefit under Medicare Part D, which represents the most significant change to Medicare in the program's 40-year history. From a regulatory standpoint, the pharmacy profession will be impacted by Medicare Part D in three main areas: electronic prescribing (e-prescribing) standards, medication therapy management (MTM), and recordkeeping requirements.

E-prescribing Standards

The MMA addresses the quality of medical care in the area of prescription writing by establishing standards for e-prescribing. On November 7, 2005, the United States Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS) published a final rule in the *Federal Register* adopting a first set of final standards ("foundation standards") for an e-prescription drug program under Title I of the MMA.

The most significant component of the e-prescribing standards for the state boards of pharmacy is the preemption provision of the rule. As of January 1, 2006, the provision makes unenforceable any state law or rule that restricts the ability of prescribers to electronically transmit prescriptions for Medicare-eligible patients to pharmacies for covered medications.

The provision would preempt some categories of state laws. CMS is planning future preemption assessment if specific laws or rules prove to be problematic. For now, categories of state laws that are subject to preemption include:

- Express prohibition of e-prescribing;
- Prohibitions on transmission of e-prescriptions through intermediaries such as networks and switches or pharmacy benefit managers, or prohibitions on access to e-prescriptions by

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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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Part D

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plans, their agents, or other duly authorized third parties;
- Requirements that certain language be used, such as "dispense as written," to indicate whether or not generic drugs may or may not be substituted, insofar as such language is not consistent with the adopted standard; and
- Requirements for handwritten signatures or other handwriting on prescriptions.

CMS requested comments on whether or not the preemption provision applies only to transactions and entities that are part of a specific e-prescribing program under Part D, or a broader set of transactions and entities. A concern among some commentators was that a narrow interpretation of the provision would create one set of rules for beneficiaries enrolled in Part D and another set of rules for other Medicare beneficiaries.

In April 2005, NABP submitted comments on CMS's proposed e-prescribing standards addressing this subject, as well as on the need to maintain prescription security and patient privacy. NABP commented that

" . . . [T]he federal preemption of state laws language in the Act specifically addresses electronic prescribing systems used for Part D drugs for Part D enrolled individuals. An attempt to expand the interpretation of the Act would be contrary to the intent of the legislation and undermine the authority of the state boards of pharmacy in critical regulatory and patient care areas."

CMS interprets the provision as applying to all prescriptions transmitted electronically for "Part D-eligible individuals" for "drugs that may be covered by Part D in at least some circumstances, whether or not that particular prescription is covered under Part D in those specific circumstances."

Drugs that are excluded from the Part D program include:

- Those for which payment "as so prescribed and dispensed or administered" to an individual under Parts A and B; and
- Those that may be excluded under Medicaid, except for smoking cessation agents (excluded drugs may be paid for by Medicaid);
- Agents used for anorexia, weight loss, or weight gain;
- Agents used to promote fertility;
- Agents used for cosmetic purposes/hair growth;
- Agents used for symptomatic relief of coughs and colds;
- Prescription vitamin and mineral products (except for prenatal vitamins and fluoride preparations);
- Nonprescription drugs;
- Covered outpatient drugs for which the manufacturer seeks to require associated tests or monitoring as a condition of sale;
- Barbiturates; and
- Benzodiazepines.

Mindful of the potential that separate e-prescribing rules for Medicare-eligible patients and non-Medicare-eligible patients will exist in some states, NABP urges states to consider reviewing their laws and rules, and revise them if this is the case. To assist the state boards in this area, NABP is planning to review its own *Model State Pharmacy Act and Model Rules* in the near future.

Medication Therapy Management

Final regulations for Medicare Part D included guidelines for Medication Therapy Management Programs (MTMPs), which may include elements designed to promote:

- Enhanced enrollee understanding through beneficiary education counseling and other

means that promote the appropriate use of medications and reduce the risk of potentially adverse events associated with the use of medications;
- Increased enrollee adherence to prescription medication regimens; for example, through medication refill reminders, special packaging, compliance programs, and other appropriate means; and
- Detection of adverse events and patterns of overuse and under-use of prescription drugs.

When CMS issued the final regulation in January 2005, it acknowledged that, notwithstanding a consensus definition submitted by 11 pharmacy organizations, no widely agreed-upon definition of MTMP or MTMP standards and measures exist. As a result, CMS adopted a flexible approach to defining MTMP as set forth in the proposed rule. Responding to comments from some in the pharmacy profession who advocated flexibility in MTMP development, CMS stated its position that " . . . [F]urther premature regulatory requirements at this time might not only fail to improve MTMPs, but could negatively impact their development."

Although MTMP standards have been kept flexible, Kim A. Caldwell, RPh, vice president of the Texas State Board of Pharmacy, informed NABP's Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions about MTMP qualification criteria during a meeting in October 2005. Caldwell previously served with CMS as director – Division of Clinical and Economic Development in the Center for Beneficiary Choices and helped lead the development and

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102nd Annual Meeting Travel Grant Offered

NABP is pleased to announce that it will again offer a travel grant to voting delegates for its 102nd Annual Meeting, held April 8-11, 2006, at the Westin St Francis in San Francisco, CA. This year the maximum reimbursement for the Annual Meeting Travel Grant Program has been raised to $1,000. For more than 100 years, the Association's mission has been to aid and support pharmacy regulators in creating uniform standards that protect the public health. It is for this reason that NABP believes Annual Meeting attendance to be of high importance, for it is during the Annual Meeting that Association policies and priorities are voted upon, Executive Committee members and officers are elected, and members are provided with educational opportunities regarding current issues facing pharmacy regulators.

NABP realizes that budget limitations can prevent state boards of pharmacy from sending representatives to meetings. As such, the Annual Meeting Travel Grant Program will reimburse designated voting delegates up to $1,000 in travel expenses, including airfare, hotel rooms, meals, taxis, parking, and gratuities. Monies are limited and grants are available on a first-come, first-serve basis. Grant monies do not include Annual Meeting registration fees.

Grant applications may be obtained by contacting NABP Headquarters and must be received at NABP Headquarters prior to the Annual Meeting. NABP will inform applicants whether or not they have qualified for the grant, which is made possible by Pfizer Inc, prior to the event.

Executive Committee

Donna M. Horn
Chairperson, District I
One-year term

Dennis K. McAllister
President, District VIII
One-year term

Lawrence H. Mokhiber
President-elect, District II
One-year term

Charles R. Young
Treasurer, District I
One-year term

Charles Curtis "Curt" Barr
Member, District V
Serving second year of a three-year term

Reginald B. "Reggie" Dilliard
Member, District III
Serving first year of a three-year term

John R. Dorvee, Jr
Member, District I
Serving first year of a two-year term

Patricia F. Harris
Member, District VIII
Serving first year of a three-year term

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Serving third year of a three-year term

Gary A. Schnabel
Member, District VII
Serving third year of a three-year term

William T. Winsley
Member, District IV
Serving first year of a three-year term

NABP's Executive Committee is elected each year at the Association's Annual Meeting. The 102nd Annual Meeting is April 8-11, 2006, at the Westin St Francis in San Francisco, CA.

A Learned Profession at Last

A physician, licensed in the state of Florida, treated a patient for ongoing neck and back pain. In doing so, he prescribed six varieties of drugs including OxyContin®/oxycodone, Percocet®, Soma®, Xanax®, and diazepam. He allegedly issued additional prescriptions for these drugs prior to the time of the depletion of these same drugs from prior prescriptions. In addition, the physician prescribed contraindicated narcotic drugs.

The prescriptions were correctly filled by two separate pharmacies. Allegedly, prescriptions for narcotics were dispensed by each of these pharmacies within days of having filled like prescriptions for the same drugs. The patient, at age 46, collapsed in her home and died the following day in the hospital. The cause of death was "Combined drug overdose" (oxycodone and diazepam). Lab results were positive for atropine, diazepam, nordiazepam, oxycodone, benzodiazepines, and opiates – all allegedly prescribed by the physician and dispensed by the two pharmacies.

The surviving spouse instituted legal proceedings against the pharmacies, claiming that they had a legal duty to protect the health of the patient commensurate with the prevailing professional standards of care. The trial court granted motions to dismiss that were filed by each of the pharmacies, finding that the pharmacists had no duty to warn a patient of potential dependency or addiction to prescription drugs. It further found that Florida did not recognize negligence claims against pharmacists. This finding would appear to be consistent with previous cases we have reported in the *NABP Newsletter* where the courts have applied the doctrine of the "learned intermediary," holding the physician the only party liable and excusing the pharmacist who correctly fills a prescription.

However, without mentioning the learned intermediary doctrine, the District Court of Appeals of Florida, Fourth District, reversed the trial court decision. The appellate court recognized the growing trend of Florida courts and courts of other jurisdictions permitting negligence actions against pharmacists. It cited Section 465.003(6) of the Florida Pharmacy Practice Act, which states:

> As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug

called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary.

While the court ruled that this section does not create a separate cause of action, it found that it expresses a strong policy suggesting a pharmacist's duty to warn patients of the risks involved in certain drug therapies. After citing several cases decided in Florida and other jurisdictions in support of this concept, it confirmed that Florida will recognize negligence claims against pharmacists but was quick to limit its decision in the instant case to overturning the lower court's decision based on a motion to dismiss.

The *Powers* case is not a case of first impression in the state of Florida and, in fact, is in conflict with previous Florida Court of Appeals decisions. The court notes that its decision in *Powers* contradicts holdings in *Johnson v Walgreen Co*, 675 So.2d 1036, and *Estate of Sharp v Omnicare Inc,* 879 So.2d 34. The court in *Johnson* found that the pharmacist had no duty to warn a customer, who had died from multiple-drug toxicity, of potential adverse reactions or drug interactions when the prescriptions were accurately filled. In *Estate of Sharp*, which also involved a death of a patient, the court dismissed a negligence claim against a pharmacist based upon his alleged failure to review a customer's drug regimen or to account and reconcile the use of controlled substances by the customer. The court in the instant case certified its *Powers* decision to be in conflict with *Johnson* and *Estate of Sharp.*

It appears that courts are trending toward allowing negligence claims against pharmacists, which we look upon as a long overdue recognition by the courts of the pharmacist as a professional.

NABP filed an amicus brief (friend of the court) in the case of *Happel v Wal-Mart* (see "Happel Case – Finally a Breakthrough," 98th Annual Meeting Report of Counsel, *NABP Newsletter*, May/June 2002, Vol 31, No. 5, pg 60), which was likely instrumental in a decision by the Illinois Supreme Courts recognizing the duty of a pharmacist, on a limited basis, to warn patients of potential adverse reactions of drugs. Failure to warn, when recognized, is viewed as negligence on the part of the pharmacist.

It appears that courts are trending toward allowing negligence claims against pharmacists, which we look upon as a long overdue recognition by the courts of the pharmacist as a professional. Several cases regarding pharmacist liability have been reported in past *NABP Newsletters* and, undoubtedly, there will be more to come as this concept continues to develop.

Powers v Thobhani, 903 So. 2d 275 (App. Ct. FL 2005)

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

Purchasing Foreign Drugs Online – May be Less Expensive, but More Risks are Involved

For many United States residents who rely on daily medications, paying full price hits hard – especially for senior citizens, who may be living on a fixed income. In an attempt to save money, many patients continue to purchase drugs from foreign countries via the Internet despite the inherent dangers. But in the end, the cost savings may not be worth the many risks involved with purchasing drugs from foreign countries.

The Dangers Involved

Aside from the danger of receiving counterfeit drugs, patients are at risk for dangerous mix-ups in prescription medication.

According to a January 27, 2005 *ISMP Medication Safety Alert!* article titled "New dangers in the drug reimportation process: Will we know what our patients are taking?", a factor US residents must consider before purchasing a drug from foreign countries is that the drug may have the same US brand name but contain different ingredients and be used to treat different diseases, which can result in inappropriate treatment and a host of unanticipated adverse effects. For example, in the US, Dilacor® contains diltiazem and is used to treat angina and hypertension, whereas Dilacor in Serbia contains digoxin and is used to treat congestive heart failure and arrhythmia. Another example of the "same brand name, different drug" is the drug Norpramin®; in the US its active ingredient is desipramine and the drug is used to treat depression, but in Spain its active ingredient is omeprazole and is used to treat peptic ulcers and gastroesophageal reflux disease. US residents must also remember that drugs and regulations vary from country to country and Food and Drug Administration (FDA) only is responsible for ensuring the integrity of those drugs that are approved for use in the US.

The article also goes on to note two additional problems related to purchasing foreign drugs:

- A wide range of drug name suffixes are used in the US for different dosage forms, so frequent errors occur due to the lack of standardization;
- Look- and sound-alike brand names; For example, **Amyben**, a branded product for amiodarone in the United Kingdom used to treat arrhythimia, is very similar in spelling to **Ambien**® in the US, which contains zolpidem tartrate and is used as a sleeping aid – if these drugs were mixed up the results could be fatal.

FDA also warns consumers about purchasing certain drugs online or from foreign sources that have serious risks and only are available in the US under risk management programs. Some of these drugs are as follows:

- Accutane® (isotretinoin)– indicated for the treatment of severe nodular acne;
- Clozaril® (clozapine) – indicated for the management of severe schizophrenia in patients who fail to respond to standard drug treatments for schizophrenia;
- Mifeprex® (mifepristone or RU-486) – indicated for the medical termination of early intrauterine pregnancy; and
- Tracleer® (bosentan) – indicated for the treatment of severe pulmonary arterial hypertension.

Consumer Protections

To protect themselves, consumers should visit NABP's Web site for a list of online pharmacies accredited by the Association's Verified Internet Pharmacy Practice Sites™ (VIPPS®) program. Web sites that have earned the VIPPS® Seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication, and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

For safety reasons, NABP urges consumers to look for the VIPPS Seal and heed FDA's warning to not purchase foreign medications, even if it means a cost savings.

Patients must also keep in mind that even though they may think nothing of purchasing their medications from a foreign Web site, these drugs have not been FDA-approved and therefore have not gone through the same rigorous inspection system as US drugs.

NABP Comments on Medication Safety, Communication in ACPE's Draft Revised Standards and Guidelines

During the comment period for the Accreditation Council for Pharmacy Education's (ACPE) Revision of *ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* ("Standards 2000") in November 2005, NABP made recommendations intended to help the pharmacy profession achieve the critical goals of error reduction and improved communication with patients. The ACPE Board of Directors will vote on a revised draft incorporating stakeholder comments this month, marking the first changes in the standards since they were first adopted in 1997.

While applauding ACPE's initiatives aimed at strengthening the standards designed to ensure the consistency and quality of pharmacy education, NABP commented that the draft revision should incorporate additions in two key areas: medication safety and error reduction, and communication skills.

Overall, the draft revision attempts to clarify ACPE's standards and guidelines for pharmacy education while making achievement of compliance more measurable. The proposed revisions are driven by ACPE's goals in its strategic plan, which include improving the standardization and consistency of the organization's accreditation procedures for both the professional degree and continuing education provider accreditation programs through the use of standards-related process and outcome measures.

According to Mike Rouse, ACPE's assistant executive director, international and professional affairs, the proposed revisions are designed to simplify the intent of standards, standardize terminology as well as revision procedures for both standards and guidelines, and increase educational outcome measurability. The revision will provide additional scope and detail to the guidelines, including those relating to evaluation and assessment; didactic and experiential, instruction in the sciences, and expectations for practice experiences; and admission requirements. The number of guidelines has greatly increased in the draft revised standards.

Medication Safety, Error Reduction

Emphasizing safety and error reduction, NABP commented on two of the new standards. NABP recommends a greater emphasis on standards aimed at patient safety and medication error reduction throughout all components of the curriculum. The comments referred to research that indicates that system processes external to individual pharmacists, though often beyond the individual's control, contribute to patient safety and thus an understanding of the processes affecting the safe preparation and dispensing of medication is necessary.

Standard No 12, Professional Competencies and Outcome Expectations, would require the attainment of specific competencies according to the American Association of Colleges of Pharmacy's Center for the Advancement of Pharmaceutical Education's *Educational Outcomes 2004*. In ACPE's draft version released for comment in July 2005, Standard No 12 states that graduates must be competent to "provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution" and, under Guideline 12.1, "manage medication use systems, through the ability to apply . . . quality assurance strategies, and research processes to minimize drug misadventuring and optimize patient outcomes." NABP suggested adding the phrase "via patient safety and medication error reduction programs" to this guideline.

Standard No 13, Curricular Core: Knowledge, Skills, and Abilities, suggests under the "Pharmacoepidemiology" subject of Guideline 13.3 that instruction in "methods for continual monitoring for unwanted effects and other safety-related aspects of drugs" and under the subject of "Pharmacy Law and Regulatory Affairs" include instruction in the "pharmacist's role in reducing liability by reducing drug related misadventure." NABP suggests the addition of references within this section. Instruction in the subject of "Medication Dispensing and Distribution Systems" should incorporate education in "continuous quality improvement programs" or "medication error reduction programs" for improving patient safety, according to NABP's comments. NABP stressed that introducing patient safety and medication error principles and programs early in a degree program curriculum would provide a sound foundation for application of that knowledge in pharmacy practice.

Guideline 14.13 in Standard No 14, Curricular Core: Pharmacy Practice Experiences, directs that students in Advanced Pharmacy Practice Experiences participate in "managing the medication use system and apply

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San Francisco: A Picturesque Setting for Attendees to Connect at 102nd Annual Meeting

Known for its wealth of history, culture, and natural beauty, San Francisco serves as the perfect backdrop for attendees of NABP's 102nd Annual Meeting at the Westin St Francis, April 8-11, 2006. After a day of attending important business sessions and thought-provoking continuing education sessions, attendees will have the opportunity to relax and explore "The City by the Bay" and its diverse neighborhoods and attractions, including its steep rolling hills and "Painted Lady" Victorian homes.

From the Ashes, a Great American City is Born

As with many cities in the United States, San Francisco was first inhabited by Native Americans, in this case the Yelamu tribe. The city's foggy weather made it difficult for explorers to navigate near the San Francisco area, but in 1770 a Spanish party, directed by Don Gasper de Portolà discovered the San Francisco Bay, claiming it in the name of Spain and recording it on official maps. Six years later, the sites for the Presidio of San Francisco and Mission San Francisco de Asis were established by Juan Bautista de Anza. Between 1770 and 1822 the San Francisco area was home to many Spanish and other settlers from elsewhere in Europe. In 1821 the area even became part of an independent Mexico due to its proximity to Mexico City.

In 1822, English whaler William Richardson redeveloped a section of the small town Yerba Buena, which is now Portsmouth Square in Chinatown. On January 30, 1847, a naval force under Commodore John D. Sloat claimed Yerba Buena in the name of the US and renamed it "San Francisco" after the Catholic Saint Francis of Assisi.

San Francisco's population exploded between January 1848 and December 1849, when the population increased from 1,000 – a large city population at that time – to 25,000. The California Gold Rush brought an increase in immigration, which included many workers from China who came to mine for gold and, later, to work on the Transcontinental Railroad. This was also the time when the city's oldest neighborhood, Chinatown, was established. Also during this time, many companies still in existence were created – Levi Strauss & Co, Ghirardelli Chocolate, and Wells Fargo.

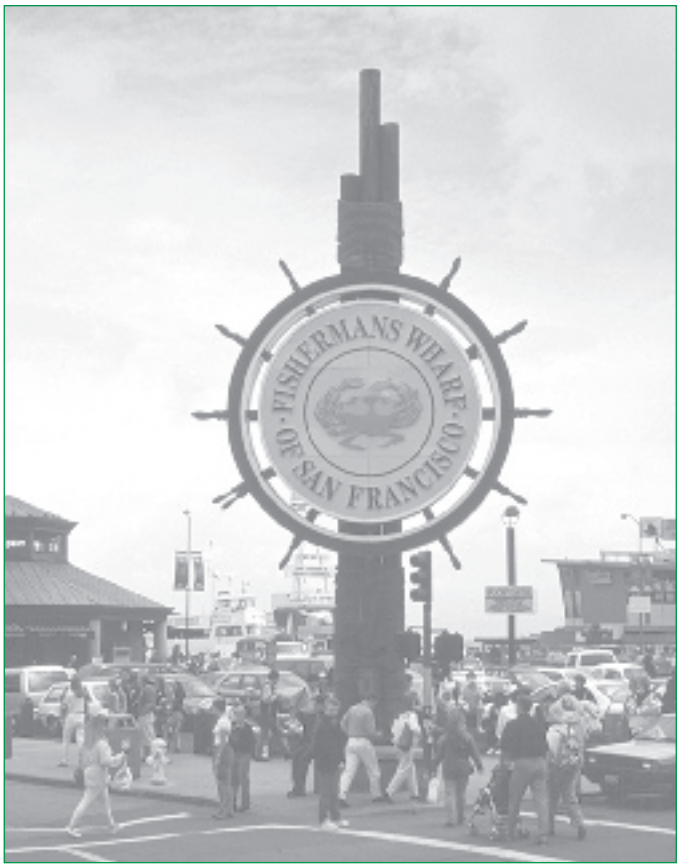
During the next 50 plus years, San Francisco saw many changes including the development of a city government; California gaining statehood in 1850; becoming the largest city west of the Mississippi River; and briefly serving as the state capital in 1851.

On April 18, 1906, the city suffered a devastating 7.8 earthquake, which caused a rupture of more than 270 miles of the San Andreas Fault, from San Juan to Eureka, centered immediately offshore of San Francisco. Many water mains ruptured throughout the city, and fires burned out of control for days, destroying approximately 80% of the city. At the time the official death toll was 478, but in 2005 it was

officially revised to 3,000-plus. Both the city's flag and city seal show a phoenix rising from the ashes, a symbol that San Francisco has risen from the ashes of the fires caused by the 1906 earthquake.

The rest of the 20th century saw the growth of San Francisco into the 14th largest city in the US. The San Francisco-Oakland Bay Bridge opened in 1936, followed by the Golden Gate Bridge in 1937. Throughout the years, San Francisco has been the site for the country's counterculture; in the 1950s, the City Lights Bookstore was an important publisher of Beat Generation literature, and during the following decade, the city was the center of the hippie movement and other alternative cultures. In 1967, thousands of young people flooded into the Haight-Ashbury district during the "Summer of Love."

The city then saw a development boom in the 1970s – many skyscrapers were built – mainly in the Financial District. On October 17, 1989, San Francisco suffered a 7.1 earthquake. Nicknamed the "World Series Quake" because it happened only a few minutes before game three of the World Series, it caused great destruction and loss of life throughout the Bay Area. But, just as after the 1906 earthquake, the city rose again and the 1990s saw entrepreneurs and computer software professionals moving to the city due to the dot-com boom. In 2005 San Francisco hosted the United Nations annual World Environment Day Conference – the first time that it was held in the US.



San Francisco Convention & Visitors Bureau Photo

Fisherman's Wharf, with its shops and museums, is San Francisco's most popular tourist destination.

The Many Unique Attractions in San Francisco

Annual Meeting attendees will not be at a loss finding things to do after a day of exhilarating events while in San Francisco. From Fisherman's Wharf to Chinatown to winery tours, the city offers a

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San Francisco

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plethora of attractions for all interests.

No visit to San Francisco would be complete without a visit to Fisherman's Wharf, the city's most popular tourist destination. The Wharf was developed as Meiggs Wharf by Henry Meiggs to initially serve the lumber trade and, later, was the former headquarters of fish markets. The Wharf is home to the Museum of the City of San Francisco, which offers extensive information on the 1906 earthquake and the motion picture industry; the Cannery at Del Monte Square is home to more than 30 stores and restaurants; and the Wax Museum, which costs $12.95 per person for admission, is one of the largest wax museums in the world. The Wharf is also located near Alcatraz.

Located close to the bay in the northeast part of the city and surrounded by such neighborhoods as North Beach, the Financial District, Nob Hill, and Russian Hill, is Chinatown, the largest Chinatown in the US and home to one of the largest Chinese populations outside of China. Attendees can sample many of the authentic restaurants in Chinatown. Also located in Chinatown are the Bank of Canton and the Sing Chong Building, which was one of the first buildings rebuilt after the 1906 earthquake.

San Francisco Attraction Contact Information

For additional information on the San Francisco sights and attractions mentioned in this article, please refer to these Web sites, e-mail addresses, and phone numbers.

Blue & Gold Fleet – 415/705-5555, www.blueandgoldfleet.com

The Cannery of Del Monte Square – 415/771-3112, www.delmontesquare.com

Fisherman's Wharf – 415/956-3493, www.fishermanswharf.org

Golden Gate National Recreation Area – 415/561-4700, www.nps.gov/goga

Museum of the City of San Francisco – curator@sfmuseum.org, www.sfmuseum.org

San Francisco Chinatown – info@sanfranciscochinatown.com, www.sanfranciscochinatown.com;

Wax Museum – 800/439-4305, www.waxmuseum.com

San Francisco Convention & Visitors Bureau Photo

San Francisco's Chinatown is home to one of the largest Chinese populations outside of China.

For those attendees who enjoy nature and history, the Golden Gate National Recreation Area is the place to visit. The park consists of 75,398 acres of land and water and extends north of the Golden Gate Bridge to Tomales Bay and south to San Mateo County, comprising 59 miles of bay and ocean shoreline. The park encompasses many historical and cultural resources, including Alcatraz, Muir Woods National Monument, and the Presidio of San Francisco – and these sites contain archeological sites, military forts, and other historic structures that represent San Francisco's rich history. It consists of 19 separate ecosystems and seven distinct watersheds, and 1,273 plant and animal species make the area their home including 80 sensitive, rare, threatened, or endangered species, such as the Northern Spotted Owl, the California Red-legged Frog, and the Coho Salmon.

Various tours are also available; attendees should contact the Concierge office at the St Francis Westin for further information, including times, location, and cost. But, no trip to San Francisco is complete without visiting Napa Valley and its many award-winning wineries; tours are available at many wineries including the Robert Mondavi Vineyards, the Chateau Montelena Winery, and Merryvale Vineyards. Many different types of wines are produced in Napa Valley – from Pinot Noir to Chardonnay to dessert wines. Attendees may also be interested in taking the Blue & Gold bay cruise at sunset, which leaves Pier 41 at Fisherman's Wharf at 6 PM and lasts an hour; the price is $21 and tickets do not need to be purchased in advance.

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April 8-11, 2006 — Westin St Francis — San Francisco, CA

(Program subject to change.)

Saturday, April 8, 2006

9 AM - 6:30 PM
Registration Desk Open

1 - 2:30 PM
FDA Discussion on Medical Gases

1 - 4:45 PM
Optional Spouse/Guest Tour

1 - 5 PM
Educational Presentation Area Open/Poster Session

1 - 5 PM
Hospitality Suite in Presentation Area

5:45 - 6:45 PM
New Member Seminar

7 - 10 PM
President's Welcome Reception
Honoring NABP President Dennis K. McAllister
Buffet Dinner will be served.
Dress: business casual

Sunday, April 9, 2006

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

7:30 AM - 6:15 PM
Registration Desk Open

8 - 10 AM
Continental Breakfast
(*in Presentation Area*)

8 AM - noon
Educational Presentation Area Open/Poster Session

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

4:45 - 5:45 AM
Open Microphone Session

Monday, April 10, 2006

7 AM - 4:45 PM
Registration Desk Open

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

8:15 - 10:15 AM
CE Programming

10:15 - 10:30 AM
Refreshment Break

10:30 AM - noon
CE Programming

Noon - 12:15 PM
Break

12:15 - 1:15 PM
Second Business Session

1:15 - 2:45 PM
Meet the Candidates Session (Lunch will be provided.)

2:45 - 3 PM
Break

3 - 4:15 PM
Third Business Session

Tuesday, April 11, 2006

7:30 AM - 4 PM
Registration Desk Open

8 - 9 AM
Continental Breakfast

9 - 10:30 AM
CE Programming

11 AM - 12:30 PM
Luncheon

12:30 - 12:45 PM
Break

12:45 - 3:45 PM
Final Business Session

2:30 - 2:45 PM
Refreshment Break

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

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.

Call for Committee, Task Force Volunteers

NABP is seeking volunteers from its active member boards of pharmacy to serve on the Association's 2006-2007 committees and task forces. Interested executive officers and board members, and staff are encouraged to submit a letter of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone by Friday, May 26, 2006.

Letters should outline the volunteer's applicable experiences and accomplishments, along with the reasons he or she wishes to be considered for appointment to a committee or task force.

All materials will be forwarded to NABP President-elect Lawrence H. Mokhiber, who will make the appointments when he becomes NABP president following the Association's 102nd Annual Meeting, held April 8-11, 2006, at the Westin St Francis in San Francisco, CA.

Around the Association

Minnesota Board Names New Executive Director

Cody C. Wiberg, PharmD, was hired as the Minnesota Board of Pharmacy's executive director on September 14, 2005. Wiberg most recently held the position of director of pharmacy programs for the Minnesota Department of Human Services and is a graduate of the University of Minnesota. Among his contributions to the health care profession, Wiberg assisted in a study titled *Affording Prescription Drugs: State Initiatives to Contain Costs and Improve Access*, by Neva Kaye of the National Academy for State Health Policy that was published in July 2002. He succeeds **David Holmstrom, RPh,** who retired on September 20, 2005.

New Board Members

The Virgin Islands Board of Pharmacy has added several new members.

- Chairperson **Susanna Brin's, RPh,** term expires

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ACPE

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the systems approach to medication safety" and "the pharmacy's quality improvement program." NABP recommended that it is necessary to include the same content in Introductory Pharmacy Practice Experiences.

Communication Skills

NABP also recommended that the revision include a greater number of provisions designed to achieve competence in written and oral communications with patients and other health care practitioners.

Guideline 13.3 in Standard No 13 provides guidance on topics of study in the basic biomedical sciences; pharmaceutical sciences; social, behavioral, and administrative sciences; and clinical sciences. A "Social and Behavioral Aspects of Practice" subcategory of the social, behavioral, and administrative sciences area of study allocates hours of study suggests the following areas of study:

- Pharmacy as a profession;
- Professionalization of the student;
- Image of pharmacist held by patients;
- Role of the pharmacist related to patient care; and
- Role of pharmacist related to interaction with other health care professionals.

NABP recommended that ACPE add "communication techniques with patients and other health care providers" to this subcategory.

A "Medication Dispensing and Distribution Systems" subcategory of Clinical Sciences suggests topics of study within these areas:

- Prepare and dispense prescriptions;
- Patient medication profiling; and
- Issues of distribution systems associated with all types of practice settings.

NABP suggested that ACPE add "effective communication with patients" to this subcategory.

ACPE plans to adopt final revised standards and guidelines in January 2006. For more information about ACPE's standards and guidelines, visit www.acpe-accredit.org.

San Francisco

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San Francisco Transportation

Muni is a city-owned public transit system that operates the Muni Metro light rail system, the F Market heritage streetcar line, and the cable car system, together with buses and trolleybuses. A one-way ticket costs $1.50. The cable cars cost $5 for a one-way trip between 7 AM and 9 PM; otherwise, a one-way ticket costs $1.

San Francisco also has a regional transit system, or Bay Area Rapid Transit (BART), which connects San Francisco with the East Bay through an underwater tunnel and Northern San Mateo County, other communities, and the San Francisco International Airport on the San Francisco Peninsula. BART connects to the Oakland International Airport also; a one-way ride from each airport costs between $5 and $6. BART's Powell Station stop is only three blocks away from the Westin St Francis.

Taxi fares from San Francisco International Airport to the Westin St Francis range from $40 to $45, and fares from Oakland International Airport to the hotel range from $60 to $65. Also, attendees may ride the Supershuttle from either airport; the cost from San Francisco Airport is $15 per person and $25 per person from Oakland International Airport. To book a trip on Supershuttle, attendees may call either 1-800/258-3826 or 415/558-8500 or visit www.supershuttle.com.

For more information about the 102nd Annual Meeting, please call the Meetings Desk at 847/391-4400 or visit NABP's Web site at www.nabp.net.

Part D

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implementation of the Medicare Part D program.

Caldwell noted that three criteria must be met for a beneficiary to qualify for an MTMP:

- The beneficiary must have multiple chronic diseases. Information that must be included in the MTMP description includes the number of chronic diseases the beneficiary must have and, if necessary, the list of chronic diseases must be provided;
- The beneficiary must have had prescriptions filled for multiple covered Part D drugs. Each program must provide the number of Part D drugs for which a beneficiary has had prescriptions filled and, if necessary, the type of covered Part D drugs that apply must be listed; and
- The beneficiary must be likely to incur annual costs of at least $4,000 (2006 amount) for all covered Part D drugs. Caldwell notes that this amount will likely be established on an annual basis and points out that the annual costs are those incurred by the program and are not limited to the beneficiary's out-of-pocket costs. Each program must provide a description of the analytical procedure used to determine whether or not the beneficiary is likely to incur the minimum annual costs for all covered Part D drugs.

In addition to the requirements for information that the prescription drug plan must provide when submitting MTMP descriptions that fall into the three qualification criteria listed above, Caldwell also pointed out other information that is required. The information includes:

- Type and frequency of beneficiary interventions;
- Type and frequency of provider interventions;
- Frequency of evaluation of whether or not individuals in the program qualify for MTM services according to the MTMP's criteria;
- Methods of enrollment/ disenrollment;
- Policies and procedures;
- A description of the resources used and the time required to provide the prescribed MTMP service, if outside personnel is used to administer the program; and
- The amount of management, dispensing fees, or other payment, if establishing fees for pharmacists or others.

Caldwell went on to clarify other MTMP qualification criteria and examples. The following activities qualify as MTMP interventions:

- Reminding a beneficiary or the beneficiary's caregiver by letter or telephone to refill a prescription; and
- Face-to-face intervention in which the beneficiary has an appointment with a pharmacist or other qualified health care provider – diabetes education, for example.

Caldwell also covered which activities do not qualify as MTMP interventions:

- OBRA 90 counseling; and
- Long-term care (LTC) consultant pharmacist services (which are already required in LTC facilities).

Recordkeeping Requirements

Under the MMA, pharmacists are to retain prescription records for 10 years. Due to the costs associated with filing so many paper prescriptions, which would particularly impact smaller community pharmacies, paper prescriptions should be kept on file for three years. Following this period, the prescriptions can be transferred to an electronic format and retained for the remainder of the 10-year period. CMS stresses that this administrative requirement applies only to prescriptions; other records that must be retained for Medicare under Parts C and D should be retained in the formats required by either state law or the Health Insurance Portability and Accountability Act of 1996 or, if applicable, according to the plan's discretion.

CE Session Provides Overview

Caldwell provided an overview of the impact of Medicare Part D implementation during a continuing education session titled "Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Implications for Boards of Pharmacy" on December 2, 2005 at NABP's 2005 Fall Educational Conference in Sunny Isles Beach, FL. Attendees gained insight into beneficiaries' MTM eligibility criteria, examples of activities that qualify as MTM interventions, and advantages of e-prescribing, among other areas of Medicare Part D. See page 21 of this *Newsletter* for a summary of his presentation.

FDA Issues Warning about Accidental Ingestion of Lindane

The June 3, 2005 *Morbidity and Mortality Weekly Report* disclosed 870 cases of illness from 1998 to 2003 that were caused by the unintentional ingestion of lindane, a topical second-line treatment for scabies and lice, when it was mistaken for a liquid oral medication such as cough syrup.

In 2003 Food and Drug Administration (FDA) issued an advisory on the potential neurologic toxicity of lindane, stressing that the treatment should be limited to one application and dispensed only in single-use 1- or 2-oz containers. This recommendation intended to reduce the possibility that patients will apply an excess amount or reapply the product. The article notes that before the changes in 2003, bottles of bulk lindane were sometimes repackaged by pharmacies into smaller bottles that resembled those used for oral medications such as cough syrup.

The article cites other possible reasons why so many accidental ingestions have occurred. Bottles of bulk lindane already in use were not recalled from pharmacies after the 2003 advisory, some repackaging might still be occurring, and some consumers might still have repackaged lindane in their homes.

The article has several important reminders about the appropriate use and packaging of the product:

- Lindane should be used only if other treatments have failed or are intolerable;
- It should not be used for children and small adults who weigh less than 110 pounds;
- Because of the risk of toxicity, the treatment should not be repeated;
- Pharmacists should not transfer lindane to other containers; and
- They should dispense lindane only in the 1- or 2-oz single-use containers provided by the manufacturer.

Instruction on Use of Fentanyl Patches Urged

Overdoses of fentanyl, a potent opioid agonist, have prompted FDA to issue a public health advisory. The overdoses have caused cases of serious injury or death when pain-relieving transdermal patches containing fentanyl, eg, Duragesic® have been misused.

In June 2005 the Duragesic product label was updated to add new safety information in several areas of labeling, and a "Dear Healthcare Professional" letter about these changes was issued by the manufacturer. The label stresses the importance surrounding the proper use of the product, such as:

- The risk of abuse and diversion;
- Avoidance of applying direct heat sources to the patch;
- Avoidance of using the patch while taking other medicines that increase the elimination half-life of fentanyl (such as cytochrome P450 3A4 inhibitors); and
- Proper disposal.

The letter includes warnings about not using the patch on children under 2 years old and the risk of hypoventilation. It also includes cautions about:

- Chronic pulmonary disease;
- The drug's adverse effects on those with head injuries; and
- Interactions with other central nervous system depressants, alcohol, and illicit drugs.

In addition, the product should always be prescribed at the lowest dose needed for pain relief, and patients and caregivers must be fully informed of the directions for safe use of the patch. These directions are provided in the product label and in the patient package insert and are also available at www.fda.gov/cder/drug/infopage/fentanyl/DuragesicPPI.pdf. The manufacturer's "Dear Healthcare Professional" letter is available at www.fda.gov/medwatch/SAFETY/2005/duragesic_ddl.pdf.

FDA's advisory reminds practitioners that fentanyl patches should only be used by patients who have chronic pain that is not well controlled with shorter-acting painkillers, and who are tolerant to opiates. They should not be used to treat short-term, intermittent, or post-operative pain.

FDA also provides a warning of how patients should be instructed to safely store and dispose of the patches. Patients are advised to keep the patches out of the reach of children. Used patches, or those that are no longer needed, should be folded in half so that the sticky side of the patch sticks to itself and then flushed down the toilet.

The advisory also points out the importance of counseling patients and their caregivers to recognize the signs of fentanyl overdose. Signs include trouble breathing, extreme sleepiness, or the inability to think, talk, or walk normally. Patients exhibiting these signs, or

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Fake Flu Vaccine, Stockpiling of Tamiflu Cautioned

Amid fears of avian bird flu and seasonal flu outbreaks, instances of counterfeit flu vaccines and other antiviral medications have caused added concerns for health care regulators.

In a November 3, 2005 edition of the *Houston Chronicle*, it was reported that about 1,000 Exxon Mobil Corporation employees had received bogus flu vaccines. The article went on to report that a Houston man tried to defraud federal health agencies after providing the fake vaccines, which contained nothing more than purified water, to senior citizens and Exxon Mobil Corporation employees.

Another counterfeiting issue involves the antiviral medication Tamiflu®. According to an October 28, 2005 *FDA Week* article, Food and Drug Administration (FDA) is monitoring Tamiflu more closely this year due to the high fears of avian bird flu and seasonal flu – making Tamiflu a target for counterfeiters. Due to its high demand, FDA reports that Tamiflu costs between $80 and $90, also making it a prime target. But, according to FDA Acting Commissioner Andrew von Eschenbach, FDA has not found any specific sources of fake Tamiflu.

Von Eschenbach noted that "These medicines need to be administered in the context of [a] doctor/patient relationship. . . . We're [FDA] concerned about self-medication. [Counterfeit drugs] will make it harder to identify adverse events."

Another growing problem is individual patients attempting to stockpile supplies of Tamiflu and other antiviral medications in an attempt to protect themselves against the potential spread of avian flu, also known as H5N1.

The American Pharmacists Association (APhA) reported in an October 28, 2005 news release that "Stockpiling to protect against an as-yet undefined threat creates its own real danger – that the antiviral products will not be available to mitigate the real threat of this season's influenza."

In response to concerns about counterfeiting, APhA recommends the following:

- Pharmacists should have a contingency plan to access appropriate quantities of medications, vaccines, and supplies to serve patients, or be prepared to refer patients to other sources;
- Patients should not stockpile antivirals or antibiotics. Keeping these drugs for an extended period of time requires complying with certain storage conditions and monitoring expiration dates; antibiotics or antivirals can be rendered ineffective if they are not properly stored;
- Stockpiling of antivirals or antibiotics can create a product maldistribution in times of need. Hoarding of these products can disrupt the flow of medicines to patients who really need them; and
- Patients should also be discouraged from taking antivirals or antibiotics without an appropriate diagnosis.

Around the Association

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on August 16, 2009;

- **Yvette R. Garbutt's, RPh,** term expires on October 7, 2009; and
- The terms of **Richard Ashmore, RPh**; **Gerard Christian, RPh**; and **Danielle deChabert, RPh**, expire on August 16, 2009.

New Board Officers

The Maryland Board of Pharmacy has elected the following officers:

- **John Balch, RPh**, president;
- **Jeanne Gilligan Furman, RPh**, secretary; and
- **Mark Levi, RPh**, treasurer.

New Internet Address for Kansas Board

The new Web site address for the Kansas State Board of Pharmacy is www.kansas.gov/pharmacy.

New Agency Authority, Contact Information for Indiana Board

In a move designed to cost-effectively merge operational functions and maintain the delivery of quality services to the state of Indiana, the umbrella agency that houses the Indiana Board of Pharmacy staff has changed from the Health Professions Bureau to the Professional Licensing Agency. The new contact information for the Indiana Board is:

Indiana Board of Pharmacy
402 W Washington St,
Room W072
Indianapolis, IN 46204-2739
www.in.gov/pla.bandc/isbp
e-mail: pla4@pla.in.gov
direct phone: 317/234-2067
fax: 317/233-4236

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their caregivers, should get medical help right away.

Further RU-486 Labeling Changes Announced

Additional FDA labeling changes for Mifeprex® (mifepristone) – also known as RU-486 – an orally administered drug used for the termination of early pregnancy, have been issued that disclose rare cases of death that occurred when the drug was used along with vaginally administered misoprostol. Earlier labeling changes had warned health care practitioners and patients to be on the alert for rare but serious risks, including infection, bleeding, and ectopic pregnancy.

Four deaths resulted from sepsis that occurred as a result of the administration of 200 mg of mifepristone followed by 800 mcg of misoprostol. In two of the cases, the bacterium was identified as *Clostridium sordellii*. These two cases were not characterized by the usual signs and symptoms of an infection. The other two cases are still under investigation.

A Medication Guide for patients recommends that they seek medical attention if they develop certain symptoms more than 24 hours after taking misoprostol. These symptoms include:

- General malaise;
- Abdominal pain and discomfort;
- Weakness;
- Diarrhea;
- Nausea; and
- Vomiting, with or without fever.

FDA will issue further alerts as more information becomes available. In the meantime, FDA recommends that health care professionals and patients be aware of the following:

- Medical abortion providers and emergency room health care providers should investigate the possibility of sepsis in patients who are undergoing medical abortion via mifepristone. These personnel should be vigilant for symptoms of nausea, vomiting, or diarrhea and weakness (with or without abdominal pain and without fever or other signs of infection) in patients more than 24 hours after they have taken misoprostol. To help identify those patients with hidden infections, personnel should strongly consider obtaining a complete blood count.
- Immediate treatment with antibiotics that includes coverage of anaerobic bacteria such as *Clostridium sordellii* is recommended for patients displaying these symptoms.
- FDA does not yet have sufficient information to recommend the use of prophylactic antibiotics, which carry their own risk of serious adverse events such as severe or fatal allergic reactions. Also, prophylactic use of antibiotics can promote resistance. Finally, it is not known which antibiotic and regimen (what dose and for how long) will be effective in similar cases.
- The safety and effectiveness of other Mifeprex dosing regimens, including the use of oral misoprostol tablets intravaginally, has not been established by FDA.

More about Mifeprex can be found at www.fda.gov/cder/drug/infopage/mifepristone/default.htm.

New Raptiva Warning Issued

Raptiva® (efalizumab) manufacturer Genentech has issued a warning about serious blood-related disorders and infections associated with the drug, which is used to treat some patients 18 years and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

New labeling warns about immune-mediated hemolytic anemia, which can become apparent several months after treatment begins, and cautions prescribers to discontinue use of the drug if this occurs. The new labeling also includes expanded warnings about serious infections and thrombocytopenia associated with Raptiva.

A letter to health care providers reveals that two cases of immune-mediated hemolytic anemia were observed in clinical trials for Raptiva and two more in the postmarketing setting. The diagnoses occurred four to six months after Raptiva treatment began. While no causal relationship has been established between the drug and these cases, one cannot be excluded.

New safety information from the manufacturer raises awareness of serious infections in postmarketing, including necrotizing fasciitis, tuberculous pneumonia, bacterial sepsis with seeding of distant sites, severe pneumonia with neutropenia (ANC 60/mm^3), and worsening of infection (eg, cellulitis, pneumonia), even when antimicrobial treatment has occurred.

A warnings section of the safety information has been renamed "Immune-Mediated Thrombocytopenia" and now includes postmarketing reports. Patients should be watched closely for signs and symptoms of thrombocytopenia, platelet counts should be assessed, and use of Raptiva should be discontinued if thrombocytopenia develops.

More about the new safety information is available at www.fda.gov/medwatch/safety/2005/safety05.htm#Raptiva.

Register Now for the 102nd Annual Meeting

San Francisco, CA, will be *the* place for "Unifying Members, Candidates, and the Profession – A Journey to the Core of NABP," during NABP's 102nd Annual Meeting April 8-11, 2006, at the Westin St Francis. You will see this unification theme come to fruition through events that offer something for all attendees, including the business sessions, continuing education programming, the Meet the Candidates session, the New Member Seminar, and the Annual Awards Dinner.

Registration is now available on NABP's Web site, www.nabp.net. When registering, please indicate if you plan to participate in the Fun Run/Walk and/or the optional Spouse/Guest Tour of Alcatraz.

NABP has arranged a special meeting rate of $189 with the Westin St Francis for single/double occupancy plus applicable taxes. To guarantee the special rate, call Westin Hotel & Resorts' reservation office toll-free at 1-800/937-8461 by April 21, 2006. Be sure to mention that you are attending NABP's 102nd Annual Meeting.

Special air travel and rental car rates are available through NABP's designated travel agency Options Travel at 1-800/544-8785. When calling Options Travel, identify yourself as a registrant of NABP's 102nd Annual Meeting and mention our special code, NABP102.

San Francisco Facts

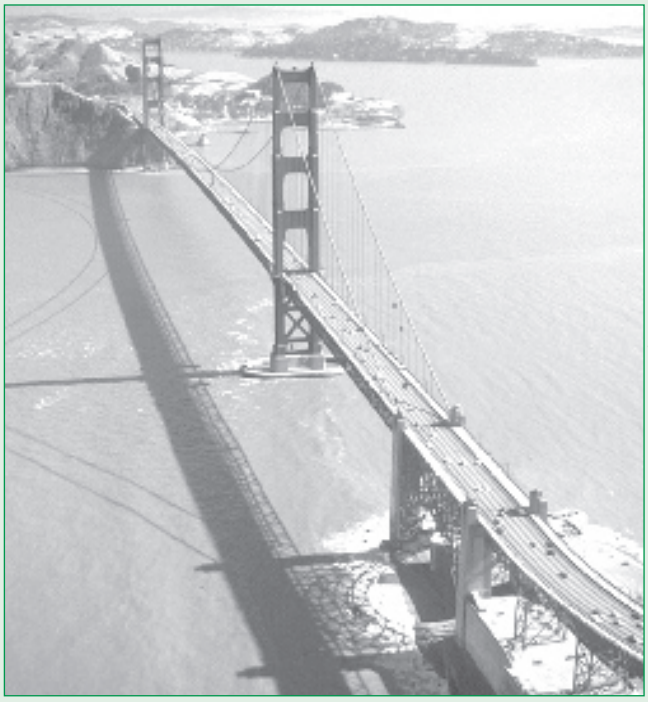
Site of NABP's 102nd Annual Meeting

April 8-11, 2006, Westin St Francis, San Francisco, CA

After more than four years of construction, the Golden Gate Bridge opened to vehicular traffic on May 28, 1937 – ahead of schedule and under budget – when President Franklin D. Roosevelt pressed a telegraph key in the White House announcing the event.

The 1.7 mile Golden Gate Bridge was the brainchild of Joseph Strauss, an engineer who designed more than 400 draw bridges. Others who played a key role in the bridge's construction were architect Irving Morrow, who was responsible for its Art Deco design and choosing its color, International Orange, and engineer Charles Alton Ellis and bridge designer Leon Moisseiff, who collaborated on the complicated mathematics involved.

The bridge, which has a 4,200-foot-long main suspension span, connects the northern San Francisco Peninsula with southern Marin County. The bridge's center span was the longest among suspension bridges until 1964 when the Verrazano Narrows Bridge was built connecting Staten Island and Brooklyn in New York City. Also, the Golden Gate Bridge's two towers rise 746 feet, making them 191 feet taller than the Washington Monument.



San Francisco Convention & Visitors Bureau Photo

The Golden Gate Bridge's two towers are nearly 200 feet taller than the Washington Monument.

(Sources: http://en.wikipedia.org/wiki/Golden_Gate_Bridge and www.inetours.com/Pages/SFNbrhds/Golden_Gate_Bridge.html)

Fall Educational Conference Highlights

NABP's 2005 Fall Educational Conference, held December 2-4, 2005, at the Trump Sonesta Hotel in Sunny Isles Beach, FL, drew approximately 90 attendees to continuing education sessions covering several issues of foremost importance in the pharmacy profession. These issues ranged from the counterfeiting threat to Medicare Part D implementation to the future of pharmacy education.

Above, Kim A. Caldwell, RPh, Texas State Board of Pharmacy member, explains some of the key impacts that Medicare Part D implementation will have on state boards of pharmacy. Session moderator Patricia F. Harris, member, NABP Executive Committee, looks on.

At right, featured speaker Katherine Eban (right), investigative reporter and author of Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply, *provided insight into typical counterfeiting schemes as well as how she conducted research for the book.*

Above, Kenneth W. Schafermeyer, RPh, PhD, director of education, Institute for the Advancement of Community Pharmacy, discussed "Pharmacy Technicians: A Need to Standardize Education, Training, and Scope of Duties?" and was joined by (left to right) moderator Gary A. Schnabel, RPh, RN, member, NABP Executive Committee; Eleni Z. Anagnostiadis, RPh, Professional Affairs director, NABP; and Melissa Murer Corrigan, RPh, executive director, Pharmacy Technician Certification Board.

At left, Michael J. Rouse, BPharm, MPS, assistant executive director, International & Professional Affairs, Accreditation Council for Pharmacy Education (ACPE), participated in the ACPE Open Hearing on Improving the Quality of CE.

At right, Luke Vander Bleek, RPh, president of Fitzgerald and Eggleston Pharmacies, advocated the protection of pharmacists' rights of conscience in "Refusal to Dispense." Joining him are (left to right) session moderator Reginald B. "Reggie" Dilliard, DPh, member, NABP Executive Committee, and fellow speaker Edward R. Martin, Jr, JD, attorney and director for the Rights of Conscience at Americans United for Life.

Above, John D. Jones, RPh, JD, vice president, Legal & Regulatory Affairs at Prescription Solutions and member of the California State Board of Pharmacy, described how he helped develop rules for prescription vending machines in California in "Telepharmacy, Remote Dispensing/Verification, and Automated Dispensing Devices: Increasing Access to Pharmacist Care Initiatives."

At right, Michelle Ferritto, MBA, Drug Enforcement Administration (right), updated the audience on new regulations in "Federal Regulatory Update on Controlled Substances: Discussion with Drug Enforcement Administration."

Members of NABP catch up at the Fall Educational Conference Welcome Reception. Pictured from left to right are James T. Carder, executive director, Wyoming State Board of Pharmacy; Alison Kay McManus, RPh, member, Wyoming State Board of Pharmacy; Cathryn J. Lew, RPh, member, Oregon State Board of Pharmacy; Grace Y. Cheung, RPh, chief investigator, Washington State Board of Pharmacy; Gary A. Schnabel, RPh, RN, member, NABP Executive Committee; Linda Dawn Howrey, RPh, member, Oregon State Board of Pharmacy; and Dale Atkinson, JD, NABP legal counsel.

Experts Discuss Key Pharmacy Regulatory, Practice Issues at Fall Educational Conference

Attendees of the National Association of Boards of Pharmacy®'s (NABP®) Fall Educational Conference, held December 2-4, 2005, at the Trump Sonesta Hotel in Sunny Isles Beach, FL, had a unique opportunity to increase their professional knowledge through exposure to continuing education (CE) sessions. The sessions were designed specifically for the Association's state boards of pharmacy, which are composed of executive officers and board staff, pharmacist and public members, compliance staff, and board counsel, as well as those in the pharmacy profession. Attendees were able to earn up to 11 hours of Accreditation Council for Pharmacy Education (ACPE)-approved CE credit at sessions covering the most important issues affecting the pharmacy profession, from controlled substances (CS) regulations to implementation of the new Medicare Part D prescription drug benefit.

Friday, December 2

Michelle Ferritto, MBA, of the Regulatory Drafting Unit of the Drug Enforcement Administration's (DEA) Office of Diversion Control summarized new regulations in **"Federal Regulatory Update on Controlled Substances: Discussion with Drug Enforcement Administration."**

Ferritto reported that a federal rule went into effect on May 31, 2005, that allowed an electronic ordering system for CS. The voluntary Controlled Substances Ordering System incorporates digital signature technology and public key infrastructure to sign CS orders. If used, the system can only be used for Schedule I and II drugs. She noted that the system must have the same capabilities electronically and on paper. The three performance standards that measure these capabilities are authentication (the person who signed the order is authorizing it), nonrepudiation (the person who signed the document has the ability to verify the signature), and record integrity (alterations of the document have to be discernable after signature).

Ferritto also explained that the Appropriation Act for Fiscal Year 2005 clarifies the definition of the Diversion Control Program and expands it to include activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of CS and listed chemicals. She added that DEA fully funds all diversion control activities, whereas before, DEA used to receive funds from Congress.

When dispensing a Schedule II drug, Ferritto also pointed out, the pharmacy must have the original prescription prior to dispensing unless an emergency situation exists. Alternatively, the original prescription must be written and can be faxed or called in, but the pharmacy must have it before the pharmacist can dispense the prescription.

In regard to CS that are dispensed but not used, a state can take custody of the drug through a state-sponsored program and law enforcement must take possession of the drug and then destroy it. Ferritto added that, once these medications are dispensed, the pharmacy cannot take them back.

The goal of the Drug Addiction Treatment Act of 2003 (DATA), Ferritto reported, is to provide avenues of treatment of narcotic addiction and narcotic dependence in an office setting using Food and Drug Administration (FDA)-approved Schedule III-V drugs for maintenance and detoxification treatment. The Act allows the prescriber to write prescriptions and dispense from a local pharmacy. Qualified practitioners must have gone to the Center for Substance Abuse and Treatment and have demonstrated the knowledge to dispense these medications. The drug being prescribed must be approved by FDA and contain the DEA number and an "X" that replaces one of the alpha characters.

DEA finalized a rule that allows voluntary Automated Dispensing Systems (ADS) in long-term care facilities (LTCFs), but it must be installed and operated by a retail pharmacy and the state law issues a permit for the ADS, Ferritto noted. Each facility must be registered, but the pharmacy can

operate as many ADS as needed at the LTCF. The prescription goes back to the retail pharmacy and the distribution of the retail pharmacy's drug supply is treated as taking place between two retail locations.

A rule covering the reporting of theft or significant loss of CS clarifies "immediately" as the submittal of the initial report in writing within one business day of discovery and filed with the local DEA office, Ferritto reported. The initial report can be faxed or e-mailed, but a DEA Form must be filed soon thereafter. In determining what constitutes a significant loss, DEA lists certain factors that should be reported to local law enforcement: actual quantity lost with relation to the type of business; the specific substance lost; access by other persons; unique activities; and whether or not the drugs stolen/lost are candidates for diversion.

The impacts of the most significant change to the Medicare program in its 40-year history was the focus of **"Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA): Implications for Boards of Pharmacy,"** presented by Kim A. Caldwell, RPh, vice president of the Texas State Board of Pharmacy, who formerly served as director – Division of Clinical and Economic Development in the Center for Beneficiary Choices and helped lead the development and implementation of the Medicare Part D program.

Caldwell discussed the Medicare Part D guidelines for Medication Therapy Management Programs (MTMP), noting that beneficiaries must meet three criteria to qualify for an MTMP. He or she:

- Must have multiple chronic diseases;
- Must have had prescriptions filled for multiple covered Part D drugs; and
- Must be likely to incur annual costs of at least $4,000 (2006 amount) for all covered Part D drugs.

The following are examples of activities that qualify as MTMP interventions under Part D:

- Reminding a beneficiary or the beneficiary's caregiver by letter or telephone to get a prescription refilled; and
- Face-to-face intervention in which the beneficiary has an appointment with a pharmacist or other qualified health care provider.

He also revealed that OBRA 90 counseling and long-term care (LTC) consultant pharmacist services (which are already required in LTCFs) do not qualify as MTMP interventions.

Caldwell noted that the MMA establishes standards for e-prescribing. He pointed out that paper faxes do not qualify as electronic; however, computer-generated faxes qualify. The e-prescribing provision would preempt some categories of state laws, including express prohibition of e-prescribing; prohibitions on transmission of e-prescriptions through intermediaries such as networks or pharmacy benefit managers, or prohibitions on access to e-prescriptions by plans, their agents, or other duly authorized third parties; requirements that certain language be used, such as "dispense as written," to indicate whether or not generic drugs may or may not be substituted, insofar as such language is not consistent with the adopted standard; requirements for handwritten signatures or other handwriting on prescriptions; and other state laws or rules such as state privacy laws with certain digital signature or prescriber authentication requirements.

Caldwell also informed the audience that, under the MMA, pharmacists are to retain prescription records for 10 years. Paper prescriptions should be kept on file for three years, after which the prescriptions can be transferred to an electronic format and retained for the remainder of the 10-year period.

Saturday, December 3

NABP Professional Affairs Director Eleni Z. Anagnostiadis, RPh, opened **"Pharmacy Technicians: A Need to Standardize Education, Training and Scope of Duties?"** by stating that the evolving nature of the pharmacy profession – eg, increased utilization of cognitive services, OBRA 90 counseling, and the upcoming medication therapy management services as part of the new Medicare Part D benefit – has necessitated the regulation of pharmacy technicians. She then provided a history of NABP's role in the training and certification of pharmacy technicians. Melissa Murer Corrigan, RPh, executive director

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CE Sessions

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and chief executive officer of the Pharmacy Technician Certification Board (PTCB), provided insight into PTCB examination development and a discussion of a recently completed comprehensive analysis of the practice of Certified Pharmacy Technicians that took about one year to complete. She reported that the analysis covered 4,000 pharmacy technicians – the largest sample ever – and represented technicians from all areas of the United States, as well as all practice settings. Using the practice analysis, PTCB creates technician functions, responsibilities, knowledge and skills, practice profiles and, finally, test specifications.

Kenneth W. Schafermeyer, RPh, PhD, director of education, Institute for the Advancement of Community Pharmacy and a professor of pharmacy administration and director of graduate studies at the St Louis College of Pharmacy, shared his view that no consensus exists about whether or not pharmacy technician training, education, and duties should be standardized. He also stated that technicians from various practice settings could benefit from a choice of examinations. Schafermeyer provided an overview of the Institute for the Advancement of Community Pharmacy's computer-based Exam for the Certification of Pharmacy Technicians (ExCPT), which is available to technicians practicing anywhere in the country. The examination is divided into regulations and duties (25%), drugs and drug products (25%), and the dispensing process (50%), and state-specific questions can be substituted, Schafermeyer added.

The session titled **"Contemporary Issues in the Education of Pharmacists: Is the Quality of Pharmacy Education in Jeopardy?"** explored educational quality standards and implications of a decline in the number of pharmacists in the workforce.

In addressing the question of whether or not the quality of pharmacy education has been maintained, Peter H. Vlasses, PharmD, BCPS, FCCP, executive director of ACPE, stated that ACPE has studied North American Pharmacist Licensure Examination™ results covering more than a decade and has not discerned meaningful differences among the results. Regarding the quality of schools and colleges of pharmacy programs, Vlasses described the process of reviewing programs through site visits and annual reports, as well as cautionary notice and probation procedures for underperforming programs. He concluded by reporting that changes to ACPE's educational standards and guidelines resulting from comments regarding the *Draft Revision of ACPE Standards 2000 and Proposed Guidelines* were expected to be available in February 2006, adding that ACPE has set objectives of improving its educational standards by identifying rigorous, valid outcome measures to improve accreditation procedures for both CE and professional degree programs.

Potential future shortages of pharmacists was the subject of a contribution to this session from Katherine K. Knapp, PharmD, dean of Touro University's College of Pharmacy and founder and project director of the Aggregate Demand Index, a monthly survey of the pharmacy profession labor force. Knapp reported a continuing pharmacist shortage in the US, despite a surprising downturn in the prescription growth rate since January 1, 2000. With several new schools and colleges of pharmacy to open in the next few years, Knapp stated that the number of annual pharmacy graduates is expected to increase from its current level of 7,000-8,000 to 10,200 by 2020. However, manpower capacity within the profession – as measured by pharmacists' 40-hour work week full-time equivalency – is expected to decline in future years as older pharmacists retire and are increasingly replaced by females (annually, about two thirds of pharmacy graduates are females, who tend to work fewer hours per week). Despite an increasing supply of pharmacy graduates, the profession has a long way to go to counter the prevailing manpower trends, Knapp concluded.

Daniel A. Hussar, PhD, Remington professor of pharmacy, Philadelphia College of Pharmacy at the University of Sciences at Philadelphia, finished the session by stating that the pharmacy profession needs a critical self-examination to determine how it has addressed the pharmacist shortage. In terms of improving the quality of the practice of pharmacy, Hussar suggested that three hours of CE in the area of reducing errors might be a worthwhile requirement.

Sunday, December 4

In the session **"Telepharmacy, Remote Dispensing/Verification, and Automated Dispensing Devices: Increasing Access**

to Pharmacist Care Initiatives," John D. Jones, RPh, JD, vice president, Legal and Regulatory Affairs, at Prescription Solutions and a member of the California State Board of Pharmacy, and William T. Winsley, RPh, MS, executive director of the Ohio State Board of Pharmacy, spoke about how their boards of pharmacy have dealt with these new technologies.

A California State Board of Pharmacy member, Jones was involved in developing rules for prescription vending machines. In California, if pharmacies want to operate prescription vending machines, they must petition for waiver from the California Board and be interviewed by the Board. The pharmacist-in-charge must present to the board a plan of how the pharmacy is going to use the machine.

Though many consider vending machines a threat to the profession, Jones believes that rather than taking away jobs from pharmacists, these vending machines are a tool that can aid pharmacists. Regarding safety, Jones noted that pharmacists decide which prescriptions to put in the delivery system and, more importantly, which ones to exclude, and which drugs will be available or unavailable through machines. In addition, errors that can occur when technicians give patients their medications are eliminated with vending machines. Of 12,500 prescriptions filled through the system in California to date, there have been no documented errors.

In Ohio, the Board of Pharmacy will first determine that prescription vending machines are "approvable" by the Board, then the pharmacies may install the machines, at which time the Board will send an inspector to further assess the machine while it is functioning. Ohio has several stipulations on the operations of the machines such as a requirement that the machine be attached to the pharmacy so that the back of the machine is accessible only by pharmacy staff, the machine can operate only while the pharmacy is open, and there must be physical identification of those who are using the machine.

Both Jones and Winsley noted that telepharmacy is an excellent way to serve remote areas. Winsley noted that Ohio does not consider any part of the state underserved; therefore, telepharmacy has limited applications in his state. To meet recent Joint Commission on Accreditation of Healthcare Organization guidelines, Ohio has begun using telepharmacy for hospitals that do not have 24-hour pharmacists on staff. Stipulations include that the pharmacist at remote locations must have access to all patient records in real time and online. The off-site pharmacy must be licensed and the system used must be approvable by the Ohio Board pending final inspection.

In the session **"Refusal to Dispense,"** Edward R. Martin, Jr, JD, attorney and director of the Center for Rights of Conscience at Americans United for Life, and Luke Vander Bleek, RPh, owner of Fitzgerald and Eggleston Pharmacies, discussed their stance on current legislation that affects pharmacists' rights of conscience. Martin, lawyer for Vander Bleek in his lawsuit against the state of Illinois, which has ruled that pharmacies must dispense Plan B contraceptives despite their moral beliefs, began the discussion with an overview of cases (Roe v Wade and Doe v Bolton) that brought the discussion of conscience protection to the forefront.

Currently, two states have very broad rights of conscience laws, of which Illinois is one; 45 states have conscience laws that only protect certain health care professionals and are focused on abortion; and three states have no protections. According to Martin, shortcomings of current conscience laws are that they often cover only abortion and not the Plan B emergency contraception pill, cloning, or research. In addition, these laws usually cover only doctors and nurses and are focused on individuals, not institutions. The laws have weak remedies and procedural protections, making it more difficult for individuals to get into court. For example, Vander Bleek has been having difficulties getting his case into court because no procedural action has been brought against him.

Vander Bleek discussed Illinois' rule, which states that pharmacies must provide all contraceptives including Plan B or none at all. He notes that the onus of the rule is being put on the pharmacy owner, not the pharmacist. "This rule creates a precedent for government to use license capacity to coerce private business owners and the citizens to abandon deeply held moral principals," he stated. Vander Bleek urged attendees to consider the impact of rules such as Illinois' on the pharmacy profession and the importance of finding consensus. He considers protection of rights of conscience a "middle-of-the-road" option that will meet all the needs of those involved.

The NABP Task Force on Standards for Compounding met at the NABP Headquarters in Mount Prospect, IL, on November 11, 2005. Pictured from left to right are Roger Williams, MD, executive vice president and CEO, US Pharmacopeia; Wallace E. Nelson, North Carolina Board of Pharmacy; John R. Dorvee, Jr, NABP Executive Committee liaison, Vermont Board of Pharmacy; Samia Nasr, Food and Drug Administration (FDA); Brenda Uratani, FDA; Judy Lynn Gardner, Georgia State Board of Pharmacy; Sheila Mitchell, Tennessee Board of Pharmacy; Richard R. Smiga, Pennsylvania State Board of Pharmacy; Charles L. Haytaian, Rhode Island Board of Pharmacy; Susan L. Warren, program director, Colorado State Board of Pharmacy; and Dennis M. Jones, executive secretary, South Dakota State Board of Pharmacy.

Reminder

Proposed amendments to NABP's Constitution and Bylaws must be submitted between Monday, January 9, 2006, and Thursday, February 23, 2006, to be considered during NABP's 102nd Annual Meeting, April 8-11, 2006, at the Westin St Francis in San Francisco, CA.

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