



newsletter

National Association of Boards of Pharmacy®

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aid to government
the profession
the public
1904 to 2006

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102nd Annual Meeting

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Anthropologist Dr Jeff Salz
to Share Inspiring Life
Lessons at NABP's 102nd
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NABP's 102nd Annual
Meeting Provides an
Opportunity to Discuss
Regulatory Issues

Upcoming Meetings

**Thursday-Friday
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and Bylaws
NABP Headquarters
Mount Prospect, IL

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

**Sunday-Tuesday
August 6-8, 2006**
NABP/AACP District III
Meeting
Charleston, SC

**Thursday-Saturday
August 10-12, 2006**
NABP/AACP District V
Meeting
Winnipeg, Manitoba, Canada

**Saturday-Tuesday
May 19-22, 2007**
NABP 103rd Annual Meeting
Hilton Portland & Executive
Tower
Portland, OR

Groups Advocate Various Plan B Classifications as FDA Delays Decision on OTC Application

At the end of 2005, Food and Drug Administration (FDA) found itself embroiled in a controversy in the highly charged area of reproductive medicine or, more specifically, emergency contraception (EC). As of press time, FDA had yet to issue a final decision on whether or not to categorize an emergency contraceptive marketed as Plan B® as an over-the-counter (OTC) drug.

Two dedicated EC medications have been available by prescription for the last several years – Preven®, containing estrogen and progesterin, which was approved by FDA in 1998, and Plan B, containing only progesterin, which was approved in

1999. If taken as directed within 72 hours after unprotected intercourse or contraception failure, these EC drugs have been shown to reduce the risk of pregnancy by 89%, and they are more effective the earlier they are taken. Since they largely impede pre-fertilization events such as release of an egg from the ovary or fertilization of the egg by the sperm and do not interfere with an established pregnancy (after the fertilized egg has implanted in the uterus), ECs are not medically or legally considered abortifacients.

Proponents of EC feel that it holds great promise for improving public health and affecting social policy, some of which has already

been realized. If women know about and have access to EC, proponents say, the number of unintended pregnancies could be cut dramatically – as could the subsequent emotional, financial, and physical costs to women; the costs to society of overburdened families, teen mothers, or neglected children; and the health care and social services costs to governments. Moreover, it has been estimated that nearly half of unintended pregnancies are terminated by induced abortion, so widespread use of EC could substantially reduce the abortion rate. Indeed, the Alan Guttmacher Institute estimated in a 2002 report

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Plan B

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that 51,000 abortions were averted by women's use of EC in 2000, and that 43% of the decrease in total abortions between 1994 and 2000 could be attributed to EC.

Efforts to broaden the availability of EC are moving slowly on a state-by-state basis, giving many public and women's health advocates greater hope in FDA's consideration of an application to allow the marketing of Plan B as an OTC drug. This proposal has, however, also raised great concerns among other groups, and the prospect of making Plan B available on an OTC basis has met with less than universal support.

Based on responses provided to FDA during a recent comment period regarding the Plan B application, some of this resistance stems from a basic confusion of Plan B with abortion-inducing drugs such as mifepristone. Others object to EC on the grounds that it might prevent implantation, and the belief that life begins with fertilization of the egg, not implantation of the fertilized egg in the uterus. Still others are concerned that some women, particularly young teens, would rely on Plan B as their primary means of birth control and would increase their sexual activity or risk-taking

behaviors, such as failing to take precautions that would prevent sexually transmitted diseases as well as pregnancy.

The issue has created a moral dilemma for some pharmacists as well. In the continuing education session "Refusal to Dispense" at NABP's 2005 Fall Educational Conference in Sunny Isles Beach, FL, in December 2005, 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 state 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 emergency contraceptives despite their moral beliefs, pointed out that 45 states have conscience laws that only protect certain health care professionals and are focused on abortion, and three states have no protections. Shortcomings of current conscience laws are that they often only cover abortion and not emergency contraception, cloning, or research. Vander Bleek discussed how Illinois' rule, which states that pharmacies must provide all contraceptives, including Plan B, or none at all. He noted that the onus of the rule is being put

on the pharmacy owner, not the pharmacist. "This rule creates a precedent for [the] government to use license capacity to coerce private business owners, and the citizens they are, to abandon deeply held moral principals," he says.

A Third Class of Drugs

NABP has long advocated an alternative classification for medications that do not seem entirely appropriate for OTC status, yet have characteristics that present compelling reasons to remove the drug from the prescription-only category: Create a third, transitional or "counseling" class of drugs that could be dispensed without a prescription, but only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs.

NABP has been urging the adoption of this counseling class of drugs since 1995, when the Association passed a resolution at its 91st Annual Meeting calling for its creation. In his comments to FDA this fall, NABP Executive Director/Secretary Carmen A. Catizone wrote, "NABP believes that a counseling class of drugs could significantly contribute to the overall safety of the public health as more drugs are transitioned from 'prescription drug' status. A counseling class of drugs

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2006-2007 Open Executive Committee Officer, Member Positions Announced

In accordance with NABP's Constitution and Bylaws, the following individuals are seeking a position on NABP's Executive Committee. The election will be held during NABP's 102nd Annual Meeting, April 8-11, 2006, at the Westin St Francis Hotel in San Francisco, CA.

Officer Positions

President-elect (one-year term)

- Charles Curtis "Curt" Barr, Nebraska Board of Pharmacy
- Oren M. Peacock, Jr, Texas State Board of Pharmacy

Treasurer (one-year term)

- John R. Dorvee, Jr, Vermont Board of Pharmacy

Member Positions

District VI (three-year term)

- Malcolm J. Broussard, Louisiana Board of Pharmacy
- Robert Joseph "Bob" Dufour, Arkansas State Board of Pharmacy

District VII (three-year term)

- Gary A. Schnabel, Oregon State Board of Pharmacy

District I (one-year term)

- Karen M. Ryle, Massachusetts Board of Registration in Pharmacy

The Executive Committee member representative for District I, John R. Dorvee, has declared his intent to seek the office of Treasurer on NABP's Executive Committee. This creates an open member position for District I for a one-year term.

District V (one-year term)

- Open

The Executive Committee member representative for District V, Charles Curtis "Curt" Barr, has declared his intent to seek the office of President-elect on NABP's Executive Committee. This creates an open member position for District V for a one-year term.

Requirements for Floor Nomination

According to NABP's Constitution and Bylaws, Article IV, Section 3, (b)(ii) and (c)(ii), nominations for both officer and member positions may be made from the floor during the designated business session of the 102nd Annual Meeting. Only those individuals from active member boards who have notified the Executive Director/Secretary in writing 30 days (**March 10, 2006**) prior to the Annual Meeting of his or her intention to seek office and have been determined by NABP to

meet all qualifications for office shall be eligible to be nominated from the floor. The letter of intent should include a short (no longer than one page) narrative highlighting relevant experience and attributes that qualify the affiliated member for consideration to be nominated to the Executive Committee, the term expiration date on the active member board on which the affiliated member presently serves, and a current résumé or curriculum vitae.

Schedule

During the First Business Session on Sunday, April 9, NABP President Dennis K. McAllister will announce the final ballot.

At the Second Business Session on Monday, April 10, 2006, there will be time for designated candidate speeches and/or speeches given on the candidate's behalf. A maximum of two speeches may be given for each candidate, including a candidate's own speech. Those individuals making such speeches must limit their remarks to **two minutes**. Those individuals giving candidate speeches must be affiliated members of NABP. Following the Second Business Session, the "Meet the Candidates Session" will take place

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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

Richard A. Palombo
Member, District II
Serving second year of a three-year term

Oren M. Peacock, Jr
Member, District VI
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.

Gimme a Break!!!

By Dale J. Atkinson, JD

Boards of pharmacy are statutorily created and empowered to protect the public through enactment by the legislature of enabling legislation, usually referred to as a practice act. While authorized to use their expertise to promulgate rules/regulations intended to add detail to the regulatory scheme set forth in the practice act, the adoption of such rules/regulations by the boards is also limited by the statutory authority of the enabling legislation. The scope of authority provided to the boards must be examined to determine if a proposed rule/regulation is within these statutory mandates. On occasion, judicial interpretation of board authority defies logic. Consider the following.

The North Carolina Board of Pharmacy is the occupational licensing board for pharmacists and is the executive branch agency responsible for the enforcement of the North Carolina Pharmacy Practice Act. The Board is responsible for enforcing the Act and the laws pertaining to the distribution and use of drugs. The Board is empowered to adopt rules related to its duties and responsibilities under applicable administrative procedures. North Carolina has a Rules Review Commission (RRC) responsible for reviewing submissions from regulatory boards to determine

whether or not a proposed rule is within the authority of the Board, is clear and unambiguous, is reasonably necessary, and was adopted in accordance with the procedural requirements of the Administrative Procedures Act.

In 1998, the Board of Pharmacy published required notices regarding the adoption of administrative rules addressing pharmacist working hours. Following the applicable procedures, the Board held hearings and eventually adopted final language of the rule. The proposed rule submitted to the RRC for approval stated:

A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time to take a 30-minute break and one additional 15-minute break.

The RRC objected to the proposed rule based upon a finding that the Board lacked the statutory authority to enact the rule. The Board did not change the rule, leading to a stalemate between the RRC and the Board. In March 1999, the Board filed a Petition for Declaratory Ruling with the RRC seeking a declaration as to the validity of the proposed rule. The RRC did not issue a ruling or response which, under applicable procedures, results in a denial of the petition.

Thereafter, the Board filed a complaint against the RRC and its members in their official capacities seeking a judgment recognizing the statutory authority to enact the proposed rule, as well as a declaratory judgment that the actions of the RRC were unconstitutional. The lower court held in favor of the RRC, and the Board appealed.

On appeal, the Board argued that the lower court erred by (1) concluding that the Board lacked the statutory authority to adopt the proposed rule and (2) refusing to rule on the constitutional challenge to the authority of the RRC to “veto” the proposed rule. Initially, the appellate court addressed the standard of review identifying that agency and lower court determinations will only be disturbed under certain circumstances. Questions of law are reviewed under a *de novo* standard whereby the court assesses the matter anew and is free to substitute its own judgment for that of the agency. Questions of fact are reviewed under a whole record test whereby the court recognizes deference to the agency determinations and cannot freely substitute judgment except under limited circumstances.

In addressing the statutory authority basis for the appeal, the court reviewed the statutes cited by the Board as supportive of the encompassing authority of the Board to regulate the practice of pharmacy in the interest of the legislative mandate of public protection. The Board argued that it has not only the authority but the duty to regulate pharmacies, under applicable administrative procedures. In rejecting the argument that such authority empowered the Board to promulgate the

proposed rule, the court held that the practice act did not specifically grant the authority to regulate the working hours at a pharmacy.

The Board cited the statutory authority to annually register each pharmacy and require the identification of all personnel employed in the pharmacy as a basis for exercising authority over the number of hours worked. This argument was also rejected by the court, which stated that even a liberal construction of the plain meaning of the statute did not extend Board authority to the working hours of pharmacists.

Finally, the Board argued that the section of the practice act that authorizes the Board to “adopt rules governing the filling, refilling, and transfer of prescription orders” in an effort to “assure the safe and secure distribution of drugs” provided a basis for the authority to adopt the proposed rule. Again, the court rejected the argument stating that “setting limits on the number of hours a pharmacist can work and requiring breaks for meals and otherwise, clearly does not concern the filling, refilling, and transfer of prescriptions.” The court continued stating that the North Carolina Department of Labor is the only entity with the authority to regulate working hours of pharmacists and such

regulation is solely through the Wage and Hour Act.

Thus, the appellate court upheld the lower court determination that the Board of Pharmacy was not acting within the authority delegated to it by the General Assembly when adopting the proposed rule.

Next, the court turned its attention to the second issue of whether or not the rule-making process and the veto authority of the RRC were within the constitutional bounds of authority. The court cited the well-established rule that rulings on constitutional questions are only undertaken when such a determination is unavoidable and necessary to resolve the matter. In the current matter, the appellate court upheld the lower court determination refusing to address the constitutional claim. The appellate court noted that the Board did not challenge the constitutionality of the process until it received an unfavorable outcome from the RRC. Citing a North Carolina Supreme Court decision, the court stated that “... one who voluntarily proceeds under a statute and claims benefits thereby conferred will not be heard to question its constitutionality in order to avoid its burdens.”

Thus, the appellate court upheld the lower court

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

NABP Testifies at Counterfeiting Hearing Before Congressional Subcommittee

A sense of urgency characterized a November 1, 2005 House Subcommittee on Criminal Justice, Drug Policy, and Human Resources hearing that featured testimony by NABP Executive Director/Secretary Carmen A. Catizone, among other experts, on solutions to the growing public health threat of counterfeit drug infiltration of the United States drug supply. The experts noted that the urgency is driven by circumstances that are creating tremendous incentives for unscrupulous individuals who stand to profit enormously from prescription drug counterfeiting: the avian flu threat, the proliferation of global organized crime, and the existence of a significant “gray market” in which prescription drugs are sometimes purchased from unregulated wholesalers and resold at a significant price markup, to name a few.

Representative Mark Edward Souder (D-IN), the subcommittee chairman, opened the hearing by listing several reasons why the need for implementing counterfeiting safeguards is so urgent. A significant amount of counterfeit avian flu treatment could compound the health threat from a flu epidemic; organized crime is proliferating on a global scale, and many of these groups see tremendous profit potential in the illegal prescription drug trade; the gray market exists because no uniform

enforcement standards have yet been implemented among states. Peter Pitts of the Center for Medicines in the Public Interest and a former associate commissioner of Food and Drug Administration (FDA) later testified that counterfeit drugs will comprise an estimated 16% of the global drug market by 2010 – a 72% increase over a five-year period. Subsequent expert testimony illustrated for the subcommittee the gravity of the counterfeiting problem by touching on the progress and status of legislative and

regulatory safeguarding efforts as well as one case that serves as a typical example of how easily drugs can be counterfeited on the wholesale market.

Amid some testimony that gave specifics as to the urgency of the counterfeiting threat, the subcommittee members cited the efforts of NABP and several state boards of pharmacy, such as the Indiana Board of Pharmacy, to safeguard the US drug supply at the wholesale level of the supply chain.

State Efforts Credited

In his opening remarks, Elijah Cummings (D-MD), senior member of the subcommittee, credited the work of NABP and the state boards, several of which have incorporated NABP’s Model Rules for the Licensure of Wholesale Distributors, a component of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, into legislation addressing wholesale drug distribution. In his testimony, Catizone stated that, should Congress draft federal legislation to safeguard the US wholesale drug supply, it should follow the example of states such as Indiana. In May 2005, Indiana passed a law giving the Indiana Board of Pharmacy authority to recognize NABP’s Verified-Accredited Wholesale Distributors™ (VAWD™)

accreditation and require pedigrees.

Several times during their testimony, experts indicated the need for “track and trace” requirements for prescription drugs at every stage of distribution, as in a bill introduced by Representative Steve Israel (D-NY) that primarily calls for paper pedigrees to accompany drug shipments at all points in the supply chain. During his testimony, however, Catizone asked the subcommittee not to assume that federal legislation would completely eliminate the counterfeiting threat. He pointed out that some wholesalers still have not agreed to uniform pedigree standards that were proposed by FDA more than 17 years ago, following passage of the Prescription Drug Marketing Act (PDMA) by Congress.

Other testimony at the hearing revolved around two major themes: how safe the US prescription drug supply chain is from counterfeiting and the urgent need for the implementation of pedigree requirements.

Drug Supply Security Scrutinized

Randall Lutter, acting associate commissioner for policy and planning with FDA, testified that the quality of drugs that consumers purchase from US pharmacies remains high; however, he added that FDA cannot offer the same

quality assurances for drugs purchased outside of FDA’s regulatory jurisdiction. He noted that while domestic counterfeiting is not widespread, counterfeiting activity is increasing. Lutter credited stepped-up FDA enforcement efforts in this area, including the establishment of the FDA Counterfeit Task Force in 2003 and the February 2004 report titled “Combating Counterfeit Drugs: A Report of the Food and Drug Administration,” which recommended a multi-tiered approach to safeguarding the US drug supply, including securing drug products, packaging, and movement through the supply chain; enhanced regulatory enforcement; stricter penalties for counterfeiters; and increased international collaboration.

Lutter also credited NABP and the state boards for aiding this multi-tiered safeguarding approach. He cited efforts such as NABP’s Model Rules for Licensure of Wholesale Distributors as well as several states’ adoption of them, the VAWD program, and Indiana’s legislation requiring VAWD accreditation.

Lutter also noted that FDA’s Office of Criminal Investigations initiated 58 counterfeit drug cases in 2004 compared with 30 cases initiated in 2003. He also cited several highly publicized FDA investigations that prevented

the sale of counterfeit variations of drugs such as Lipitor® and Viagra®. He added that less than 1% of the legitimate US prescription drug supply is counterfeit although, upon further questioning by subcommittee members, he acknowledged that no reliable statistical data exists to support his claim.

None of the remaining expert testimony provided a similarly positive view that the US drug supply is protected from counterfeiting. These included testimonies from Investigative Reporter Katherine Eban and family members of two individuals who were killed by taking counterfeit drugs that entered the legitimate US drug supply.

Eban, author of *Dangerous Doses: How Counterfeiters are Contaminating America’s Drug Supply*, described the complicated path through the gray prescription drug market that counterfeit Epogen® took from the manufacturer to Timothy Fagan who, in 2002, was 16 and recovering from a liver transplant. What Fagan’s family purchased from a local chain pharmacy was low-dosage Epogen that was relabeled as having a higher dose by a counterfeiter in Florida and resold within a loose network of distributors. Eban displayed a chart tracing the path of the medication from sale, repackaging, resale,

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Updated *Model Act* Incorporates Amendments Addressing Key Professional Issues

In January 2006, NABP re-released its amended *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, which incorporates recommended changes that were approved by NABP's Executive Committee from 2003-2005. The recommendations were made by the NABP Committee on Law Enforcement/Legislation (LE/L) (2003-2004 and 2004-2005); the Task Force on Limited Distribution and Shortage of Medication (2003-2004); and a revised version of changes to the Model Rules on the Licensure of Wholesale Distributors resulting from input from the Task Force on Counterfeit Drugs and Wholesale Distributors (2003-2004), the wholesale distributor industry, and regulatory and state legislative activity (2005).

The updated *Model Act* is available online in Microsoft® Word format on NABP's Web site at www.nabp.net.

Committee on Law Enforcement/Legislation

In December 2003, the LE/L made two

recommendations for changes to the *Model Act* that were approved by the Executive Committee.

The first recommendation called for language specifying the roles and responsibilities of the PIC in drug shortages/discontinuances. Section 2A(2)(a) Comment of the *Model Act* was added and reads:

The [PIC], as part of the responsibilities to manage as effectively as possible a patient's therapy to avoid a harmful interruption of therapy because of a shortage or limited distribution of medications, can proactively improve pharmacy operations by developing a systematic approach to address such circumstances. References such as the *ASHP Guidelines in Managing Drug Product Shortages* could be used as resources for developing policies and procedures if appropriate.

The other recommendation called for amended *Model Act* language providing Continuous Quality

Improvement (CQI) Programs privilege from discovery in litigation. Section 105(q) of the Definitions reads:

["CQI"] means a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use.

The recommendation called for the addition of the following sentence to the end of Section 105(q):

All information, communications, or data maintained as a component of such a system shall be privileged and confidential and not subject to discovery in civil litigation.

A new comment was also recommended for Section 105(q):

States should continue efforts to develop and implement requirements for [CQI] programs in pharmacies, recognizing that

CQI programs enhance patient safety and operate most effectively when privilege of discovery laws and/or regulations protecting CQI data and information are enacted and included as a component of the CQI process.

In May 2005, the Executive Committee approved further recommended changes to the *Model Act* put forth by the LE/L. Updates to the *Model Act* included those sections addressing telepharmacy and sterile pharmaceuticals as well as the integration of provisions and language from the Model Rules for the Licensure of Wholesale Distributors.

Several recommendations were made and approved concerning telepharmacy, as the LE/L recognized that the practice has evolved, no longer limited to just interstate practice, but also intrastate practice. This evolution, and the current status of drug importation, prompted the LE/L to recommend that it be specifically stated in the definition of "Practice of Telepharmacy" that such practice is limited to pharmacies and patients

located within United States jurisdictions.

Ultimately, the LE/L recommended that the Executive Committee commission a task force to examine the evolving practices of telepharmacy in the context of the regulatory issues that the state boards of pharmacy are being asked to define and address. The LE/L determined that the existing *Model Act* should be amended to incorporate contemporary telepharmacy concepts; however, the LE/L recommended that it was prudent for NABP to convene a task force to amend the model language in consideration of:

1. Regulatory and patient safety standards;
2. Scope of practice;
3. Personnel; and
4. Quality assurance.

Additionally, in conjunction with the 2004 revisions to the Model Rules for the Licensure of Wholesale Distributors, the LEL recommended amendments to the language of the *Model Act* in Article II (Board of Pharmacy), Article III (Licensing), and Article V (Licensing of Facilities).

Lastly, as a result of Resolution 100-11-04, Sterile Products, which was passed by the NABP delegation during the

Association's 100th Annual Meeting and Centennial Celebration in Chicago, IL, in April 2004, the LE/L's final recommendation was to amend *Model Act* language in the Model Rules for Sterile Pharmaceuticals. The Resolution directed NABP to communicate to its member boards information concerning United States Pharmacopeia (USP) Tests and Assays Chapter 797: Pharmaceutical Compounding – Sterile Preparations, and its integration into the *Model Act*. Although the *Model Act* cites the current USP – National Formulary chapters on compounding and sterile product preparation in its Good Compounding Practices Applicable to State Licensed Pharmacies, the LE/L agreed that the NABP Model Rules for Sterile Pharmaceuticals warranted amending to generally reflect the USP Chapter 797 content and provisions.

Task Force on Limited Distribution and Shortage of Medication

This Task Force met in November 2003 in response to Resolution 99-3-03, which had called for formation of the Task Force at NABP's 99th Annual Meeting in Philadelphia, PA, in May 2003.

One recommendation put forth by the Task Force amended the *Model Act* to incorporate the following amendment:

Change the comment section of the Model Act, Model Rules for Pharmaceutical Care, Section 2, Part A, Subsection 2 [(Duties and Responsibilities of the Pharmacist-in-Charge (PIC))] to read:

The PIC must develop, implement, and maintain policies and procedures that address drug shortages or drug product discontinuance. References such as the American Society of Health-System Pharmacists' *ASHP Guidelines on Managing Drug Product Shortages* could be used in developing the policies and managing medication shortage or discontinuance situations.

Licensure of Wholesale Distributors

In March 2005, NABP amended and re-released the Model Rules for the Licensure of Wholesale Distributors following

feedback and comments received from the state boards of pharmacy, the pharmacy profession, the wholesale distributor industry, and regulatory and state legislative activity after NABP's initial release of the Model Rules for the Licensure of Wholesale Distributors in February 2004, pursuant to the recommendations of the Task Force on Counterfeit Drugs and Wholesale Distributors. The Model Rules were initially provided to aid the state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors and is the result of an intensive effort between NABP and other representatives from the pharmacy profession, Food and Drug Administration (FDA), Drug Enforcement Administration, state regulatory authorities, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

Having received wide-ranging feedback on the Model Rules for the Licensure of Wholesale Distributors, the EC approved several significant changes. (For a summary of changes, see the May 2005 *NABP Newsletter*, page 94.)[®]

More Opportunities to Share Information and to Network

Once again, NABP's 102nd Annual Meeting programming and optional events will offer participants the chance to share information and network with other attendees. The Association's 102nd Annual Meeting, to be held April 8-11, 2006, at the Westin St Francis in San Francisco, CA, will include the popular Spouse/Guest Tour, the New Member Seminar, and the Fun Run/Walk.

Alcatraz Excursion

Attendees will have the opportunity to take a tour of Alcatraz Island, which starts at Fisherman's Wharf, and experience "The Rock" firsthand from 1 to 5 PM on Saturday, April 8, 2006. Participants will be led by a tour guide on the island, followed by an audio tour of the prison.

Tour participants will explore the Golden Gate National Recreation Area's most popular destination, Alcatraz Island, which was used as a military fortress from 1850-1933 and then as a maximum security prison from 1934-1963. Presently, Alcatraz is a historic site managed by the National Park Service.

During its 29 years of use, the prison held such infamous criminals as Al Capone; Robert Franklin Stroud, the Birdman of Alcatraz; and Alvin Karpis, who served more time at



Alcatraz Island was home to some of America's most notorious criminals, none of whom were thought to have successfully escaped.

Alcatraz than any other inmate. Throughout its operation no officially successful escapes from the penitentiary were ever recorded. Thirty-six prisoners attempted to escape; seven were shot and killed, two drowned, five are unaccounted for, and the rest were recaptured. Two prisoners made it off the island but were returned in 1945 and 1962.

Also, from 1969-1971, Native American Indians affiliated with the American Indian Movement attempted to reclaim the land, stating that an 1868 federal treaty allowed Native Americans to use all federal territory that the government was not actively using. After nearly two years of occupation President Richard M. Nixon allowed the Federal Bureau of Investigation to use a removal plan and the

government forced them off the land.

After visiting Alcatraz, attendees have the option to stay at Fisherman's Wharf to explore on their own. Fisherman's Wharf has a wide array of shops where attendees can shop for fine art and jewelry, clothing, and souvenirs.

Guests who are interested in staying longer than the allotted time at Fisherman's Wharf must find their own transportation back to the hotel. The tour company recommends Desoto Cabs (415/970-1300), but there are many cabs available at the Wharf. Another option is taking a cable car, which operate until midnight. The Wharf is open from 9 AM to 9 PM.

The cost of the tour, which is \$50 per person, includes motor-coach and ferry transportation. Those interested in the Alcatraz


Tour must register by March 24, 2006, as space is limited.

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, April 8 from 5:45 to 6:45 PM, where they will hear about the Association's many programs and service offerings as well as procedures followed during the Annual Meeting Business Sessions.

Annual Fun Run/Walk

NABP will offer its Fun Run/Walk for the eighth consecutive year – providing attendees a chance to kick off their day with some fitness and fresh air. The three mile walk/run begins at Union Square across from the Westin St Francis from 6:30 to 7:30 AM on Sunday, April 9, and guides participants past such attractions as Chinatown, North Beach, the Embarcadero, the Ferry, and then back to Union Square. Participants must register (for no charge) by March 24, 2006.

For more information about the 102nd Annual Meeting or to register, visit NABP's Web site at www.nabp.net. 

San Francisco Convention & Visitors Bureau Photo

April 8-11, 2006

Westin St Francis (Program subject to change.)

San Francisco, CA

Saturday, April 8, 2006

9 AM - 7 PM

Registration Desk Open

1 - 5 PM

Educational Presentation
Area Open/Poster Session

1 - 5 PM

Hospitality Suite in
Presentation Area

1 - 5 PM

Spouse/Guest Tour: Alcatraz
Island Tour

5:45 - 6:45 PM

New Member Seminar

7 - 10 PM

President's Welcome
Reception

*Dinner will be served.
Dress: business casual*

Sunday, April 9, 2006

6:30 - 7:30 AM

Fun Run/Walk

7:30 AM - 6 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

Dr. Jeff Salz, Cultural
Anthropologist, Explorer

2 - 2:15 PM

Refreshment Break

2:15 - 4:45 PM

First Business Session

4:45 - 5:45 PM

Open Microphone Session

Monday, April 10, 2006

7 AM - 4:30 PM

Registration Desk Open

7 - 8 AM

NABP/USP Breakfast
*Sponsored by United States
Pharmacopeia, Inc*

8:15 - 10:15 AM

Joint CE Programming

Public Policy Decisions: An
Analysis of Issues That Have
Dramatically Changed Health
Care in the United States
*Program #: 205-000-06-001-L04
(0.2 CEUs - 2.0 contact hours)*

10:15 - 10:30 AM

Refreshment Break

10:30 AM - noon

Joint CE Programming

A Legislative Update for State
Boards of Pharmacy
*Program #: 205-000-06-002-L03
(0.15 CEUs - 1.5 contact hours)*

Noon - 12:15 PM

Break

12:15 - 1:30 PM

Second Business Session

1:30 - 2:30 PM

Meet the Candidates Session
(Lunch will be provided.)

Tuesday, April 11, 2006

7:30 AM - 4:15 PM

Registration Desk Open

8 - 9 AM

Continental Breakfast

9 - 10:30 AM

Executive Officer and Board
Member Programming

Medical Gases: A Discussion
with Food and Drug
Administration
*Program #: 205-000-06-003-L03
(0.15 CEUs - 1.5 contact hours)*

Compliance Officer
Programming

USP Chapter 797: Surveying for
Sterile Compounding
Compliance
*Program #: 205-000-06-004-L04
(0.15 CEUs - 1.5 contact hours)*

Professional Development
Programming

Effective Communication and
Delivery of Board Policy in
Public Meetings and with
the Media
*Program #: 205-000-06-005-L04
(0.15 CEUs - 1.5 contact hours)*

10:30 - 10:45 AM

Refreshment Break

10:45 AM - 12:30 PM

Joint CE Programming

Structuring an Effective Disaster
Plan: Lessons Learned

*Part I: Rising to the Occasion:
The State Boards of Pharmacy
Vital to Hurricane Relief and
Recovery Efforts*

*Part II: Where Do We Go
From Here? Open Forum and
Panel Discussion on the State
Boards of Pharmacy Role in
Emergency Preparedness and
Response*

*Program #: 205-000-06-006-L04
(0.15 CEUs - 1.5 contact hours)*

11:30 - 11:45 AM

Refreshment Break
(Lunch will be provided.)

12:30 - 1 PM

Break

1 - 4 PM

Final Business Session

2:30 - 2:45 PM

Refreshment Break

5:45 - 6:45 PM

NABP/NACDS Reception

*Sponsored by the National
Association of Chain Drugs Stores*

7 - 10:30 PM

Annual Awards Dinner

*Dress: semiformal
Entertainment: Casino Night*



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 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 NABP. A validated Statement of Continuing Pharmacy Education Credit 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 Continuing Pharmacy Education Credit."

Plan B

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would serve as a beneficial adjunct to FDA's plan to reclassify prescription drugs by ensuring that patients are properly educated in medication use. In addition, it would serve as a means to implement any subpopulation requirements to risk manage specific drugs. . . . If emergency contraceptives are placed in a new counseling class of drugs, pharmacists, the nation's most accessible health care professionals, will be able to provide . . . necessary information and assistance. Additionally, this classification would provide a mechanism for the verification of the patient's age, if necessary, or any other subpopulation requirements."

State Laws Facilitate Access

Because of the positive public health and policy implications of EC, and the documented difficulty of women gaining access to EC within the 72-hour effective window, several states have moved to facilitate access to ECs by allowing direct dispensing by pharmacists, with no physician's prescription required. (See "States Increase Access to Emergency Contraception Through Pharmacists," *NABP Newsletter*, March 2003.) Washington state pioneered such a program in the late 1990s. By the end of 2005, eight US

states were permitting women to obtain EC directly from pharmacists: Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, and Washington. Generally, states use either existing collaborative practice agreement protocols to allow pharmacists to dispense EC on their own judgment, or pass separate legislation that grants pharmacists independent prescribing authority to provide EC.

With EC available from pharmacists, women are more often able to obtain the medication during evenings, weekends, or holidays. At the same time, the pharmacist can provide patient counseling to ensure that the medication is taken correctly and provide referrals to family planning resources or physicians – often giving previously marginalized patients access to the health care system.

Nonetheless, disagreements over such issues as scope of practice or liability can make it difficult for states to adapt their collaborative practice agreements to permit pharmacists to provide EC. Politics also plays a role, of course. And other concerns regarding a state government's perception of pharmacists' competence and role as health care professionals were laid bare in a December 2005 incident in Illinois. That state's governor, Rod Blagojevich, made comments equating pharmacists with non-health

care professionals while making an appearance on a news program. The American Pharmacists Association (APhA) and the Illinois Pharmacists Association (IPHA) strongly objected to his statements. "If the governor sincerely wants to expand access to emergency contraception, he will act to allow pharmacists working in collaboration with physicians to prescribe and dispense emergency contraception under specific written protocols," the associations said in a statement issued shortly after the appearance. "Since April 2005, when Governor Blagojevich issued his emergency order that requires pharmacies to dispense prescriptions 'without delay,' both APhA and the Illinois pharmacy community have tried to work with and educate his administration about the critical role pharmacists play on the health care team. The governor's most recent statements [equating the pharmacist's role as equivalent to a non-health care professional] gravely insult the profession's contribution to health care and the patient care services pharmacists provide." To some, misunderstandings such as this do not increase acceptance of state-mandated pharmacist-facilitated access to EC.

FDA Under Fire

In this highly politicized atmosphere, FDA has come under fire for its handling of the Plan B application. As

the switch application passed through the normal review process, reviewers almost universally deemed the drug safe to market OTC. Two advisory committees met in a joint public meeting during the process; they voted 23 to 4 to recommend approving Plan B's switch to OTC status. The review staffs of the Offices of Drug Evaluation relevant to the Plan B application also recommended the switch to OTC marketing status "without restriction." However, the acting director of the Center for Drug Evaluation and Research (CDER), Steven Galson, felt strongly that the studies submitted in support of the application did not adequately demonstrate that young adolescents, due to their undeveloped cognitive skills, could safely use Plan B as intended without adverse effect on their behavior. A "not approvable" letter was sent with Galson's signature in May 2004, to Barr Laboratories, Inc, the marketer of Plan B.

After FDA sent this letter, nearly 50 members of the US Senate and House of Representatives asked the Government Accountability Office (GAO) to investigate and report on FDA's decision-making process. In November 2005, the GAO issued its audit report. In that report, the GAO pointed to four aspects of the FDA review process that it found "unusual":

1. The directors of the Offices of Drug Evaluation III and V, who would normally have signed a Plan B action letter, disagreed with the not-approvable finding and did not sign it, nor did the director of the Office of New Drugs;
2. High-level FDA management was more involved in the Plan B application than in other OTC switch applications;
3. The GAO received conflicting accounts of whether or not the decision to deny the switch application was made before or after the scientific reviews were completed; and
4. The GAO felt that the rationale used by the CDER acting director in denying the application was “novel and did not follow FDA’s traditional practices.”

FDA has publicly disputed these findings. In a statement at the time of the audit’s release, FDA stood by its rejection of the switch application, maintaining that its actions were “typical for high-profile, controversial applications.” Ultimately, according to FDA, “rather than introducing a ‘novel’ approach to this OTC switch application, the Acting Director . . . reached a different conclusion

than that of the review Divisions based on his view of the adequacy of the data supporting the switch.”

More Controversy

While the GAO audit examined events only leading up to the May 2004 not-approvable letter, Plan B’s switch application process has continued to draw fire since that time.

In the initial not-approvable letter, Galson, the CDER’s acting director, told Barr Laboratories that, before the application could be approved, Barr Laboratories would need to either provide data demonstrating that Plan B could be used safely by the younger adolescent population segment or, alternatively, could supply “additional information in support of the revised indication to allow for marketing of Plan B as a prescription-only product for women under the age of 16 years and a nonprescription product for women 16 years and older.”

Barr Laboratories took the latter approach, resubmitting the application in July 2004, asking for Plan B’s switch to OTC status for women 17 years of age and older; for women under 17, the drug would remain prescription-only.

FDA did not take public action on this revised application until August 2005, when then-Commissioner Lester M. Crawford (who resigned for

undisclosed but reportedly unrelated reasons in September) announced on August 26, 2005, a 60-day comment period, further postponing a decision.

“The issues we were asked to resolve, and the proposal that was put forward by Barr Labs, presented us with many difficult and novel policy and regulatory issues,” Crawford said.

“ . . . The answers to these questions can establish very broad and far-reaching policies that could have a significant effect on the way FDA regulates many different drugs.”


In his letter to Barr Laboratories denying a change to OTC status for Plan B, Crawford outlined the three major issues he identified as well in his public announcement:

- “While [FDA] has allowed the same active ingredient to be marketed both Rx and OTC based on indication, strength, dosage form and route of administration, the Agency has never determined whether a drug may be both Rx and OTC based on the age of the individual using the drug”;
- “A related concern is how, as a practical matter, an age-based distinction could be enforced”;
- “In addition, we have never been confronted with whether the Rx

and OTC versions of the same active ingredient may be marketed in a single package.”

The public comment period ended November 1, 2005, and FDA is currently reviewing the results. The public comments posted last fall revealed a variety of opinions, including those who viewed the dual OTC/prescription concept as opening a Pandora’s Box, and others who saw huge record-keeping nightmares, particularly if packaging is the same for both, or logistical nightmares if it is not. Many advocates of the switch to OTC pointed out that age restrictions had been more or less successfully carried out before for alcohol and tobacco or nicotine products, and that bar codes that trigger a request for identification at the cash register were easily added.

Meanwhile, pressure continued on FDA with at least one internal staff resignation and a number of Congressional initiatives designed to force a decision on the Plan B application.

It remains to be seen what FDA will decide in the Plan B switch application. Nonetheless, if the controversy over emergency contraception moves regulators closer to establishing a third, counseling class of drugs, that in itself would provide a victory for public health. 

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Testimony

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and final sale – an indication of what can happen without effective regulations and pedigrees.

Fagan's father, Kevin, testified about severe, painful cramping that Fagan experienced due to the insufficient dosage, which caused Fagan to scream out in pain. In concluding his testimony, Kevin Fagan asked the subcommittee members to vote in favor of Israel's bill.

Status of Pedigrees

During his introduction, Souder noted that FDA has been forced to delay a requirement for paper pedigrees until December 2006, in the hope that Radio


Frequency Identification (RFID) track and trace technology will be available for wholesale drug packaging by that time. During Lutter's testimony, Souder asked why FDA had not implemented the regulations for universal pedigree requirements that it had published in 1999. Lutter replied that, following publication of the regulations, the wholesale drug distribution industry petitioned FDA to issue a stay of a requirement for a written agreement with a manufacturer establishing that a drug wholesaler is an authorized distributor, and for unauthorized distributors to provide a pedigree showing all prior drug sales extending back to the manufacturer.

In response to these concerns, FDA delayed the

effective date of certain regulations relating to written authorization agreements and drug pedigrees until October 1, 2001. In June 2001, FDA submitted a Report to Congress required by the FDA Appropriations Act for 2001. The report noted that in order for secondary wholesalers to comply fully with the pedigree requirements, Congress would have to amend the Food, Drug, and Cosmetic Act to make the pedigree requirement universal and allow "secondary wholesalers" to obtain the transaction history from all prior purchasers of the drug, including those currently designated as authorized distributors. Amid petitioning from wholesalers and the Small Business Administration (SBA), and

in order to allow Congress to consider the information contained in the report, FDA has annually delayed the effective date of the authorization and pedigree requirements of the PDMA rule from 2001 to 2003. Then, in February 2004, when FDA's Counterfeit Drug Task Force Report was released, FDA further extended the stay of these provisions until December 2006.

Wholesalers and the SBA have claimed that pedigree requirements would add a significant cost burden. Given the uncertain prospects for implementing electronic track and trace technology, Israel's bill would require paper pedigrees and would also set aside \$300 million for spot checks of drug supplies and other measures.

Whether or not federal legislation or regulations mandating paper or electronic pedigrees, and/or wholesale distributor authorization is passed, Catizone indicated that NABP and the state boards will continue working to uniformly implement these safeguards at the state level. After Catizone's testimony, Souder asked how pedigree requirements could help small community pharmacists avoid dispensing counterfeit drugs. "A pedigree allows tracing, and if you can alert people to not accept drugs without a pedigree, you have put a major dent in the counterfeit drug market," Catizone replied. 

San Francisco Facts

The Transamerica Pyramid

**NABP's 102nd Annual Meeting
April 8-11, 2006, Westin St Francis, San Francisco, CA**

Since 1972 the Transamerica Pyramid has been a signature landmark of the San Francisco skyline. Located in the heart of the Montgomery Financial District, at 48 floors, the Transamerica Pyramid was the tallest building in the United States west of the Mississippi River from 1972 to 1974. The idea for the Pyramid was born in 1968

when then Transamerica President John R. Beckett noticed that all of the trees in a city park, unlike the buildings, allowed natural light and fresh air to filter down to the streets below. Beckett wanted to achieve the same natural effect with Transamerica's new headquarters, so a pyramid design was chosen.

According to Transamerica, The Transamerica Pyramid is now both a distinctive structure revered by San Franciscans and a landmark of international recognition.



San Francisco Convention & Visitors Bureau Photo

(Sources: www.transamerica.com/company_profile/about_the_pyramid/ and www.mustseesanfrancisco.com/attractions/transamerica-pyramid.html)



As More States Move Toward Pedigree Requirements, List of Counterfeit-susceptible Products Eliminated

Although many states have begun to revise their wholesale distributor regulations based upon the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* and the concept of “Normal Distribution Channel,” no state has adopted the National Specified List of Susceptible Products (List) concept or recognized the List as an interim approach until full pedigree implementation is required. As a result, the NABP Executive Committee decided in December 2005 to disband the National

Drug Advisory Coalition (NDAC) and eliminate the List and its inclusion in the Model Rules on the Licensure of Wholesale Distributors (Model Rules) by mid-year 2006. NABP will also issue an updated revision of the Model Rules by mid-year 2006.

The appointment of the NDAC – composed of representatives from government agencies, various professional organizations, and the wholesale distribution and pharmaceutical manufacturer industry – came at the direction of the NABP Executive

Committee in response to a recommendation from the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, which released the Model Rules in February 2004. In March 2005, an updated revision of the Model Rules was subsequently released.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandated specific pedigree requirements for products that are

particularly prone to adulteration, counterfeiting, or diversion. The List, which contains products that are particularly prone to counterfeiting, was an attempt by NABP to assist states and reduce redundancy and confusion as state wholesale distributor regulations were updated and adopted.

Currently, Florida is the only state that recognizes and maintains a “Specified Drug List for Pedigree Papers,” which is expected to dissolve in mid-year 2006 once its full pedigree requirements are implemented (see State Board News, page 41).[®]

Legal Briefs

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refusal to rule on the constitutional claims and upheld the findings that the proposed rule regarding limitations on the number of hours a pharmacist may work and establishing certain breaks was beyond the statutory authority of the Board of Pharmacy.

In a compelling dissent, one judge respectfully disagreed with the majority’s findings that the Board of Pharmacy lacked the authority to adopt the proposed rule. The dissent observed that

setting limits on the number of hours a pharmacist can work does, in fact, concern the filling, refilling, and transfer of prescriptions. He articulated the criticality of accurate filling of prescriptions and the very basis for the enactment of the practice act, emphasizing the consequences of an improperly filled script. In fact, the North Carolina Board of Pharmacy adopted a rule effective in 1996 that states:

Pharmacists shall not dispense and permit holders shall not allow a pharmacist to dispense prescription drugs at a rate per hour or per

day as to pose a danger to the public health or safety.

The dissent argued that the proposed rule was merely a refinement of the existing rule.

Finally, the dissent argued that the welfare interests of the Wage and Hour Act is to balance the welfare of workers, through insuring reasonable wages and working hours, against any competing interests of business for the benefit of the workers. Conversely, the Pharmacy Practice Act addresses the need for regulation in the interest of protecting the consuming

public. Thus, the dissent concluded that the proposed rule was well within the authority of the Board of Pharmacy.

This matter presents the interesting perspective of rule-making procedures and the grant of authority to boards of pharmacy. While the practice act may seem to broadly empower the Board to regulate in the interest of public protection, not all activities may be interpreted as fulfilling such a mission.

North Carolina Board of Pharmacy v Rules Review Commission, 620 S.E. 2d 893 (App. Ct. NC 2005).[®]

nabp newsletter

How FDA Reviews Drug Names

By Carol Holquist, RPh,
FDA, Office of Drug Safety

Food and Drug Administration (FDA) has received approximately 18,000 reports of actual or potential medication errors since 1992 and continues to improve the process by which these errors are assessed. Over the past nine years, FDA has increased the safe use of drug products by minimizing user errors attributed to nomenclature, labeling, and/or packaging of drug products. The group in charge of these activities is the Office of Postmarketing Drug Risk Assessment (OPDRA) under FDA's Center for Drug Evaluation and Research. Ten clinical pharmacists and physicians make up OPDRA's medication error staff.

Since October 1999, OPDRA has reviewed approximately 400 drug products. Proprietary names undergo a multifactorial review designed to improve consistency and minimize risk with soundalike and lookalike names. The process includes:

- *Expert panel review.* An expert panel meets weekly to exchange opinions on the safety of a new proprietary name. The panel comprises OPDRA medication error prevention staff and representatives from the Division

of Drug Marketing and Advertising Communications, who rely on their clinical, regulatory, and professional experiences to decide on the acceptability of a proprietary name.

- *Handwriting and verbal analyses.* These are conducted within FDA to determine the degree of confusion in visual appearance or pronunciation between the proposed proprietary name and names of other United States drugs. FDA health professionals (nurses, pharmacists, and physicians) are requested to interpret both written inpatient and outpatient prescriptions and verbal orders in an attempt to simulate the Rx ordering process.
- *Computer-assisted analysis.* Currently, OPDRA utilizes existing FDA databases to identify potential soundalike and/or look-alike proprietary names. In the future, OPDRA plans to use validated computer software that will improve the ability to detect similarities in spelling and sound among proprietary names.
- *Labeling and packaging analysis.* OPDRA provides a safety assessment of the container labels, carton and package insert labeling, and proposed packaging of each

product to identify areas of potential improvement.

- *Overall risk evaluation.* This final phase of the name review process weighs the results of each phase of the review as well as additional risk factors such as overlapping strengths, dosage forms, dosing recommendations, indications for use, storage, labeling, and packaging, and important lessons learned from the agency's post-marketing experience.

Pharmacists and other health professionals can assist FDA in minimizing medication errors by reporting any actual or potential medication errors to MedWatch, FDA's medical product reporting and safety information program launched in June 1993. All identification of reporter, institution, and patient are kept confidential and are protected from disclosure by the Freedom of Information Act.

Medication errors can easily be reported to MedWatch via telephone (1-800/332-1088), Web site (www.fda.gov/medwatch), and fax (1-800/FDA-0178). In addition, a standardized MedWatch adverse event reporting form (FDA Form 3500) is available to aid in submitting voluntary reports of medication errors. You should provide a complete description of the error; level of staff (eg, pharmacist, nurse, physician) involved;

medication involved; patient outcome; setting of the incident (eg, inpatient, outpatient); relevant patient information (eg, age and gender); date of event; manufacturer of the drug; dosage form and strength; and size of container. Finally, you will need to check both "Product Problem and/or Adverse Event" and "other" on the form.

We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

Safeguards for Severe Acne Medication Announced

Because isotretinoin (Accutane®) carries significant risks of birth defects for women who are pregnant or might become pregnant, FDA has unveiled safeguards for its distribution. (See related article, March 2005 *NABP Newsletter*, page 61.) The manufacturers of isotretinoin are launching a program called iPLEDGE™ in which doctors and patients register with the program and agree to accept certain responsibilities as a condition of prescribing or using the drug. Wholesalers and pharmacies must also comply with the program to be able

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Florida Law to Curb Counterfeiting Goes Into Effect in July

Beginning July 1, 2006, all wholesaler distributors in Florida must provide pedigree papers for each drug they sell. Verifying pedigree papers will help Florida close loopholes in the distribution chain that could otherwise allow illicit drugs into the wholesale market. This component of the law will be enforced through department inspections and the inspectors can request pedigree documentation as a part of that inspection. Failure to comply with the pedigree requirements may result in criminal and/or administrative penalties.

According to Sandra R. Stovall, compliance manager for the Florida Department of Health, the key component of this bill is an authentication requirement – wholesalers must authenticate each step of the distribution process from when a drug leaves

the wholesaler’s facility to when it goes on the shelves to be sold. But the pedigrees do not have to be in paper form. According to Stovall, “Wholesalers will be authorized to make the pedigree available in an electronic format and state on the invoice specifically how the pharmacy can obtain that pedigree electronically.”

The requirement of the pedigree papers is a proactive goal and the state is hoping these pedigree papers will help detect a counterfeit or diverted drug before it reaches the hands of the patient. A November 25, 2005 *Orlando Business Journal* article states that “. . . The state’s wholesale pharmaceutical industry ‘has been corrupted by the infiltration of a criminal element, which is making a fortune while tainting our drug supply,’ according to a 2003 report by a statewide grand jury.”

The first part of the law, which took effect July 1, 2003, has three components. The requirements regarding prescription wholesalers were enhanced to include (1) more extensive wholesaler forms; (2) a \$100,000 bond requirement; and (3) a criminal background check and fingerprinting.

Any wholesaler found guilty of selling counterfeit or diverted drugs now faces the tougher penalty of a second- or third-degree felony charge whereas before this law, these crimes were considered misdemeanors.

Until July 1, 2006, Florida will use its current list of 34 commonly counterfeited or diverted drugs that require pedigree papers. Other drugs that are currently shipped from one wholesaler to another do not have to provide a pedigree unless the wholesaler is not an Authorized Distributor

of Record (ADR). If the wholesaler is an ADR, it does not have to provide a pedigree for drugs not on the list of 34. If the wholesaler is not an ADR, the wholesaler must provide a pedigree when it distributes the drug to another wholesaler. All this changes July 1, 2006, when all wholesalers must provide pedigrees to all of their customers, the end user, and the practitioner.

The law was passed unanimously – it was realized that the law was developed with patient safety in mind. According to the *Orlando Business Journal*, there has been a mixed response from the wholesale prescription drug distribution industry to the new legislation, but the industry recognizes there is a problem on both a state and a national level, and the law was passed to curtail the problem of counterfeiting and diverting drugs. ☺

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, and the Annual Awards Dinner.

Registration is now available on NABP’s Web site at www.nabp.net or by returning the inserted registration form. When registering, please indicate if you plan to participate in the Fun Run/Walk and/or

the Spouse/Guest Tour of Alcatraz Island.

NABP has arranged a special meeting rate of \$195 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 March 3, 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. ☺

Around the Association

New Board Members

The Arizona State Board of Pharmacy has added **Louanne Honeyestewa, CPhT**, as a new technician member. Her term expires on August 10, 2010.

Keith W. Macdonald, RPh, has replaced **Michael Triolo, PharmD**, as a member of the Nevada State Board of Pharmacy. Macdonald's term expires on October 31, 2008.

Board Reappointments

Ray Seidlinger, PharmD, has been reappointed to the Nevada State Board of Pharmacy. His new term expires on October 31, 2008.

The Rhode Island Board of Pharmacy has reappointed two members:

- **Felix M. Baez, RPh**, whose term expires on November 30, 2008; and
- Public member **Richard Hathaway**, whose term expires on May 31, 2008.

The Utah Board of Pharmacy has reappointed **Betty Yamashita, RPh**, who is also the Board's chairperson. Her term expires on June 30, 2009. ①

Scores Released for December 2005 FPGEE; June 2006 Date Announced

On Saturday, December 3, 2005, 1,753 candidates sat for NABP's administration of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The FPGEE was administered in three United States locations: San Francisco, CA; Northlake, IL (Chicago); and New York, NY. Candidates who sat for the December 3 examination received their scores in January 2006. The next FPGEE is scheduled for June 24, 2006.

NABP provides the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program as a means of documenting the educational equivalency of a candidate's foreign pharmacy education, as well as his or her license and/or registration. During the FPGEC Certification process, candidates are required to submit certain documents or have the documents submitted to

NABP from educational or licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Candidates are also required to pass the FPGEE, the Test of English as a Foreign Language™ (TOEFL®), and the Test of Spoken English™ (TSE®). Candidates who have passed the FPGEE but have not satisfied the language requirements for the portion required for the FPGEC Certificate need to be aware that the TOEFL and TSE will be phased out in 2006 and replaced with the TOEFL Internet-based Testing (iBT), an online version of the TOEFL. During the phase-out period of the TOEFL and TSE and the phase in of the TOEFL iBT, either minimal acceptable TOEFL iBT scores or a combination of minimal acceptable TOEFL and TSE scores will satisfy the language requirements

for the FPGEC Certificate. The FPGEC Certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the states that recognize the certification. NABP continuously alerts candidates that the FPGEC Certificate is not a license to practice pharmacy. Applicants who receive the FPGEC Certificate are qualified by the state boards of pharmacy that accept the FPGEC Certificate to continue the licensure process and take the North American Pharmacist Licensure Examination™ and other required examinations in those jurisdictions that accept this certification. To date, 50 states recognize the FPGEC Certificate.

Candidates with questions about the FPGEE or Pre-FPGEE®, the practice examination for the FPGEE, may visit NABP's Web site at www.nabp.net for updated information. ②

Elections

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during which time the membership will have an opportunity to interact with the candidates running for open officer and member positions.

The election will take place during the Final Business Session on Tuesday, April 11, 2006. The results of the

election will be announced immediately and the installation ceremony will follow for the new 2006-2007 Executive Committee officers and members.

For updates to the list of nominations, NABP's Constitution and Bylaws, and the Nomination

Procedures for Open Positions, please visit the Association's Web site at www.nabp.net or contact the Executive Office at 847/391-4406, or e-mail custserv@nabp.net. ③

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to distribute and dispense the drug.

In the wake of a February 2004 joint meeting between FDA's Drug Safety and Risk Management Advisory Committee and Ophthalmic Drugs Advisory Committee, major improvements were recommended for the restricted distribution program for isotretinoin, which has proven effective in treating severe recalcitrant nodular acne. Under the recommendations, patients who could become pregnant are to have negative pregnancy testing and birth control counseling before receiving the drug. In addition, patients must complete an informed consent form and obtain counseling about the risks and requirements for safe use of the drug. Starting December 31, 2005, all patients and prescribers must register and comply with requirements for office visits, counseling, birth control, and other program components. After October 31, 2005, wholesalers and pharmacies were required to register with iPLEDGE in order to obtain isotretinoin from a manufacturer.

Program information and registration is available at www.ipledgeprogram.com or 866/495-0654.

To increase available information about isotretinoin and its associated risks, FDA also issued a Public Health Advisory and revised the Patient

and Health Care Provider Information Sheets that detail the new patient and practitioner restrictions and responsibilities under the program. A reporting and collection system for serious adverse events associated with the use of the drug has also been established. Pregnancy exposures to isotretinoin must be reported immediately to FDA at the MedWatch phone number (1-800/332-1088), the iPLEDGE pregnancy registry (866/495-0654), or on the iPLEDGE Web site.

Besides approving the iPLEDGE program, FDA approved changes to the existing warnings, patient information, and informed consent form to help patients and prescribers better identify and manage the risks of psychiatric symptoms and depression before and after taking the medication.

FDA Warns Marketers of 'Alternative Hormone Therapies'

Food and Drug Administration (FDA) has warned 16 firms that are marketing "Alternative Hormone Therapies" that these therapies have not been approved as safe and effective drugs for treatment or prevention of serious or life-threatening health conditions. The marketers represent dietary supplements or hormone creams, which the marketers claim can treat or prevent cancer, heart disease, arthritis, and osteoporosis. The products have been

promoted as natural or safer treatments that can be substituted for approved hormone treatments.

In the letters, FDA advises the firms that, under the federal Food, Drug, and Cosmetic Act, a product is considered to be a drug if it claims to diagnose, cure, mitigate, treat or prevent disease or, for products other than foods and dietary supplements, if it claims to affect the structure or function of the body. The letters further state that FDA considers these products "new drugs" that require FDA approval before marketing.

Partnering with FDA in this enforcement effort is the Federal Trade Commission (FTC), which has jurisdiction over advertising. FTC has sent letters to 34 Web sites that are promoting Alternative Hormone Therapies and using similar claims without reliable scientific evidence to support the claims.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health, has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk

from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the United States and the trend of non-medical use of prescription drugs.

For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

FDA Announces the Use of New Electronic Drug Labels

Effective November 2, 2005, FDA began requiring drug manufacturers to submit prescription drug label information to FDA in a new electronic format. This electronic format will allow health care providers and the general public to more easily access the product information found in the FDA-approved package inserts (labels) for all approved medicines in the US. The new electronic product labels will be the key element and primary source of medication information for *DailyMed*—a new interagency online health information clearinghouse that will provide the most up-to-date medication information free to consumers, health care providers, and health care information providers. This information can be accessed through the National Library of Medicine at <http://dailymed.nlm.nih.gov>. This information will also be provided through facts@fda.gov, an online resource to be launched in 2006 to give one-stop access to information about all FDA-regulated products. 

Reminder

Annual Meeting
Travel Grant Program
applications may be
obtained by contacting
NABP Headquarters
and must be received
at NABP Headquarters
prior to the 102nd
Annual Meeting, to
be held at the Westin
St Francis in San
Francisco from April
8-11, 2006.



nabp newsletter

National Association of Boards of Pharmacy

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