Paving Approval Pathway for Biosimilars Presents Unique Challenges for FDA

With several patents on biologics scheduled to expire in the coming years, the need to establish an approval pathway that will ensure the safety and efficacy of follow-on biologic products is becoming more pressing. Certain complexities associated with innovator biologic products, make challenging the establishment of a Food and Drug Administration (FDA) approval process for follow-on biologics. The degree to which follow-on biologics can be equivalent to their reference biologic counterparts is in fact the question; thus, the products are often dubbed biosimilars and the developing approval process will likely be more complex than the approval pathway for generic versions of innovator pharmaceutical products.

FDA has taken its first steps toward establishing an approval pathway for biosimilars, with a public meeting held in November 2010, and a subsequent open comment period, highlighting in the process the hot-button issue of potential trade-offs between health care affordability and patient safety. The process to create the approval framework for follow-on biologics is directed by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), signed into law as part of the landmark Patient Protection and Affordable Care Act signed by President Obama in March 2010. As evidenced by their comments to FDA and in public media, many consumer advocates and other stakeholders hope that establishing a biosimilars approval pathway will introduce competition to the biological pharmaceuticals market, bringing down prohibitive costs and increasing accessibility. The complex nature of biologics, however, raises patient safety concerns which seem likely to scuttle hopes of achieving the same degree of savings accomplished by the introduction of generics in other parts of the pharmaceutical marketplace.

Biosimilars vs Generics

The appeal of creating “generic” versions of biologics is clear: Allow...

(continued on page 70)
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National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
847/391-4406
www.nabp.net
custserv@nabp.net

Carmen A. Catizone
Executive Director/ Secretary

Larissa Doucette
Communications Manager

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Association News

CSA Task Force Convenes for Second Meeting

On January 25-26, 2011, the Task Force to Review and Recommend Revisions to the Controlled Substances Act convened for a second time at NABP Headquarters. During the meeting, the task force reviewed items discussed during the initial October 2010 meeting as well as topics covered during the conference calls held in October and November 2010 among the four task force subgroups. The task force report has been compiled and will be released upon review and approval by the NABP Executive Committee.

Pictured back row from left to right: Task Force Chairperson Jay Campbell, RPh, JD, executive director, North Carolina Board of Pharmacy; Ross Brickley, RPh, MBA, CGP, past president, American Society of Consultant Pharmacists; Susan Ksiazek, RPh, member, New York State Board of Pharmacy; Suzanne Neuber, RPh, assistant compliance officer, Omnicare, Inc; Virginia Herold, MS, executive officer, California State Board of Pharmacy; Patricia D’Antonio, RPh, MS, MBA, CGP, executive director, District of Columbia Board of Pharmacy; and Suzan Kedron, JD, member, Texas State Board of Pharmacy. Front row from left to right: Jeanne Waggener, RPh, member, Texas State Board of Pharmacy; Lawrence Mokhiber, MS, RPh, executive secretary, New York State Board of Pharmacy; Cathryn J. Lew, RPh, Executive Committee liaison; Danna Droz, RPh, JD, program administrator, Prescription Drug Monitoring Program, Ohio State Board of Pharmacy; and Kristi Dover, PharmD, senior area director of medical liaisons, Purdue Pharma L.P.

Biosimilars (continued from page 69)

market forces to act as a brake on prohibitive drug prices. Biologics cost an average of 22 times as much as ordinary drugs, and are expected to make up 50% of sales from the pharmaceutical industry’s top 100 products by 2014, according to an editorial published by public policy and health experts Anthony D. So, MD, and Samuel L. Katz, MD, in The New York Times.

Often representing cutting-edge research, biologics, according to FDA, “in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.” Their desirability is clear – but consumer advocates note that, with potential costs to patients of up to tens or even hundreds of thousands of dollars per year for a medication, fewer patients are able to afford potentially life-saving or life-changing treatment, treatment adherence drops, and overall health care costs continue to skyrocket.

While generic drugs have introduced competition and offered some cost relief for non-biologic drugs, thus far, no comparable generics exist for biologics due to the unique nature of these products. What most consumers think of as “typical” drugs are manufactured through chemical synthesis, using the principles of organic chemistry, and generally feature a well-defined chemical structure that can be analyzed in a laboratory to determine its components. To receive FDA approval for these “small-molecule” generic medications, a drug must have the same active molecule in the same strength, dosage form, and route of administration as its reference product, and must be bioequivalent. Different manufacturing processes can produce the same results. The approval (continued on page 78)
Customizable Inspection and Compliance Assistance Services Now Available for Boards of Pharmacy

With state resources dwindling, NABP continues to evaluate ways to provide further assistance to the boards of pharmacy through new programs and services. As one of its newer endeavors, NABP is pleased to be able to offer added support in the realm of inspection and compliance services. An integral component in licensing requirements, inspections are often a necessity for boards of pharmacy to ensure licensee compliance with certain regulations. However, with more boards facing limited staffing due to loss of human and fiscal resources, work furlough programs, and hiring freezes, conducting these inspections may at times prove to be a challenge.

As a result, many states are forced to make decisions between conducting routine inspections, for cause investigations, or taking on other special projects in the interest of the public health.

To ease the burden on the boards, NABP has developed its customizable inspection and compliance services with the intent to meet the varying needs of the boards of pharmacy. The program can be tailored to match board-specific inspection and compliance related issues and is composed of three tiers of service: (1) assisting in updating and/or revising inspection processes and documents; (2) providing classroom and/or field training; and (3) conducting inspections.

NABP can provide support with the board’s overall inspection processes. Through this first tier of service, the Association can offer additional expertise to the boards when they review existing language in these processes and can assist with any necessary updates to inspection strategies, methods, and forms.

The second tier of NABP’s inspection and compliance services consists of adaptable classroom and field training for new and existing board of pharmacy compliance officers. Currently, NABP holds an annual training session for its accreditation program surveyors. To expand these services to its members, the Association will hold an Interactive Compliance Officer Forum on December 1-2, 2011. This specialized forum is the third in a series of NABP meetings targeted to specific board of pharmacy audiences. The first was held in September 2010 and catered to board members and the second, the Interactive Executive Officer Forum, will take place September 21-22, 2011. More details on both the NABP Interactive Executive Officer Forum and the NABP Interactive Compliance Officer Forum will be available in future issues of the NABP Newsletter.

Utilizing NABP’s existing pool of accreditation surveyors, the Association is fully equipped to offer its third tier of service as an inspecting agent for the boards of pharmacy, for any number of pharmacy practice and business settings. With this fee-based service, the boards of pharmacy are able to designate NABP as the inspector on their behalf, freeing up valuable board time to focus on investigations and other compliance matters. The Association can also offer additional assistance in situations where specialized inspection services are necessary, including shopper surveys, background investigations, and nonresident inspections.

As an added benefit, some states have taken this a step further and now recognize certain NABP accreditation programs as part of meeting specific licensing requirements because the programs include comprehensive surveys. By recognizing accreditation, boards are able to utilize NABP’s surveyor resources and regulatory experience to help them meet inspection mandates.

NABP continues to evaluate ways to provide customizable support to the boards of pharmacy. Additional details on the inspection and compliance services will be provided during the 107th Annual Meeting held May 21-24, 2011, in San Antonio, TX. Questions may also be directed to the NABP Government Affairs Department at GovernmentAffairs@nabp.net.
If It Walks Like a Florida Nurse and Quacks Like a Massachusetts Physician, It Must Be a Massachusetts Nurse
By Dale J. Atkinson, JD

With technological advancements and the ability of licensed professionals to practice their chosen vocations in several jurisdictions, sometimes without physical presence, practitioners will be more likely to hold licenses in multiple states. Indeed, some practitioners may have licenses in multiple professions as well. This increased presence by licensees in multiple states places increased emphasis on the regulatory boards to not only make final disciplinary actions available to the public via their Web sites, but to use all available mechanisms to share such information with other jurisdictional regulatory boards.

The NABP Electronic Licensure Transfer Program® provides boards of pharmacy with a venue to submit and access licensure and disciplinary actions when determining eligibility for licensure through the endorsement process. At times, discipline in one state may (or should) constitute grounds for discipline in another. Pharmacy boards must be aware of the impact of discipline in one jurisdiction on the licensure status within their own states. Some regulatory boards exhibit sympathy to the practitioner and manipulate what constitutes “discipline” for purposes of fashioning a sanction, which attempts to avoid reporting to the Healthcare Integrity and Protection Data Bank (HIPDB) or prohibits availability to the public. Such creative sanctions not only defeat the essential public protection mission of all regulatory boards, but may affect the legal arguments of other jurisdictions seeking to protect the public through reciprocal discipline proceedings. Consider the following.

In 1976, a practitioner was granted a registered nurse license in the state of Florida. In 2003, such licensed nurse was the subject of a complaint filed by the Department of Health alleging that she had been dismissed from a graduate nursing program in Florida, in part because she had failed a clinical course. In addition, the complaint alleged that she falsely represented herself to a practicing physician as a current enrollee in the graduate program in order to obtain his agreement to act as her preceptor for the clinical course she had failed and that while under his supervision she saw patients, prescribed treatment plans and medication, and disclosed to third parties confidential medical information.

The Florida matter proceeded to an administrative hearing and the nurse participated in the proceedings. The administrative law judge concluded that the nurse had violated multiple rules of professional conduct regarding her educational misrepresentations, practiced as an unlicensed advanced registered nurse practitioner, and violated rules governing patient confidentiality. The Florida Board of Nursing adopted the administrative law judge recommendations of a professional reprimand and probation, along with a $1,000 fine. In lieu of those penalties, the nurse offered
to voluntarily relinquish her license permanently. After emphasizing that the surrender of her license would be considered “discipline,” the Florida Board issued a final order acknowledging the relinquishment and that such order was considered discipline. The licensee did not challenge the Florida Board order.

Meanwhile, the nurse was also licensed in 1987 as a registered nurse in Massachusetts. In 2005, and based upon the Florida order, the Massachusetts Board of Registration in Nursing (Massachusetts Nursing Board) issued an order to show cause, providing the nurse with an opportunity to state why her Massachusetts license should not be subject to discipline based upon the Florida action. After multiple procedural appeals involving indefinite suspensions, the Massachusetts Nursing Board suspended the nurse license for a period of five years with two years credit since the time of the original suspension. It found that the facts underlying the Florida proceedings constituted violations of multiple portions of the Massachusetts Nurse Practice Act. The nurse appealed the Massachusetts suspension.

On appeal, the nurse argued several issues. First, she argued that the final order of the Florida Board did not constitute discipline and therefore cannot form the basis of the Massachusetts action. To support this position, the nurse argued that the Florida decision had no findings of fact, that she did not understand that the voluntary relinquishment would be considered discipline, that she did not admit to any wrongdoing, and that she did not agree not to contest the allegations against her.

The court quickly determined that the first three arguments had no merit. It cited previous Massachusetts judicial opinions, which held that neither admissions of wrongdoing nor findings of fact are necessary to treat as discipline the resolution of charges by agreement in another jurisdiction. Furthermore and related to the fourth argument, the court held that the nurse’s agreement to permanently relinquish her Florida license effectively amounts to an agreement not to contest the allegation against her.

Next, the nurse pounded an estoppel argument based upon a Massachusetts Nursing Board letter previously provided to the nurse. The letter stated that “while allegations were pending in Florida, that it would not, based upon the then-unresolved allegations in Florida, open its own proceedings against her Massachusetts nursing license.” The nurse argued that such a letter precluded the Massachusetts Nursing Board from now initiating action against her Massachusetts license. The court rejected this argument citing the fact that the letter was not an “adjudication” in her favor regarding the Florida proceedings. Further, the Massachusetts letter predated the final order of the Florida Board. Therefore, the letter did not waive any rights of the Massachusetts Nursing Board to pursue action against the nurse.

Finally, the nurse argued that the Massachusetts Nursing Board action was arbitrary and capricious and that the sanction was excessive. The nurse argued that the Massachusetts decision was based upon facts not in the record, namely that the Florida action was considered discipline, when in fact she was not aware of such a conclusion. But, the court noted that the administrative record in the Massachusetts matter contained evidence, including testimony, that the nurse had indicated her understanding and acceptance (continued on page 74)
Association News

Are You AWARxE?
Proper Disposal of Unused Medications Helps Prevent Misuse and Abuse

Three in five teens say prescription pain relievers are easy to get from a parent’s medicine cabinet, and more than 50% of people who abused prescription drugs in 2008 and 2009 got them from friends or family for free.

Share the news to raise AWARxEness among colleagues, friends, and family.

- The next Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day will take place Saturday, April 30, 2011. More information is available at www.AWARERx.ORG.
- DEA drug take-back events, coordinated with local law enforcement agencies across the country, provide a safe means for the disposal of unwanted, unused prescription medications – including controlled substances – for authorized disposal. The DEA drug take-back site locator is available on the AWARxE Web site.
- The first National Prescription Drug Take-Back Day on Saturday, September 25, 2010, saw participation from 3,000 state and local law enforcement agencies and collected approximately 242,000 pounds of medications.

Additional facts and resources to help educate patients about prescription drug abuse trends, safe medication use, and medication disposal are available on the AWARxE Web site.

Boards of pharmacy that wish to place the AWARxE logo on their Web site, hyperlinked to www.AWARERx.ORG, may obtain information by sending an e-mail to AWARERx@nabp.net.

GET INFORMED | www.AWARERx.ORG

Legal Briefs
(continued from page 73)

of the relinquishment being treated as discipline.

While not emphasized in its opinion, the court did make note of the fact that the nurse had also been previously licensed by the Massachusetts Board of Medicine as a physician and that such physician license had been the subject of a suspension since 1987. Apparently, the suspension of the physician license by the Massachusetts Board of Medicine did not result in any action against the registered nurse license by the Massachusetts Nursing Board. The nurse also argued that the Massachusetts Nursing Board improperly considered as an aggravating factor the suspension of her Massachusetts medical license, in spite of the fact that the Massachusetts Nursing Board declined to take action against her nursing license based upon this medical license suspension. The court rejected this argument, finding that the Massachusetts Nursing Board had every right to consider the medical board licensure suspension as an aggravating factor in determining the nursing license sanction.

Finally, the court rejected the nurse’s argument that the sanction was excessive. In her arguments, the nurse referred to the indefinite suspension of her license as excessive. However, the court noted that the Massachusetts Nursing Board, upon remand of the matter, had issued a five-year suspension. The court found the suspension to be comparable and, thus, sustainable.

Under many circumstances, reciprocal discipline can be dependent upon the characterizations placed upon the proceedings and findings of the initial administrative disciplinary proceedings. Categorizing the board action as non-disciplinary, allowing consent agreements without admissions of wrongdoing, not reporting actions to the HIPDB or NABP data banks, along with many other factors may provide sanctioned licensees with legal fodder in any subsequent administrative proceedings, both intra and interstate. With what appears to be more licensees seeking representation by counsel, such requests may be on the increase. Boards of pharmacy should seek legal assistance in crafting final orders, whether based upon consent agreements or after contested hearings. Future boards and fellow NABP member boards depend upon it.

Lankheim v Board of Registration in Nursing, 2011 WL 6895 (Supreme Judicial Ct MA 2011) ☞
School of Pharmacy Study Finds Value in PCOA as Integral Component of Student and Curricular Assessment

Serving as a comprehensive assessment tool, the Pharmacy Curriculum Outcomes Assessment® (PCOA®) was recently cited in one school of pharmacy’s study as a valuable assessment tool. Conducted by the Palm Beach Atlantic University (PBAU), Lloyd L. Gregory School of Pharmacy, the study concluded that the PCOA provides a standardized national assessment that can be used as a benchmark for comparing the performance of students at various schools and colleges of pharmacy, as well as within programs as students progress through curricula. Additionally, the study encourages more participation by other schools and colleges of pharmacy as this could increase the value of the PCOA. Since its operational launch in 2008, the assessment has been administered to approximately 10,000 students across 40 schools and colleges of pharmacy.

Having participated in the PCOA since it was first offered, PBAU focused its research on student results garnered over a period of three years, comparing these results with national averages, percentiles, and student grade point averages (GPAs). According to the study, a strong correlation between GPA and PCOA scale score was observed for P3 students in 2008. Additionally, though not as strong, in 2009 and 2010 there remained a positive correlation of GPA to scale score, suggesting that pharmacy students with higher grades also performed better on the PCOA. The study also found a strong correlation between a pharmacy student’s year in the program and his or her PCOA scale score, indicating that scale scores increase as students advance in the curriculum.

The study points out the need for an objective assessment that aligns with Standard 15 of the Accreditation Council for Pharmacy Education (ACPE) 2006 revision of the Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, which calls for pharmacy programs to “incorporate periodic, psychometrically sound, comprehensive, knowledge-based and performance-based formative and summative assessments . . . that allow comparisons and benchmarks with all accredited and peer institutions.” The PCOA offers a viable standardized national assessment for evaluating pharmacy student performance to meet criteria set forth in Standard 15. PBAU suggests that additional participation from United States schools and colleges of pharmacy could increase the value of potential outcomes and performance data when comparing student performance nationally across curriculums.

Developed and piloted in 2006, the PCOA was created as a response to the need expressed by US Department of Education, ACPE, and some US schools and colleges of pharmacy for a tool to assist with curriculum development and review. The most recent administration was held January 24 to February 4, 2011.

More detail on the PBAU study can be found in the December 2010 American Journal of Pharmaceutical Education article “Pharmacy Curriculum Outcomes Assessment for Individual Student Assessment and Curricular Evaluation.” Additional information regarding the PCOA is available at www.nabp.net/programs/assessment/pcoa.

Newly Accredited VAWD Facilities

The following facilities were accredited through the NABP Verified-Accredited Wholesale Distributors™ (VAWD™) program:

AmerisourceBergen Drug Corporation
Bethlehem, PA

Axia Medical Solutions, LLC
Carlsbad, CA

Cardinal Health 110, Inc dba Cardinal Health
Swedesboro, NJ

Frank W. Kerr Company
Novi, MI

Cardinal Health 200, LLC dba Cardinal Health
Olive Branch, MS

Cardinal Health
Swedesboro, NJ

Fresenius USA Manufacturing, Inc dba Fresenius Medical Care North America
Shasta Lake, CA

Hospira Worldwide, Inc dba Aspen Distribution, Inc
Denver, CO

Ino Therapeutics, LLC
Fremont, CA

Kuehne + Nagel, Inc
Cranbury, NJ

Lewisville, TX

Whittier, CA

Merz Aesthetics, Inc
Franksville, WI

A full listing of more than 450 accredited VAWD facilities is available on the NABP Web site at www.nabp.net.
Conscience Clause Controversy on Back Burner, but Still Simmering

While public controversy over “conscience clauses” for health care providers, particularly pharmacists, has been muted in recent years, especially when compared to the furor that took place around 2005 and 2006, the issue has not disappeared. While technically a concern could arise over any drug a pharmacist feels he or she cannot dispense without violating a strongly held moral or ethical belief, the “right to refuse” (without disciplinary consequence) versus “must fill” controversy has centered primarily around medications related to reproduction, particularly contraception.

Reproductive rights activists remain concerned about patients’ ability to easily access needed medications (including emergency contraception), while right-to-life proponents worry that pharmacists could be punished for adhering to their moral beliefs. And every so often, controversy erupts into the headlines.

Recent Controversies

One recent eruption occurred in Idaho, when a pharmacist declined to fill a prescription called in by a Planned Parenthood nurse practitioner for Methergine® (methylergonovine maleate), a drug generally used, as its label states, “for the prevention and control of postpartum hemorrhage.” According to Planned Parenthood of the Great Northwest (PPGNW), the pharmacist asked if the drug was needed for post-abortion care; when the practitioner said she could not disclose that information for reasons of health information confidentiality, the pharmacist said she would not fill the prescription. The pharmacist hung up when requested for a referral to another pharmacy. PPGNW filed complaints with Walgreens (the pharmacist’s employer) and the Idaho State Board of Pharmacy.

Further controversy arose in January 2011, when the Board’s investigation into the incident found no violation “of state laws the board is tasked with enforcing.” Refusing to fill the prescription did not violate the Idaho Pharmacy Act, the Board found. Moreover, the Idaho legislature passed a law in 2010 granting health care providers, including pharmacists, the right to refuse to provide services or dispense medications that violate their conscience.

The Washington State Board of Pharmacy found itself in the news in late 2010, when it voted, in essence, to maintain a rule that prohibits pharmacies from refusing to dispense all legal drugs, including emergency contraception. A few months before, the Board had begun a rulemaking process to see “whether additional rules would improve and better assure patients have access to medications,” according to a Washington State Department of Health press release. The December decision, following topical research and review of thousands of public comments, stopped the rulemaking process, concluding that existing rules “adequately remove any barriers” to patients’ access to time-sensitive medications.

The Washington Board originally adopted the recently upheld rules on pharmacist and pharmacy responsibility in 2007. The rules require pharmacies to ensure that “all valid prescriptions in stock are delivered when needed for effective use.” Pharmacists may refuse to dispense medications, provided
the pharmacy has in place policies and procedures “to provide timely access to medications”; these policies and procedures do not include referral to another pharmacy to avoid filling a prescription due to moral or ethical considerations. The rules had been challenged in a lawsuit that had been on hold during the rulemaking process.

Rights of Conscience, Nationwide

Despite various proposals discussed each year in state legislatures, not every state has laws that specifically address the legality of pharmacists or pharmacies refusing to dispense or carry a particular medication—but several do. According to the Guttmacher Institute, pharmacists in Arkansas, Georgia, Idaho, Mississippi, and South Dakota have the right to refuse to fill a prescription if doing so violates their firmly held moral beliefs. Similar legislation was passed in Arizona, but at press time was not in effect, pending the outcome of litigation challenging the law. Other states have broadly worded refusal clauses that might protect pharmacists or pharmacies, granting them the right to refuse to fill a prescription if doing so violates their firmly held moral beliefs. Similar legislation was passed in Arizona, but at press time was not in effect, pending the outcome of litigation challenging the law. Other states have broadly worded refusal clauses that might protect pharmacists or pharmacies, granting them the right to refuse to fill: Colorado, Florida, Maine, and Tennessee.

In California, a pharmacist may refuse to fill a prescription, provided his or her employer approves the refusal and the patient can still access the medication in a timely manner. Similarly, a number of states require pharmacists either to provide a referral if the pharmacist is unwilling to fill a prescription for reasons of conscience, or not to obstruct the patient’s access to his or her prescription; many simultaneously require pharmacies to accommodate a pharmacist’s conscience while ensuring delivery of services to the patient. According to the National Women’s Law Center (NWLC), these states include Alabama, Delaware, New York, North Carolina, Oregon, Pennsylvania, and Texas.

As this implies, states grant less leeway to pharmacies than to the individual pharmacists who work in them. According to the Guttmacher Institute, Wisconsin requires pharmacies to fill valid contraceptive prescriptions; Illinois and Washington require pharmacies to deliver FDA-approved drugs, specifically including emergency contraception. In the latter two states, along with Maine, Massachusetts, Nevada, and New Jersey, pharmacies must dispense valid prescriptions, according to the NWLC. In Mississippi, on the other hand, both pharmacists and pharmacies have a clear, legal right to refuse to dispense valid prescriptions because of reasons of conscience.

Some boards of pharmacy have adopted policies or guidance regarding conscience-related refusals to fill, in the absence of specific language in the laws or regulations. The North Carolina Board of Pharmacy, for example, encourages pharmacists to “discuss and resolve any questions about emergency contraception prior to employment... The Board notes that although pharmacists have a right to avoid moral or ethical conflict, they do not have a right to obstruct otherwise legitimate prescription dispensing or delivery solely on the basis of conscientious objection... If a pharmacist refuses to fill a prescription for emergency contraception then that pharmacist has an obligation to get the patient and the prescription to a pharmacist who will dispense that prescription in a timely manner.”

Survey Says...

On request from the Washington Board, NABP last September conducted a short survey of the state boards of pharmacy on issues related to refusal to fill and unprofessional conduct. Sixteen states responded.

Almost all respondents stated that their state did not require pharmacies to give patients a timely alternative when a prescribed drug was not available, although one respondent noted that (continued on page 82)
Biosimilars
(continued from page 70)

process does not require additional clinical trials on humans. (See “FDA’s ANDA Review Process Designed to Ensure Safety and Efficacy of New Generic Medications,” NABP Newsletter, June-July 2008.)

Biosimilars, on the other hand, typically are derived from living organisms. FDA defines them broadly: “Biological products include a wide range of products such as vaccines, blood and blood components, allergens, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologicals can be composed of sugars, proteins, or nucleic acids or complexes of these substances, or may be living entities such as cells and tissues.” Biologics can pose unique challenges. They work by causing an immunologic reaction in the patient; different physiologic responses may be seen, particularly among certain patient populations, and immunogenicity (stimulation of antibody production in patients, sometimes with the danger of neutralizing the medication and the body’s own protein) can be an issue.

As the Biotechnology Industry Organization (Bio) describes it, biologics are “made by genetically engineering living cells to become miniature factories producing the desired molecules (proteins).” The greater variability inherent to living cells means that small changes in process (including temperature changes or materials (a particular cell line, for example) can produce very different results. “[I]t is important to emphasize that minor differences in primary amino acid sequences can cause significant alterations in protein molecule’s secondary and tertiary structures, resulting in a biosimilar protein with vastly different effects,” said Gregory Schimizzi, a practicing rheumatologist representing the Coalition of State Rheumatology Organizations (CSRO), at FDA’s November public hearing.

According to Bio, current technology does not yet allow a determination of equivalency in the laboratory. “[T]he complexity of biologics currently makes it impossible to show in the laboratory that a follow-on biological product will work the same as another in patients,” states Bio. And while a number of biosimilars have been approved in the European Union since 2006, the United States has hitherto lacked a legal framework to approve such products.

Areas of Contention

Margaret A. Hamburg, MD, Commissioner of Food and Drugs, stated at the Generic Pharmaceutical Association Annual Meeting, February 18, 2011, that as FDA works “to set the scientific parameters of determining just how similar is similar enough when it comes to complex biologic products . . . we want to rely on what is known to the greatest degree possible, and avoid any unnecessary animal or human testing.” Hamburg noted that while there will be many questions initially, science will serve as the guide.

At the same time, due to the difficulties in analyzing a biosimilar’s equivalence to its reference product—as well as the potential differences in therapeutic responses to a particular biologic—some patient advocates (and current manufacturers of biologics) are emphasizing to FDA the importance of proving a biosimilar’s safety and efficacy through clinical trials, as well as vigorous post-marketing monitoring. “There simply is no substitute for testing these products given their degree of complexity and their effects,” said Schimizzi.

While all stakeholders presenting views to FDA public meeting emphasized safety, opinions differed on the need for mandated clinical trials for all biosimilars. One argument against universal clinical trials is that biosimilars would lose much of their cost advantage (and cost-dampening effect) if FDA required clinical trials for all applications. Some stakeholders, including companies that manufacture generics, promote a more case-bycase approach, suggesting that with proper scientific justification and a thorough understanding of a biologic’s mechanism of action, some safety and efficacy data could be extrapolated.

Biosimilars or Interchangeable Biologics?

The BPCI Act specifies two possibilities for FDA approval of follow-on biologics: biosimilars and interchangeable biologic products. The latter presents a much higher hurdle to clear: FDA would have to conclude that the interchangeable product “can be expected to produce the same clinical result as the reference product in any given patient” and that “the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.”

Again, some experts doubt the current feasibility of interchangeability. The CSRO’s Schimizzi told FDA’s November panel, “Practicing rheumatologists believe that there is no sufficient scientific understanding of potential biosimilars to allow for an interchangeability of biologic products at this time.” Other experts pointed out features of biologics that could hamper interchangeability trials. For small-molecule drugs, noted Laszlo Endrenyi, PhD, professor emeritus at the University of Toronto, switchability and interchangeability are generally determined through cross-over studies, in which each drug product is administered to each subject so that each subject receives more
than one form of the drug, and preferably all forms being tested. Biologics often have a long half-life, however, he pointed out, rendering crossover trials potentially ineffectual. And even for those biologics without long half-lives, he noted, other factors intrinsic to biologics, including unpredictable sensitivity in patients and potential deviations, would indicate exercising caution in seeking switchability or interchangeability.

The issue of how to name biosimilars forms another area of disagreement that could ultimately affect cost. Should the non-proprietary drug name for the biosimilar be the same as the reference drug’s? The same (or very similar) name could cause confusion for patients and prescribers, some fear, risking medication error; proponents, on the other hand, argue that it would reduce confusion for patients. Moreover, different non-proprietary names would require more marketing on the part of biosimilars makers, again reducing cost savings. Current biologics makers favor different names; prospective biosimilars makers lean the other way.

**Patent Exclusivity**

While the BPCI Act leaves most of the scientific discretion and judgment of an appropriate biosimilars approval pathway up to FDA, it goes into greater detail as it spells out market exclusivity periods and the processes to address patent disputes between a biosimilar maker and its reference product manufacturer. Indeed, though the BPCI Act formed one of the less controversial sections of the overall health care bill, one of its most contentious aspects is its specifications for market exclusivity. The act grants reference biologics makers 12 years of marketing exclusivity; that is, FDA cannot approve a biosimilar application using the reference product’s data until 12 years after the reference product was first licensed (under the Hatch-Waxman Act that deals with non-biologic generic drug approval, exclusivity is five years), and FDA cannot accept an application for a biosimilar within four years of a reference product’s initial license. The act also specifies a 12 to 14 month exclusivity period for the first interchangeable follow-on biologic for a given reference product, depending on the date it is first marketed or the date it is licensed by FDA and whether it is the subject of patent litigation.

The BPCI Act does not establish a timeline for FDA to develop its biosimilars approval pathway, but Hamburg noted in her February speech that “It is among our highest priorities at FDA to move forward on this as quickly and effectively as possible.” A detailed analysis of the BPCI Act that appeared last year in *Pharmaceutical Law & Industry Report*, stressed that legal battles are anticipated, including potential challenges to FDA regulations and decisions. The authors also noted that Congress will likely face pressure to amend the law. It also is expected that, sooner or later, regulatory questions regarding biosimilars will bring themselves to the attention of the state boards of pharmacy, which typically oversee laws and rules concerning drug product selection and therapeutic substitution of medications.

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**Past Studies Determined Similares Are Not Generics**

Past NABP efforts to help ensure that drug products entering the US supply chain are safe and effective explored issues with *similares*. Specifically, to help in the fight against counterfeit drugs threatening to enter the US supply chain, NABP partnered with Food and Drug Administration (FDA) and Eli Lilly in 2004 to examine the problem of *similares*, drugs touted as generics or biosimilars that were available in several countries, and predominantly in Latin America. FDA and manufacturer analysis of so-called *similares* obtained by NABP revealed that the drugs were not the equivalent of their brand name counterparts. (See “State, Federal Legislation Seeks to Protect Patients from Counterfeit Drugs; NABP Aids Officials in Fight,” *NABP Newsletter*, August 2005.)

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**Newly Approved e-Advertisers**

The following entities were accredited through the NABP e-Advertiser Approval Program:

- **Double S Pharmacy, Inc dba Choice Compounding Pharmacy**
  - www.choicecompoundingpharmacy.com
- **Jones Pharmacy Enterprises, Inc dba Giant Genie Pharmacy**
  - www.giantgenie.com
- **OC Pharmacy**
  - www.ocpharmacy.net
- **Target Corporation dba Target Pharmacy**
  - www.target.com/pharmacy

A full listing of NABP approved e-Advertisers is available on the NABP Web site at www.nabp.net.
Meeting Program

May 21-24, 2011
San Antonio Marriott Rivercenter
San Antonio, TX

Saturday, May 21, 2011

9 AM - 7 PM
Registration/Information Desk Open

2 - 4 PM
Pre-Meeting CPE

International Pharmacy Practice - Bridging the Globe
Sponsored by Medco Health Solutions, Inc
ACPE #205-000-11-001-L03-P
(0.2 CEUs – 2 contact hours)

5 - 6 PM
Annual Meeting and District Meeting Orientation

7 - 10 PM
President’s Welcome Reception
Sponsored by Medco Health Solutions, Inc
Honoring NABP President William T. Winsley and his wife Betsy
Dinner will be served
Dress: business casual

Sunday, May 22, 2011

6:30 AM - 5:15 PM
Registration/Information Desk Open

7:30 - 8:30 AM
Fun Run/Walk
Sponsored by Celgene Corporation

8 - 11:30 AM
Hospitality Brunch
Sponsored by Omnicare, Inc

Educational Table Top Displays

8 - 11:30 AM
Joint CPE

Educational Poster Session - Strengthening Public Protection
ACPE #205-000-11-002-L04-P
(0.1 CEU – 1 contact hour)

Noon - 4 PM
First Business Session

Monday, May 23, 2011

7 AM - 2 PM
Registration/Information Desk Open

7 - 8:15 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention

8:15 - 10:15 AM
Joint CPE

DEA Update - What’s New at the Agency?
Sponsored by Walgreen Co
ACPE #205-000-11-004-L03-P
(0.2 CEUs – 2 contact hours)

10:30 AM - noon
Second Business Session

Noon - 12:30 PM
Informal Member/Candidate Discussion

1:30 - 5:15 PM
Optional Tour

History and Merriment: San Antonio Style
Reservation required

Tuesday, May 24, 2011

7:15 AM - 4:15 PM
Registration/Information Desk Open

7:45 - 8:45 AM
Continental Breakfast

8:45 - 10:15 AM
Executive Officer and Board Member CPE

Social Media - To Tweet or Not to Tweet?
Sponsored by CVS Caremark
ACPE #205-000-11-005-L03-P
(0.15 CEUs – 1.5 contact hours)

10:30 AM - noon
Joint CPE

Rogue Internet Pharmacies - Can Collaboration Break the Link?
ACPE #205-000-11-007-L05-P
(0.15 CEUs – 1.5 contact hours)

Noon - 1:30 PM
Lunch Break
(On your own)

1:30 - 4 PM
Final Business Session

5:45 - 6:45 PM
Awards Dinner Reception

7 - 11 PM
Annual Awards Dinner
Dress: semiformal

Note: Additional information on the continuing pharmacy education sessions is available at www.nabp.net/meetings. The 107th Annual Meeting schedule is subject to change.

NABP and the NABP Foundation is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). ACPE Provider Number: 205. Participants may earn ACPE-accredited CPE credit by completing a Statement of Continuing Pharmacy Education Participation online and submitting it to NABP. Full attendance and completion of the program evaluation for each session are required to receive CPE credit and a Statement of Continuing Pharmacy Education Credit.

Continuing Legal Education (CLE) Policy: NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending CPE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.
NABP 107th Annual Meeting Offers Participants Opportunity to Earn Nine Hours of Continuing Pharmacy Education Credit

The NABP 107th Annual Meeting, “Boards of Pharmacy and NABP: Bridging to Unity and Strength” to be held May 21-24, 2011, at the San Antonio Marriott Rivercenter in San Antonio, TX, offers attendees the chance to earn up to 9 contact hours (0.9 continuing education units) of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education (CPE) credit. The CPE is designed to address current and important issues affecting the regulation of pharmacy practice. All Annual Meeting participants will have the opportunity to attend four joint CPE sessions as well as one of two concurrent sessions: one geared for state board of pharmacy executive officers and members and the other for compliance staff. In addition, there will be one pre-meeting CPE session.

Saturday, May 21

Pre-Meeting CPE
International Pharmacy Practice – Bridging the Globe

This special pre-meeting session will focus on international pharmacy practice and how other countries regulate the practice of pharmacy. Attendees will learn how various countries allow for use of technology, therapeutic management, pharmacist intervention, and prescriptive authority. Presenters from around the world will provide their countries’ regulatory schemes, practice standards, and model rules with an emphasis on new practices regarding medication therapy management, collaborative practice, and pharmacy ownership. Attendees can earn 2 contact hours (0.2 CEUs) of CPE credit. This session is sponsored by Medco Health Solutions, Inc.

Sunday, May 22

Joint CPE
Educational Poster Session – Strengthening Public Protection

Boards of pharmacy and schools and colleges of pharmacy representatives will present various poster displays as they relate to strengthening public protection during this educational poster session. Attendees can earn 1 contact hour (0.1 CEU) of CPE credit though interactive participation with presenters for one hour during the three and one-half hour offering.

Joint CPE
Legal and Government Affairs Update – San Antonio Confidential

During this session, NABP Legal Affairs representatives will provide participants with the current laws regarding the protection of confidential information that might be required or accessed by boards of pharmacy and what information can be required in order to validate identities. In addition, information on the limits and protections of the Americans with Disabilities Act in regard to examinations and test site accommodations as well as states’ efforts to develop and operate prescriptive monitoring programs will also be presented. Participants will earn 1 contact hour (0.1 CEUs) of CPE credit. This session is sponsored by Walgreen Co.

Monday, May 23

Joint CPE
DEA Update – What’s New at the Agency?

This joint CPE session, presented by a Drug Enforcement Administration representative, will provide an overview of current issues such as e-prescribing for controlled substances, agency relationships, and new regulations pursuant to the Secure and Responsible Drug Disposal Act. Participants will earn 2 contact hours (0.2 CEUs) of CPE credit. This session is also sponsored by Walgreen Co.

Tuesday, May 24

Executive Officer and Board Member CPE
Social Media – To Tweet or Not to Tweet?

During this session, a regulatory expert will provide attendees with information regarding today’s social media technology, including Facebook and Twitter. Attendees will learn what the state boards of pharmacy can learn, share, and obtain from using these social media networks, the legal implications involved, and how to deal with these changing audiences and resources.

Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit. This session is sponsored by CVS Caremark.

Compliance Officer CPE
FDA Update – A Guide for APIs and INDs

During this session, Food and Drug Administration representatives will provide compliance officers with information on how to deal with active pharmaceutical ingredients (API) and investigative new drugs (IND) while conducting compounding pharmacy inspections. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Joint CPE
Rogue Internet Pharmacies – Can Collaboration Break the Link?

The world of rogue Internet drug outlets continues to rise and be a threat to the well-being of public health. Statistics show that abuse of prescription medication has become an epidemic, particularly due to the ease with which drugs can be obtained over the Internet. Patients are also exposed to dangerous counterfeit and unapproved medications. During this joint CPE session, attendees will learn what NABP, government, and the industry are doing to combat this danger and advance patient safety. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Additional information about the 107th Annual Meeting is available on the Meetings section of NABP’s Web site, www.nabp.net/meetings.
NABP Continues to Accept Travel Grant Applications for the 107th Annual Meeting in San Antonio, TX

NABP is still accepting travel grant applications from qualified voting delegates to attend the 107th Annual Meeting held May 21-24, 2011, at the San Antonio Marriott Rivercenter in San Antonio, TX. The travel grant assists boards in sending voting delegates to the Annual Meeting so they may participate in important business sessions where they discuss and vote upon resolutions and amendments to the NABP Constitution and Bylaws and elect NABP Executive Committee members and officers. In addition, they can attend educational sessions regarding current issues facing pharmacy regulators.

Qualified voting delegates can receive up to $1,500 in grant monies that may be used to lessen the costs for travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. The travel grant does not include Annual Meeting registration fees.

Travel grant applications may be obtained from NABP upon the direct requests of executive officers of the state boards of pharmacy. Applications can be submitted by mail to Dana Oberman, executive meeting planner supervising coordinator, at NABP Headquarters or via fax at 847/391-4502. NABP requests that applications be submitted prior to the Annual Meeting. All applicants will be informed of whether or not they have qualified for the travel grant.

For more information on the Annual Meeting travel grant, contact the NABP Executive Office at exec-office@nabp.net.

Conscience Clause

(continued from page 77)

failure to do so “could, however, be a basis for discipline as negligence in the practice of pharmacy.” A similar member indicated that their state allowed a pharmacy to refer a patient to another pharmacy to avoid filling a prescription due to moral or ethical objections; two of the responding states had dealt with a challenge to their rules on the subject.

Most of respondents answered “yes” when asked if their state provided grounds for discipline when a pharmacy engages in or permits unprofessional conduct; the same held true for unprofessional conduct on the part of pharmacists, pharmacy interns, or other pharmacy personnel. In comments, however, respondents indicated that, while some states’ laws and rules outline unprofessional conduct specifically, others leave the term more generally defined. Moreover, refusal to fill a prescription did not necessarily appear even in specified lists of unprofessional activities. Three-quarters of responding states said their state did not prohibit a pharmacist from delegating to pharmacy support staff the decision to not dispense a lawfully prescribed drug or device.

As the survey results show, boards of pharmacy have to address issues of conscience differently depending on the laws and rules in their states. And while conscience clause controversies have not become a major issue for every board of pharmacy, they will continue to crop up, as demonstrated by the flare-ups in Idaho and Washington. The difficulty of ensuring adequate patient access to care while respecting the rights of practitioners almost guarantees continued board involvement in this contentious issue.
Launch of CPE Monitor to Streamline Reporting of Continuing Pharmacy Education Activity, Saving Boards Time and Resources

The new NABP CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers, will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. In addition, the service will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011.

When pharmacists and technicians complete an ACPE-accredited CPE activity, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists’ or technicians’ CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal or for random audits. This process eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers. Further, this new service’s central repository of CPE information may also reduce the need for boards to conduct state-based audits of their licensees.

All information will be maintained in a highly secure environment. NABP will not distribute any personal information for commercial purposes without consent.

**Identification Numbers Should be Obtained Now**

As of March 10, 2011, pharmacists and pharmacy technicians may visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) or the NABP Web site, [www.nabp.net](http://www.nabp.net), to create an NABP e-Profile and obtain their permanent identification number. The Pharmacists section on the NABP Web site, and a new section for pharmacy technicians, provide detailed information on the use of CPE Monitor, and instructions for obtaining the NABP e-Profile ID.

In the latter part of 2011, the NABP e-Profile ID plus birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider. Registrants will then be known in the ACPE provider’s system by two additional identifiers: their month and day of birth (MMDD) and NABP e-Profile ID. Please note that CPE Monitor does not currently track CPE from providers not accredited by ACPE. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit proof of credit from CPE providers not accredited by ACPE directly to their board of pharmacy when required to do so.

**Communicating to CPE Participants**

Both ACPE and NABP, coordinating with other stakeholders, have developed communications to inform pharmacists and technicians about this new process for verifying ACPE-accredited CPE credit.

ACPE is partnering with CPE providers to alert CPE participants about the new system and the need to obtain an NABP e-Profile ID. Specifically, ACPE is providing messaging that can be integrated into CPE registration and/or course materials to help educate pharmacists and technicians about CPE Monitor. Further, ACPE will continue to support CPE providers through Webinars presenting the CPE Monitor service.

**CPE Monitor at APhA**

NABP helped to educate pharmacists on the new resource at the American Pharmacists Association (APhA) Annual Meeting and Exposition, March 25-28, 2011, in Seattle, WA. NABP staff provided information and answered questions about the CPE Monitor service, and informed participants how to obtain their NABP e-Profile ID.

To encourage pharmacists to participate, those who stopped by the NABP booth had the opportunity to enter a drawing for the chance to win an Apple iPad® valued at $499, along with one of six $50 American Express gift cards.

**Benefits for Pharmacists and Technicians**

The system will benefit pharmacists and pharmacy technicians by streamlining the process of tracking and reporting CPE units to state boards of pharmacy. This new process will be particularly beneficial to pharmacists who are licensed in multiple states, which often have different CPE requirements. Beginning in the latter part of this year, the NABP e-Profile will be available for viewing a comprehensive list of the CPE activities completed 24/7.

NABP will continue to keep boards of pharmacy informed about the CPE Monitor service.
2011-2012 NAPLEX Review Committee Members Announced

NABP is pleased to introduce two new members and commend the 23 returning members of the 2011-2012 North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee.

Composed of faculty and pharmacists who are representative of the diversity of pharmacy practice, the NAPLEX Review Committee is responsible for reviewing the examination questions, attending and participating in meetings, and writing new test questions. These dedicated volunteers, acting under the policy and planning guidance of the Advisory Committee on Examinations and the NABP Executive Committee, share the task of safeguarding the integrity and validity of the Association's examination. NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements, which, in essence, determine the question pool. The NAPLEX Review Committee members began their terms on February 1, 2011.

NAPLEX Review Committee Members
- Marie A. Abate, West Virginia University
- Loyd V. Allen, Jr, Edmond, OK
- Jennifer Beall, Samford University
- Christopher Betz, Sullivan University*
- Michael Cockerham, University of Louisiana at Monroe
- Mark Decerbo, University of Southern Nevada*
- Betty Dong, University of California, San Francisco
- Darla Gallo, Philadelphia, PA
- W. Franklin Gilmore, University of Montana
- Robert P. Henderson, Samford University
- William A. Hopkins, Jr, Big Canoe, GA
- Tom M. Houchens, London, KY
- Arthur I. Jacknowitz, West Virginia University
- William Kehoe, University of the Pacific
- Susan C. Lutz, Altoona, IA
- David W. Newton, Shenandoah University
- Stephen M. Ouellette, Oakland, ME
- Roy Parish, University of Louisiana at Monroe
- David B. Roll, Granbury, TX
- Theresa Salazar, Indianapolis, IN
- Eric F. Schneider, University of Arkansas for Medical Sciences
- Cindy Sieck, Vancouver, WA
- John L. Szarek, Commonwealth Medical College
- Neal F. Walker, Hibbing, MN
- Siu-Fun Wong, Loma Linda University

*Denotes new committee members

NABP Newsletter Celebrates 75 Years of Informing Members

NABP is pleased to announce this year as the 75th anniversary of the NABP Newsletter. With the purpose of promoting a closer relationship among the boards of pharmacy, the Newsletter was initially launched in October 1935 as a confidential, 20-page typewritten manuscript to be published as news warranted it. Known then as the NABP Bulletin, it was described by NABP President Mac Childs at the NABP 32nd Annual Meeting as one of the Association's most important accomplishments of the year.

As boards indicated a need for ready access to pharmacy news, plans for a more frequent publication developed and NABP transformed the Bulletin into the NABP Quarterly in 1967. The NABP Quarterly was regularly published four times a year and provided the state boards of pharmacy with state and national levels of information.

Expanding the Newsletter both textually and visually, in 1972 the NABP Quarterly eventually became what is now known as the NABP Newsletter. As a monthly publication, the NABP Newsletter aimed at keeping the member boards of pharmacy informed and up to date on the practice of pharmacy, often including items on regulatory matters and NABP programs and services.

To maintain a fresh look as the practice of pharmacy continued to evolve, the NABP Newsletter was redesigned as a two-color publication in 1996, containing special features such as Legal Briefs, State Board News, and Around the Association. The Newsletter was again updated in 2004 with a more contemporary look to coincide with the Association's 100th Anniversary. In addition, to keep up with technological advancements, in 2000 NABP began archiving all electronic back issues of the NABP Newsletter on its Web site, www.nabp.net.

Ultimately serving the same purpose it did when initially established 75 years ago, the NABP Newsletter continues to uphold its focus as an important resource for the member boards of pharmacy. To ensure that the Newsletter maintains this mission, NABP recently gathered feedback from its members through a Newsletter readership survey. The Association values the input provided and is currently in the process of reviewing all suggestions and incorporating any possible updates to the Newsletter.
Newly Accredited VIPPS Facilities

The following Internet pharmacies were accredited through the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) program:

- Care Services, Inc dba Diabetic Care Services & Pharmacy
  Eastlake, OH
  www.diabeticcareservices.com

- ESI Mail Pharmacy Service, Inc dba Express Scripts
  St Louis, MO
  www.express-scripts.com

- Humana Pharmacy, Inc dba RightSource
  Louisville, KY
  www.rightsourcerx.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies is available on the NABP Web site at www.nabp.net.®

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Advisory Committee on Examinations Convenes, Three Ex Officio Members Recognized for their Dedication and Contributions

On March 3, 2011, the Advisory Committee on Examinations met at NABP Headquarters to oversee the development and administration of the Association’s examination and certification programs. **Pictured above, from left to right:** David Todd Bess, PharmD, assistant dean for Middle Tennessee and director, Clinical Education Center, University of Tennessee Health Science Center College of Pharmacy; Michael Duteau, RPh, member, New York State Board of Pharmacy; Joseph L. “Joe” Adams, RPh, NABP Executive Committee liaison; Carl W. Aron, RPh, member, Louisiana Board of Pharmacy; Betty Dong, PharmD, professor of clinical pharmacy, University of California, San Francisco; Arthur I. Jacknowitz, MS, PharmD, professor and distinguished chair, West Virginia University School of Pharmacy; Kevin Rynn, PharmD, FCCP, DABAT, associate dean for clinical affairs, Rosalind Franklin University of Medicine and Science, College of Pharmacy; and Richard “Dick” Morrison, RPh, pharmacy investigator, Office of Investigations and Inspections, Washington State Department of Health. **Pictured at right, from left to right:** Rynn, Dong, and Morrison received awards for their dedication and contributions as ex officio members of the Advisory Committee on Examinations.®
FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at www.fda.gov/Drugs/DrugSafety/ucm239821.htm.

FDA Alert Regarding Liver Injury Associated with Dronedarone

FDA alerts health care providers about cases of rare, but severe liver injury, associated with dronedarone (Multaq®), a drug used to treat abnormal heart rhythm in patients who have had an abnormal heart rhythm (atrial fibrillation or atrial flutter) in the past six months. Two patient cases resulted in acute liver failure leading to liver transplant. FDA reports that dronedarone was approved with a Risk Evaluation and Mitigation Strategy with a goal of preventing its use in patients with severe heart failure or who have recently been in the hospital for heart failure. Information about the potential risk of liver injury from dronedarone will now be added to the warnings and precautions and adverse reactions sections of the dronedarone labels. Detailed information for patients and health care providers is available in an FDA Drug Safety Communication at www.fda.gov/Drugs/DrugSafety/ucm240011.htm.

Surescripts Publishes Guidance for Electronic Prescriptions

Surescripts has released a guidance document that “attempts to set the measurement standard against which electronic prescriptions can be assessed for accuracy and completeness.” The document offers guidance to prescribers and their staffs, and e-prescribing and electronic medical record software vendors, and can serve as a resource for community pharmacists, their staffs, and their local prescribers. The document provides key principles and best practices for the writing of prescription orders – particularly, new electronic prescriptions – to help ensure that electronic prescriptions convey to the pharmacist and the patient the clinician’s therapeutic intent in an accurate, understandable, complete, unambiguous, and efficient manner. The document, “Guidelines for Creating High-Quality Electronic Prescriptions In The Ambulatory Healthcare Setting,” is available for download on the Surescripts Web site at www.surescripts.com/eprescribingquality/file.axd?file=2010%2f8%2fSurescripts+Quality+E-prescription+Guideline+s+V1+0b.pdf.

FDA Seeks Information on Stolen GSK Products

FDA, Office of Criminal Investigations (OCI) seeks information on the theft of GlaxoSmithKline (GSK) consumer health products stolen on January 9, 2011, while being transported from a GSK manufacturing facility in St. Louis, MO, to a GSK Regional Distribution Center. The products stolen included Os-Cal® Lemon D (120 count), Tums® Ultra Tropical Fruit, and other Tums® products. Specific products, lot numbers, and quantities stolen are listed in an FDA notice available at www.fda.gov/ICECI/CriminalInvestigations/ucm240206.htm.

FDA notes that the stolen product is finished product ready for retail sale and advises physicians, retailers, and consumers to check all products for signs of tampering or damage prior to use. FDA reminds retailers and consumers to purchase product only from trusted and reliable sources and to be aware that an unusually low price may be an indication that the product may have been stolen. GSK, along with FDA, Federal Bureau of Investigation, and local authorities, have initiated efforts to locate the stolen product and identify the individuals involved in the theft. Anyone who has information regarding this incident or has received suspicious or unsolicited offers for the product in question after January 9, 2011, the date of the theft, is encouraged to contact the FDA OCI by calling 1-800/551-3989 or by completing the Report Suspected Criminal Activity form on the OCI Web Site at www.accessdata.fda.gov/scripts/email/oc/fda/contact.cfm.
Alaska Board Proposes Regulation Project to Provide Medical Marijuana

The Alaska Board of Pharmacy has proposed a regulation project to provide a safe means of providing medical marijuana to Alaska residents. The Board states that this will require establishing a safe, clean source of marijuana grown within the state, creating quality control measures to scrutinize the product, providing medical marijuana in a pharmacy by prescription, and tracking the recipients.

The Board’s vision toward this goal would involve requiring medical marijuana growers to be licensed by the Board of Pharmacy, obtain a manufacturer’s license, obtain a wholesale drug license, provide security as set forth by state and federal law, and provide record keeping including quantities and weights as set forth by state and federal law. Alaska growers would also need to cooperate with Drug Enforcement Administration, and maintain quality assurance including lab testing of all lots. A grower’s operations will be at least partially owned by a licensed pharmacist and be overseen operationally by the same. The number of licensed facilities would be determined by region to minimize shipping distances. The growing facility would be expected to develop a commercial product including packaging properly labeled according to Food and Drug Administration regulations and product distribution to retail outlets. Retail outlets would be licensed pharmacies only.

Board members plan to introduce this project and the statutory changes deemed necessary to sympathetic legislators in anticipation of the legislative session.

Louisiana Seeks Pharmacists and Pharmacy Technicians to Join Disaster Team

The Louisiana Board of Pharmacy is encouraging pharmacists and pharmacy technicians to join the newly formed Louisiana 1 Disaster Medical Assistance Team (LA-1 DMAT), that is planned to also include physicians, nurses, physician assistants, nurse practitioners, and other medical providers. In particular, pharmacists with a hospital affiliation are desired.

Developed in 1981 by then President Ronald Reagan, the Emergency Mobilization Preparedness Board, which is now known as the National Disaster Medical System (NDMS), is composed of 75 local Disaster Medical Assistance Teams (DMATs); Louisiana is one of the most recent additions to the system. NDMS can be activated by a presidential declaration of a disaster, or by a request for major medical assistance from a state health officer. Once activated, DMATs (primarily funded by the United States Department of Health and Human Services) are deployed to stricken areas to establish acute care medical facilities. The team then receives, stabilizes, treats, and evacuates sick and injured patients to more definitive care facilities around the US.

For more information about the LA-1 DMAT, visit www.la1dmat.com.

New Oklahoma Regulation Blocks PSE Sales to Meth-Related Drug Offenders

The Oklahoma State Board of Pharmacy has implemented a new regulation stating that any person with a previous meth-related drug offense may not possess pseudoephedrine (PSE). The Board states that if a pharmacy sells PSE over the counter, then the customer’s name is automatically checked against the Meth Registry and the sale will be blocked if the individual has a meth-related drug offense. In addition, the pharmacy must manually check the Meth Registry on the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) Web site if the customer has a prescription for a medication containing PSE. The Board notes that all PSE-containing medications must be now classified as Schedule V prescriptions and be submitted to the prescription monitoring program (PMP) database. For more information regarding proper identifications, PMP submission, or the Meth Registry Act, contact the OBNDD at 405/521-3815.
Newly Accredited DMEPOS Facilities

The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

- ABC Drugs Inc
  Bronx, NY
- Carry Drug
  Jersey City, NJ
- Fusion Pharmacy Corp
  Brooklyn, NY
- Hillsborough River Pharmacy
  Tampa, FL
- McInnis House Clinic
  Pharmacy
  Boston, MA
- The Medicine Shoppe
  Pharmacy
  Milford, PA
- Montgomery City, MO
  Palm Springs, CA
  Yorkville, NY

A full listing of the nearly 1,000 accredited DMEPOS companies representing close to 30,000 facilities is available on the NABP Web site at www.nabp.net.