

INNOVATIONS



NABP Launches the



*Verified-Accredited
Device Integrity Program*

to Further Shield US Medical Supply Chain



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*NABP Executive
Committee elections
are held each year at the
Association's Annual
Meeting.*

Innovations

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NABP Mission Statement

NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

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113th Annual Meeting

Prominent Political Journalist to Offer Perspective on Health Care Regulation During Keynote Address

VIPPS-Accredited Pharmacies to Register, Use .Pharmacy Domain Names to Maintain Accreditation Status

To further assist consumers in finding safe online pharmacies and expand the secure pharmacy community, pharmacies accredited through NABP's Verified Internet Pharmacy Practice Sites® (VIPPS®) program will need to register and use a .pharmacy domain name through the .Pharmacy Top-Level Domain (TLD) Program. Beginning September 1, 2017, all VIPPS-accredited pharmacies must register and use a .pharmacy domain name in order to maintain their accreditation status.

NABP developed the VIPPS program in 1999 in response to concerns from regulatory agencies regarding the safety of internet pharmacy practices. For the last 17 years, VIPPS accreditation has been the gold standard for pharmacies with an internet presence in the United States. However, as online safety and security challenges continue to evolve, NABP recognizes that its internet programs, including VIPPS, must likewise evolve and progress to protect public health. NABP believes the .pharmacy verified TLD is the way to turn the tide against sophisticated criminals who can easily duplicate

verification logos on authentic-looking sites to trick unsuspecting consumers into thinking they are visiting a legitimate online pharmacy. With .pharmacy, the "seal of quality" is built into the web address.

“NABP believes the .pharmacy verified TLD is the way to turn the tide against sophisticated criminals who can easily duplicate verification logos on authentic-looking sites to trick unsuspecting consumers.”

All VIPPS-accredited sites are automatically eligible to register a domain name through the .Pharmacy TLD Program. In addition, VIPPS-



accredited pharmacies are exempt from the .Pharmacy application fee and are automatically approved to register .pharmacy domains for their accredited websites. However, the annual domain name registration fee charged by registrars still applies. Registration fees are approximately \$1,050 per year and vary by registrar.

NABP began the process of consolidating its Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®) and e-Advertiser Approval^{CM} programs into the .Pharmacy TLD Program in August 2016.

All the websites that NABP operates have transitioned to a .pharmacy domain, including:

- www.nabp.pharmacy
- www.awarerx.pharmacy
- www.safe.pharmacy
- www.nabplaw.pharmacy

The Association also transitioned to .pharmacy email addresses. ■



Newly Accredited VIPPS Facilities

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

**Commcare Pharmacy FTL, LLC,
dba Commcare Specialty Pharmacy**
www.commcarepharmacy.com

**Unicare Pharmacy, Inc,
dba MedicoRx Specialty Pharmacy**
www.medicorx.com

**Vitalab Pharmacy, Inc,
dba Vasco Rx Specialty Pharmacy**
www.vascorx.com

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

Prescription Points Prohibited



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

“Failure to adhere to duly enacted statutes or promulgated rules/regulations may subject the respondent to administrative or criminal sanctions.”

Boards of pharmacy are legislatively delegated with the authority to promulgate rules/regulations using the expertise of the board members to add specificity to the practice act. Such rules/regulations provide necessary details to the law and give the board an additional basis for enforcement in the interest of public protection. Because rules/regulations have the force of law, they are promulgated following specified administrative procedures that allow for notice, comment periods, and under some circumstances, public hearings. Failure to adhere to duly enacted statutes or promulgated rules/regulations may subject the respondent to administrative or criminal sanctions.

Professional standards and ethics are areas ripe for the specificity of rules/regulations to which pharmacies and pharmacists must comply. One such area of potential regulation may include incentive programs offered to patients regarding where their prescriptions are filled. Award programs, bonus points, and other offers intended to incentivize or induce patients to frequent pharmacies create interesting legal issues. Consider the following. (As this judicial ruling is from British Columbia, Canada, terms such as registrant (rather than licensee), college (rather than board), and bylaw (rather than rule/regulation) will be used throughout this article. In addition, Schedule III drugs in British Columbia are drugs that may be sold by a pharmacist to any person from the self-selection Professional Products Area of a licensed pharmacy.)

In 2013, the College of Pharmacists of British Columbia (College) promulgated bylaws that prohibit pharmacies from making “customer

incentive programs” to induce the purchase of pharmacy services, drugs, or devices from particular pharmacies or pharmacists. Specifically, incentive was defined as “money, gifts, discounts, rebates, refunds, customer loyalty schemes, coupons, goods or rewards.” The bylaws further stated:

- 15 (1) A registrant must not provide or distribute, or be a party to the provision or distribution of, an incentive to a patient or patient’s representative for the purpose of inducing the patient or patient’s representative to
 - (a) deliver a prescription to a particular registrant or pharmacy for dispensing of a drug or device specified in the prescription, or
 - (b) obtain any other pharmacy service from a particular registrant or pharmacy.
- (2) Subsection (1) does not prevent a registrant from
 - (a) providing free or discounted parking to patients or patient’s representatives,
 - (b) providing free or discounted delivery services to patients or patient’s representatives, or
 - (c) accepting payment for drug or device by a credit or debit card that is linked to an incentive.
- (3) Subsection (1) does not apply in respect of a Schedule III drug or an unscheduled drug, unless the drug has been prescribed by a practitioner.

Such bylaws were unanimously adopted by the College in September 2013 and forwarded to the minister of health under administrative procedures.

The minister may declare the bylaws or a portion thereof to be disallowed. Failure of the minister to timely address a submitted bylaw will result in its automatic adoption. The referenced bylaws were adopted based upon the failure of the minister to timely act.

Shortly after their adoption, the bylaws were challenged through a judicial filing initiated by the operators of Safeway and Thrifty Foods stores (collectively referred to as Petitioners). The Petitioners alleged that the purpose of the bylaw amendments was to prevent patients from choosing a pharmacy based upon price and to reduce or eliminate competition among pharmacies on the basis of price in violation of relevant Canadian competition laws. The Petitioners also argued that no research or data supported the prohibition from a patient care perspective and that evidence showed that customers want incentives for pharmacy services. In fact, they argued, research actually concludes that incentive programs improve pharmacist-patient relationships and encourage patient compliance with medication regimens. A motion by the Petitioners to impose an interim injunction prohibiting enforcement of the bylaws was denied by the lower court.

The lower court also rejected arguments of the College as illogical and “outside the range of possible acceptable outcomes.”

On the merits, the College argued that the bylaws were a necessary and reasonable means to protect consumers who are primarily made up of a vulnerable public and that inducements to obtain prescription drugs are detrimental. In addition, incentive programs promote an atmosphere focusing on the incentives, rather than on the necessity of the medication, and

may promote increased prescriptions based upon awards. The College also argued that incentive programs infringe on the counseling time on which patients rely and deserve.

The lower court held that there was no empirical evidence of harm and that the bylaws were more broad than necessary. As a result, it struck down the entire bylaws as unreasonable.

The College appealed the decision, arguing that the lower court erred on its interpretation and application of the reasonableness standard of review. In particular, the College argued that the lower court erroneously followed a standard whereby such court effectively required the introduction of empirical evidence of harm to the public as a basis for substantiating the reasonableness of the bylaws. The College argued that the standard actually allows for preventative approaches to regulating on behalf of the public.

After a lengthy review of the issue of what constitutes a record for review, the Court of Appeals turned its attention to the standard of review. The court agreed that the lower court erred by failing to consider the bylaws as a whole when determining the range of reasonableness as a legal basis for upholding the bylaws. The court recognized the necessary deference to the expertise of the College members when assessing duly promulgated bylaws. It asked whether the bylaws represented a reasonable response to the concerns of the College and the harm or threat of harm to be remedied. As noted by the court:

A bylaw is not unreasonable merely because particular judges might think that it goes further

than is prudent or necessary or convenient or because it is not accompanied by a qualification or an exception which some judges may think ought to be there.

Acting with a bona fide approach, the College determined that incentive programs created a public health concern and that there was some anecdotal evidence to support this notion. Further, at least one additional province had adopted such a prohibition. Taking into consideration the need for the preservation of standards across the province along with the important public protection mission, the court found that the bylaws did not fall outside the range of possible and acceptable outcomes. Thus, the substance of the bylaws did conform to the relevant standard and were able to withstand the Petitioners’ challenge. The Court of Appeals reversed the lower court and upheld the validity of the bylaws prohibiting pharmacy and pharmacist incentive programs.

Boards of pharmacy are delegated with the authority to promulgate rules/regulations/bylaws. Distinguishing between statutes, rules/regulations/bylaws and policies can be a difficult task. Boards are encouraged to seek legal advice when exercising their authority. The legal basis for upholding challenged bylaws may differ from jurisdiction to jurisdiction. In British Columbia, the standard will focus on a reasonableness test under the circumstances. The judiciary should defer to the expertise of the board when assessing the sustainability of such bylaws.

Sobeys West Inc v. College of Pharmacists of British Columbia, 2016 BCCA 41 (Court of Appeal for British Columbia 2016) ■

NABP Launches the Verified-Accredited Device Integrity Program to Further Shield US Medical Supply Chain, Protect Public Health



to take sensitive measurements of their blood sugar levels to monitor their insulin requirements. The burgeoning “gray market” of reselling test strips is placing at risk the health of patients with diabetes. Whether it involves sellers advertising “unused” test strips online, or device distributors diverting them from international channels and reselling them to domestic distributors, such products may be adulterated or counterfeit. Further, when diverted diagnostic OTC devices such as test strips are reintroduced to the legitimate supply chain, records of the products’ handling or storage conditions are nonexistent.

More specifically, the term “gray market” refers to products that are traded or sold outside of the manufacturer’s authorized distribution channels. One example of gray market products includes products that have been diverted from a country where they are approved for use into another country where they are not approved. For instance, in 2015, Abbott Laboratories and its diabetes care units won a court order barring pharmacies and wholesalers distributing diagnostic OTC medical devices from importing and selling versions of Abbott’s FreeStyle® diabetes test strips in the US, which were only intended for international distribution. Abbott argued that these wholesalers diverted the foreign-market test strips to US pharmacies, which in turn sold them to consumers and submitted fraudulent claims to insurance companies, Medicare, Medicaid, and other third-party payers while claiming to have sold domestic strips.

Such gray market diagnostic OTC medical devices pose substantial health and safety risks to patients.

NABP has a long history of working with wholesale distribution facilities to protect the integrity of the medication distribution system and employing appropriate security and best practices. NABP expanded these efforts in September 2016 and launched the Verified-Accredited Device Integrity Program™ (VDIP™), which accredits distributors of diagnostic over-the-counter (OTC) medical devices that may be delivered by a pharmacy pursuant

to a prescription. As an extension of the Verified-Accredited Wholesale Distributors® (VAWD®) program, VDIP helps prevent diverted or substandard diagnostic OTC medical devices from entering the United States medical supply chain.

Gray Market: Diverted and Counterfeit OTC Devices

Diabetes medical supplies are an example of diagnostic OTC medical devices. Over 10 million Americans measure their blood glucose daily, relying on at-home diabetes tests

Several differences in the international test strip packaging and instructional inserts are capable of confusing US consumers. For example, instruction inserts are often in a different language, a US toll-free number to call for assistance is missing, and storage temperatures may be listed in Celsius instead of Fahrenheit.

In addition, there are cases of distributors advertising online or on signage posted by the side of the road to buy unused test strips from consumers. These strips, which are now adulterated, are then ultimately resold to pharmacies that may be unaware of the product's history.

Further, the danger of counterfeit medical products infiltrating the legitimate supply chain through gray market channels is also a concern. For instance, counterfeit copies of the OneTouch® Test Strip sold by Johnson & Johnson's LifeScan unit appeared in US and Canadian pharmacies in 2006. Specifically, the fake test strips were found in at least 35 states and in Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia, and Turkey. An investigation revealed that the counterfeit test strip kits were manufactured in China, made their way through Canada, and ended up on pharmacy shelves in the US. Johnson & Johnson learned of the counterfeit test strips after patients complained of faulty results. While no injuries were reported, this case demonstrates the potential for diabetics to inject the wrong amount of insulin, causing injury and possible death due to inaccurate test readings.

Accreditation Criteria Help Protect Supply Chain

Established in 2004, the VAWD program helps protect the public health from counterfeit, adulterated, and substandard drugs that enter the supply chain, and the initiative

receives support from Food and Drug Administration. Currently, 24 states recognize VAWD and three states – Indiana, North Dakota, and Wyoming – require VAWD as a component of licensure for wholesale distributors.

Like VAWD, VDIP allows diagnostic OTC device distributors a means to assure pharmacies that they are receiving products from a legitimate source.

With the VAWD program as a basis, NABP developed the VDIP criteria to assess diagnostic OTC device distributors. The criteria includes the following:

- Diagnostic OTC medical devices are purchased from the manufacturer or a distributor who purchased the devices from the manufacturer.
- Licensee complies with all applicable statutes in all applicable jurisdictions.
- Facility where diagnostic OTC medical devices are stored and handled has adequate temperature and security conditions, and inventory controls for detecting theft, counterfeiting, and diversion.
- Personnel are qualified for supervising and handling the products.
- Records and inventories are maintained and readily available for inspection.
- Policies and procedures are established to ensure authenticity of purchase orders, and processes are in place for handling devices deemed unfit for human use.

NABP continuously reviews and updates its accreditation criteria for all its programs and will continue this practice for VDIP. For example, in 2012, NABP held a task force meeting to review and revise the VAWD criteria with the protection of public health at the forefront of the charge. In addition,

NABP updated the VAWD criteria in 2015 to align with the Drug Supply Chain Security Act. (See *Innovations*, August 2016.)

Team of Experts

In addition to NABP conducting an extensive examination of a diagnostic OTC device distributor's licensure status, disciplinary history, record keeping, product verification processes, and policies and procedures, the Association's surveyors perform on-site surveys as part of the accreditation process. These surveyors represent a wide range of experience, from pharmacist to former regulatory specialist to former law enforcement. Further, NABP's annual surveyor training keeps surveyors up-to-date on new regulations and procedures. The trainings ensure that surveyors operate consistently with the applicable standards of the accreditation program as well as relevant jurisdictions.

For more information about the VDIP program, contact the Accreditation department at vdip@nabp.pharmacy. ■

“Further, the danger of counterfeit medical products infiltrating the legitimate supply chain through gray market channels is also a concern.”

NABPF Offering Six Grants to Board Members or Staff to Attend APhA Institute on Alcoholism and Drug Dependencies

The NABP Foundation® (NABPF™) is offering six grants to assist qualified board of pharmacy members or staff with some of the costs associated with attending the American Pharmacists Association (APhA) Institute on Alcoholism and Drug Dependencies. Held in Salt Lake City, UT, on June 1-4, 2017, the APhA Institute sessions will offer attendees educational information on alcohol and drug dependency and how to effectively support pharmacists who are in recovery. Continuing the annual University of Utah School on Alcoholism and Other Drug Dependencies program, which was discontinued in 2014, the APhA Institute of Alcoholism and Drug Dependencies is a four-day educational conference designed to support those active in state-level pharmacist recovery programs and other leaders in this area. The conference sessions provide information and instruction to assist these individuals in providing programs to support pharmacists in recovery.

Attendees may earn continuing pharmacy education through participation in this program. More information about



the APhA Institute on Alcoholism and Drug Dependencies is available on the APhA website at www.pharmacist.com/apha-institute-alcoholism-and-drug-dependencies.

To apply for a grant, qualified board of pharmacy members and staff should contact the NABP Executive Office at ExecOffice@nabp.pharmacy by March 1, 2017. Grants will be assigned on a first-come, first-served basis. ■

Current VPP Inspection Reports Help Boards of Pharmacy Assess Compliance

To support the state boards of pharmacy in licensure decision making, NABP encourages pharmacies to maintain current inspection reports by participating in the Verified Pharmacy Program® (VPP®) and proactively requesting inspections from NABP based on their state requirements. Based on review of various state laws and regulations, NABP recommends that pharmacies engaged in sterile compounding undergo an annual inspection, and pharmacies engaged in nonsterile compounding or general pharmacy practices undergo a biennial inspection.

At press time, at least 536 pharmacies have applied to VPP and currently, or soon will, have verified data available for the boards to view. Of the 536 VPP pharmacies, more than 105 have chosen to reapply for a more

current inspection, having previously been inspected through the program. Additionally, of approximately 536 pharmacies:

- 254 pharmacies engage in only nonsterile compounding;
- 54 pharmacies engage in only sterile compounding (two of which are also registered as outsourcing facilities);
- 157 pharmacies engage in both sterile and nonsterile compounding (four of which are also registered as outsourcing facilities);
- 67 pharmacies are general retail or mail-order pharmacies with no compounding; and
- 4 pharmacies are nuclear pharmacies.



Completed VPP inspection reports are easily accessible to the state boards of pharmacy. Each report is uploaded to NABP e-Profile Connect. Additionally, state boards of pharmacy may upload their own inspections directly to e-Profile Connect. Participating state boards can access this shared data from fellow boards, which can assist them when making licensure decisions.

For more information about VPP, visit the Programs section of the NABP website. ■

Board of Pharmacy Members Gather at Interactive Forum to Discuss Common Challenges, Advance Their Shared Mission

“Stand Up and Be Counted to Advance Our Shared Mission” was the theme of NABP’s 2016 Interactive Member Forum, held November 30 to December 1, 2016, in Rosemont, IL. The biennial networking event gave 46 board of pharmacy members and other board representatives an opportunity to collaborate and discuss common challenges faced by the state boards. It also reinforced the partnership between the boards of pharmacy and NABP and the shared mission to protect the public health.

The two-day meeting included five sessions focused on topics relevant to all board of pharmacy members. During each session, panelists – who were also attendees of the meeting – provided a brief overview of the topic to spark discussion among all attendees. Each day also included a shared topics session with subjects gleaned from a survey sent to attendees prior to the meeting.

Forum Overview: Day One

Day one of the Interactive Member Forum kicked off with a networking lunch, followed by NABP Chairperson Edward G. McGinley, MBA, RPh, DPh, welcoming board members to the event. McGinley noted that it was the Association’s goal that the collaboration facilitated among meeting attendees would provide them with insight and knowledge to help them in their work. He also pointed out that the attendees represented varied levels of experience serving on boards of pharmacy – from less than two years to more than 20 years – and various types of pharmacy practice experience, including community, hospital, chain, and independent pharmacist; academic; and public board members. McGinley encouraged interaction, questions, and discussion among attendees for the meeting to have significant impact.

Attendees followed McGinley’s suggestion and engaged in a rich, nuanced discussion on the first session, “What Can We Learn From the 2016 Race?” This session provided panelists an opportunity to share differing perspectives on what serving on a board of pharmacy entails.

In the second session, “How to Beat a Rigged System,” panelists discussed the Multistate Inspection Blueprint created by the boards of pharmacy and NABP, as well as updates on state implementation of United States Pharmacopeia Chapter <797> guidelines. Topics requested

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Panelists presenting on “What Can We Learn From the 2016 Race?” included (from left to right) Jenny Downing Yoakum, RPh, member, Texas State Board of Pharmacy; Donna Wall, PharmD, RPh, member, Indiana Board of Pharmacy; T. Morris Rabb, RPh, member, Louisiana Board of Pharmacy; Kevin Dang, PharmD, RPh, member, Arizona State Board of Pharmacy; and session moderator Edward G. McGinley, MBA, RPh, DPh, chairperson, NABP Executive Committee.



Panelists presenting on “How to Beat a Rigged System” included (from left to right) Bill Cover, RPh, NABP member relations and government affairs director; session moderator Gay Dodson, RPh, member, NABP Executive Committee; Linda Witzal, RPh, member, New Jersey State Board of Pharmacy; Jody Allen, RPh, member, Virginia Board of Pharmacy; and Nicole Chopski, PharmD, RPh, member, Idaho State Board of Pharmacy. Pictured on the right is shared discussion topics moderator Richard B. Mazzoni, RPh, member, NABP Executive Committee.

Interactive Forum

continued from page 9

by members in their pre-meeting survey were then introduced during the first of two shared topic discussion sessions. Topics addressed included factors that contribute to medication errors, pharmacists' work conditions, medication assistance in dying regulations/standards and collaboration with other health care practitioners, implementation of

security measures in community pharmacies, and physician dispensing.

The first day of the forum ended with a group dinner, which provided attendees with an additional networking opportunity. NABP President Hal Wand, MBA, RPh, greeted and thanked attendees

for their participation in the day's discussions.

Forum Overview: Day Two

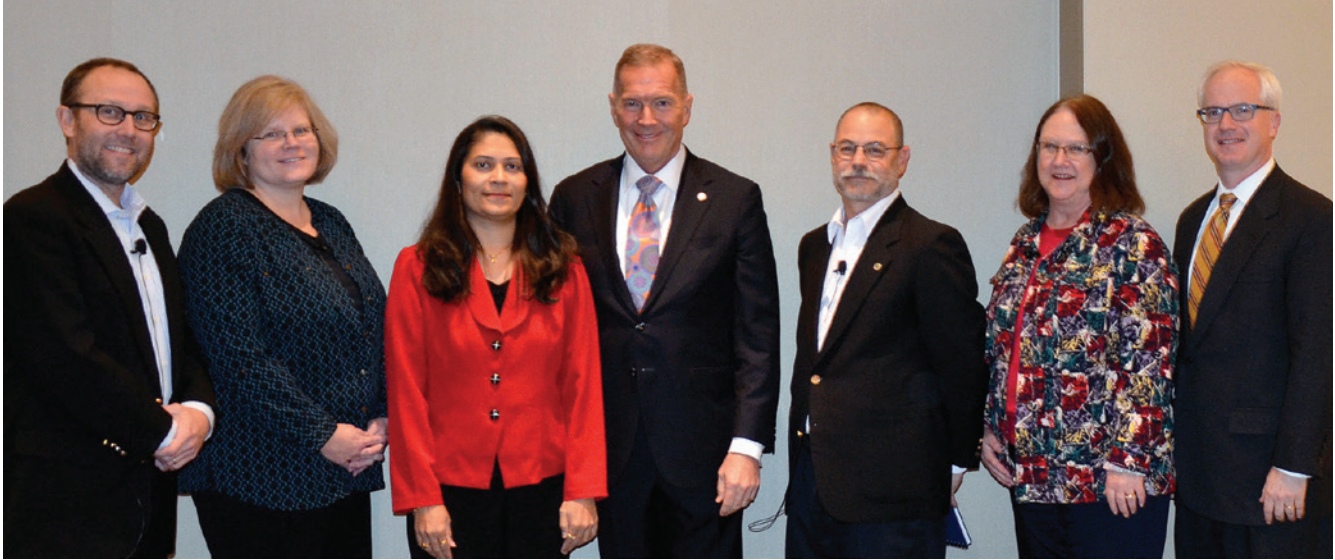
Attendees continued lively discussions during day two of the Interactive Forum, which began with the session "Crossing Party Lines – Trending Practices." This session's



Panelists presenting on "Crossing Party Lines – Trending Practices" included (from left to right) session moderator Mark D. Johnston, RPh, DPh, member, NABP Executive Committee; Michael Moné, BS, JD, RPh, member, State of Ohio Board of Pharmacy; Kate James, RPh, member, Oregon State Board of Pharmacy; Garrett Cavanaugh, RPh, member, Massachusetts Board of Registration in Pharmacy; Janet MacDonnell, BScPharm, member, New Brunswick College of Pharmacists; and William "Bill" Gerla, member, Saskatchewan College of Pharmacy Professionals.



Panelists presenting on "The Ballots on Prescription Drug Abuse Have Been Counted – Who's Winning?" included (from left to right) Kevin Robertson, PharmD, RPh, BCPS, member, Arkansas State Board of Pharmacy; session moderator Gary W. Dewhirst, RPh, DPh, member, NABP Executive Committee; Christian Tadrus, PharmD, RPh, member, Missouri Board of Pharmacy; Kevin Eidson, PharmD, member, Tennessee Board of Pharmacy; Cathy Hanna, RPh, member, Kentucky Board of Pharmacy; James Bialke, BA, MA, member, Minnesota Board of Pharmacy; and David Schoech, RPh, member, Kansas State Board of Pharmacy.



Panelists presenting on “Politics Aside – Whose Role Is It Anyway?” included (from left to right) Justin Wilson, DPh, member, Oklahoma State Board of Pharmacy; Diane Halvorson, RPhTech, CPhT, member, North Dakota State Board of Pharmacy; Tejal Patel, RPh, member, Delaware State Board of Pharmacy; session moderator Philip P. Burgess, MBA, DPh, RPh, member, NABP Executive Committee; Robert Frankil, RPh, member, Pennsylvania State Board of Pharmacy; and Kerri Kilgore, RPh, member, Wyoming State Board of Pharmacy. Pictured on the right is shared discussion topics moderator Jack W. “Jay” Campbell IV, JD, RPh, member, NABP Executive Committee.

“The final session of the Interactive Member Forum, ‘Politics Aside – Whose Role Is It Anyway?’ examined the expanding role of pharmacy technicians, mandates for board composition, and challenges in the legislative and regulatory process.”

topics included state and province updates on expanded provider roles, and the status of state and provincial laws and regulations for medical marijuana. Both topics were introduced by US and Canadian board member panelists.

During the second session, “The Ballots on Prescription Drug Abuse Have Been Counted – Who’s Winning?” attendees discussed current trends in opioid abuse and increasing patient access to naloxone and updates on state prescription monitoring programs.

The final session of the Interactive Member Forum, “Politics Aside – Whose Role Is It Anyway?” examined the expanding role of pharmacy technicians, mandates for board composition, and challenges in the legislative and regulatory process. Attendees then shared their experience and insights during the second shared topics discussion session, which included issues such as unauthorized e-prescribing by

providers’ agents, and electronic health records used in nursing homes and assisted living facilities.

Closing the meeting, NABP President-elect Jeanne D. Waggener, RPh, DPh, thanked attendees for their participation, commending forum attendees for their hard work and dedication to protecting the public health.

For information about future meetings, visit the Meetings section on the NABP website at www.nabp.pharmacy. ■

NABP Cosponsors USP CPE Course to Help Licensees Meet Requirements of Chapter <800>

Health care personnel who handle hazardous drug preparations and all entities that store, prepare, transport, or administer hazardous drugs are mandated to meet the requirements of United States Pharmacopeia (USP) General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings beginning July 1, 2018. To support board efforts to help licensees in meeting these requirements, NABP is cosponsoring a comprehensive continuing pharmacy education (CPE) course on the new standards. The course, titled “General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings,” will be offered both in a classroom setting in Rockville, MD, and as an on-demand webinar that licensees can take at their convenience. The course will provide an introduction to the Chapter, including practice areas affected; identify documentation requirements; and discuss facility and engineering control requirements in detail. It will also describe the roles and responsibilities of individuals handling hazardous drugs, as well as personnel training and proper use of personal protective equipment.

Pharmacists and pharmacy technicians may earn 6.5 hours (0.65 CEUs) of Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credit after finishing the knowledge-based course, passing the post-session test, and completing the course evaluation. To participate in the course, find dates for live class sessions, or to register for the home study webcast, visit USP’s website at www.usp.org under the Meetings & Courses section. Claims for ACPE-accredited CPE credit must be submitted on NABP’s CPE submission website, which can be accessed by visiting the Meetings section of the NABP website at www.nabp.pharmacy within 60 days of completing the CPE activity.

General Chapter <800> is available in both the First Supplement to USP 39—National Formulary 34 and the *USP*

Compounding Compendium. Details about Chapter <800> can be found at www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.

More USP CPE Opportunities Available on Compounding

Like USP Chapter <800>, Chapters <795> and <797> are enforceable standards. NABP is cosponsoring additional USP courses for ACPE-accredited CPE credit, including the courses “USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations” and “USP <795> Pharmaceutical Compounding—Nonsterile Preparations.” Visit USP’s website at www.usp.org to learn more about and sign up for upcoming USP courses. ■



NABP and the NABP Foundation® are accredited by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmacy education (CPE). ACPE Provider Number: 0205. Participants may earn ACPE-accredited CPE credit by completing a Statement of Continuing Pharmacy Education Participation online and submitting it electronically to NABP. Full attendance and completion of the program evaluation and learning assessment for each session are required to receive CPE credit and for the credit to be recorded in the CPE Monitor® system. If you do not submit your CPE claim within 60 days of the date you completed the CPE activity, you will be unable to receive credit, as this is the maximum amount of time allowed for providers to transmit CPE claims to ACPE for credit. Please submit your claim as soon as possible to ensure that you receive credit.

NABP Surveyors Participate in Annual Training

NABP surveyors met in Rosemont, IL, on December 12-13, 2016, for their annual training workshop. The surveyor workshop included compliance updates on accreditation programs and inspection processes, an overview of the Drug Supply Chain Security Act, a look at how outsourcers impact the Verified Pharmacy Program® and Verified-Accredited Wholesale Distributors® program, an overview of the Verified-Accredited Device Integrity Program™ and the Health Insurance Portability and Accountability Act, and an open forum with questions and answers. Surveyors who inspect sterile compounding facilities also completed a gown and garb exercise. ■



Task Force Addresses Pharmacist Integrated Communications Skills Examination



Members of the Task Force on the Pharmacist Integrated Communications Skills Examination met on December 13-14, 2016, in Rosemont, IL, to review the present status of pharmacy competency assessment as it relates to pharmacists' communications skills and to discuss the concept of a pharmacist integrated communications skills examination. Pictured from left to right are Rebecca Deschamps, RPh, Montana Board of Pharmacy; Roger Fitzpatrick, RPh, Utah Board of Pharmacy; Jim Bracewell, BBA, Georgia State Board of Pharmacy; Randy Forbes, JD, Kansas State Board of Pharmacy; Rebecca "Suzette" Tijerina, RPh, Texas State Board of Pharmacy; Richard A. Palombo, RPh, New Jersey State Board of Pharmacy; Daphne Bernard, PharmD, RPh, District of Columbia Board of Pharmacy; Michael Bertagnolli, MBA, RPh, FACHE, Montana Board of Pharmacy; Caroline Juran, RPh, DPh, Executive Committee liaison, NABP; Stuart Williams, JD, Minnesota Board of Pharmacy; Maria Mantione, PharmD, RPh, CGP, FAPhA, New York State Board of Pharmacy; Brenda McCrady, RPh, Arkansas State Board of Pharmacy; and John Marraffa, Jr, RPh, New York State Board of Pharmacy.



Newly Accredited VAWD Facilities

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

Cardinal Health 200, LLC, dba Cardinal Health
Grand Prairie, TX

H. D. Smith, LLC
Flower Mound, TX

Sanofi-Aventis US, LLC
Taylor, PA

A full listing of more than 580 accredited VAWD facilities is available on the NABP website at www.nabp.pharmacy.



Newly Accredited DMEPOS Facility

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

The Medicine Shoppe Pharmacy #0588
Jacksonville, IL

A full listing of nearly 450 accredited DMEPOS companies representing almost 28,500 facilities is available on the NABP website at www.nabp.pharmacy.



EXPLORE, DISCOVER, ACT

Imagineering the Future of Pharmacy Regulation

NABP 113TH Annual Meeting
 May 20 - 23, 2017
 Orlando, FL



Schedule of Events

Saturday, May 20, 2017

10 AM - 5 PM

Registration/Information Desk Open

1:30 - 3:30 PM

Pre-Meeting CPE

4 - 5 PM

From District Meeting to Annual Meeting – Learning About NABP

6 - 9 PM

President's Welcome Reception
 Honoring NABP President
Hal Wand, MBA, RPh
 Dinner will be served.
 Dress: Business casual

Sunday, May 21, 2017

7:30 AM - 4:30 PM

Registration/Information Desk Open

7:30 - 8:30 AM

NABP AWARxE Fun Run/Walk

8:30 - 11:30 AM

Hospitality Brunch and Educational Table Top Displays

8:30 - 11:30 AM

Joint CPE
 Educational Poster Session

Noon - 3:15 PM

First Business Session

3:45 - 4:45 PM

Joint CPE

Monday, May 22, 2017

7:30 AM - 12:30 PM

Registration/Information Desk Open

7:30 - 9 AM

USP Update and Breakfast
Breakfast served plated from 7:30 - 8 AM

9:15 - 10:15 AM

Joint CPE

10:30 AM - Noon

Second Business Session

Noon - 12:30 PM

Informal Member/Candidate Discussion

Free Afternoon: No programming

Tuesday, May 23, 2017

7:30 AM - 4 PM

Registration/Information Desk Open

7:30 - 8:30 AM

NABP Breakfast

8:30 - 10 AM

Executive Officer CPE Session

8:30 - 10 AM

Compliance Officer CPE Session

10:30 AM - Noon

Expanding on Forum Discussions – the Magic of Networking on Shared Topics

Noon - 1:30 PM

Lunch Break
 (On your own)

1:30 - 4:15 PM

Final Business Session

6 - 6:45 PM

Awards Dinner Reception

7 - 9 PM

Annual Awards Dinner
 Dress: Semiformal

Note: The 113th Annual Meeting schedule is subject to change. The final schedule will be posted online at www.NABPAnnualMeeting.pharmacy.



NABP and the NABP Foundation[®] are accredited by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmacy education (CPE). ACPE Provider Number: 0205. Details on the continuing pharmacy education sessions and the overall conference learning objectives will be provided in future issues of Innovations and on the Annual Meeting Information and Registration Website. Instructions for claiming CPE credits, including continuing legal education, will also be provided in future annual meeting communications.

Prominent Political Journalist to Offer Perspective on Health Care Regulation During Keynote Address

Howard Fineman, one of the nation's most prominent political journalists and correspondents, will provide attendees with an informative bipartisan perspective on health care regulation in his keynote speech, "Politics: From the Top and the Inside," during the NABP 113th Annual Meeting. Throughout his remarkable international career, Fineman has interviewed and written about every major presidential candidate since 1984 and proved himself to be one of the leading reporters in Washington, DC. As boards of pharmacy face ever-changing political landscapes, Fineman will share his perspective on today's complicated issues and political decisions with approachability, humor, and candor during his keynote address.

Fineman is currently global editorial director of the Huffington Post Media Group, a position he has held since March 2011. He joined *The Huffington Post* in September 2010 and helped it become one of the world's top news sites. In April 2012, *The Huffington Post* became the first commercial news website to win a Pulitzer Prize. Fineman also makes regular appearances on MSNBC's *Hardball with Chris Matthews*, NBC's *Today Show*, and ESPN Radio's *Tony Kornheiser Show*, where he offers his keen views on current events. From 1983 to 1995 he was a regular panelist on PBS' *Washington Week in Review*, and he has also appeared on *Fox News Sunday* and *The Daily Show with Jon Stewart*.

Before joining *The Huffington Post*, Fineman held several influential positions with *Newsweek*, including senior editor and columnist, chief political correspondent, and deputy Washington bureau chief. His work

has also appeared in *The New York Times* and *The Washington Post*, and his 2008 best-selling book, *The Thirteen American Arguments: Enduring Debates That Define and Inspire Our Country*, explored complex topics such as national identity, free speech, and the political process. Fineman was the first journalist to thoroughly interview President George W. Bush after the events of September 11, 2001, and his *Newsweek* cover story "Bush and God" was part of a series of articles that won the 2003 National Magazine Award for General Excellence. His many other awards and honors include a "Silver Gavel" from the American Bar Association and a "Page One" from the Headliners Club of New York.

Originally from Pittsburgh, PA, Fineman received his bachelor of arts degree from Colgate University, his master of journalism from Columbia University Graduate School of Journalism, and his juris doctor degree from University of Louisville School of Law. In 2006, Columbia University honored him with the Alumni Award. His journalism career began in Louisville, KY, where he wrote for *The Courier-Journal* about topics such as the coal industry and state politics. In 1978, he joined the newspaper's Washington bureau.

Fineman will deliver the keynote address during the First Business Session of the NABP 113th Annual Meeting, on Sunday, May 21, 2017, at the Hyatt Regency Orlando on International Drive in Orlando, FL. More information will be available on the Annual Meeting website at www.NABPAnnualMeeting.pharmacy. ■



“Throughout his remarkable international career, Fineman has interviewed and written about every major presidential candidate since 1984 and proved himself to be one of the leading reporters in Washington, DC.”

Still Time to Request a Travel Grant

Are you an active board of pharmacy member or administrative officer who is attending the Annual Meeting?

NABP has travel grant opportunities available for qualified individuals to cover costs for needed expenses. Eligible individuals may receive up to \$1,500 to cover the costs of travel, hotel rooms, meals, taxis, parking, and tips. The grant does not include Annual Meeting registration fees.

- One grant will be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board's administrative officer.
- Active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

To obtain a grant application, board administrative officers may contact the NABP Executive Office at ExecOffice@nabp.pharmacy. ■



**Online Registration
Available in February
at**

www.NABPAnnualMeeting.pharmacy



Important Deadlines

- Early Registration Rate – April 7
- Early Hotel Reservation Rate – April 20
- Voting Delegate Submissions – April 21

NABP Seeks Proposals for Educational Poster Session

NABP seeks proposals for the annual Educational Poster Session to take place on Sunday during the Annual Meeting. Proposed posters should reflect the overall theme of "Imagineering for the Protection of Public Health." Those displaying posters have the opportunity to share information about their organization's latest legislative issues, technology, policy development, and/or disciplinary cases as they relate to this year's theme.

To submit a poster concept for consideration, please send the proposed poster topic to NABP Professional Affairs staff via email at Prof-Affairs@nabp.pharmacy by **Friday, March 3, 2017**.

Board of pharmacy members and staff as well as schools and colleges of pharmacy are invited to participate. Student presenters are welcome and must be accompanied by a licensed pharmacist.

Poster Session presenters may be eligible to earn ACPE-accredited continuing pharmacy education credit. Details will be provided to individuals selected to present at the session. ■

Around the Association

Executive Officer Changes

- **Kimberly A. Leonard, RPh**, has been appointed executive secretary of the New York State Board of Pharmacy, replacing Lawrence “Larry” H. Mokhiber, MS, RPh. Leonard began work at the Board of Pharmacy in 2012 as the pharmacy supervisor of practice and registration. Before working for the Board, she was a supervisor for the New York State Department of Health, Medicaid Program, Bureau of Pharmacy Policy and Operations. Prior to state service, she worked for more than 15 years as a community pharmacist. Leonard graduated in 1989 from Albany College of Pharmacy and Health Sciences.

Board Member Appointments

- **Jennifer L. Hardesty, PharmD, RPh**, has been appointed a member of the Maryland Board of Pharmacy. Hardesty’s appointment will expire May 1, 2020.
- **Kevin Morgan, RPh**, has been appointed a member of the Maryland Board of Pharmacy. Morgan’s appointment will expire May 1, 2020.
- **Ryan Harper, PharmD, RPh**, has been appointed a member of the Mississippi Board of Pharmacy. Harper’s appointment will expire June 30, 2021.
- **Sabrina Beck, PharmD, RPh**, has been appointed a member of the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit. Beck’s appointment will expire November 30, 2018.
- **Charlene Dunbar** has been appointed a public member of the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit. Dunbar’s appointment will expire November 30, 2021.
- **Robert Sullivan** has been appointed a public member of the Nevada State Board

of Pharmacy. Sullivan’s appointment will expire October 31, 2019.

- **Dan Somsen, RPh**, has been appointed a member of the South Dakota State Board of Pharmacy. Somsen’s appointment will expire October 30, 2019.
- **Katy Wright, MBA, PharmD, RPh**, has been appointed a member of the Tennessee Board of Pharmacy. Wright’s appointment will expire July 15, 2021.
- **K. Kumar Shah** has been appointed a public member of the Utah Board of Pharmacy. Shah’s appointment will expire June 30, 2020.
- **Sam Kapourales, RPh**, has been appointed a member of the West Virginia Board of Pharmacy. Kapourales’ appointment will expire June 30, 2021.

Board Member Reappointments

- **Lenora Newsome, PD, RPh**, has been reappointed a member of the Arkansas State Board of Pharmacy. Newsome’s appointment will expire June 30, 2022.
- **Ryan Brooks** has been reappointed a public member of the California State Board of Pharmacy. Brooks’ appointment will expire June 1, 2020.
- **Victor Law, BPharm, RPh**, has been reappointed a member of the California State Board of Pharmacy.

Law’s appointment will expire June 1, 2019.

- **Gregory Lippe** has been reappointed a public member of the California State Board of Pharmacy. Lippe’s appointment will expire June 1, 2020.
- **Albert Wong, PharmD, RPh**, has been reappointed a member of the California State Board of Pharmacy. Wong’s appointment will expire June 1, 2020.
- **Carolyn Ma, PharmD, RPh**, has been reappointed a member of the Hawaii State Board of Pharmacy. Ma’s appointment will expire June 30, 2019.
- **Winifred A. Landis, RPh**, has been reappointed a member of the Indiana Board of Pharmacy. Landis’ appointment will expire October 15, 2020.
- **Donna S. Wall, PharmD, RPh**, has been reappointed a member of the Indiana Board of Pharmacy. Wall’s appointment will expire August 31, 2020.
- **Richard M. Indovina, Jr, MBA, RPh**, has been reappointed a member of the Louisiana Board of Pharmacy. Indovina’s appointment will expire June 30, 2022.
- **James Stevenson, PharmD, RPh, FASHP**, has been reappointed a member of the Michigan Board of Pharmacy. Stevenson’s appointment will expire June 30, 2020. ■

Next FPGEE Administration to Be Held April 25, 2017

Information about registering for and scheduling the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) is available to candidates in the Programs section of the NABP website at www.nabp.pharmacy.



Virginia Passes Legislation Related to DSCSA

In response to the Drug Supply Chain Security Act (DSCSA), also referred to as Title II of the Drug Quality and Security Act (DQSA), the Virginia General Assembly passed House Bill (HB) 528, which amends several sections of law regarding supply chain requirements. The amendments to HB 528 are summarized below.

- Defines a “third-party logistics provider” in 54.1-3401 to distinguish them from wholesale distributors and requires in-state providers to be permitted by the Virginia Board of Pharmacy.
- Requires every pharmacy, nonresident pharmacy, wholesale distributor, and nonresident wholesale distributor to comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.
- Creates a new licensing category for registering nonresident manufacturers shipping into the Commonwealth, in lieu of registering them as nonresident wholesale distributors.
- Specifies that bulk drug substances used for compounding drugs distributed by a supplier other than a licensed wholesale distributor or registered nonresident wholesale distributor must be provided by a supplier who is approved by the Board as well as the federal Food and Drug Administration.

The Board’s October 2016 newsletter, which is available in the Boards of Pharmacy section of the NABP website, has more details on new laws affecting the practice of pharmacy.

New Hampshire Board Updates Rest Breaks for Pharmacists Rule

The New Hampshire Joint Legislative Committee on Administrative Rules approved the revision of Pharmacy Rule 704.01, which mandates that pharmacists take a 30-minute break if they are working more than an eight-hour shift. This rule requires pharmacists to take a 30-minute rest break in an effort to give pharmacists a mental/physical break and thereby improve patient safety. Pharmacy Rule 704.01 took effect at the September New Hampshire Board of Pharmacy meeting, when it was adopted by the full Board. The rule is posted on the Board website at www.nh.gov/pharmacy.

South Dakota Provides Update on Naloxone Bill

HB 1079 was passed by the 2016 South Dakota Legislature, signed by the governor, and became effective on July 1, 2016. SDCL 34-20A-105 states, “A licensed health care professional may, directly or by standing order, prescribe an opioid antagonist to a person at risk of experiencing an opioid-related overdose, or prescribe to a family member, friend, or other close third party person the health care practitioner reasonably believes to be in a position to assist a person at risk of experiencing an opioid-related overdose.” This allows pharmacies to develop collaborative practice agreements (CPAs) with physicians to be able to write the order based upon the CPA or “protocol” as it is used in SDCL 36-11-19.1.

The South Dakota State Board of Pharmacy notes that education will need to be provided when dispensing. A video that teaches how to administer

naloxone is available at www.youtube.com/watch?v=uGkBCcFJRHI.

The Board also suggests that the availability of naloxone is discussed with individuals who are chronically taking opioids.

Arizona Board Expands Role to Provide Certificate of Free Sale and GMP Certificate

The Arizona State Board of Pharmacy has expanded its role in providing the following certificates.

- The certificate of free sale is evidence that goods, ie, nutraceuticals, are legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin (United States).
- The Good Manufacturing Practice (GMP) certificate validates a system in place to ensure that products are consistently produced and controlled according to quality standards and covering all aspects of design, monitoring, and control of manufacturing processes and facilities to ensure that products do not pose any risk to the consumer or public. This would include, but is not limited to, a positive GMP inspection according to Title 21 Code of Federal Regulations Parts 210-211.

Additional information may be found in the Board’s October 2016 newsletter, available in the Boards of Pharmacy section of the NABP website. ■

CDC Brochure Offers Pharmacists Tips for Addressing Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, *Pharmacists: On the Front Lines*, offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf.

FDA Approves Labeling Changes for All Prescription Testosterone Products

Food and Drug Administration (FDA) approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA in an announcement. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated

with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement can be found at www.fda.gov/Drugs/DrugSafety/ucm526206.htm.

Health care providers may report any adverse reactions with the use of testosterone products to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.

DEA Schedules Deadly Street Drug U-47700

With 46 confirmed deaths linked to U-47700, a synthetic opioid, Drug Enforcement Administration (DEA) took emergency action and placed the deadly street drug into Schedule I of the Controlled Substances Act. Effective November 14, 2016, this scheduling action will last 24 months.

Of those 46 fatalities associated with U-47700, 31 occurred in New York and 10 in North Carolina, indicates DEA in a news release. The news release also notes that abuse of U-47700 “parallels that of heroin, prescription opioids, and other novel opioids.” According to law enforcement agencies, the drug has been seized in powder form and in counterfeit tablets that mimic pharmaceutical opioids. DEA states that substances like U-47700 are often manufactured in illicit labs overseas. The DEA news release is available at www.dea.gov/divisions/hq/2016/hq111016.shtml.

FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the Center for Drug Evaluation and Research presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of abuse-deterrent opioids and drug shortages. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars. ■

Health care providers and patients are encouraged to report adverse events and quality problems to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.



INNOVATIONS

National Association of Boards of Pharmacy
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UPCOMING EVENTS

PARE Administrations

February 13-24, 2017
June 5-16, 2017

2017 Tri-Regulator Meeting

February 22, 2017
Tampa, FL

Committee on Constitution and Bylaws

April 12, 2017
Teleconference

FPGEE Administration

April 25, 2017

NABP 113th Annual Meeting

May 20-23, 2017
Orlando, FL