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National Association of Boards of Pharmacy®

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VAWD Program Not Preempted by Federal Law

NABP Continues to Support Member Boards' Efforts to Maintain Secure Drug Supply Chain

Generally, United States consumers do not question the safety of the prescription medications they take, and with good reason. "The US drug supply chain remains one of the safest in the world," proclaims Food and Drug Administration (FDA). The drug supply chain is not invulnerable, however, and regulators are all too aware that diverted, counterfeit, and adulterated drugs sometimes make their way to consumers. Recent reminders of the supply chain's fallibility include two cases announced in 2012. In one case, a number of doctors' offices were found to have purchased and used a counterfeit version of the oncology drug Avastin®, although the low prices of the drugs should have alerted them to a potential problem. In another case, a network of individuals and companies diverted and resold drugs with false pedigrees to pharmacies across the country; such products might be dispensed to unsuspecting patients. Similar but smaller schemes come to light with regularity, including several during the last few months alone.

How are criminals able to infiltrate the wholesale distribution network? Over the years, particularly since the early 2000s, state governments have intensified regulation of wholesale prescription drug distributors in order to help safeguard the integrity of the US drug supply chain, often instituting stronger licensure and drug-tracking (or pedigree) requirements. However, as NABP noted in a white paper released last October, unscrupulous actors may manipulate their way into the drug distribution system

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by exploiting regulatory differences between states, and seeking out those states with less-stringent licensing requirements and/or enforcement. Rogue wholesalers also frequently exploit loopholes in the language of various laws, such as those that permit pharmacies to sell inventory to wholesalers through "five percent" or emergency transfer exemptions, or those that allow intracompany transfers. Virtual distribution by wholesale distributors, in which ownership of a drug is transferred without the selling wholesaler ever

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Upcoming Events

August 2-5, 2014
NABP/AACP District 3 Meeting
Charleston, SC

August 14-16, 2014
NABP/AACP District 5 Meeting
Deadwood, SD

August 28, 2014
ACE Meeting
NABP Headquarters

September 21-24, 2014
NABP/AACP Districts 6, 7, & 8 Meeting
Whitefish, MT

October 5-7, 2014
NABP/AACP Districts 1 & 2 Meeting
Williamsburg, VA

October 14-15, 2014
NABP Interactive Executive Officer Forum
Northbrook, IL

In This Issue. . .

The *NABP Newsletter* (ISSN 8756-4483) is published 10 times a year by the National Association of Boards of Pharmacy® (NABP®) to educate, to inform, and to communicate the objectives and programs of the Association and its 64 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $35 per year.

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Drug Supply Vulnerabilities

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taking physical possession of the medication, has also opened up vulnerabilities for counterfeiting or diversion. Virtual manufacturers and other drug chain security issues are addressed in the Association's Verified-Accredited Wholesale Distributors® (VAWD®) program criteria. Through the VAWD program, and by providing language regarding wholesale distributors in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, NABP supports member board efforts to address the loopholes that continue to threaten the safety of prescription drugs.

VAWD Accreditation

Along with and in support of the states, NABP strives to safeguard the nation's drug supply chain, most notably through the VAWD program, which has accredited more than 530 facilities across the US since 2004. In order to receive VAWD accreditation, facilities undergo a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. The facilities are reviewed annually, and undergo a site survey every three years. By the end of 2013, 21 states recognized VAWD accreditation, and three states required it as a component of licensure. Indeed, the Institute of Medicine, in its 2013 report *Countering the Problem of Falsified and Substandard Drugs*, strongly recommended that, to improve security of the drug distribution chain, the US wholesale market be restricted to distributors that have received VAWD accreditation.

In 2013, in order to maintain and strengthen VAWD's role in protecting the public health, and to respond to changing business models, NABP updated its criteria that wholesale distributors must meet in order to obtain or retain VAWD accreditation. Based on comprehensive recommendations made by the 2012 Task Force on Virtual Manufacturers and Virtual Wholesale Distributors, the updated criteria allow virtual wholesalers to seek accreditation, and also provide stronger assurance that drugs obtained by wholesale distributors come only from legitimate sources. To help ensure that medications diverted from pharmacies and other unlawful sources do not enter the supply chain, the criteria prohibit wholesalers from distributing drugs purchased or received from pharmacies or practitioners, for example. VAWD criteria also now require wholesale distributors to have a quality improvement program. (More details about the new criteria are included in the article "Task Force Recommends Changes to *Model Act* and VAWD Criteria to Address Virtual Manufacturers and Wholesalers" in the May 2013 *NABP Newsletter.*)

During 2013, NABP systematically implemented the program changes pursuant to the new criteria. New and existing VAWD applicants, as of May 2013 when the changes were adopted, were subject to the revised criteria immediately. Previously accredited facilities, meanwhile, confirmed their compliance with the new criteria, or submitted a corrective action plan articulating a time frame for implementing compliance, by September 2013. Almost all accredited entities did so, with only a handful choosing to cancel their application or accreditation. Since that time, NABP has been reviewing documentation and conducting on-site surveys in order to verify facilities' compliance with the new criteria.

NABP also supports the states in their efforts to draft effective rules regarding wholesale distributors through the Association's Model Rules for the Licensure of Wholesale Distributors, a section of the *Model Act.*

Federal Action

The federal government has also taken recent measures to affect the regulation of wholesale distributors by planning the implementation of Title II of the Drug Quality and Security Act (DQSA), the Drug Supply Chain Security Act. This Act, signed into law on November 27, 2013, addresses drug track-and-trace requirements as well as the licensing of wholesale distributors. The law was particularly notable because

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NABP Welcomes Newly Appointed 2014-2015 Advisory Committee on Examinations Members

NABP is pleased to announce that the following individuals have been appointed to serve on the 2014-2015 Advisory Committee on Examinations (ACE). This standing committee, established by NABP in 1912, was created to safeguard the integrity and validity of NABP examinations.

ACE oversees the development and administration of all of the Association's examination and certification programs. ACE also considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

ACE typically convenes three to four times per year. The committee consists of individuals who are affiliated members of NABP, including current active board of pharmacy members and administrative officers, individuals who have served within the last five years as a member or administrative officer of a board of pharmacy, and non-affiliated individuals who are practicing pharmacists or serving as pharmacy school faculty. Members serve three-year terms and ex officio members serve one-year terms.

2014-2015 ACE Members

The following members began their terms on June 1, 2014. Philip P. Burgess, MBA, DPh, RPh, is serving as the Executive Committee liaison.

Carl W. Aron ..... Monroe, LA

Michael Duteau..... Baldwinsville, NY

Kay L. Hanson .....Brooklyn Park, MN

Sara St Angelo ..... Indianapolis, IN

*Neal F. Walker ..... Hibbing, MN

David Chikao Young ..... Salt Lake City, UT

Mark Decerbo .....Las Vegas, NV
(Ex Officio Member, one-year term)

Holly L. Mason .....West Lafayette, IN
(Ex Officio Member, one-year term)

Amy Mattila .....Washburn, WI
(Ex Officio Member, one-year term)

*Denotes new member

April 2014 FPGEE Score Results Now Available

The score reports from the April 28, 2014 Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) administration are now available. Candidates who sat for the April 28 administration may now enter their equivalency examination number and date of birth to access their score report through the NABP secure network login page. The login page may be accessed through a link available at *www.nabp.net/programs/examination/fpgee*.

A total of 893 candidates sat for the April 28, 2014 administration. The next FPGEE is scheduled for October 7, 2014. More information about the FPGEE is available in the Programs section of the NABP website at *www.nabp.net/programs*.

Executive Committee

Karen M. Ryle
Chairperson
One-year term

Joseph L. Adams
President
One-year term

Edward G. McGinley
President-elect
One-year term

Hal Wand
Treasurer
One-year term

James T. DeVita
Member, District 1
Serving second year of a second three-year term

Susan Ksiazek
Member, District 2
Serving second year of a three-year term

Jack W. "Jay" Campbell
Member, District 3
Serving first year of a three-year term

Philip P. Burgess
Member, District 4
Serving first year of a three-year term

Gary Dewhirst
Member, District 5
Serving second year of a three-year term

Jeanne D. Waggener
Member, District 6
Serving third year of a three-year term

Mark D. Johnston
Member, District 7
Serving third year of a three-year term

Richard Mazzoni
Member, District 8
Serving first year of a three-year term

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

110th Annual Meeting Report of Counsel: Preemption Does Not Always Reign Supreme

By Dale J. Atkinson, JD

The 2014 NABP Report of Counsel focuses on the complex and difficult subject of preemption and the role of state and federal laws as they act and react together and independently. In general, the states enjoy the authority to regulate the professions in the interest of protecting their residents with limited "interference" from the federal government. Under certain circumstances, however, the federal government is entitled to legislate to the exclusion of and/or to set standards for matters of national concern and where state activity might impede interstate commerce. Of course, there are certain specified areas where the federal government is granted sole and exclusive authority to legislate.

This Report of Counsel is divided into sections addressing the Supremacy Clause of the United States Constitution, the concept of federalism, the Tenth Amendment, and various cases necessary to establish a foundation for each principle. It also provides an overview of recent cases addressing the application of these principles, specifically where states have elected to act. Finally, the Report will provide a brief overview of these principles regarding the recent federal legislation, the Drug Quality and Security Act (DQSA).

Supremacy Clause

Article Six Clause 2 of the US Constitution states:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

In short, the US Constitution, federal statutes, and US treaties control issues in our legal system when there are conflicts between federal law and any state constitution and/or state law. This notion of federalism, whereby federal law controls or is the "supreme" law of the land when there are conflicts, defines the governance structure in the US and results in a balancing of authority between the federal government and the state governments.

The Supremacy Clause does not grant authority to a federal branch of government, but allows for a resolution in favor of federal supremacy where valid federal laws have been enacted. The operative issue is whether the federal law is valid under a separation-of-powers analysis. In its simplest form, the Supremacy Clause is a straightforward conflict-of-law rule designed to resolve conflicts between state and federal law touching on the same subject.

Federalism

The concept of federalism establishes a system of shared governance or dual sovereignty whereby certain enumerated powers are designated to the federal government with the remaining powers

reserved for the states. This balance of shared governance is subject to intense scrutiny and significant jurisprudence and has been referred to as "the oldest question of constitutional law." Case law regarding the interplay between state and federal law and the notion of federalism takes shape in the form of legal arguments over the Supremacy Clause and the Tenth Amendment, among other legal theories.

The powers reserved to the states under the Tenth Amendment only have meaning in light of those powers specifically granted to the federal government. Equally important is the fact that the states may also be subject to accusations of an abuse of power by enacting legislation that infringes on the authority of the federal government. Federalism is a two-way street, and recent state action illustrates the potential for states to subject themselves to scrutiny under this constitutional tenet. Over the last several years, US Supreme Court decisions addressing the Patient Protection and Affordable Care Act (ACA), immigration, and legalization of marijuana set the stage for continued evolution of this dual form of governance.

Tenth Amendment

The Tenth Amendment of the US Constitution was ratified in 1791 under the Bill of Rights and provides:

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people.

The recognized intent of the Tenth Amendment was generally to allay fears that the federal government might exercise powers not granted to it and that the states could be precluded from exercising such reserved powers. While the federal government can create incentives for the states to comply with federal law (eg, monetary), Congress cannot directly compel states to enforce federal regulations.

Relevant Cases

Under what is referred to as the "anti-commandeering doctrine," the US Supreme Court has interpreted the Constitution as prohibiting the federal government from infringing on state sovereignty under certain circumstances. This judicial restraint prohibits the federal government from commandeering or coercing the states to enact or enforce federal programs. Basically, four cases have developed and defined the anti-commandeering doctrine.

In 1842, the US Supreme Court held that the federal government could not force the states to implement or carry out the Fugitive Slave Act of 1793 (*Prigg v. Pennsylvania,* 41 U.S. 539 (1842)). The court noted that states cannot be compelled to enforce the act and to do so is " . . . an unconstitutional exercise of the power of interpretation, to insist that the states are bound to provide means to carry into effect the duties of the national government . . . "

In 1992, the US Supreme Court held that because the Low Level Radioactive Waste Policy Amendments Act of 1985 was coercive, such violated the Tenth Amendment. (*New York v. United States,* 505 U.S. 144 (1992)). It noted that the act offers the states a "choice between two unconstitutionally coercive alternatives – either accepting ownership of waste or regulating according to Congress' instructions – the provision lies outside Congress' enumerated powers and is inconsistent with the Tenth Amendment."

In 1997, the US Supreme Court addressed the Brady gun bill that required county law enforcement officers to administer part of the background check program. Under legal scrutiny, the court found the law unconstitutional. (*Printz v. United States,* 521 U.S. 898 (1997)).

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

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The majority found " . . . it is apparent that the Brady Act purports to direct state law enforcement officers to participate, albeit only temporarily, in the administration of a federal enacted regulatory scheme." The federal government is prohibited from issuing directives requiring the states to address certain problems. As stated by the court, "[i]t matters not whether policymaking is involved, and no case by case weighing of the burdens or benefits is necessary; such commands are fundamentally incompatible with our constitutional system of dual sovereignty."

Finally, in 2012, the US Supreme Court ruled that the federal government cannot force the states to act against their will by withholding funds in a coercive manner. The court found that the federal government cannot compel the states to expand Medicaid by threatening to withhold funding for Medicaid programs already in place. (*National Federation of Independent Business v. Sebelius,* 132 S. Ct. 2566 (2012)). Under the Spending Clause (Article I, Section 8, Clause 1 of the United States Constitution), the court held that the legitimacy of spending power rests on "whether the states voluntarily and knowingly accept the terms of the 'contract' . . . Respecting this limitation is critical to ensuring that Spending Clause legislation does not undermine the status of the States as independent sovereigns in our federal system." Among several issues whereby significant portions of the ACA were upheld as a valid exercise of federal government authority, the Supreme Court found that the amendments to Medicaid amounted to an impermissible commandeering of the states. Its opinion was based upon the argument that the consequences to the states for failure to comply with the ACA mandates would result in significant loss of federal funding. This finding likely paves the way for future arguments that withholding of funding by the federal government may constitute violations of the anti-commandeering principles.

These cases provide the basis for establishing and affirming that the federal government has no authority to force states to cooperate in implementing or enforcing its acts. In short, the federal law can regulate people, but it cannot regulate states.

It must also be acknowledged that the states are prohibited from commandeering aspects within the federal domain in that the principles of federalism protect all sovereignty, not just state sovereignty. While the federalism of US Supreme Court jurisprudence has a long history, the recent movements of state legislation subject to this "reverse" commandeering has resurrected the notion of preemption and scrutiny of the Tenth Amendment.

In a case decided in 2012 (*Arizona v. United States,* 132 S. Ct. 2492 (2012)), the United States Supreme Court held as constitutional that portion of the Arizona Senate Bill 1070 that requires law enforcement officers to make a reasonable attempt to determine the immigration status of a person stopped, detained, or arrested if there is reasonable suspicion that such person is in the country illegally. Additional portions of the law were struck down by the court as unconstitutional in that they infringed on the exclusive authority of the federal government to address immigration and enforcement thereof. In recognizing the power of state law enforcement officers to attempt to determine immigration status of detainees, the court noted that constitutional principles allow the states to partner with the federal government in immigration enforcement.

In 2011, (*Chamber of Commerce v. Whiting,* 131 S. Ct. 1968 (2011)), the US Supreme Court addressed the Legal Arizona Workers Act, which allows superior courts in Arizona to suspend or revoke business licenses of employers who knowingly or intentionally hire unauthorized aliens and mandates that all employers participate in E-Verify (a federal system that verifies employment eligibility through the US Department of Homeland Security and the Social Security Administration). The court upheld as constitutional the Arizona statute and rejected arguments that such law was preempted by federal statutes, including the federal Immigration Reform and Control Act of 1986.

In a case of first impression in 2014, the California Supreme Court addressed the eligibility of an undocumented alien for licensure as an attorney. While the litigation was pending, the California legislature enacted legislation that explicitly recognizes as eligible for licensure as an attorney otherwise qualified applicants not lawfully present in the US. (Cal. Bus & Prof Code section 6064 (2014)). The applicable sections of the federal laws related to immigration allow for the states to enact legislation that allows for licensure of professionals who are undocumented aliens. (8 U.S.C. section 1621). Thus, arguments regarding federal preemption of immigration issues were nullified and the California Supreme Court ruled in favor of the applicant and ordered the Board to license the applicant. (*In Re Sergio Garcia,* 2014 Cal. LEXIS 1 (CA 2014))

As demonstrated above, the complexities of immigration laws and the exclusive authority of the federal government to occupy this field do not necessarily prohibit the states from legislating in certain aspects of this arena.

Marijuana

The next significant jurisprudence addressing federalism and the articulation of dual sovereignty is over the growth of state activity in legalizing marijuana. Currently there exists a conflict between state

marijuana legalization and the blanket prohibition of marijuana under the federal Controlled Substances Act (CSA). This conflict clearly illustrates the federalism crisis between federal and state sovereignty.

Anti-commandeering principles under the Tenth Amendment are applicable if there are mandates by the federal government for states to arrest and seize marijuana possessors. However, this question remains blurred. Equally complex is the Supremacy Clause argument that calls for federal prohibition to preempt state law in the few jurisdictions that legalize marijuana.

The authority of Congress to regulate persons within a state is undisputed, including where such regulation may conflict with state laws. In the CSA, Congress has exercised this right and prohibits persons, regardless of location, from possession or use of marijuana. In a 2005 opinion, the US Supreme Court upheld the federal prohibition of the manufacture and possession of marijuana under the CSA. (*Gonzales v. Raich,* 545 U.S. 1 (2005)). The Court recognized the authority of Congress under the US Constitution Commerce Clause and reaffirmed the authority of the federal government to prosecute offenders. This CSA prohibition applied to intrastate manufacture and possession of marijuana, in spite of California law recognizing the right to the possession and use of medicinal marijuana.

Since 1996, however, states have exercised their rights as independent state sovereigns to legalize both medicinal and recreational marijuana. Thus the conflict, for which there are no clear answers. Must state or local law enforcement officers arrest and seize marijuana offenders and product or comply with conflicting state laws legalizing its possession and use? Can the federal government authority to impose general laws trump the states' right to legalize marijuana? The CSA is a general law that carries with it Supremacy Clause applicability.

Currently, 21 states and the District of Columbia have enacted laws that remove criminal penalties for the possession, use, and cultivation of marijuana for medical purposes. Colorado and Washington have legalized recreational marijuana possession and use, but impose state controls on its availability in commerce.

In 1970, as part of the "war on drugs," federal law

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2013-2014 Annual Report of NABP Legal Affairs

NABP enjoyed robust growth this past year. Milestones in education, intellectual property, and public health protection are among the many significant Association achievements since the 109th Annual Meeting. To better support the expansion of NABP, Legal Affairs augmented its staff, assumed additional responsibilities, and engaged in staff educational outreach efforts.

Board Support

In collaboration with several Association departments, Legal Affairs hosted a successful meeting for board attorneys as part of the Interactive Compliance Officer and Legal Counsel Forum. Educational information was provided covering trends in pharmacy practice and administrative law. Board counsel were able to discuss a variety of topics with colleagues and share recommendations based upon their experiences. Similarly, Legal Affairs staff were able to forge stronger relationships with board attorneys, which will promote efficient contract negotiations and afford better and more timely access to Association services, whether they are the NABP PMP InterConnect® or inspection sharing network services.

Intellectual Property

NABP owns a robust intellectual property portfolio comprised of patents, copyrights, and trademarks. Particularly noteworthy is the patent awarded in April 2014 for NAR$_X$CHECK® software – the first patent in the Association's 110-year history. NABP holds several pending patent applications related to its testing services and owns more than 50 trademarks. Legal Affairs regularly coordinates with Association staff to identify and take action to halt misuse of NABP copyrighted material and trademarks.

.Pharmacy gTLD

Legal Affairs is actively working with the Association .pharmacy team to complete the final tasks necessary to operationalize the .pharmacy generic Top-Level Domain. Staff are reviewing Internet Corporation for Assigned Names and Numbers documents and are developing associated legal material to foster the seamless roll-out of NABP's key global consumer health protection program.

Exciting Year Ahead

As NABP continues to forge new ground and engage in innovative efforts to assist its members in safeguarding public health, the Legal Affairs department will support the Association every step of the way. The strength of the relationship between NABP and the boards of pharmacy is critical in making these consumer safety efforts, and the partnership, successful.

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criminalized marijuana under the CSA. The purpose of the CSA is to combat drug abuse, prevent diversion, and eliminate illegal importation, manufacture, distribution, and possession and improper use of controlled substances. Marijuana is a Schedule I drug, falling in the most restricted category.

The interplay between federal and state law related to marijuana will be played out in the judiciary, and answers to these difficult questions will be formulated.

Canadian Drugs

Part and parcel to the Supremacy Clause and Tenth Amendment debates are attempts by states to regulate access to Canadian drugs by state residents. The Federal Food, Drug, and Cosmetic Act (FD&C Act) is regarded as the "supreme law of the land" and establishes a national closed system of domestic distribution of approved prescription drugs. The FD&C Act looks to ensure drug safety and integrity and establishes the standard by which drug distribution is evaluated from legal and practical perspectives. The primary purpose of the FD&C Act is to protect the public. In an effort to provide less expensive drugs to its citizens, some states have enacted laws, policies, initiatives, and regulations aimed at allowing state citizens to import their drugs from foreign pharmacies. The Food and Drug Administration (FDA) states such conduct contravenes Sections 331 and 355 of the FD&C Act, again providing a basis for stimulating legal debate over supremacy, states rights, and the interplay between federal and state law and authority.

In 2007, the 7th Circuit Court of Appeals affirmed US District Court for the Northern District of Illinois and held that the federal government had the authority to seize and condemn a commercial shipment of Lipitor® from Brazil and Zocor® from Argentina. (*United States v. Grenendo,* 485 F. 3d 958 (7th Cir. 2007)). This opinion focused on the federal government authority over drugs produced in foreign jurisdictions and outside of FDA-approved facilities, yet intended for introduction into interstate commerce in the US. It is this same analysis that prohibits the importation of drugs from Canada.

To ensure a safe and effective drug supply, the FD&C Act establishes a closed system of drug distribution. It limits the types of drugs that may be imported into the US. Congress gave FDA the authority to limit the importation of unapproved foreign versions of FDA-approved drugs based upon safety concerns. Congress also found that unrestricted reimportation of US-manufactured drugs also created unacceptable risks of counterfeit, adulterated, misbranded, subpotent, or expired drugs being introduced into commerce.

Several states, however, have moved toward legitimizing foreign pharmacies by approving or licensing Canadian pharmacies. Indeed, some states have attempted to set up systems to "approve" these Canadian pharmacies, in spite of the fact that there is no mechanism under state law for state recognition of foreign pharmacies.

Other states have fashioned laws to permit the purchase and introduction of drugs from Canadian pharmacies to the extent such is permitted under federal law or exemptions established thereunder. Furthermore, some states have attempted to specifically authorize the state board of pharmacy to license Canadian pharmacies for the purpose of allowing the shipment of Canadian drugs into the state.

These state initiatives exhibit a departure from the joint regulatory effort between the federal government and states to protect the public from dangerous drugs.

Any such attempts by the states to permit the introduction of foreign drugs into commerce may eventually be challenged under the Supremacy Clause. Such a legal challenge will stimulate a preemption argument pitting the United States Constitution against the rights of the states under the Tenth Amendment. The basic legal argument will debate the right of the federal government, likely under the Supremacy Clause, to preempt states' rights under the circumstances, thus nullifying the right of the state to act. To the extent federal legislation allows the state to act in the relevant arena, such as in the field of immigration, such deference by the federal government to the states' rights will diminish federal preemption arguments.

Drug Supply Chain Security Act

In November 2013, President Barack Obama signed into law the DQSA that contains Title II Drug Supply Chain Security Act (Title II). Title II amends the FD&C Act and calls for FDA to set standards for tracking and tracing pharmaceuticals, and phases in requirements for specified trading partners across the health care supply chain. In pertinent part, it also prohibits states from establishing or enforcing standards for licensure of wholesalers that are inconsistent with or less stringent than those within the new federal law.

In response to correspondence received from a few member state boards of pharmacy, NABP issued a memo dated January 16, 2014. The issue addressed is whether, and the extent to which, Title II of the DQSA may preempt state law relative to the licensure of wholesalers and the use or recognition of the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program. The January 2014 memo is reproduced in the Report of Counsel posted in the Members section of the NABP website.

It must be emphasized that preemption by federal law over state law is premised

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NABP Appoints John Clay Kirtley to ACPE Board

NABP is pleased to announce that John Clay Kirtley, PharmD, executive director, of the Arkansas State Board of Pharmacy, has been appointed by the Association to the Accreditation Council for Pharmacy Education (ACPE) Board of Directors for a six-year term ending in 2020. As an active member of NABP, Kirtley has served on numerous NABP committees and task forces, including serving as chairperson for the Task Force on the Control and Accountability of Prescription Medications and as a member of the Task Force on Medication Collection Programs and the Committee on Constitution and Bylaws.

Kirtley has served as the executive director for the Arkansas Board since 2011. Prior to this position, he was the assistant/deputy director of the board. In addition, he has served as an assistant professor of pharmacy practice at University of Arkansas for Medical Sciences (UAMS) College of Pharmacy, and as an assistant manager at Tanglewood Drug Store in Little Rock, AR. In 2011, he received the Preceptor of the Year award from UAMS College of Pharmacy.

Kirtley is active in leadership roles at several pharmacy and professional organizations, including the Arkansas Pharmacists Association and the American Pharmacists Association. Since 2008, he has been a member of ACPE's Continuing Pharmacy Education Commission. He has also been published in multiple pharmacy journals and has drafted multiple pieces of legislation that were ultimately passed in Arkansas, including legislation related to accountability measures for controlled substances. Kirtley received his doctor of pharmacy degree from UAMS and completed his pharmacy prerequisites at Ouachita Baptist University.

Kirtley replaces Donna S. Wall, PharmD, BCPS, FASHP, who completed her term as an NABP appointee to the ACPE Board of Directors this year. Kirtley joins two other ACPE members appointed by NABP: Michael A. Moné, JD, RPh, vice president, anti-diversion and senior regulatory counsel at Cardinal Health, whose term runs from 2012 to 2018; and Dennis K. McAllister, RPh, FASHP, director, pharmacy regulatory affairs at Medco Health Solutions, Inc, whose term runs from 2010 to 2016.

NABP, the American Association of Colleges of Pharmacy, and the American Pharmacists Association each appoint three members to the ACPE Board of Directors.

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upon a conflict between the two laws. Where the federal and state laws do not conflict, there is no preemption argument. The DQSA requires states to meet or exceed certain requirements related to the licensure of wholesalers. To the extent that state law is compliant with or establishes more stringent requirements than that of the DQSA, such state law will survive preemption scrutiny by the judiciary. The VAWD program complies with federal legislation in that its criteria for recognition exceed those mandated by the federal law. Thus, any notion of invalidation of state laws or prohibition of states' use of the VAWD program is likely misguided. The 2014 NABP Annual Meeting included a continuing education session on the details of this legislation and its effect on the pharmacy regulatory community.

Conclusion

The concept of federalism and the mutual recognition of governance between the federal and state governments is complex and subject to intense legal debate. The regulation of pharmacy, pharmacists, and drug distribution is fraught with interplay between state and federal authority. The notion of preemption, sometimes referred to as anti-commandeering, where state and federal authority are potentially in conflict, may sometimes be resolved through an analysis of the US Constitution via the Supremacy Clause and Tenth Amendment. Nowhere is overlapping and dual governance more present than in pharmacy regulation and pharmaceutical distribution. A healthy balance between state and federal authority promotes safe and effective regulation. Under their police powers, states enact legislation and regulate pharmacy practice and drug distribution, providing a state-based system of regulation. Where interstate commerce is affected, federal legislation has been enacted to provide uniformity in regulation and diminish impediments to activities across state lines. As referenced, preemption and/or a Supremacy Clause debate is triggered when states are asked to enforce federal mandates. While Title II of the DQSA is intended to establish a national uniform standard and may be construed as preempting state law related to wholesale prescription drug distribution, such relevant portions of the legislation establish a benchmark for recognition. To the extent state law contravenes this benchmark, preemption may be a legitimate scholarly debate. However, the VAWD program meets and exceeds such a federal benchmark, thereby allowing states to recognize VAWD and remain in compliance. Readers are encouraged to look to NABP for further information about DQSA. It is hoped that this Report of Counsel establishes a general awareness of the complexities of the Supremacy Clause and preemption arguments.

Drug Supply Vulnerabilities

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it preempts existing state requirements regarding drug pedigrees and also requires FDA to establish licensing requirements for wholesale distributors and third-party logistics providers. Not all implications of the new law are clear, particularly as to licensing, but immediately upon enactment, the Act preempted state pedigree requirements "inconsistent with, more stringent than, or in addition to" the federal track and trace requirements.

An important consideration of the DQSA is the recognition of the VAWD program and other state inspection efforts. Under Section 583, "NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS," the law specifically states the following:

> c) INSPECTIONS. – To satisfy the inspection requirement under subsection (b)(6), the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor.

NABP worked closely with the authors of the law to ensure that such a provision would be included and allow for continued recognition and use of the VAWD program by the states.

NABP is working with FDA as that agency develops regulations required by the new law, and, as the Association noted in a January press release on the topic, "is working with FDA and states to ensure uniformity among the VAWD criteria, provisions in the new federal law, and the subsequent regulations that FDA will develop."

> The law specifically states that the licensing authority may accept an inspection "by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor."

Regulatory Loopholes

While awaiting regulations from FDA, states should not ignore other areas of weakness and loopholes in laws that can allow diverted or counterfeit drugs into the supply chain and that still fall within states' ability to control.

In its 2013 white paper, "Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply," NABP highlighted several methods unscrupulous distributors use to infiltrate the drug supply chain. Several of these begin with "special pricing," when particular pharmacies or types of pharmacies may be able to obtain certain medications from a manufacturer at a price cheaper than that available to wholesalers. This can create a financial incentive for pharmacies to sell their cheaper product back to the wholesale market. Under general circumstances, pharmacies are not allowed to sell medications back into the wholesale supply chain. Emergency transfers, however, may be allowed, and may be worded ambiguously enough to allow pharmacies to sell drugs to other pharmacies or to wholesalers using "emergency transfer" as a legal fig leaf.

"Five percent rules," which may permit a pharmacy to sell a certain quantity of prescription drugs (sometimes five percent of its annual prescription drug sales) to a licensed practitioner for office use, also provide a loophole for pharmacies to act as wholesalers. This has become such a wide area of abuse, in fact, that NABP's members approved a resolution on the topic at the Association's 109th Annual Meeting. Resolution 109-2-13 directs NABP to "urge its member boards of pharmacy to revise their 'five percent' rules to allow the transfer, distribution, or sale of prescription drugs between pharmacies, or from pharmacies to practitioners, only for the purpose of dispensing or administration, but not for resale; and to prohibit the transfer, distribution, or sale of prescription drugs from pharmacies to wholesalers for resale."

Rules allowing intracompany drug transfers have also seen abuse, when a transfer appears to be happening between two related companies under common ownership, but is not. Entities seeking to exploit the distribution system in this way use a number of strategies, such as using the same name, address, or both for a pharmacy and a wholesaler, making it almost impossible to distinguish an audit trail.

Reverse distribution provides another potential weak point in the distribution system. Generally, pharmacies send unused medications to the reverse distributor to process, either returning drugs to the manufacturer or disposing of them. Not all states regulate reverse distributors, or require pharmacies or manufacturers to obtain verification of proper disposal, to ensure that no medications can return to the supply chain. (A more detailed discussion of issues surrounding regulation of reverse distributors is available in the article "Regulators Review Reverse Distribution Process to Prevent Diversion, Environmental Hazards," in the January 2012 issue of the *NABP Newsletter*.)

NABP remains committed to looking at areas where the states can direct their resources in order to continue having a positive impact on public safety, and to assisting the states as they fulfill their missions of protecting their citizens.

NARxCHECK Integrates Directly Into Workflow of Largest Health Care System in Ohio Using EPIC EHR Solution

NABP Foundation™ is pleased to announce that NARxCHECK®, the software tool that generates risk-based scores reflecting a patient's controlled substance (CS) prescription medication history, has been deployed directly into the provider workflow of the largest health care system in the state of Ohio.

NARxCHECK's Newest Client

In May 2014, NARxCHECK was made available as a tool to prescribers at The Jewish Hospital – Mercy Health (Jewish Hospital), in Cincinnati, OH. This addition makes The Jewish Hospital the 24th hospital to implement the NARxCHECK software into provider workflow, and the first of two hospitals in the Catholic Health Partners (CHP) health care system. CHP, the largest health care system in the state of Ohio, is a nonprofit health care system that owns and operates hospitals, long-term care facilities, and other health care organizations in Ohio, Kentucky, and contiguous states. The integration with NARxCHECK has been instrumental in providing improved delivery and access of prescription monitoring program (PMP) data explained Shawn A. Ryan, MBA, MD, chair of quality and patient safety, The Jewish Hospital-Mercy Health and chair, prescription drug abuse task force, Mercy Health Southwest Ohio. He noted the importance of the speed and quality of the information. "The physicians are all very pleased with this faster and more informative [PMP] system. I personally think it has the potential to profoundly change the way that we are able to assess drug seeking behavior in the emergency department, and by extension, help us combat the epidemic," stated Ryan.

The deployment of NARxCHECK into The Jewish Hospital will include the delivery of its patented analytical reports directly into the hospital's electronic health record (EHR) system, EPIC CarePATH solution. Epic, one of the largest EHR vendors in the United States, is a highly regarded software developer that specializes in integrated software for health care providers that supports functions related to patient care, including registration and scheduling, and clinical systems for doctors, nurses, emergency personnel, and other care providers. NARxCHECK is accessible as a tab within the patient's Epic medical record. This build-out makes provider access to a NARxCHECK Score and Report a seamless experience by eliminating the need for a separate login to the state's PMP and the manual search function to obtain a patient's medication history. Instead, providers will be able to access the NARxCHECK and PMP data with a single click, which will display the following:

- an interactive NARxCHECK Report featuring a risk assessment score for the patient;
- an interactive prescription graph that represents the patient's entire CS prescription history over the last two years;
- the complete records of a patient's CS prescriptions, providers, and pharmacies; and
- additional data analysis.

NABP notes that the NARxCHECK and Epic software integration deployed at Jewish Hospital's system can be replicated at other Epic facilities, which is good news for health care systems using Epic as their primary EHR vendor nationally.

PMP Mandatory Use

The delivery of PMP data into provider workflow has become imperative for many health care systems as they seek to meet the nationally growing mandatory use requirements. Several states are now mandating that providers access PMP data prior to prescribing or dispensing a CS. Currently, 48 states have a PMP in place. Of those 48, 17 states require PMP use; 12 states require PMP registration; and five states are considering, or have considered, legislation that would prompt some form of PMP use requirement.

For example, recently passed legislation in Ohio (HB 341) mandates the review of PMP data before initially prescribing a controlled substance prescription. The law goes into effect on April 1, 2015. Until that time, Ohio's current statutory mandate requires providers to access PMP data if the physician "believes or has reason to believe that a patient may be abusing or diverting drugs." Further, "the physician shall use sound clinical judgment in determining whether or not the reported drug should be prescribed or personally furnished to the patient under the circumstances." On February 11, 2014, NABP testified before the Ohio House of Representatives' Opiate Addiction Treatment and Reform Subcommittee – Health and Aging that was then considering the bill. NABP staff provided information on how two of the Association's valuable tools and services – NARxCHECK and NABP PMP InterConnect® – may assist health care providers in meeting these legislative requirements. Through NARxCHECK and NABP InterConnect, the Association has a rich and recent history of successfully delivering PMP data into provider workflows. For example, through pilots supported by both Bureau of Justice Assistance and Office of the National Coordinator for Health Information Technology, NARxCHECK has facilitated interoperability in health care systems in Indiana, Ohio, Kansas, and Michigan, with plans for pilots in both Virginia and Illinois by the end of 2014. In addition, NABP InterConnect now connects 26 participating states and provides the secure exchange of PMP data to authorized users.

Looking ahead, NABP Foundation and The Jewish

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PCOA Forum Participants Discuss Student Progress and Development of Pharmacy School Curricula

The third annual Pharmacy Curriculum Outcomes Assessment® (PCOA®) Forum brought together representatives from schools and colleges of pharmacy, the American Association of Colleges of Pharmacy, and the Accreditation Council for Pharmacy Education (ACPE) at NABP Headquarters on April 24, 2014.

Each year, the PCOA forum is held to provide an opportunity for PCOA users, prospective users, stakeholders, and developers to convene and share insights and experiences regarding the assessment in an educational, communicative environment.

This year's forum began with an overview of the PCOA, including information about the background and developmental history of the examination and an overview of the past years' administration results. Attendees also reviewed program development updates regarding computer-based testing and the Curriculum Survey of the Colleges of Pharmacy PCOA subcommittee.

Following the program updates, a representative from ACPE provided information about the *Draft Revised Standards for the Professional Program Leading to the Doctor of Pharmacy Degree (Draft Standards 2016)*, which is expected to be finalized and effective by July 2016. ACPE's presentation included an explanation of the next steps and implementation for the draft standards, and how stakeholders could submit feedback.

The remainder of the meeting consisted of presentations of research initiatives at institutions utilizing the PCOA. Research topics included a survey addressing the implementation of the PCOA in United States doctor of pharmacy curricula, the PCOA's role in predicting candidate success on the North American Pharmacist Licensure Examination®, and how pre-professional education influences the academic success of pharmacy students enrolled in US programs.

The PCOA is an independent, objective, and external measure of student performance in US pharmacy curricula. Since its operational launch in 2008, the assessment has been administered to more than 24,000 students from 60 different schools and colleges of pharmacy. Schools and colleges of pharmacy that registered for the next PCOA testing window will be sent an informational e-mail in late summer 2014.

The PCOA is the only standardized national assessment that compares school outcomes with national scores, providing a way for institutions to monitor student progress and pharmacy curricula in compliance with ACPE recommendations for assessment.

At the end of the forum, staff encouraged attendees to share how the PCOA program could further assist the schools with curricula and student evaluation. NABP is currently reviewing all of the suggestions and evaluating their suitability for implementation into the infrastructure of the examination program.

More information about the PCOA can be found at *www.nabp.net/programs.*

2015 Testing Windows

- **January 12, 2015 - February 6, 2015**
  Register by October 14, 2014
- **March 30, 2015 - April 24, 2015**
  Register by December 30, 2014
- **August 24, 2015 - September 18, 2015**
  Register by May 26, 2015

PCOA Forum Attendees Convene to Discuss Testing Perspectives

On April 24, 2014, representatives from schools and colleges of pharmacy, the American Association of Colleges of Pharmacy, and the Accreditation Council for Pharmacy Education gathered at NABP Headquarters for the third annual Pharmacy Curriculum Outcomes Assessment® (PCOA®) Forum. Pictured left: Justine Schuller Gortney, PharmD, BCPS, assistant professor (clinical) of pharmacy practice and coordinator of postgraduate pharmacy teaching certificate program, Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences shares with attendees her experiences regarding the assessment with other representatives.

Twenty-Six States Now Connected to NABP PMP InterConnect

Two additional states, New Jersey and Utah, are now live with NABP PMP InterConnect® and a total of 26 states are now connected and sharing interstate prescription monitoring program (PMP) data with authorized users. With more than half of the states now sharing PMP data via this secure communication platform, authorized PMP users in those states are able to see a more complete history of patients' controlled substance prescriptions, helping health care providers identify possible misuse or abuse.

The New Jersey Prescription Monitoring Program and the Utah Controlled Substance Database Program joined the following participating state PMPs: Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Nevada, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Virginia, West Virginia, and Wisconsin.

NABP InterConnect participation is expected to continuously grow in 2014, with some states having executed a memorandum of understanding (MOU) to participate, and other states currently reviewing their MOUs.

The NABP InterConnect Steering Committee convened July 8-9, 2014, at NABP Headquarters to discuss these recent state participation updates and other information as it relates to the administration and function of the program. Exclusively composed of representatives of PMPs that participate in the NABP InterConnect program, the Steering Committee serves as the governing and advisory body of the program. The Steering Committee meets at least once per calendar year in person or by teleconference. Additional information about the committee, including reports of past committee meetings, are available in the Programs section of the NABP website under NABP PMP InterConnect. More information about the meeting will be available in future NABP Communications.

Launched in 2011, NABP InterConnect was designed to facilitate interoperability and interstate data sharing between state PMPs by providing a secure communications exchange platform for participating states. The system does not house any data and ensures that each state's data access rules are enforced.

States that seek further information about NABP InterConnect may contact NABP Member Relations and Government Affairs staff at GovernmentAffairs@nabp.net or by calling 847/391-4406. Additional information about NABP InterConnect, including the most up-to-date information on state participation, is available in the Programs section of the NABP website at *www.nabp.net.*

Newly Approved e-Advertisers

The following entities were granted approved e-Advertiser status through the NABP e-Advertiser Approval℠ Program:

Compounding Pharmacy of Beverly Hills
www.compounding-expert.com

Empower Clinic Services, LLC
www.empowerrxpharmacy.com

Empower Pharmacy
www.empowerrxpharmacy.com

Franklin Square Pharmacy
www.franklinsquarepharmacy.com

Life Advisors, LLC
www.yourpharmacycard.com

PetPlus, LLC
www.petplus.com

Quality Pharmacy Management, Inc
www.qpmhealthcare.com

Revive Low T, LLC
www.revivelowt.com

YoDerm, Inc
https://yoderm.com

A full listing of NABP approved e-Advertisers is available on the NABP website at *www.nabp.net.*

Review Committee Members Convene at NABP Headquarters to Provide Expertise on Association's Examinations

MPJE Review Committee Convenes in June 2014 at NABP Headquarters

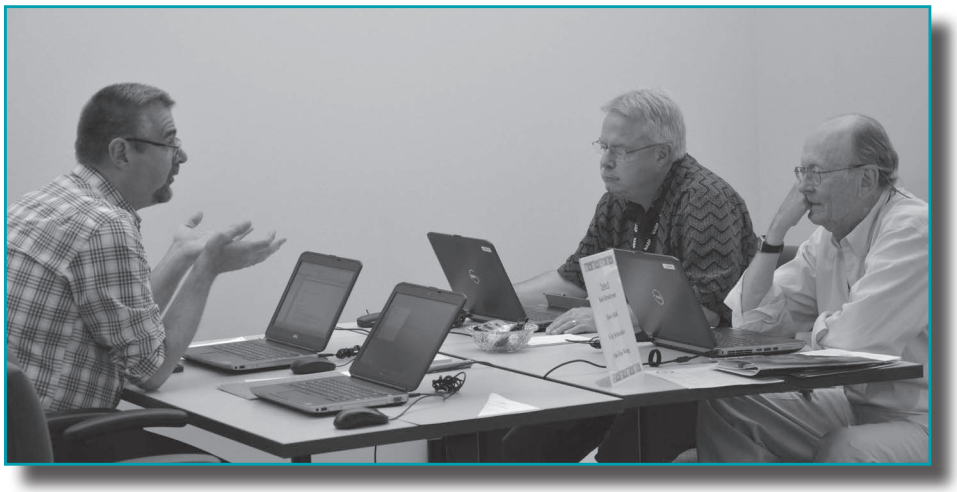
In June 2014, review committee members for the Multistate Pharmacy Jurisprudence Examination® (MPJE®) convened for its Annual Meeting at NABP Headquarters. Pictured right: MPJE review committee members Mark Brown, RPh, of Lahaina, HI, and Richard Morrison, RPh, of Bothwell, WA.

Fellow MPJE Review Committee Members Network During June 2014 Meeting

Pictured left: MPJE review committee members Vance Alexander, JD, RPh, member, Alabama State Board of Pharmacy, and Alan M. Shepley, RPh, of Mount Vernon, IA, take a moment to network during the June 2014 meeting.

Review Committee Members Discuss NAPLEX Examination Questions

The North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee convened at NABP Headquarters in July 2014. Pictured right: Eric F. Schneider, PharmD, University of Waterloo (left) shares his thoughts with fellow review committee members Robert P. Henderson, PharmD, Samford University (middle) and David B. Roll, PhD, University of Utah (right).



State Boards of Pharmacy Report Nearly 1,600 Disciplinary Actions to NABP Clearinghouse During First Quarter 2014

The NABP Clearinghouse continues to track actions against licensees to provide a broad picture of the scope of actions being reported by the state boards.

During the first quarter of 2014, the state boards of pharmacy reported a total of nearly 1,600 disciplinary actions to the NABP Clearinghouse, including actions taken against pharmacists, pharmacy technicians, pharmacy interns, pharmacies, wholesalers, manufacturers, and other licensees. Of the 1,600 actions taken in first quarter:

- 788 actions or 49% were taken on pharmacists;
- 425 actions or 27% were taken on pharmacies;
- 328 actions or 20% were taken on pharmacy technicians;
- 35 actions or 2% were taken on pharmacy interns;
- 18 actions or 1% were taken on wholesalers and manufacturers; and
- 1 action or less than 1% was taken against a controlled substance licensee.

Of all the actions reported in the first quarter to the NABP Clearinghouse, publicly available fines/monetary penalties accounted for the most actions reported, comprising 610, or 38.1% of the total actions. Following this category, probation of license was the second most reported action with 197, or 12.3%, of the actions reported. The third most common action reported to the Clearinghouse was reprimand or censure, with 133 or 8.3% of the total actions. Finally, the action categories of suspension of license or certificate; voluntary surrender, limitation, or restriction of license or certificate; and summary or emergency limitation or restriction of license each accounted for 6.7% (107) of the total records. (See Figure A for a full breakdown of the actions taken during first quarter 2014.)

The state boards of pharmacy also report to the Clearinghouse the basis for all actions taken. In the first quarter, 466 or 30.9% of the reported bases for actions were violations of federal or state statutes, regulations, or rules. Following this category are bases for actions included in the miscellaneous category, such as deferred adjudication, failure to meet licensing board reporting requirements, and failure to comply with patient consultation requirements. This category accounted for 11.6% (175) of bases for actions reported.

Another 10.4% (157) of the bases reported during the first quarter were alcohol and/or other substance abuse. (See Figure B for a full breakdown of the bases for actions taken during first quarter 2014.)

The Clearinghouse is regularly updated to serve as a comprehensive resource for the boards of pharmacy. Housing a tremendous amount of disciplinary data provided by the boards, the Clearinghouse is an important resource for the license

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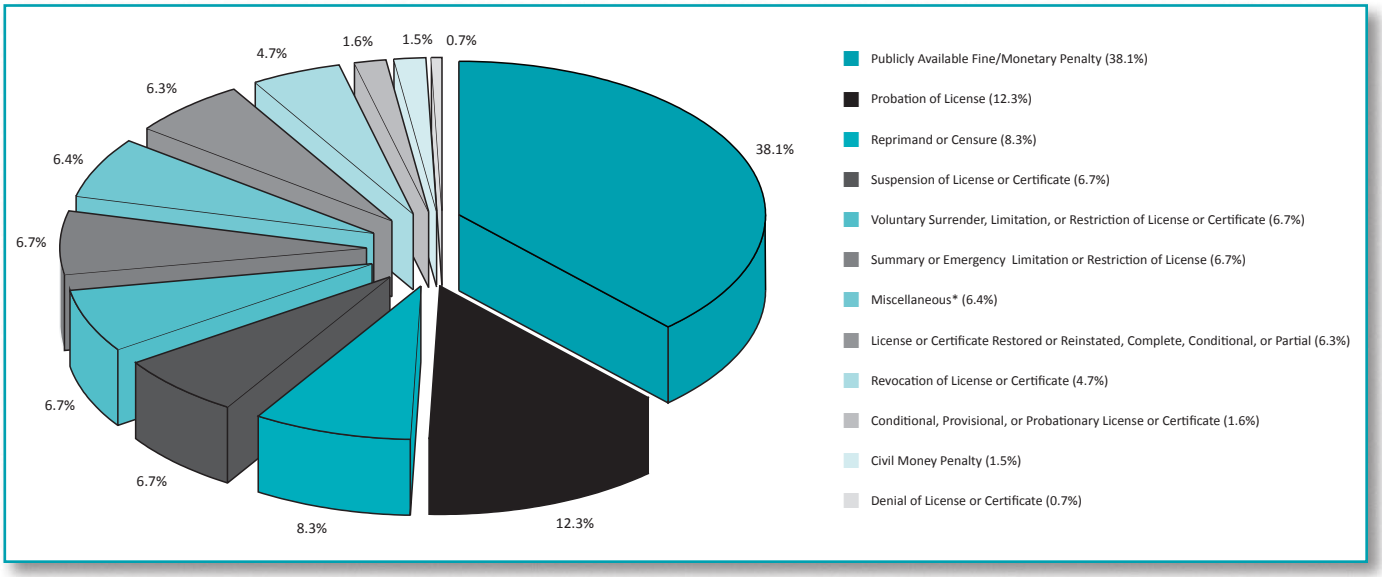
Figure A: Disciplinary Actions Reported in First Quarter 2014



*The miscellaneous category includes interim action; monitoring; summary or emergency action; reduction of previous licensure action; modification of previous licensure action; other licensure action - not classified; reduction of previous licensure action; extension of previous licensure action; and directed plan of correction.

Clearinghouse

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transfer process as it tracks everything from the actions taken against pharmacists, pharmacy technicians, and pharmacies to the basis for these actions.

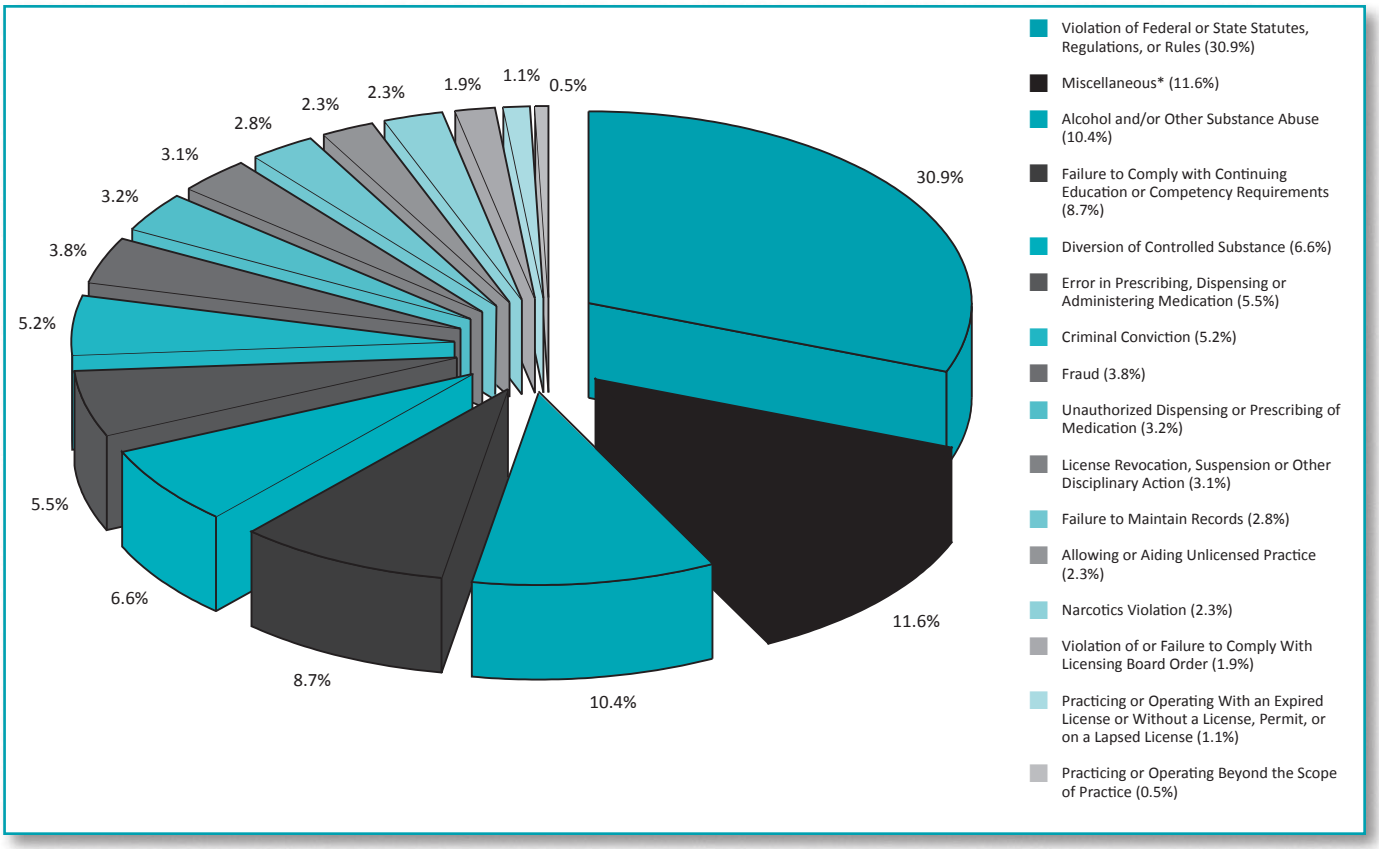
Reporting to the Clearinghouse is required by the NABP Constitution and Bylaws, and the Association continues to encourage the state boards of pharmacy to report disciplinary actions. Reports are submitted through Board e-Profile Connect, which assists the boards by providing real-time access to adverse actions or statements of charges being reported to the Clearinghouse. In addition, Board e-Profile Connect allows the information to be communicated among all boards of pharmacy where a licensee may be practicing or doing business.

NABP also offers its services as a reporting agent for the National Practitioner Data Bank (NPDB), which now houses Healthcare Integrity and Protection Data Bank data. Boards that have designated NABP as their reporting agent for NPDB can utilize Board e-Profile Connect to transmit the disciplinary data directly to the federal data banks. Currently, 32 boards of pharmacy have designated NABP as their NPDB reporting agent.

Boards of pharmacy that wish to request search queries of the NABP Clearinghouse data may do so by contacting the NABP Licensure Programs Department. NABP is able to provide the boards of pharmacy with specified reports whenever needed. Boards may request a report by calling 847/391-4406 or by sending an e-mail to clearinghouse@nabp.net.

Additional information about the NABP Clearinghouse and designating NABP as a reporting agent is available at *www.nabp.net/programs/member-services/nabp-clearinghouse.*

Figure B: Basis for Disciplinary Actions Reported in First Quarter 2014



*The miscellaneous category includes failure to cooperate with board investigation; improper or abusive billing practices; conduct evidencing moral unfitness; conduct evidencing ethical unfitness; failure to meet the initial requirements of a license; other - not classified; incompetence; negligence; expired drugs in inventory; substandard or inadequate care; failure to pay child support/delinquent child support; unable to practice safely due to psychological impairment or mental disorder; deferred adjudication; lack of appropriately qualified professionals; financial insolvency; failure to take corrective action; nolo contendere plea; misappropriation of patient property or other property; unable to practice safely; unprofessional conduct; improper or inadequate supervision or delegation; immediate threat to health or safety; inadequate or improper infection control practices; failure to meet licensing board reporting requirements; failure to comply with patient consultation requirements; other unprofessional conduct; and inadequate security for controlled substances.

High Rates of Opioid-Related Deaths Prompt State and Federal Agencies to Increase Access to Naloxone

In 2009, over 15,500 Americans died after overdosing on opioid prescription painkillers, a 300% increase since 1999. The recent spike in overdose deaths is a tragic outcome of the prescription drug abuse epidemic of the last decade that lawmakers, regulators, and organizations throughout the country continue to combat. These stakeholders are now also taking action to reduce the high rate of opioid overdoses by increasing access to the overdose reversal drug naloxone hydrochloride (Narcan®). Since 2001, at least 25 states have passed legislation to expand naloxone access and availability, with varied requirements on who may prescribe, dispense, and administer the drug. (see Table A below).

In use since the 1970s, naloxone is a drug that can be administered as an injection (intravenous, intramuscular, or subcutaneous). If administered to an overdose victim, the medication can quickly reverse the respiration-depressing effects that can be fatal in the event of an opioid overdose. The drug can be life-saving for individuals experiencing an overdose of prescription opioids or heroin.

Many experts now believe that the abuse of prescription opioids and heroin use are interconnected and that prescription drug abusers who lose access to a preferred opioid painkiller may turn to heroin. In fact, while some states, including Kentucky, Utah, and Georgia, report decreases in prescription drug overdoses in the last few years, Substance Abuse and Mental Health Services Administration reports the number of heroin users nationwide has climbed from an estimated 370,000 in 2007 to nearly 670,000 in 2012.

Centers for Disease Control and Prevention reports that naloxone programs for drug users and their caregivers have reversed over 10,000 overdoses from 1996 to 2010. With multiple studies providing similar evidence that naloxone access saves lives, many states have passed or amended legislation to make it easier to prescribe and dispense the drug without risk of criminal or civil liability, and/or to increase access to the drug for lay persons by allowing third-party prescribing for family and friends of those at risk of an overdose. At least seven more states have been considering some form of naloxone legislation in 2014.

Increasing access to naloxone presents a number of regulatory questions. Who can prescribe and administer the medication? Under what circumstances may it be prescribed? Who can possess it? What training should be required?

Broadly, existing naloxone laws can be divided into two types: "Good Samaritan" laws and prescribing authority laws. "Good Samaritan" laws remove the threat of civil and criminal liability from prescribers and/or administrators of the medication. For example, health care providers in Illinois who prescribe or dispense an opioid antidote to a patient who may need the drug in an emergency cannot be "subject to disciplinary or

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Table A: State Overview of Naloxone Access Laws

	CA	CO	CT	DC	DE	FL	GA	IL	KY	MA	MD	ME	MN	NC	NJ	NM	NY	OH	OK	OR	RI	TN	UT	VT	VA	WA	WI
Increased Access *									•		•	•		•				•	•	•		•	•		•		•
Good Samaritan Law **					•	•												1	2						3		
Both †	•	•	•	•			•	•		•			•		•	•	•				•			•		•	

* **Increased Access:** State has passed one or more law(s) to expand authority to prescribe and/or administer naloxone. ** **Good Samaritan Law:** State has passed one or more law(s) to protect prescribers and administrators from criminal and/or civil liability. † **Both:** State has passed both increased access and Good Samaritan laws.

1. Ohio law protects a person who administers naloxone from criminal charges of practicing medicine without a license if the person meets certain requirements. 2. Family members administering an opiate antagonist shall be covered under Oklahoma's Good Samaritan Act. 3. Participants of a Virginia pilot program are protected from some civil liabilities when rendering treatment.

Table above is based on information from "Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws," by The Network for Public Health Law.

Access to Naloxone

(continued from page 137)

other adverse action" under any professional licensing statute. These types of laws may allow health care providers to more freely offer naloxone to at-risk patients and their caregivers. Some Good Samaritan laws may also allow witnesses to an overdose to provide medical assistance, such as naloxone administration and notification of emergency services, without fear of being arrested for certain drug-related crimes. Fourteen states and the District of Columbia have enacted some version of Good Samaritan laws.

Other states have passed legislation to allow for third-party prescribing, or increased prescribing authority. In early 2014, New Mexico became the first state to grant pharmacists authority to prescribe naloxone. Pharmacists who wish to exercise this authority must meet yearly training requirements under a protocol developed by the New Mexico Board of Pharmacy. A similar law under consideration in California (AB 1535) would allow pharmacists to dispense the drug under certain conditions.

With accessibility to naloxone becoming more common, several state and county agencies now provide training programs for emergency responders and lay administrators. For example, by the end of May 2014, over 1,200 law enforcement officers from 26 police departments were trained to use the drug in DuPage County, IL. In Albany, NY, the state's Division of Criminal Justice, the Department of Health, and the Office of Alcoholism and Substance Abuse Services have collaborated to provide naloxone training to officers from 42 agencies.

At the federal level, United States Attorney General Eric Holder has advocated increased training for and access to naloxone for first responders and law enforcement agencies. "The transition to – and increase – in heroin abuse is a sad but not unpredictable symptom of the significant increase in prescription drug abuse we've seen over the past decade," Holder stated in a March 2014 video message. "Confronting this crisis will require both a combination of enforcement and treatment. The Justice Department is committed to both." In April 2014, Food and Drug Administration approved a new hand-held auto-injector device designed to be used by family members and caregivers in a suspected or known overdose emergency. Once turned on, the device provides verbal instruction to the user describing how to deliver the medication.

Through its biweekly electronic newsletter, website, and social media platforms, the AWAR$_X$E® Prescription Drug Safety Program provides information about local naloxone training opportunities and related legislative and regulatory developments at the state and federal levels. NABP and AWAR$_X$E will continue to monitor trends and to provide updates in the interest of protecting the public health.

.Pharmacy gTLD Moves Closer to Launch; Program to Help Consumers Identify Safe, Trustworthy Internet Pharmacies

NABP is taking major steps toward providing consumers worldwide with an easy way to identify legitimate Internet pharmacies and related resources through its .Pharmacy generic Top-Level Domain (gTLD) Program. In June 2014, NABP executed a Registry Agreement with the Internet Corporation for Assigned Names and Numbers (ICANN) for the .pharmacy domain, which will be available only to legitimate online pharmacies and related entities located in the United States or other countries. The Registry Agreement includes a number of safeguards intended to protect consumers. NABP will implement additional standards to protect the public health such as:

- Requiring registrars approved to sell .pharmacy domain names to notify registrants, such as Internet pharmacies, that they must comply with all applicable laws and pharmacy standards, and
- Requiring registrants to provide proof that they are licensed to operate a pharmacy and to practice pharmacy.

The next step for the .pharmacy gTLD is the registry onboarding process, which includes performance of pre-delegation testing to ensure that NABP and its technical partners have the capacity to operate the new .pharmacy gTLD in a stable and secure manner. Additionally, as the registry operator, NABP will contract with registrars that agree to ensure domain name registrants are in compliance with the established standards. NABP plans to launch the .pharmacy gTLD in October 2014.

For more information about the .Pharmacy gTLD Program, visit *www.dotpharmacy.net.*

NABP Releases Report Warning That Illegal Online Sellers Are Most Frequent Distributors of Counterfeit Drugs

In April 2014, NABP issued a report stressing that illegal online drug sellers are the most frequent conduits of counterfeit drugs and pose a continued threat to global public health. The NABP report, *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: April 2014*, stated that most of these rogue Internet drug outlets sell prescription drug products directly to consumers without requiring a valid prescription. Further, many are distributing controlled substances, putting patients at a high risk for abuse and addiction, since they are receiving these drugs without legitimate medical care. To protect consumers, NABP and a global coalition of stakeholders are moving forward plans to launch the .Pharmacy generic Top-Level Domain (gTLD) program. Further, the Association and its member state boards of pharmacy continue to encourage and work with federal regulators and other public and private entities to educate the public about the dangers of unapproved drugs and other risks of buying medications from rogue Internet drug sellers.

Pharmaceutical and health care products were one of the top five categories of counterfeit goods seized by United States officials in 2013, and many of these shipments were tied to illegal online drug sellers. The April 2014 report includes an overview of testimony presented at a February 27, 2014 Congressional hearing by public health, industry, regulatory, and academic leaders. A Food and Drug Administration spokesperson emphasized that when rogue sellers operate on the Internet, an added layer of complexity and more players are involved, expanding the criminal's ability to reach consumers. This complexity makes it easy for operators to hide behind the façade of the fake pharmacy website, never seeing their victims face to face, and also makes it difficult for cybercrime experts to track down these operations.

> [W]hen rogue sellers operate on the Internet, an added layer of complexity and more players are involved, expanding the criminal's ability to reach consumers.

A US Government Accountability Office spokesperson indicated that the "proliferation and widespread patronage of rogue Internet pharmacies has prompted public officials to identify them as a continuing public health threat." To help protect consumers, Immigration and Customs Enforcement called for a three-prong approach focusing on "[p]ublic education, demand reduction, and global collaboration." Expert participants highlighted the Verified Internet Pharmacy Practice Sites® (VIPPS®) accreditation program and the .Pharmacy gTLD program, among other efforts, as vital to educating patients about the risks of purchasing medications online and offering a means for finding safe Internet pharmacies.

NABP has executed a Registry Agreement with the Internet Corporation for Assigned Names and Numbers (ICANN) to be the registry operator of the .pharmacy gTLD, which will be available only to legitimate online pharmacies and pharmacy-related entities located in the US or other countries. The Registry Agreement between the Association and ICANN includes a number of safeguards intended to protect consumers and the public health. Thus, consumers buying medications from .pharmacy websites will be able to trust that their medications are being dispensed by a licensed, legitimate Internet pharmacy.

Findings on the more than 10,750 Internet drug outlets reviewed by NABP are also presented in the April report. Nearly 97% of the sites reviewed operate out of compliance with US pharmacy laws and practice standards and those of many other developed countries, and are listed as Not Recommended on NABP's prescription drug safety website, *www.AWARExRx.org*. The 10,392 Internet drug outlets listed in the April report as Not Recommended are characterized as follows:

- 5,102 (49%) offer foreign or non-FDA-approved drugs
- 9,164 (88%) do not require a valid prescription and 1,254 (12%) dispense controlled substances
- 2,426 (23%) have a physical address located outside of the US, and most (62%) rogue sites post no address whatsoever
- 1,668 (16%) do not have secure sites, exposing customers to financial fraud and identity theft

The full April report with detailed findings on the characteristics of rogue websites, is available on the Not Recommended page of the AWAR$_X$E website.

To find the safest sources for purchasing medicine online, consumers are encouraged to look for the VIPPS Seal on an accredited site and check NABP's list of accredited sites on its prescription drug safety website, *www.AWARExRx.org*.

AWARxE Campaign Encourages Safe Disposal of Unused Medication, Reaches Nearly 12 Million Internet Users

Although over one million emergency department visits related to prescription drug misuse or abuse occur annually, approximately 50% of teens believe prescription drug abuse is safer than abusing street drugs. Further, three in five teens say prescription drugs would be easy to obtain from a parent's medicine cabinet. In response to these facts, AWARxE® focused its spring social media campaign on raising public awareness about the importance of safely disposing of unneeded medications and encouraged consumers to participate in the eighth Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day on April 26, 2014.

Through radio public service announcements (PSAs), targeted online banner displays, a social media press release, and an Internet media tour featuring blogger interviews with Carmen A. Catizone, RPh, DPh, executive director/secretary of NABP, AWARxE had an estimated audience reach of over 11.7 million consumers. All elements of the campaign reached out to parents, seniors, and caregivers, as they are the individuals often responsible for safeguarding medications in the home.

Radio PSAs on Pandora.com and conventional radio stations stressed the urgency of helping to prevent prescription drug abuse while providing tips for how to properly store medications, and how to dispose of those that are no longer needed. Listeners were encouraged to dispose of unused medications at a DEA Take-Back Day location, and to avoid storing medications in easily accessible areas such as a bathroom cabinet. AWARxE web banners on the Pandora site played the PSAs with one click, and also took listeners to the AWARxE website for more information. More than 3,300 listeners clicked on the Pandora PSAs. The PSAs continue to be aired on conventional radio stations. Between mid-March and the end of May, the PSAs have been aired 16,000 times on 69 stations.

New for this campaign, Carmen A. Catizone participated in an Internet media tour in which he was interviewed about the dangers of prescription drug abuse, how and why to take advantage of DEA Take-Back Days, and what other steps the average person can take to ensure their medications stay out of the wrong hands. Six bloggers, whose combined audience totals more than 3.5 million, posted the videos on their websites and on YouTube.

AWARxE banners targeting interested users were displayed on websites such as Parenting.com and Health Central.com. Over one million consumers saw the banners, and more than 6,000 people clicked on the banner for more information. When clicked, the banners took users to the AWARxE website for more information about the importance of medication disposal in preventing prescription drug abuse and the DEA Take-Back Day.

The AWARxE social media press release achieved placement on hundreds of websites including Los Angeles Daily News, Boston.com, and Yahoo! Finance. The combined audience for the sites that picked up the release is more than six million users. In addition to providing information about the importance of proper drug disposal and the DEA Take-Back Day, the social media press release included images, links to the AWARxE PSAs, and links to social media websites such as Twitter, Facebook, and Technorati. With the efforts of AWARxE and other organizations helping to promote the event, the eighth DEA Take-Back Day saw excellent participation and collection sites took in more unneeded and expired medications than any previous DEA take-back event. More than 6,000 locations participated in the DEA Take-Back Day and nearly 800,000 pounds (390 tons) of unneeded medications were collected, estimates DEA. The eight DEA Take-Back days held to date have collected a combined total of 4.1 million pounds (2,123 tons) of unneeded prescription drugs, helping to prevent diversion, misuse, and abuse of the drugs.

AWARxE will continue to encourage safe disposal of unneeded medications through DEA Take-Back Days and local medication disposal programs both in the Find Disposal Information section and in the Get Local section on *www.AWARERx.org*.

Find Additional AWARxE News Online!

- Subscribe to the free, biweekly *AWARxE Prescription Drug Safety News* at *AWARERx.org*
- Like us on Facebook
- Follow us on Twitter

PBM Requirements Implemented in Washington State

The Washington State Legislature passed several bills related to health care in 2014. Three laws relate specifically to the practice of pharmacy and to the business of the Washington State Pharmacy Quality Assurance Commission.

Of note, ESSB 6137 requires pharmacy benefit managers (PBMs) to register with the Washington State Department of Revenue and to adhere to certain standards when conducting audits related to insurance claims. The standards include requirements for how audits are conducted and what is and is not allowed in that process; a specific appeals process; and reporting criteria to the pharmacy being audited. The standards also provide a much-needed path for pharmacies to challenge audit practices.

More information is available in the Bill Information section of the Washington State Legislature website, *www.leg.wa.gov.*

Louisiana Board Republishes Compounding for Prescriber Use Emergency Rule

The Louisiana Board of Pharmacy has republished the emergency rule *(Regulatory Project 2013-1.2)* that places limits on the amount of compounding for prescriber use a pharmacy may prepare without a patient-specific prescription. The Board's Regulation Revision Committee is also working on a proposal that includes new legislative language and some of the comments and testimony from the public hearing. More information about this proposal may be found in the Public Notices section of the Board's website at *www.labp.com.*

Arizona Legislature Passes Bill 1043

Senate Bill 1043, signed into law on April 22, 2014, allows naturopathic physicians to prescribe any drug that is reclassified from Drug Enforcement Administration Schedule III to Schedule II after January 1, 2014. In addition, the bill:

- Requires applicants for an initial pharmacist, intern, or technician license to submit to the Board a full set of fingerprints for the purpose of obtaining a state and federal criminal records check.
- Allows the Arizona Department of Public Safety to exchange fingerprints with the Federal Bureau of Investigation regarding criminal records checks for pharmacists.
- Removes language requiring the Board to establish a list of drugs that must not be used by dispensing pharmacists as generic equivalents and establish a two-letter code in solid dosage forms.
- Makes technical and conforming changes.

Utah Legislative Changes May Impact Pharmacy Practice

The Utah State Legislature has passed several bills that impact pharmacy practice.

Regarding drug sales between pharmacies, Senate Bill 55 Pharmaceutical Dispensing Amendments allows that a pharmacy in Utah not licensed specifically as a pharmaceutical wholesaler or distributor may sell drugs to other pharmacies if their total distribution-related sales of prescription drugs does not exceed 5% of the facility's total prescription drug sales. The law also allows a hospital pharmacy to dispense a prescription drug in a multidose container to a hospital patient being discharged if labeling requirements outlined in the bill are met. In addition, a new license classification titled "dispensing medical practitioner" was created for medical practitioners who prescribe and dispense certain drugs. A pharmacy facility license classification titled "dispensing medical practitioner clinic pharmacy" was created for clinics that dispense certain drugs in limited settings. Creating these licenses required removal of the license exemption of medical practitioners and clinics for medical practitioners who prescribe and dispense a cosmetic drug, injectable weight loss drug, or a cancer drug treatment regimen.

House Bill 119, Opiate Overdose Emergency Treatment, also passed. The law permits the dispensing of an opiate antagonist to a person who is reasonably believed to be at risk of experiencing an opiate-related drug overdose event. Under the law, it is not unlawful or unprofessional conduct for health professionals to prescribe an opiate antagonist to a person at increased risk of an overdose or to a family member, friend, or other person who would be able to assist in an overdose. The ability to administer the opiate antagonist does not establish a duty to act. Finally, the health professional will advise the person to seek help after an overdose and opiate antagonist administration.

Some amendments require drafting of administrative rules to be adopted by the Utah Department of Commerce. More detailed summaries of these legislative changes are available in the April 2014 *Utah Board of Pharmacy Newsletter* located in the State Newsletters section of the NABP website at *www.nabp.net.*

NARxCHECK

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Hospital will soon be partnering to conduct research on provider use of NARxCHECK and the clinical outcomes that follow. The research will provide insight into how workflow-ready access to PMP data impacts patient care. Updates on these research projects will be provided in future NABP communications.

More information about NARxCHECK and its services may be found at *www.narxcheck.com.*

Around the Association

Executive Officer Changes

- **Susan Alverson, PharmD,** is now serving as secretary of the Alabama State Board of Pharmacy, replacing Mitzi Ellenburg who served as interim secretary. Prior to this position, Alverson served as the Board's director of professional affairs. Before joining the Board's staff, Alverson was the associate dean for student/alumni affairs and director of continuing education at Samford University, McWhorter School of Pharmacy.
- **Mark Hardy, PharmD,** is now serving as the executive director of the North Dakota State Board of Pharmacy. Prior to this position, Hardy served as the Board's assistant executive director. Before joining the Board, Hardy worked for Thrifty White Drug for five years. In addition, he is the recipient of the Mylan Excellence in Pharmacy Award and also was awarded the honor of Pharmacist Mutual Insurance Distinguished Young Pharmacist for 2009.

Board Member Appointments

- **William Altland, RPh,** has been appointed a member of the Alaska Board of Pharmacy. Altland's appointment will expire March 1, 2018.
- **Prem Rupani, MBBS, MD,** has been appointed a member of the Illinois Department of Financial and Professional Regulation Division of Professional Regulation – State Board of Pharmacy. Rupani's appointment will expire April 1, 2015.
- **Tallie Pederson, PharmD,** has been appointed a member of the Nevada State Board of Pharmacy. Pederson's appointment will expire October 31, 2016.
- **Travis Gery** has been appointed a public member of the Pennsylvania State Board of Pharmacy. Gery is serving at the discretion of the governor's office.
- **Annmarie Arvanites, RPh,** has been appointed a member of the Rhode Island Board of Pharmacy. Arvanites' appointment will expire June 1, 2016.
- **Ryan Logan, RPh,** has been appointed a member of the Virginia Board of Pharmacy. Logan's appointment will expire June 30, 2017.

Board Member Reappointments:

- **Edward Maier, RPh,** has been reappointed a member of the Iowa Board of Pharmacy. Maier's appointment will expire April 30, 2017.
- **LaDonna Gratias** has been reappointed a public member of the Iowa Board of Pharmacy. Gratias' appointment will expire April 30, 2017.
- **James Miller, RPh,** has been reappointed a member of the Iowa Board of Pharmacy. Miller's appointment will expire April 30, 2017.

Board Officer Changes:

The Alaska Board of Pharmacy has elected the following officers to the Board:

- **Dirk White, RPh,** Chairperson
- **John Cotter, RPh,** Secretary
- **Lori DeVito, RPh,** Vice Chairperson

The Alabama State Board of Pharmacy has elected the following officers to the Board:

- **Mark Conradi, JD, RPh,** President
- **Timothy Martin, PharmD,** Vice President
- **Dan McConaghy, RPh,** Treasurer

The Arizona State Board of Pharmacy has elected the following officers to the Board:

- **James Foy, MBA, PharmD,** President
- **Dennis McAllister, RPh,** Vice President

The Georgia State Board of Pharmacy has elected the following officers to the Board:

- **Al McConnell,** President
- **Laird Miller, RPh,** Vice President

The Illinois Department of Financial and Professional Regulation Division of Professional Regulation – State Board of Pharmacy has elected the following officers to the Board:

- **Philip Burgess, MBA, RPh,** Chairperson
- **Miriam Mobley Smith, PharmD, FASHP, RPh,** Vice Chairperson

The Pennsylvania State Board of Pharmacy has elected the following officers to the Board:

- **Theresa Talbott, RPh,** Chairperson
- **Mark Zilner, RPh,** Secretary
- **Gayle Cotchen, MBA, PharmD,** Vice Chairperson

Awards and Honors

- **Marcie Bough, PharmD,** executive director, Montana Board of Pharmacy, was awarded the 2013 United States Food and Drug Administration (FDA) Commissioner's Special Citation Award. She was honored for her outstanding leadership, dedication to the advancement of the pharmacy profession, and support of FDA's mission to protect the public health. Bough's most notable contributions were related to FDA's implementation of Risk Evaluation and Mitigation Strategies.
- **Lawrence H. Mokhiber, MS, RPh,** executive secretary, New York State Board of Pharmacy, was awarded an honorary doctorate degree from Albany College of Pharmacy and Health Sciences during its 2014 commencement ceremony.

FDA Withdraws Approval of High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety.*

USP Proposed Chapter Addresses Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered, and standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum*, and may currently be viewed on the USP website at *www.usp.org/usp-nf.* Comments will be accepted until July 31, 2014.

Alli Weight Loss Medications Recalled Due to Product Tampering

In March 2014, GlaxoSmithKline (GSK) Consumer Healthcare recalled all over-the-counter Alli® sold by retailers in the United States and Puerto Rico after consumers in seven states reported "tablets and capsules that were not Alli." A range of tablets and capsules of various shapes and colors were reported to be found inside bottles, and some bottles inside the outer carton were missing labels and had tamper-evident seals that were not authentic. Authentic Alli is a turquoise blue capsule with a dark blue band imprinted with the text "60 Orlistat," and is packaged in labeled bottles with an inner foil seal imprinted with the words "Sealed for Your Protection." Consumers who are unsure or concerned about the integrity of Alli they have purchased should not use it, and should contact GSK for instructions. Consumers who have consumed questionable product should contact their health care provider. More details and GSK's contact information is available on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm391013.htm.*

New FDA Drug Info Rounds Training Video Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how to search the "Electronic Orange Book" for generic equivalents, patents, and exclusivity. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. The video can be viewed in the "Information For Healthcare Professionals (Drugs)" section of FDA's website at *www.fda.gov/Drugs/ResourcesForYou.*

Newly Accredited DMEPOS Facilities

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

Medicap Pharmacy 8282
Red Oak, IA

Powells Bloomfield Pharmacy
Macon, GA

Welcome Pharmacy
Artesia, CA

A full listing of over 500 accredited DMEPOS companies representing nearly 27,500 facilities is available at *www.nabp.net.*

nabp newsletter

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

Newly Accredited VAWD Facilities

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

McKesson Corporation, dba McKesson Drug Company
Robbinsville, NJ

McKesson Medical-Surgical, Inc
Clear Brook, VA

UPS Supply Chain Solutions, Inc
Louisville, KY

A full listing of more than 530 accredited VAWD facilities is available on the NABP website at *www.nabp.net.*