NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS

Resources on Antitrust Activities Provide Member Boards *With Tools to Evaluate Processes*

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

2016-2017 Advisory Committee on Examinations Appointments Announced, Including One New Member

NABP is pleased to announce that the following individuals have been appointed to serve on the 2016-2017 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 individuals who are either currently serving or who have served within the last five years as a member or administrative officer of an active member board of pharmacy, and non-affiliated individuals who are licensed pharmacists or serving as pharmacy school faculty. Members serve three-year terms and ex officio members serve one-year terms. The following members began their terms on June 1, 2016. Gary W. Dewhirst, RPh, DPh, is serving as the Executive Committee liaison.

2016-2017 ACE Members

- **Debra Glass, BPharm, RPh,** Tallahassee, FL
- **Theresa M. Talbott, RPh,** Stroudsburg, PA
- **Neal F. Walker, RPh,** Hibbing, MN
- **Anita Young, EdD, RPh,** Boston, MA
- **David C. Young, PharmD, RPh,** Salt Lake City, UT
- **Mark Decerbo, PharmD, RPh, BCNSP, BCPS,** Las Vegas, NV (Ex Officio Member, one-year term)
- **Holly L. Mason, PhD,** West Lafayette, IN (Ex Officio Member, one-year term)
- **Amy Mattila, PharmD, RPh,** Washburn, WI (Ex Officio Member, one-year term)

Orange color denotes new member

2015-2016 Advisory Committee on Examinations Meets at NABP Headquarters in March 2016

In March 2016, members of the 2015-2016 Advisory Committee on Examinations (ACE) met at NABP Headquarters to review the Association's examination and certification programs. ACE members pictured from left to right: Michael A. Burleson, RPh, former executive director, Kentucky Board of Pharmacy; Gary W. Dewhirst, RPh, DPh, NABP Executive Committee liaison; Holly L. Mason, PhD, Purdue University College of Pharmacy (ex officio member); Debra Glass, BPharm, RPh, member, Florida Board of Pharmacy; Anita Young, EdD, RPh, Northeastern University, Bouvé College of Health Sciences; Mark Decerbo, PharmD, RPh, BCNSP, BCPS, Roseman University of Health Sciences (ex officio member); David C. Young, PharmD, RPh, Utah Board of Pharmacy; Neal F. Walker, RPh, Fairview Range; and Amy Mattila, PharmD, RPh, Wal-Mart (ex officio member).

Get Up, Stand Up . . . Stand Up for States' Rights

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

The interplay between state and federal regulation creates complex legal and practical issues for legislatures and, ultimately, state boards of pharmacy. The purpose of the 2016 National Association of Boards of Pharmacy Report of Counsel is to address some of the principles of overlapping scopes of authority between the state and federal governments and attempt to identify where such lines are cast. Many important issues that have long been relevant have added emphasis due to the recent United States Supreme Court decision related to antitrust immunity for state actors. That case, along with the Tenth Amendment and Supremacy Clause of the US Constitution, and the concepts of federalism, states' rights, states' police powers, preemption, and evolving case law form the basis for this report.

In short, state legislatures and boards of pharmacy are empowered to regulate the profession and should continue to do so without undue threat from federal preemption or antitrust liability. State regulation through a reasoned licensure process as set forth under state law is distinguishable from the free flow of pharmaceutical products that have been the subject of significant federal law. While legal in nature, the Report of Counsel is intended for NABP constituents, particularly the members of state boards of pharmacy.

II. Constitutional Framework

A. Tenth Amendment

The US Constitution and cases interpreting it recognize the limited rights of the federal government in favor of state government. The concept of federalism in the US involves a shared governmental structure between the federal and state governments. While not without controversy and differences of opinion, the Tenth Amendment sets forth the delineation of shared governmental power.

The Tenth Amendment of the US Constitution states:

> 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.

Thus, absent any direct recognition of federal government authority, the states retain the rights to govern on behalf and in the interests of their respective citizens. Specific powers reserved to the federal government include the right to coin money/currency, regulate interstate trade and commerce, declare war, maintain an army and navy, and enact law related to immigration. Distinguishing between state and federal governmental authority is not always clear. For example, determining what constitutes interstate trade and commerce under the Constitution has been the subject of significant debate and jurisprudence. In the pharmacy arena, the Commerce Clause has provided a basis for federal government involvement dating back over a century.

B. Supremacy Clause of the US Constitution and Preemption

The Supremacy Clause of the US Constitution has relevance where state and federal law contradict one another. Article VI, Clause 2 states:

> This Constitution, and the laws of the US 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,

anything in the Constitution or laws of any State to the contrary notwithstanding.

In short, where state and federal law conflict, federal law shall be the supreme law of the land. When imposed, the Supremacy Clause results in federal law preempting state law. However, federal law only preempts state law when duly enacted and found to be within the authority of the federal government.

The concept of federal preemption and the imposition of the Supremacy Clause have been the subject of numerous judicial opinions. In short, the presumption when assessing states' rights and the potential for federal authority starts with the assumption that the historical police powers of the states were not to be superseded by federal law without a clear and manifest purpose of Congress. However, courts will infer an intention to preempt if the federal regulatory scheme is so pervasive as to "occupy the field" in that area of the law.

A relevant example of preemption by federal law in the pharmacy arena is a recent case decided by a federal court in Maine. The Maine State Legislature amended the Maine Pharmacy Practice Act to allow for the importation by Maine residents of identified drugs from certain designated countries that offer more affordable prescription prices. Upon legal challenge, the federal District Court in *Ouellette v. Mills* (2015 US Dist Ct 21137) held that the Maine law was preempted by the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, the court noted that "[the practice act] amendments' singling out of certain countries from which pharmaceuticals may be imported compromises the tightly regulated structure set up by the [FD&C Act] and the federal government's ability to 'speak with one voice' when it regulates foreign commerce."

III. Pharmacy Regulation

A. Federal Regulation

Largely based upon the free flow of drugs through interstate commerce or addressing commerce with foreign nations coupled with the Constitutional recognition of federal government authority, Congress has enacted laws that affect state boards of pharmacy. As noted above, federal laws preempt state laws that are inconsistent with the federal mandates.

The federal government's authority to exercise its rights in the pharmacy arena has a long history. In 1938, the FD&C Act was enacted. The FD&C Act replaced the Pure Food and Drug Act of 1906 and expanded the prohibition of misbranded and adulterated products to cosmetic and therapeutic devices. In addition, the FD&C Act required manufacturers to demonstrate safety before marketing new drugs. The FD&C Act also authorized factory inspections. The law has been amended on numerous occasions related to over-the-counter (OTC) drugs, prescription requirements, disclosure of side effects, and providing federal authority over advertising.

Later, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, which includes the Controlled Substances Act. This legislation created classifications of controlled substances and prescribing guidelines based on abuse potential. It also requires pharmacies to register with Drug Enforcement Administration in order to purchase certain medications, and it established various controls related to drug ordering, receiving, prescribing, and record-keeping processes.

Additional examples of federal legislative authority include the enactment of the Poison Prevention Packaging Act of 1970, requiring special packaging of drugs and certain household products; the Prescription Drug Marketing Act of 1987, related to drug samples and repurchasing of drugs; and the Omnibus Budget Reconciliation Act of 1990, requiring patient counseling by pharmacists.

More recently, Congress enacted the Health Insurance Portability and Accountability Act of 1996, related to patient privacy; the Food and Drug Modernization Act of 1997, related to compounding; the Medicare Modernization Act of 2003, related to medication management therapy services; the Combat Methamphetamine Epidemic Act of 2005, regulating OTC sales of certain ingredients; and the Drug Quality and Security Act (DQSA), related to compounding and tracing and tracking certain drugs as they navigate their way throughout the US. Title II of the DQSA, which addresses the Drug Supply Chain Security Act (DSCSA), notes that "[n]othing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing . . . or wholesale distributor and third-party logistics provider licensure . . . " However, the legislation also states that "[b]eginning [on enactment date], no State . . . may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the [DSCSA]." This federal legislation illustrates both the recognition of states' rights and the preemptive nature of federal authority.

These are but a few examples of relevant law enacted by the federal government based upon the principle of federalism and the Commerce Clause. Under these federal statutes, the federal government is exercising its authority to regulate the interstate and international flow of products related to pharmacy.

B. State Regulation

1. State Police Powers

Recognition of states' rights through the Tenth Amendment and the right of states to regulate the professions is rooted in the Constitution and through historical case law. The seminal case of *Dent v. West Virginia* (129 US 114 (1889)) upheld the West Virginia law

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that established a licensing system for physicians. In its ruling, the US Supreme Court recognized the right of a state to regulate a profession and stimulated the evolution of what is referred to as the "police powers" of the individual states. Under the Tenth Amendment, the states have the exclusive right to enact legislation governing the health, safety, and welfare of their citizens within their borders. Examples include state laws related to zoning, schooling, sanitation, crime, and others in addition to the licensing of professionals.

Under this Tenth Amendment authority, all states have exercised their right to enact legislation related to regulating the pharmacy profession by enacting enabling statutes (practice acts) that set forth the licensing of pharmacies and pharmacists. These practice acts establish a mandate that practitioners be licensed under criteria set forth in statute and provide for consequences to the unlicensed practice of pharmacy. The practice acts also create and delegate enforcement authority to the state boards of pharmacy. Further, states have exercised their rights to legislate in additional pharmacy areas.

2. Additional State Regulation

Under Constitutional authority and pursuant to the applicable legislative processes, each state has enacted numerous laws related to the pharmacy arena. Forty-six jurisdictions have enacted their own Food, Drug, and Cosmetics Act (using the exact or similar title), with only five of those verbatim to the Federal FD&C Act. Similarly, 37 individual jurisdictions have Dangerous Drug Laws, but only one (Florida) has adopted the same language used by the federal government. Every state and territory has also enacted a Controlled Substances Act, but only three use the same provisions as the federal government. Additionally, 35 states schedule controlled substances or "drugs of concern" in a manner different from the US government, demonstrating the autonomy exercised by these states in determining what laws are needed for their respective constituents.

After Congress enacted the Combat Methamphetamine Epidemic Act of 2005, many jurisdictions implemented their own laws and/or regulations to address OTC sales of pseudoephedrine. Currently, 45 states regulate OTC sales of pseudoephedrine. However, several states including Wisconsin, New Jersey, and North Carolina already had such laws on the books when the federal legislation was enacted. Seventeen jurisdictions have set specific prescription quantity limits for controlled substances, while 32 jurisdictions regulate the dispensing of prescription medical devices and 38 regulate medical oxygen.

These differing local regulatory laws illustrate the concept of states' rights and exemplify the Constitutional respect for allowing each state to determine what needs to be regulated and how.

IV. *North Carolina State Board of Dental Examiners v. Federal Trade Commission*

A. Supreme Court Opinion

The North Carolina State Board of Dental Examiners (Board) undertook an interpretative review of the scope of practice that led to a Federal Trade Commission (FTC) investigation and ultimately a highly publicized and controversial 2015 decision by the US Supreme Court. In *North Carolina State Board of Dental Examiners v. Federal Trade Commission* (135 S Ct 1101 (2015)), the Court addressed the application of the state actor immunity doctrine as applied to the Board. The Board interpreted teeth whitening to be within the scope of practice for dentists as set forth under the North Carolina statute. As a result, teeth whitening services in North Carolina were found to be limited to only those licensed to practice dentistry by the Board.

The Board issued numerous cease and desist letters to those unlicensed persons performing teeth whitening services. Cease and desist letters were also sent to suppliers of teeth whitening products and landlords of teeth whitening facilities. In response to the Board's actions, the FTC opened an investigation under applicable antitrust/anticompetitive laws. The investigation resulted in a formal administrative charge issued by the FTC against the Board. The administrative complaint was investigated and eventually went to hearing. Upon completion of the hearing, the FTC found against the Board and required the Board to notify the recipients of the cease and desist letters of the administrative ruling.

As part of the procedural motions filed by the Board in response to the FTC complaint and as part of the appeal process in federal court, the Board asserted an immunity defense to the antitrust laws under a state action doctrine. The state action doctrine is a defense to antitrust allegations that provides immunity for state actors. In short, so long as the state actor is operating under a clearly articulated state policy to displace competition, such state actor is immune from antitrust liability. Motions by the Board to dismiss the case under this doctrine were denied.

The FTC ruling was appealed by the Board to the Fourth Circuit Court of Appeals, which affirmed the FTC holdings. Thereafter, the Board appealed the Fourth Circuit opinion to the Supreme Court of the United States (SCOTUS). SCOTUS agreed with the Fourth Circuit and affirmed the antitrust violations. The Court held that the Board was a "non-sovereign" entity and, therefore, was subject to a two-part test when assessing application of any antitrust immunity principles. The Court referred to licensees on the boards as "active market participants" who cannot separate professional promotion roles from public protector roles without sufficient state oversight.

The two-part test includes acting under a clearly articulated state policy and also under active oversight by the state. The clearly articulated state policy was not in dispute in the North Carolina Board case. The Court held that the State of North Carolina lacked sufficient state

oversight and thus failed to comply with the second prong of the two-part test.

B. State Reactions to the SCOTUS Ruling

Post-SCOTUS ruling and the emphasis on state oversight have attracted the attention of the political and legal communities. In what is likely an overreaction to the decision or an opportunity for political posturing, numerous legislative initiatives have been introduced related to board structures and professional regulation. Further, executive orders by governors and attorney general opinions have been issued questioning the composition of regulatory boards and contemplating significant changes to the regulatory structures.

For example, the Oklahoma governor through Executive Order 2015-33, dated July 17, 2015, concluded that "licensure or prohibition actions (other than rulemaking) have insufficient procedures to demonstrate active supervision of boards with a majority of members who are participants of markets that are directly or indirectly controlled by the board." Thus, the order dictates that "all non-rulemaking actions proposed by any state board on which, a majority of its members are participants in the same market that the board regulates . . . shall be submitted to the Office of the Attorney General for review and written analysis of possible violation of law." The order requires the board to defer to any recommended modifications, including rescinding the proposed action.

Further, the governor of Massachusetts issued Executive Order No. 567 whereby the director of professional licensure and commissioner of public health were instructed to perform a "review of any act, rule, regulation, or policy proposed by an independent licensing board that has the potential to reduce competition in a relevant market for professional services." The order identifies that such analyses examine whether the proposed action by the board furthers an important policy goal of the Commonwealth of Massachusetts, recognizing that ensuring the health, safety, and welfare of the public is an important goal.

On June 23, 2015, the governor of Alabama issued Executive Order Number 7 noting that active supervision set forth in the SCOTUS ruling requires "substantive review of the purported anti-competitive action, veto and modification power over a board or commission decision." As a result, Executive Order Number 7, effective immediately, establishes a voluntary program for Alabama boards controlled by active market participants to comply with existing law related to active state supervision. It further ordered the establishment of the Alabama Office for Regulatory Oversight of Boards and Commissions, headed by a governor-appointed secretary, to provide administrative oversight and serve as fiscal agents, as well as to review actions submitted for consideration by participating boards. The Oversight Office has the authority to veto or modify submitted actions.

Finally, on September 10, 2015, the attorney general of California issued a lengthy letter of opinion addressing the SCOTUS ruling and applying California law to potential consequences. The letter notes the "Potential Measures for Preserving State Action Immunity," including suggestions for increasing state supervision. The letter also outlines existing legislation related to protecting board members, including the various duties of the state to defend and indemnify such members. The letter provides "Possible Improvements to Indemnification Scheme." This well-written correspondence does not advocate for significant changes but does identify existent protection measures.

C. Recognition of States' Rights

Regardless of this SCOTUS ruling, states are encouraged to understand and exercise their rights as sovereign entities to govern the practice of the professions under the authority recognized by the US Constitution. While the political overreaction to the SCOTUS ruling is evident, boards of pharmacy are encouraged to also understand their rights to regulate and continue to do so under their enabling statutes enacted by their respective states as well as be information sources for the legislative and executive branches of government.

The manufacture, distribution, sale, and dispensing of drugs implicate the Constitution's Commerce Clause and, therefore, the right of the federal government to legislate in that arena. As set forth below, the federal government has been quite active in legislation regarding pharmaceutical manufacturing and distribution. But the authority of the states to regulate the professions, including pharmacists and pharmacies, remains firmly entrenched in the states under the US Constitution and applicable police powers.

It is critical that members of state boards of pharmacy understand and accept their roles as regulators acting in the interest of public protection and leave professional promotion activities to the trade associations. This point cannot be overemphasized. State board of pharmacy members must be educated in their roles as regulators focused on public protection. The expertise of professionals (pharmacists) on state boards is essential to the effective and efficient regulation of the profession. Uninformed board members who promote the profession over public protection interests will likely stimulate changes to the composition of regulatory boards to include few, if any, professionals with expertise. Such a change to the regulatory structure defeats the effectiveness and efficiencies of boards of pharmacy.

V. State Recognition of Tenth Amendment Police Powers: Take-Home Points

The concept of state-based regulation of professions and occupations is under heightened scrutiny. Political, legal, and economic factions are reviewing the fundamental aspects of the need for regulation. Special

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interest groups argue that access to certain professions/occupations is unnecessarily limited by costly education and examination criteria. They surmise that such limitations inhibit competition and economic growth and adversely affect the economy. Fueled by the SCOTUS case, these special interest groups are challenging the need for regulation in general.

Board of pharmacy members are encouraged to consider the following take-home points.

A. Antitrust Issues: Very Few Board Decisions Implicate the Antitrust Laws. Rulemaking and/or Declaratory Judgments Are in Your Future

The SCOTUS case only addresses antitrust immunity through the assertion of the state action immunity defense. This defense is not the only means for a board to defend itself from antitrust allegation and scrutiny. Even without an immunity assertion, the complainant must allege antitrust allegations, survive relevant procedural motions propounded by the state and board, and eventually substantiate such allegations on the merits. So long as the board operates within the scope of its authority and in good faith (substantiated through legal counsel attending and participating in board business), the likelihood of success by plaintiffs under antitrust theories is remote.

Virtually all decisions made by a regulatory board do not even implicate the antitrust laws. Applications for licensure, renewals, investigations, and disciplinary actions do not involve anticompetitive decision making and do not necessarily mandate the application of antitrust laws. Unfortunately, some of the political and legal responses to the SCOTUS ruling create inefficient and ineffective oversight structures for virtually all board decisions. To the extent global decisions are considered that affect general scope of practice issues or other interpretations of a general nature that apply to all practitioners, additional scrutiny under an antitrust analysis is advisable. Of course, legal advice on an ongoing basis is critical to boards of pharmacy making informed decisions. Such global decisions may involve scope of practice interpretations, interpretations of overlapping scopes, and the like. However, boards of pharmacy have access to avenues that will not only provide oversight by the state, but also may provide a layer of protection that provides oversight and strengthens defenses to any such legal challenges.

1. Rulemaking

Under a circumstance, for example, whereby the board interprets the statute to limit a scope of practice to licensees, the board can promulgate a rule to address the issues. Such a rulemaking process involves notice, right to public comment, editing, review, and under some circumstances, a public hearing. This process likely constitutes significant oversight and allows decision making to be undertaken by those with the expertise. Indeed, some jurisdictions have a Rules Review Commission that must approve a rule before implementation. Further, some states require that rules be approved by a branch of the state legislature. While time-consuming and involving an expenditure of resources, the procedural protections to promulgating a rule provide a basis for substantiating state oversight and the state actor defense in the event of an antitrust challenge. As noted above and regardless of a state actor defense, plaintiffs must allege and prove antitrust violations in order to be successful in any litigation.

2. Declaratory Rulings

Using the same example above and to add to the repertoire of oversight options, boards have the authority to seek a declaratory ruling from the judicial branch as to an interpretation of the statute. Under such a procedure, the board would seek a court ruling in support of the board determination in question. As with the option above, declaratory rulings may take time and involve attorney's fees, but they do provide a layer of oversight and, ultimately, defenses to antitrust allegations.

3. Legislative Changes

To the extent the board has concerns over decisions that may implicate antitrust scrutiny, the board may suggest/seek legislative changes to verify its positions. Again, as with the above options, legislative changes are also time-consuming and riddled with political agendas, but such an approach clearly substantiates state oversight. Boards are reminded of the fact that they are created and authorized by legislative acts and are beholden to a legislative process. Boards are encouraged to forge relationships with their state legislatures and to view themselves as resources of valuable information based upon experience and expertise.

B. Role of Boards and Board Members: Trained Board Members Are Essential

As referenced earlier, state board of pharmacy members must be cognizant of the heightened political and legal scrutiny of the regulatory community. To ensure effective and efficient regulation of the profession, boards of pharmacy are encouraged to undertake significant training of their individual board members and staff on all aspects of regulating the profession. Of particular importance are the role of the board, role of the board member, conflict of interest, statutory navigation and interpretation, rulemaking, investigations, discipline, enforcement, and immunity. Personal and professional promotion agendas must be left to the trade associations and other special interest groups. To the extent state board members cannot separate these interests, a decision must be made to serve the interests of one or the other, not both.

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Annual Report on Association Legal Affairs

NABP charted another year of significant support for its member boards of pharmacy, with key backing from the Legal Affairs department. We share the following noteworthy accomplishments and challenges.

Board Support

Education

NABP successfully hosted an interactive educational forum for board legal counsel and compliance officers in December 2015. Important group discussion topics included the February 2015 United States Supreme Court decision in the *North Carolina State Board of Dental Examiners v. Federal Trade Commission* case and regulatory updates. Based upon feedback from attorney attendees, NABP has hosted an educational webinar for counsel and other designated board staff in July 2016.

Examination Misconduct

The Legal Affairs department partnered with Competency Assessment staff to investigate and address the online sale of North American Pharmacist Licensure Examination® questions. The Association identified key individuals involved in the sale and purchase of test questions in contravention to candidate confidentiality obligations. The affected individuals agreed to comply with their confidentiality obligations, and the sellers agreed to reimburse the Association for costs in connection with the investigation. In furtherance of its commitment to assist boards of pharmacy in protecting public health, NABP provided investigative findings to the applicable boards of pharmacy.

Pharmacy Curriculum Outcomes Assessment

In a short period of time, the Legal Affairs department secured signed memoranda of understanding from all schools and colleges of pharmacy in the US and Lebanon that are seeking accreditation or are currently accredited through the Accreditation Council for Pharmacy Education (ACPE). ACPE now requires the Pharmacy Curriculum Outcomes Assessment® (PCOA®) to be administered to pharmacy students nearing the end of their didactic training. NABP began administering the PCOA, without charge, to pharmacy schools beginning in January 2016.

Litigation

In August 2015, a candidate for certification through the Foreign Pharmacy Graduate Examination Committee™ program filed a lawsuit against NABP. The candidate claims, among other things, that NABP conspired with another testing organization to invalidate a passing score on the Test of English as a Foreign Language. The court dismissed the case against NABP; however, the candidate refiled the lawsuit. NABP submitted another motion to dismiss the case and asked the court to bar the candidate from refiling the lawsuit. NABP believes the case is unfounded. The court decision is currently pending.

Continuing Contributions

The Legal Affairs department will continue to provide vital support to NABP and its member boards through educational initiatives, examination defense, and information sharing in connection with candidate investigations. NABP's strong partnership with its members is critical to the success of the Association and furthering board of pharmacy achievements in public health protection. ■

Newly Accredited VIPPS Facility

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

Orsini Pharmaceutical Services, Inc,
dba Orsini Healthcare
www.orsinihealthcare.com

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

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Substantive training and educating of board members can help ensure that analysis, assessment, consideration, and decision making are undertaken with the appropriate public protection perspective. Further, training does not stop with the end of particular seminars but is ongoing through reminders, legal representation at meetings, updates, retreats, and more.

C. Understand Immunity: The Two-Prong Approach to State Action. Immunity Doctrine Does Not Affect Immunity Principles That Already Exist

State board members are cloaked with immunity (through statutes and/or common law) related to activities undertaken as current state board members. These protections obligate the state to defend and indemnify board members under certain circumstances. Such laws vary from state to state. Readers should not confuse the absolute and qualified immunity principles that protect the board, board members, and staff actions within the scope of the board authority with the state action immunity doctrine related to antitrust immunity that was the subject of the SCOTUS case. Boards that act within the scope of their authority and in good faith are cloaked with immunity protections for their regulatory activities. The SCOTUS case does not alter the immunity protections afforded boards and board members. So long as the actions of the board do not implicate the antitrust laws, there is no need to assert the state action doctrine, and the statutory and common law immunity doctrines protect the actions of the boards and board members.

D. Increased Litigation Is Inevitable: Be Prepared

Increased litigation has clearly resulted from overzealous attorneys that assert antitrust allegations against state boards. Boards of pharmacy are encouraged to seek legal advice on an ongoing basis and not be deterred by the threat of antitrust allegations. Indeed, fearmongering publications and letters have been circulated and have led to increased political scrutiny of the regulatory community, have stimulated attorneys to allege antitrust wrongdoing, and further promote legislative changes. Informed boards should be prepared to address the respective roles described above and confidently espouse the need for regulation and the effective and efficient means by which regulation is accomplished. Statistics and data can be helpful in fulfilling this preparedness, including data related to number of applicants, number of licenses granted and average time, number of renewal applications, number of renewals and average time, number of complaints and dispositions and average time, phone calls to board office, traffic to the board website, board meetings, minutes, attendance, continuing education data, and so on. Knowledge and data are power and can be not only a deterrent to litigation, but also continue to substantiate the need for the regulatory board.

E. Be Knowledgeable: Know Why Boards Exist and Why Professional Representation Enhances Effective and Efficient Boards

As a product of substantive training, board members will be prepared and able to articulate why the regulatory community exists, why boards of pharmacy exist, how effective and efficient boards are (and can be), and how public health, safety, and welfare benefit from this structure. Boards must also be prepared to substantiate the need for professional members (licensees) to serve on state boards. The added expertise of trained, informed board members who are licensees is essential to the effective and efficient means of regulating the profession. Such board members (referred to as active market participants by the US Supreme Court) must be knowledgeable of their roles and trained in the areas identified above. In the immediate future, boards of pharmacy must be prepared to address political maneuvers that seek to consolidate boards, reduce/eliminate professionals from serving on boards, or create "super" boards or departments that relegate boards to merely advisory panels, leaving important decisions to a bureaucratic person(s) with no knowledge or expertise of the profession. Such a departmentalized approach may defeat the effectiveness and efficiencies of the regulatory structure. Boards are a valuable information source to the legislative branch of government and should provide detailed information to the relevant authorities.

VI. Conclusion

The US Constitution and the concept of federalism recognize the rights of the states to govern in the interest of what is best for their respective citizens. Only under limited circumstances can the federal government impose its will on the individual states. The regulation of the practice of pharmacy is complex and subject to numerous state and federal laws that must coexist. Of late, heightened scrutiny is placed upon the regulatory community, in part stimulated by the February 2015 SCOTUS case. The Supreme Court ruling has limited scope and application but is being used to push numerous "anti-regulation" agendas. States and boards of pharmacy must understand and exert their respective states' rights and not become political pawns to a movement that is displaced and has little application to the regulatory systems that have served the public for over 150 years. At the same time, board members must understand and acknowledge their roles as regulators and not mix promotion of the profession with their essential public protection responsibilities. Trained board members are critical to the regulatory system and the public being protected. ■

NABP's .Pharmacy TLD Now Recognized by Major Search Engine Bing for Pharmacy-Related Advertisers

NABP is pleased to announce that online pharmacies and drug information sites approved by the Association's .Pharmacy Top-Level Domain (TLD) Program are now eligible to advertise with Microsoft Bing Ads in the United States and Canada.

Under Bing's previous advertising policy for pharmacy and health care products and services, only online pharmacies accredited by the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) and Veterinary-VIPPS® programs, as well as entities granted approval under the NABP e-Advertiser Approval℠ Program, were permitted to advertise on Bing Ads. The newly revised policy adds .pharmacy to the list of NABP approval programs recognized by Bing.

In addition, Yahoo!'s advertising policy for prescription drugs and pharmacies requires that online pharmacies must be approved by one of NABP's accreditation and approval programs, which now includes .pharmacy.

As NABP is working to streamline its online verification programs, the Association is prequalifying .pharmacy entities for e-Advertiser Approval status. Since both .pharmacy and e-Advertiser undergo a similar thorough review process establishing their compliance with NABP standards for legitimate online practice, all .pharmacy-approved content is considered prequalified and is eligible for e-Advertiser approval.

Since the program launched, NABP has granted approval for 388 .pharmacy domain names, and 231 are currently registered, including 175 pharmacies, 37 boards of pharmacy and regulatory agencies, nine resource sites, three manufacturers, two schools and colleges of pharmacy, and five professional sites. Of these registered domain names, 102 are actively in use either as a primary domain or as a redirect to the registrants' previously existing site, including five professional sites, nine resource sites, two schools and colleges of pharmacy, 27 boards of pharmacy, and 59 pharmacies. NABP currently accepts .pharmacy domain name applications from the following eligible pharmacy-related entities: pharmacies, pharmacy benefit managers, schools and colleges of pharmacy, continuing pharmacy education providers, wholesale drug distributors, pharmaceutical manufacturers, resource sites, professional sites, pharmacy automation/distributors, and boards of pharmacy and regulatory agencies. At this time, NABP has approved applicants located in the US, Canada, Great Britain, and Hong Kong.

Additional details about the .Pharmacy TLD Program, including a list of approved .pharmacy sites, are available at *www.safe.pharmacy.*

Newly Approved e-Advertisers

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

2047958 Ontario Limited, dba The Village Pharmacy
www.thevillagepharmacy.ca

CZ Services, Inc, dba CareZone Pharmacy
www.czpharmacy.com

Scripventures Group, Ltd, dba Luscinia Health
www.refillwise.com

The Duluth Clinic, Ltd, dba Essentia Health
www.essentiahealth.org

Uniprix, Inc
www.uniprix.com

Walgreen Co
www.drugstore.com

Since 2010, NABP has offered the e-Advertiser Approval Program for internet advertisers that offer only limited pharmacy services or other prescription drug-related services online. A full listing of NABP-approved e-Advertisers is available on the NABP website at *www.nabp.net.*

Resources on Antitrust Activities Provide Member Boards *With Tools to Evaluate Processes*

Every year, NABP carefully and routinely monitors the legislative and regulatory landscape at the state and federal levels. The purpose of this monitoring is to identify emerging trends and threats that could impact the boards of pharmacy and the Association as a whole. Early in 2016, the NABP Member Relations and Government Affairs department identified a significant increase in activity and dialogue related to the United States Supreme Court ruling in the case of *North Carolina State Board of Dental Examiners v. Federal Trade Commission.* In particular, staff has been closely monitoring activity that includes the introduction of state legislation, a hearing in front of the US Senate Judiciary Committee, pending federal court cases against regulatory boards, as well as state attorneys' general opinions.

> **"NABP recommends that boards that have not yet evaluated their 'active state supervision' processes do so in the near term."**

NABP has been collecting, cataloguing, and evaluating all information relevant to this activity to assess the potential impact on the membership. In the view of the Association, some of the proposed actions would be a significant and unnecessary overcorrection to the "active state supervision" processes discussed in the North Carolina case and already in place at the state level.

In response, NABP sought to build a simple, factual assessment and corresponding guidance that boards could use while evaluating their current "active state supervision" processes and determining how to address related proposed actions in their state. In March 2016, NABP distributed to member boards via the electronic mailbag two documents intended to provide member boards with a national perspective on current antitrust legal actions as well as related state level actions.

Report of NABP Outside Counsel

In addition, the annual Report of Counsel prepared by NABP outside counsel, Dale J. Atkinson, JD, is included in the Legal Briefs section of this newsletter and provides a review of the Supreme Court ruling and related activities in certain states. Mr Atkinson is also the executive director of the Federation of Associations of Regulatory Boards (FARB). A model developed by FARB may also be a useful resource for member boards of pharmacy and is available on the FARB website at *www.imis100us2.com/farb/SharedContent/Resource_pages/Press_Release_Antitrust_Model.aspx.*

Please note, these resources are provided to inform the boards and are not intended to serve as a legal opinion.

Ongoing Monitoring

NABP believes that states will continue to see an increase in activity on this issue throughout 2016 and as legislatures come back into session in 2017. NABP will continue its proactive monitoring and evaluation of these activities.

NABP is aware that many boards have utilized these resources to good effect in consultation with their board and/or agency counsel and have been able to adjust or reinforce their current "active state supervision" processes. NABP recommends that boards that have not yet evaluated their "active state supervision" processes do so in the near term. The Association also encourages member boards to share any information and activity occurring in their state so that NABP can facilitate dialogue and information sharing amongst the boards. Boards may share information by sending an email to exec-office@nabp.net or GovernmentAffairs@nabp.net.

Resources for Member Boards

The following resources were provided to member boards of pharmacy via the NABP electronic mailbag. For more information, member boards may contact NABP at exec-office@nabp.net or at GovernmentAffairs@nabp.net.

- **Federal Trade Commission (FTC) Executive Officer Overview, which includes:**
  - A compilation of excerpts regarding "active state supervision" from the Supreme Court decision,
  - A summary, from FTC's guidance document, of processes the agency suggests would not constitute active supervision sufficient to make a board immune from antitrust actions,
  - A review of state actions that may meet the FTC active supervision standards, and
  - Information related to regulatory board composition.
- **FTC Antitrust Activity Background Review Documents, which include:**
  - State and federal antitrust activity summary,
  - FTC active supervision letter and FTC Staff Guidance on Active Supervision of State Regulatory Boards Controlled by Market Participants, and
  - California attorney general opinion on North Carolina Dental Board decision by US Supreme Court.

NABP PMP InterConnect Will Remain Free to Participating States Past 2018

NABP is pleased to announce that it will provide state prescription monitoring programs (PMPs) with access to NABP's PMP InterConnect® at no cost so states can focus their resources and federal grants to support PMP operations.

Currently, 43 states have executed memorandums of understanding (MOUs) to be part of PMP InterConnect, 33 PMPs are active, and 40 states are expected to be active by the end of 2016. (See PMP InterConnect participation map below.) PMP InterConnect enhances the benefits of state PMPs by allowing authorized users in the United States to access PMP data from across state lines, for a more complete patient record.

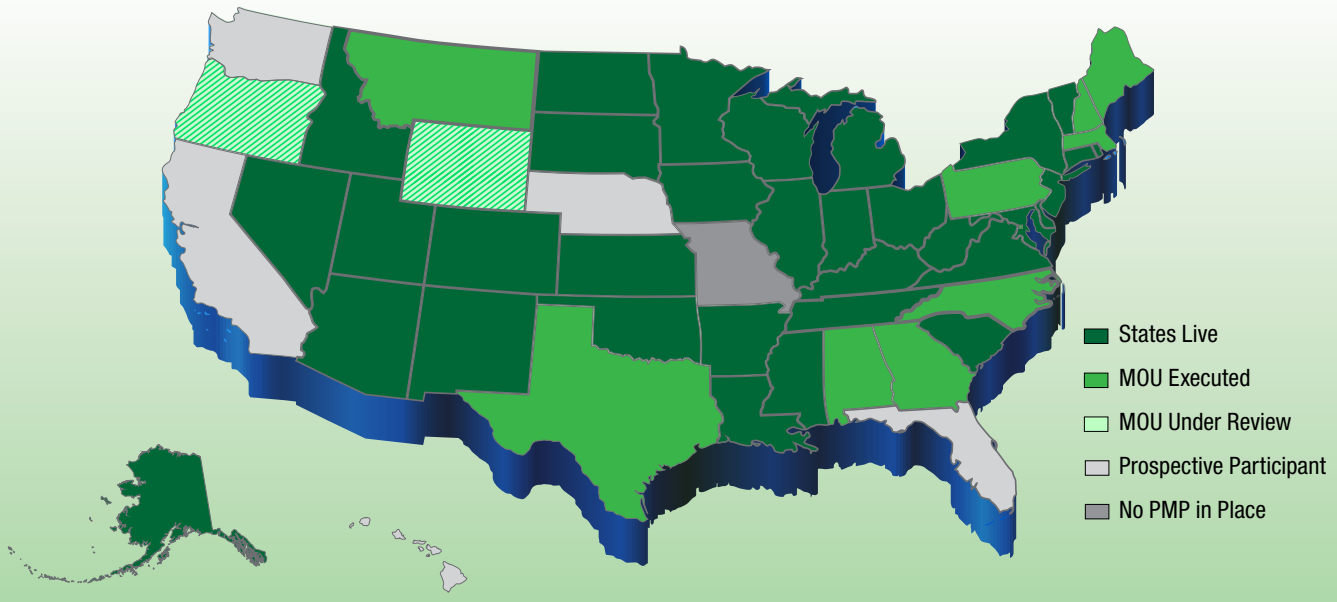
"NABP PMP InterConnect is the only national network of state-based PMPs. It furthers the mission of the boards of pharmacy and NABP, as well as other state agencies, to protect public health by assisting health care providers in identifying doctor shopping and diversion of controlled substances, as well as confirming which patients are legitimately receiving such prescriptions," notes NABP President Hal Wand, MBA, RPh, in a June 2016 press release.

The commitment by NABP to fully support PMP InterConnect will remove any resource roadblocks that states face to identifying patients with prescription drug abuse and misuse problems, especially if those patients are crossing state lines to obtain drugs. Participating state PMPs that use this highly secure communications exchange platform (which does not store data) have access to information that can be an effective means of combating drug diversion and drug abuse nationwide.

Importance of State PMPs

Throughout spring 2016, NABP highlighted the integral role that state PMPs play in the fight against prescription drug abuse. In May, NABP participated in an interview with National Public Radio and shed light on the growing epidemic and what the state PMPs are doing to combat this issue. During the May 10 interview, "49 States Combat Opioid Epidemic With Prescription Database," NABP explained how some states have passed mandatory use requirements that require prescribers and pharmacists to look up patients in the state PMP prior to prescribing and dispensing. NABP also attended a meeting with the National Conference of State Legislatures on May 13-14, 2016, in New Orleans, LA. During the meeting, NABP presented information on how states are increasing utilization of PMP data, including connecting to PMP InterConnect, passing mandatory registration and use laws, and promoting in-workflow access to PMP data through electronic medical records of vendors, health information exchanges, health care systems, and pharmacy software systems. ■

PMP InterConnect State Participation Overview



Task Force Recommends Supporting, Expanding Pharmacists' Role to Increase Access to Quality Care

Increasing pharmacists' involvement in health care delivery has benefits for patients that include improved continuity of care and more comprehensive medication management, concluded the Task Force on Pharmacist Prescriptive Authority. The task force recommended that NABP support pharmacists having limited ability to initiate, modify, and terminate drug therapy. To ensure that pharmacists have legislative and regulatory authority to do so, the task force recommended amending language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act).* In addition, task force members recommended that NABP support key messages pertaining to pharmacists' role in providing health care. The task force met September 1-2, 2015, to discuss existing regulations that allow pharmacists to manage patients' drug therapy and agreed on expanding the role of pharmacists in health care delivery systems.

The task force recommended NABP support pharmacists having limited ability to initiate, modify, and terminate drug therapy under certain circumstances including, but not limited to, collaborative practice agreements and state protocols. Members discussed today's changing health care delivery landscape, as well as the current emphasis on expanding accessible, affordable, and quality health care. Members indicated that pharmacists, who are the most accessible health care team member, may be the key to reaching patients with health care services that they may not otherwise receive or have difficulty accessing.

In addition, members discussed how some states like California and Oregon have implemented new laws and updated existing laws and rules to allow for pharmacists to initiate, modify, and terminate drug therapy in limited circumstances, while other states have expanded their collaborative practice guidelines and statewide protocols to allow for pharmacists to be more actively involved in managing drug therapy. Members agreed that with the projected demand on the current health care delivery model, the need and opportunity for pharmacists' involvement in health care delivery has never been greater.

The task force also recommended that NABP amend the *Model Act* by adding to the definition of the "Practice of Pharmacy" to ensure it includes that pharmacists have legislative and regulatory authority to initiate medication therapy based upon specific parameters. The task force members reviewed trends in collaborative practice authority along with recommendations from the National Alliance of State Pharmacy Associations (NASPA) Collaborative Practice Workgroup. Members acknowledged that state collaborative practice statutes and regulations are highly variable between states.

The task force members concluded that NABP should encourage state boards of pharmacy to review current requirements for collaborative practice agreements and revise requirements to remove barriers that may have previously prevented the greater acceptance and wider adoption of collaborative practices between physicians and pharmacists. Members agreed that state collaborative practice laws and rules should be broad in scope to allow varying degrees of collaboration and should not interfere with the extent of collaboration between a pharmacist and other health care providers. Members also agreed that the depth and scope of collaborative practice should be determined by the pharmacist and prescriber entering into a collaboration.

The task force recommended that NABP support the key messages pertaining to pharmacists' role in providing health care. Among other points, the task force recommended the following:

1. Expand pharmacists' role, consistent with their education and training, on health care teams to increase patient access to quality health care.

2. Pharmacists continue efforts to enter into collaborative agreements with practitioners to improve outcomes by increasing patient access to timely and efficient care.

Members indicated pharmacists have long provided the public with advice on over-the-counter products as part of their role as medication experts. With the public demand for more access to primary care, the pharmacist is well positioned to provide increased patient-centered services and an expanded role in patients' drug therapy. Being that the pharmacist is the most accessible health care provider and hospital emergency departments are often burdened

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Task Force Charge

The Task Force on Pharmacist Prescriptive Authority met September 1-2, 2015, and accepted the following charges:

1. **Review** existing state laws and regulations addressing pharmacists' prescriptive authority and relevant *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* language.

2. **Recommend** revisions, if necessary, to the *Model Act* addressing this issue.

3. **Propose** key messages that should be conveyed to boards of pharmacy, key stakeholders, and the public about the patient care benefits of granting pharmacists limited prescriptive authority.

Boards Encouraged to Utilize VPP for Access to Streamlined Inspection and Licensure Information

NABP continues to explore ways to better serve the state boards of pharmacy. One way is through the Verified Pharmacy Program® (VPP®), which provides boards with access to streamlined inspection and licensure information. Boards are encouraged to recognize VPP and/or require that nonresident pharmacies apply through VPP when seeking to obtain or renew licensure. An e-Profile will be created for VPP applicants and the boards of pharmacy will be alerted through the system about a pharmacy's disciplinary and inspection history when it is available. NABP provides all data directly to the applicable state boards of pharmacy and does not render any judgment on an applicant, as this authority is left to the state boards.

At press time, at least 468 pharmacies have applied to VPP and currently, or soon will, have verified data available for the boards to view. This verified data is provided to the member boards in an effort to further support them in making informed licensure decisions for their nonresident pharmacies. Of the 468 VPP pharmacies, approximately 65 have reapplied for a more current inspection, having previously been inspected through the program. Additionally, of the approximately 468 pharmacies:

- 226 pharmacies engage in only nonsterile compounding;
- 48 pharmacies engage in only sterile compounding (two of which are also registered as outsourcing facilities);
- 132 pharmacies engage in both sterile and nonsterile compounding (three of which are also registered as outsourcing facilities);
- 59 pharmacies are general retail or mail-order pharmacies with no compounding; and
- 3 pharmacies are nuclear pharmacies.

Developed by NABP in partnership with member boards of pharmacy, VPP facilitates the communication of important inspection and licensure information between the state boards of pharmacy and serves as an information hub that provides verified data to support boards' licensure processes for nonresident pharmacies.

For more information about VPP or the inspection sharing network, contact the NABP Accreditation department at vpp@nabp.net. Additional information is also available in the Programs section of the NABP website at *www.nabp.net.* ■

Errata

The total number of pharmacies listed in the May 2016 issue of *Innovations* was incorrectly reported as 483 as this number included both first-time applicants and pharmacies that have reapplied. The total number of first-time applicants at that time was 433.

Pharmacists' Role

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with patients having a noncritical need for drug therapy, the task force recommends that boards of pharmacy and departments of health support pharmacists' initiatives to provide timely drug therapy in circumstances such as preventative medicine where patient access to drug therapy is warranted yet not deemed critical. Members discussed examples in certain states and counties where regulations have been instituted to allow pharmacists to deliver travel medications, nicotine replacements, hormonal contraceptives, naloxone, antibiotic therapy for the treatment of Lyme disease, and, if warranted, a pharmacist may administer a swab test to detect influenza and streptococcal infections.

The Executive Committee reviewed the recommendations and determined that the recommendations of the task force primarily focused on collaborative practice rather than prescriptive authority. Thus, the Executive Committee determined that additional research is needed to develop specific recommendations for states to establish and recognize pharmacist prescriptive authority.

The Task Force on Pharmacist Prescriptive Authority was established in response to Resolution 111-4-15, which was approved by the NABP membership at the Association's 111th Annual Meeting in May 2015. Task force members included Dennis Wiesner, RPh, chair; Kerstin Arnold, JD; Tom Bender, RPh; Timothy D. Fensky, RPh, DPh, FACA; Cathy Hanna, PharmD, RPh; Virginia Herold, MS; Leo Lariviere, RPh; Cathy Lew, RPh; Michael Podgurski, RPh; Joyce Tipton, MBA, RPh; Cynthia Warriner, RPh; James DeVita, RPh, DPh, Executive Committee liaison; and Krystalyn Weaver (NASPA), guest.

With the addition of a note regarding the additional planned research on prescriptive authority, the task force report was approved by the Executive Committee during its February 2016 meeting and is available in the Members section of the NABP website at *www.nabp.net.* The task force's recommended revisions to the *Model Act* were reviewed and amended by the Committee on Law Enforcement/Legislation in January 2016 and were reviewed by the NABP Executive Committee during its May 2016 meeting. ■

Task Force Recommends Revised Policies for Allowing and Recognizing Sponsorships for NABP Meetings

In response to a resolution proposed at the 111th NABP Annual Meeting, the Executive Committee agreed to research the matter of accepting sponsorships for NABP meetings and convened a task force to review this issue. The Task Force on Sponsorship of NABP District and Annual Meetings concluded that there were no improprieties in the acceptance or management of sponsorships for educational and member activities at the NABP Annual Meeting. At the same time, the task force acknowledged that a perception could exist that accepting sponsorships could be problematic or perceived as diminishing NABP's ability to operate as an impartial and objective Association. To directly address that perception, the Executive Committee accepted the four recommendations of the task force to change some aspects of sponsorship acceptance and recognition at the Annual Meeting. The task force met on October 21, 2015, and discussed policies for accepting sponsorships for NABP meetings as well as alternatives to restricting or replacing such sponsorships with other means of support that would maintain objective and unbiased presentations and activities at meetings.

The task force began by discussing the funding NABP receives in order to support programming at its Annual Meeting. Members reviewed relevant NABP policy and practices, Accreditation Council for Pharmacy Education (ACPE) standards, related Federal Trade Commission guidance, and corresponding standards of the Federation of State Medical Boards and the National Council of State Boards of Nursing. The task force's first recommendation is that NABP revise its practices related to the recognition of Annual Meeting sponsors in order to address any perceived bias or potential conflicts of interest.

The task force also recommended that NABP continue to allow sponsorship of the continuing pharmacy education (CPE) sessions at the Annual Meeting because these sessions assist the member boards in their roles as regulators. The task force stressed that these sponsorships should continue to follow ACPE standards, noting that these standards include oversight and safeguards related to the acceptance and use of such sponsorships.

Moreover, the task force recommended that NABP examine and enact policy related to how non-CPE sponsors are currently recognized and determine alternate means for recognition during meetings. Members provided suggestions, two of which included listing the sponsors collectively in program materials and noting the sponsorships during the treasurer's report rather than during the President's Address. Both of these suggestions were implemented for the 112th Annual Meeting.

Lastly, the task force recommended that NABP work with districts in order to develop and implement consistent requirements and monitor processes for receiving and utilizing sponsorships parallel to those implemented by NABP. Members decided that the policy ultimately implemented for NABP and the Annual Meeting could be used in the future as a model guide for the districts to consider.

The Task Force on Sponsorship of NABP District and Annual Meetings was established in response to a resolution proposed at the Association's 111th Annual Meeting in May 2015. Task force members included Larry Mokhiber, MS, RPh, chair; Curtis Black, PhD, RPh; Rich Palombo, RPh; Stuart Williams, JD; and Jeanne Waggener, RPh, DPh, Executive Committee liaison.

The task force report was approved by the Executive Committee during its December 2015 meeting and is available in the Members section of the NABP website at *www.nabp.net*.

Task Force Charge

The Task Force on Sponsorship of NABP District and Annual Meetings met on October 21, 2015, and accepted the following charges:

1. **Review** present practices and policies for accepting sponsorships and grants for NABP District and Annual Meetings.
2. **Recommend** alternatives on whether to further restrict or replace such sponsorships and grants with other means of support that will maintain the high quality, including objective and unbiased presentations and activities at the meetings.

NABP Aims to Raise Consumer Awareness of Counterfeit Medications and *.Pharmacy* Domain Names

NABP issued a report discussing the Association's expanded efforts to raise consumer awareness about the dangers of medications purchased from unapproved and unknown online sources and the solution offered by the .Pharmacy Top-Level Domain (TLD) Program, which provides a means for finding safe internet pharmacies. As detailed in the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: April 2016*, many patients remain unaware of the dangers associated with obtaining unapproved medications from sources outside of regulated supply chains. NABP continues to recommend that patients use internet pharmacies that have been granted a .pharmacy domain name. These sites have been evaluated by NABP and found to be in compliance with pharmacy laws and meet high standards for pharmacy practice and patient safety.

.Pharmacy PSA

A new NABP public service announcement (PSA) aims to raise awareness about the dangers of buying medications from illegal online drug sellers, which often distribute drugs containing toxic ingredients or no medicine at all. The PSA highlights how difficult it can be for consumers to know what they are receiving from such unknown sources and encourages consumers to use internet pharmacies with a .pharmacy domain. The PSA is available on the .pharmacy website at *www.safe.pharmacy/buying-safely*.

NABP is also raising consumer awareness through a digital banner campaign, which displays ads online if a consumer searches for keywords related to online pharmacy. Clicking on the banners leads the user to the PSA or to the .pharmacy website. Other outreach efforts are described in the report.

NABP Findings on Rogue Sites

Through research conducted over the past eight years, NABP finds that an alarming number of websites selling prescription medications online operate illegally, importing medications from outside of safeguarded supply chains, frequently without a prescription, medical oversight, or recourse for patients who experience adverse effects. NABP has reviewed over 11,000 websites selling prescription medications online to United States consumers and has found approximately 96% of them to be operating illegally, placing patients' health at risk. Further, of the 10,685 sites found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards, the majority (89%) were found to be dispensing prescription drugs without a valid prescription. Just over half offer foreign and non-Food and Drug Administration-approved drugs. Most sites selling drugs illegally online do not post any address (62%), and nearly half have their domain names registered anonymously.

The .Pharmacy TLD Program aims to provide consumers around the world a means for easily identifying safe and legal online pharmacies and related resources. More information about the .pharmacy TLD is available on page 11 of this newsletter and at *www.safe.pharmacy*. For the full report with detailed findings on the characteristics of rogue websites and the list of Not Recommended sites, visit the Acquire Safely section of *www.AWARErx.pharmacy*.

Newly Accredited DMEPOS Facility

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

The Medicine Shoppe
Riverside, CA

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

Boards Report 1,445 Disciplinary Actions in First Quarter 2016; NABP Encourages Timely Reporting to Clearinghouse

During the first quarter of 2016, the state boards of pharmacy reported a total of 1,445 disciplinary actions to the NABP Clearinghouse, including actions taken against pharmacists, pharmacy technicians, pharmacy interns, pharmacies, wholesalers, and other licensees. Of the 1,445 actions:

- **530 actions (36.7%) were taken on pharmacists;**
- **469 actions (32.5%) were taken on pharmacies;**
- **347 actions (24%) were taken on pharmacy technicians;**
- **54 actions (3.7%) were taken on other licensees;**
- **25 actions (1.7%) were taken on wholesalers;**
- **17 actions (1.2%) were taken on pharmacy interns; and**
- **3 actions (0.2%) were taken on mail-order pharmacies.**

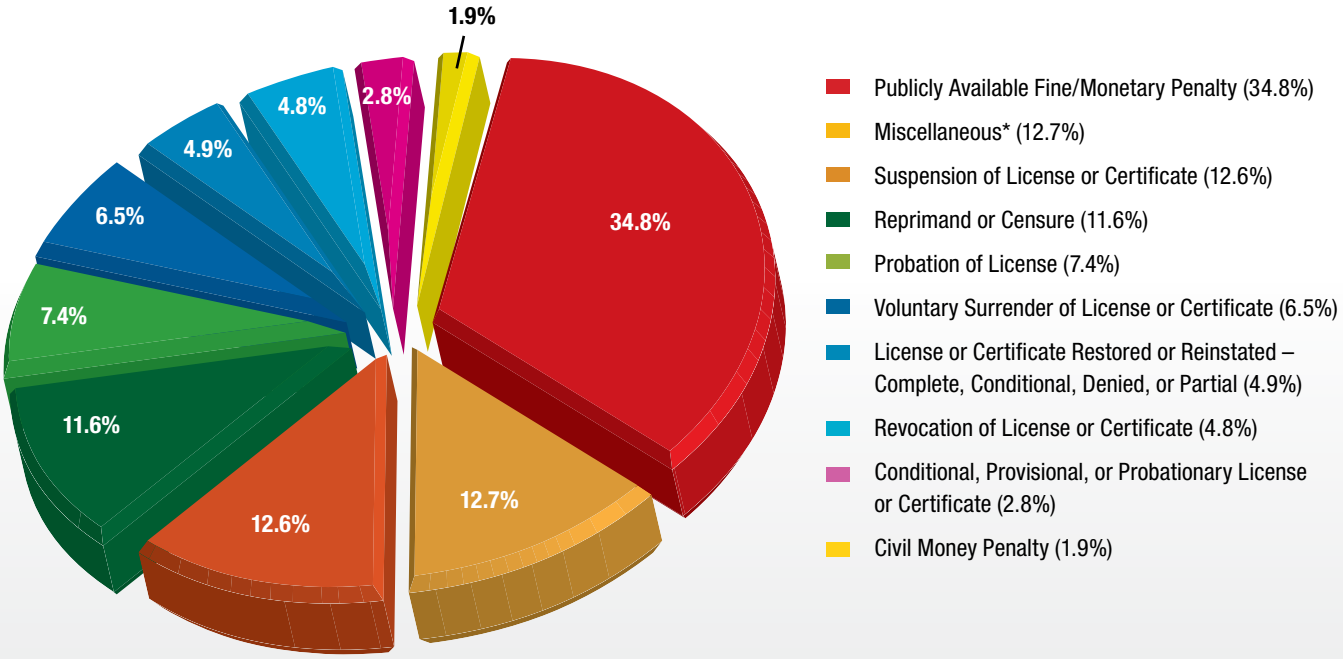
For a full breakdown of the actions taken and the bases for actions taken during first quarter 2016, see Figure A and Figure B.

Ensuring Compliance for the Boards

As stated in the NABP Constitution and Bylaws, participation in the NABP Clearinghouse is required as part of a board of pharmacy's membership to the Association. Timely reporting to the NABP Clearinghouse is essential to maintaining the integrity of the licensure transfer program. In addition, NABP encourages all boards to designate NABP as their reporting agent to the National Practitioner Data Bank (NPDB). By doing so, boards are able to free up valuable resources and staff time to focus on other board matters. To date, 33 boards of pharmacy have designated NABP as a reporting agent, allowing the Association to transmit all required records to NPDB and provide feedback on NPDB rejected or accepted data. In addition, monthly Clearinghouse reports are available for the boards in NABP e-Profile Connect.

Additional information about the NABP Clearinghouse, including how to designate NABP as a reporting agent for NPDB, is available under Member Services in the Programs section of the NABP website at *www.nabp.net.*

Figure A: Disciplinary Actions Reported During First Quarter 2016



*The miscellaneous category includes closure of facility; denial of initial license; denial of initial license or certificate; denial of license or certificate renewal; denial of license renewal; directed in-service training; directed plan of correction; extension of previous licensure action; interim action – agreement to refrain from practice during investigation; limitation or restriction on license; modification of previous licensure action; other licensure action – not classified; publicly available negative action or finding; reduction of previous licensure action; restrictions on admissions or services; summary or emergency action; summary or emergency limitation or restriction on license; summary or emergency suspension of license; and voluntary limitation or restriction on license.

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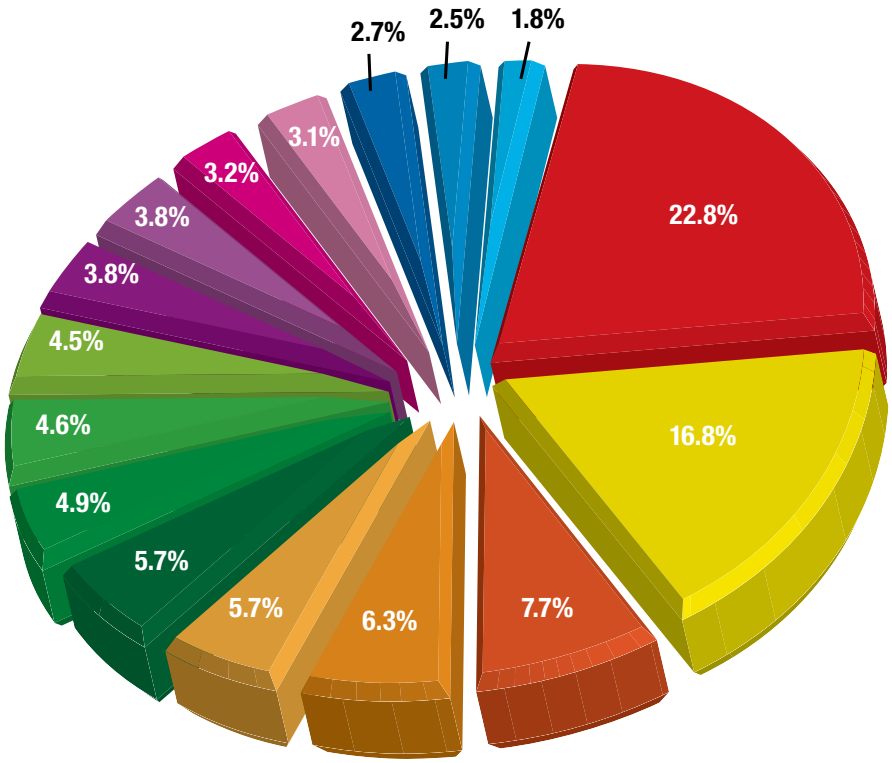
Figure B: Bases for Disciplinary Actions Reported During First Quarter 2016



- Violation of Federal or State Statutes, Regulations, or Rules (22.8%)
- Miscellaneous* (16.8%)
- Diversion of Controlled Substance (7.7%)
- Violation of Federal or State Tax Code (6.3%)
- Error in Prescribing, Dispensing, or Administering Medication (5.7%)
- Unable to Practice Safely by Reason of Alcohol or Other Substance Abuse (5.7%)
- Fraud (4.9%)
- Unauthorized Administering, Dispensing, or Prescribing of Medication (4.6%)
- Failure to Maintain Records (4.5%)
- License Revocation, Suspension, or Other Disciplinary Action (3.8%)
- Allowing or Aiding Unlicensed Practice (3.8%)
- Failure to Comply With Continuing Education or Competency Requirements (3.2%)
- Failure to Meet Licensing Board Reporting Requirements (3.1%)
- Narcotics Violation or Other Violation of Drug Statutes (2.7%)
- Practicing or Operating Without a License or Permit, With an Expired License, or on a Lapsed License (2.5%)
- Criminal Conviction (1.8%)

*The miscellaneous category includes breach of confidentiality; conduct evidencing ethical unfitness; conduct evidencing moral unfitness; deferred adjudication; drug screening violation; expired drugs in inventory; failure to comply with patient consultation requirements; failure to cooperate with board investigation; failure to maintain equipment/missing or inadequate equipment; failure to maintain supplies/missing or inadequate supplies; failure to meet the initial requirements of a license; failure to take corrective action; immediate threat to health or safety; improper or abusive billing practices; improper or inadequate supervision or delegation; inadequate security for controlled substances; incompetence; lack of appropriately qualified professionals; malpractice; misappropriation of patient property or other property; misbranding drug labels/lack of required labeling on drugs; misleading, false, or deceptive advertising or marketing; misrepresentation of credentials; negligence; nolo contendere plea; operating beyond scope of license; other disciplinary action – not classified; other unprofessional conduct; practicing beyond the scope of practice; practicing without a valid license; sexual misconduct; substandard or inadequate care; substandard or inadequate skill level; unable to practice safely; unable to practice safely by reason of physical illness or impairment; unable to practice safely due to psychological impairment or mental disorder; and violation of or failure to comply with licensing board order.

Boards Encouraged to Complete MPJE State-Specific Review Remotely Through Secure Interface

NABP offers state boards of pharmacy a convenient internet-based format to conduct their item pool review and item selection review for the Multistate Pharmacy Jurisprudence Examination® (MPJE®). State board participation is critical to ensure that the MPJE maintains the highest validity standards with the most up-to-date questions on the examinations and that the items on the MPJE are defensible. During the MPJE State-Specific Review, the responsibility of each board is to:

1. Select new items to be pre-tested for future pool, and
2. Complete review of the current operational (scored) item pool.

New federal- and state-specific items to test the pharmacy jurisprudence knowledge of candidates seeking licensure were developed by board of pharmacy-designated item writers during the MPJE Item Development Workshop held March 15-16, 2016, at NABP Headquarters in Mount Prospect, IL. In addition, some jurisdictions completed the item development task remotely. The MPJE State-Specific Review provides each participating board the opportunity to approve those questions applicable in their state or jurisdiction. To date, 49 boards utilize the MPJE and are asked to participate in at least one State-Specific Review meeting each year to determine the appropriateness of items in the MPJE for candidates seeking licensure.

Board members will conduct their pool review and item selection review remotely, and boards will be provided with access to a secure website where NABP will post each participating state's operational pool and new pretest questions. Access to the secure website will be open from August 8, 2016, to September 9, 2016. ■

Virginia Now Requires MPJE for Licensure Process

Virginia is the latest state to require NABP's Multistate Pharmacy Jurisprudence Examination® (MPJE®), raising the number of states utilizing the examination to 49. On July 1, 2016, administration of Virginia's MPJE began at Pearson VUE test centers throughout the United States.

According to Virginia Board of Pharmacy Executive Director Caroline D. Juran, "Boards of Pharmacy have been facing an increasing number of complex issues over the last few years. While Virginia has historically administered its own jurisprudence exam, the Board recently determined that the resources used to administer this exam would be better utilized addressing other issues." Juran also notes, "State boards have successfully relied on the MPJE for many years, and Virginia is pleased to become the 49th state to require applicants to successfully pass the MPJE as part of the licensure process."

> "State boards have successfully relied on the MPJE for many years, and Virginia is pleased to become the 49th state to require applicants to successfully pass the MPJE as part of the licensure process."

The MPJE combines federal- and state-specific questions to test the pharmacy jurisprudence knowledge of prospective pharmacists. It serves as the pharmacy law examination in participating jurisdictions. Among other things, the MPJE tests candidates on:

- Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients;
- Licensure, registration, certification, and operational requirements; and
- Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors.

NABP develops and administers the MPJE at no cost to the participating boards. The boards are required to attend one State-Specific Review meeting per year. In addition to evaluating items, boards of pharmacy are responsible for approving candidate eligibility and providing candidates with score reports. ■

Item Writers Volunteer at March 2016 Workshops to Develop Exam Questions for MPJE and NAPLEX

Item Writers Collaborate During MPJE Item-Development Workshop

(Pictured left) In March 2016, volunteer item writers convened at NABP Headquarters to review items for the Multistate Pharmacy Jurisprudence Examination® (MPJE®) during an item-development workshop. Pictured from left to right are Grace Cheung, RPh, Kenmore, WA, and Andrew Funk, PharmD, RPh, executive director, Iowa Board of Pharmacy.

Volunteers Meet to Discuss Exam Questions for the NAPLEX

Volunteer item writers convened at NABP Headquarters in March 2016 to develop examination questions that will be considered for the North American Pharmacist Licensure Examination® (NAPLEX®). Participating in the NAPLEX Item Development Workshop were Peter Koval, PharmD, RPh, University of North Carolina Eshelman School of Pharmacy (left), and Marlon Honeywell, PharmD, RPh, Florida A&M University College of Pharmacy and Pharmaceutical Sciences (right).

April 2016 FPGEE Scores Available at *NABP.net;* Fall Administration Approaching

Score reports from the April 1, 2016 Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) administration are now available via the NABP website. Candidates who sat for the April 1 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 the Programs section of the NABP website at *www.nabp.net.*

A total of 751 candidates sat for the April 1, 2016 administration. The next FPGEE is scheduled for October 14, 2016. More information about the FPGEE is available in the Programs section of the NABP website at *www.nabp.net.*

Deadline for Schools and Colleges to Register for Final 2016 PCOA Testing Window Is August 16

The deadline for schools and colleges of pharmacy to register their students for the final 2016 Pharmacy Curriculum Outcomes Assessment® (PCOA®) testing window (November 14 to December 9, 2016) is **August 16, 2016**.

With the inclusion of the PCOA requirement in the Accreditation Council for Pharmacy Education *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016)*, NABP is providing the assessment at no cost for all students nearing the completion of their didactic curriculum. Students in this group qualify to take the PCOA one time at no cost. If the school or college chooses to schedule an additional administration, the current fee of $75 per student will apply.

Appropriate for administration to students in all professional years, the PCOA is an excellent resource for pharmacy educators as they assess student performance in the pharmacy curriculum.

The PCOA Registration Form, as well as more information, may be found in the Programs section of the NABP website at *www.nabp.net*.

Schools and colleges that have questions regarding the November 14 to December 9 testing window are encouraged to contact the FPGEC/PCOA program manager at 847/391-4406 or via email at PCOA@nabp.net.

FPGEE and PCOA Review Committee Members Convene

In June 2016, members of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and Pharmacy Curriculum Outcomes Assessment® (PCOA®) Review Committee met to review, verify, and develop new exam questions. Pictured from left to right are Matthias Lu, PhD, professor emeritus, University of Illinois at Chicago College of Pharmacy; William Kolling, MS, PhD, RPh, Southern Illinois University Edwardsville School of Pharmacy; and Dale E. Wurster, Jr, PhD, University of Iowa College of Pharmacy.

Newly Accredited VAWD Facilities

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

Carlsbad Technology, Inc
Two facilities in Carlsbad, CA

DSC Logistics, Inc
Jefferson, GA

Fisher Scientific Company, LLC, dba Fisher Scientific and Fisher Healthcare
Nazareth, PA

J Knipper and Company, Inc
Charlestown, IN

Kuehne + Nagel, Inc
Redlands, CA

MD Logistics, Inc
Plainfield, IN

Medline Industries, Inc
Chester, VA

Owens & Minor, Inc, dba Owens & Minor Distribution
Flower Mound, TX

Schnucks Markets, Inc, dba Schnucks Pharmacy Distribution Center
Earth City, MO

ZO Skin Health, Inc
Irvine, CA

A full listing of more than 560 accredited VAWD facilities is available on the NABP website at *www.nabp.net.*

NABP Appoints LuGina Mendez-Harper to ACPE Board

NABP is pleased to announce that LuGina Mendez-Harper, PharmD, RPh, member of the New Mexico 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 2022. An active member of NABP, Mendez-Harper has participated in NABP committees and task forces, including serving as chairperson for the Committee on Constitution and Bylaws and as a member of the Task Force on the Regulation of Pharmacy Benefit Managers. In addition, Mendez-Harper served as the District 8 representative for the Resolutions Committee during the Association's Annual Meetings since 2011.

Mendez-Harper has been a member of the New Mexico Board of Pharmacy since 2010. Currently, Mendez-Harper is the director of professional practices for Prime Therapeutics in Gilbert, AZ. Prior to this position, Mendez-Harper was a pharmacist-in-charge at various community and ambulatory care pharmacies. In addition, she has served as director of professional education for the American Pharmacists Association (APhA) and associate director of sponsored programs for APhA (then called the American Pharmaceutical Association), where she developed continuing education programs. Mendez-Harper previously served as a pharmacy education fellow and adjunct faculty at Bristol-Myers Squibb and Rutgers University.

Mendez-Harper is active in leadership roles at several pharmacy and professional organizations, including the New Mexico Pharmacists Association and APhA. She has also authored content and managed various publications for the APhA. Mendez-Harper earned her bachelor of science degree in pharmacy from the University of New Mexico and her doctor of pharmacy degree from the University of Kansas.

Mendez-Harper replaces Dennis K. McAllister, RPh, FASHP, senior director, pharmacy regulatory affairs at Express Scripts, who completed his term as an NABP appointee to the ACPE Board of Directors this year. Mendez-Harper joins two other ACPE members appointed by NABP: Michael A. Moné, JD, RPh, FAPhA, vice president, associate general counsel-regulatory at Cardinal Health, whose term runs from 2012 to 2018, and John Clay Kirtley, PharmD, RPh, executive director of the Arkansas State Board of Pharmacy, whose term runs from 2014 to 2020.

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

FSMB Presents Award of Merit to NABP Executive Director/Secretary and NCSBN Past CEO

The Federation of State Medical Boards (FSMB) presented a 2016 Award of Merit to Carmen A. Catizone, MS, RPh, DPh, NABP executive director/secretary, and Kathy Apple, MS, RN, FAAN, past chief executive officer (CEO) of the National Council of State Boards of Nursing (NCSBN), during the FSMB Annual Meeting in San Diego, CA, in April.

The Award of Merit recognizes activities and contributions that positively impact and strengthen the profession of medical licensure and discipline and help enhance public protection. According to FSMB, Catizone and Apple have provided years of invaluable collaborative leadership to the organization and the state medical board community. Working closely with FSMB leadership, Catizone and Apple were instrumental in the creation of the Tri-Regulator Collaborative, a joint initiative of FSMB, NABP, and NCSBN that addresses issues of mutual concern for the nation's state boards of medicine, pharmacy, and nursing. The collaborative has been successful in holding two well-attended Tri-Regulator Symposia in 2012 and 2015, with a third planned for 2017. ■

(Pictured above) Carmen A. Catizone, MS, RPh, DPh, NABP executive director/secretary (left) and Kathy Apple, MS, RN, FAAN, past chief executive officer, National Council of State Boards of Nursing (middle) are presented with the Federation of State Medical Boards (FSMB) 2016 Award of Merit from Humayun J. Chaudhry, DO, MS, MACP, president and chief executive officer, FSMB (right).

Around the Association

Executive Officer Changes

- **Steven Saxe, MHA, RPh, FACHE,** is serving as interim executive director of the Washington State Pharmacy Quality Assurance Commission. He began working with the Washington State Department of Health as the executive director of the Washington State Board of Pharmacy in 2004, when Donald H. Williams retired. Prior to working with the Department of Health, Saxe worked in both clinical pharmacy and health care administration positions in North Carolina, California, and Washington. Saxe received his bachelor's degree from Washington State University College of Pharmacy and his master's degree in health care administration from Duke University.

Board Member Appointments

- **Richard Holt, PharmD, RPh,** has been appointed a member of the Alaska Board of Pharmacy. Holt's appointment will expire March 1, 2020.
- **Phil Sanders, RPh,** has been appointed a member of the Alaska Board of Pharmacy. Sanders' appointment will expire March 1, 2020.
- **Kevin Dang, PharmD, RPh,** has been appointed a member of the Arizona State Board of Pharmacy. Dang's appointment will expire August 20, 2020.
- **Mark Smosna, RPh,** has been appointed a member of the Indiana Board of Pharmacy. Smosna's appointment will expire July 1, 2017.
- **Craig Martin, DPh,** has been appointed a member of the Kentucky Board of Pharmacy. Martin's appointment will expire January 1, 2017.
- **Ali Raja, MD, MBA, MPH,** has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Raja's appointment will expire December 1, 2018.
- **Dianne Armstrong, CPhT,** has been appointed a pharmacy technician member of the Oregon State Board of Pharmacy. Armstrong's appointment will expire February 17, 2020.
- **Cyndi Vipperman, CPhT,** has been appointed a pharmacy technician member of the Oregon State Board of Pharmacy. Vipperman's appointment will expire February 17, 2020.
- **Stacey Ranucci, RPh,** has been appointed a member of the Rhode Island Board of Pharmacy. Ranucci's appointment will expire June 1, 2018.
- **Maybelle "May" Reyes** has been appointed a public member of the Rhode Island Board of Pharmacy. Reyes' appointment will expire September 1, 2018.
- **Tom Nelson** has been appointed a public member of the South Dakota State Board of Pharmacy. Nelson's appointment will expire October 31, 2018.
- **Jerrie Allard** has been appointed a public member of the Washington State Pharmacy Quality Assurance Commission. Allard's appointment will expire January 19, 2020.
- **Teri Ferreira, RPh,** has been appointed a member of the Washington State Pharmacy Quality Assurance Commission. Ferreira's appointment will expire January 28, 2020.
- **Kenneth Kenyon, PharmD, RPh, BCPS,** has been appointed a member of the Washington State Pharmacy Quality Assurance Commission. Kenyon's appointment will expire January 19, 2017.

Board Member Reappointments

- **Dennis K. McAllister, RPh, FASHP,** has been reappointed a member of the Arizona State Board of Pharmacy. McAllister's appointment will expire January 28, 2021.
- **Eddie Curry** has been reappointed a public member of the District of Columbia Board of Pharmacy. Curry's appointment will expire March 12, 2018.
- **Bradley Hamilton, RPh,** has been reappointed a member of the Maine Board of Pharmacy. Hamilton's appointment will expire November 30, 2018.
- **Stuart Williams, JD,** has been reappointed a public member of the Minnesota Board of Pharmacy. Williams' appointment will expire January 7, 2019.
- **Kenneth Saunders, PharmD, RP,** has been reappointed a member of the Nebraska Board of Pharmacy. Saunders' appointment will expire November 30, 2020.
- **Robert Iacobucci** has been reappointed a member of the Rhode Island Board of Pharmacy. Iacobucci's appointment will expire June 1, 2018.
- **Leonard Petrik, PharmD, RPh,** has been reappointed a member of the South Dakota State Board of Pharmacy. Petrik's appointment will expire October 1, 2018.
- **Judith Wernecke** has been reappointed a public member of the Vermont Board of Pharmacy. Wernecke's appointment will expire December 31, 2020.
- **Cheryl Adams, PharmD, RPh,** has been reappointed a member of the Washington State Pharmacy Quality Assurance Commission. Adams' appointment will expire January 19, 2020.
- **Sepideh Soleimanpour, MBA-HA, RPh,** has been reappointed a member of the Washington State Pharmacy Quality Assurance Commission. Soleimanpour's appointment will expire January 19, 2020. ■

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

Food and Drug Administration (FDA) is requiring class-wide safety labeling changes for immediate-release (IR) opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain with access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery*.

Further, FDA is requiring updated labeling for all opioids (both IR and extended-release/long-acting products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm493871.htm.*

B. Braun Medical Inc, Recalls 5% Dextrose Injection USP Due to Container Leakage and Particulate Matter

On March 28, 2016, B. Braun Medical Inc, of Irvine, CA, voluntarily recalled one lot of 5% dextrose injection USP 100/150 mL container because of container leakage and particulate matter identified as microbial growth. The affected lot is packaged in B. Braun's PAB® (Partial Additive Bag) container with 64 units per case. The recalled product (lot number J5J706, catalog number S5104-5264, National Drug Code 0264-1510-32) expires October 31, 2016, and was distributed nationwide to licensed distributors, hospitals, and pharmacies. To date, the company has not received reports of adverse events associated with the use of this product, indicates the press release posted to FDA's website, which is available at *www.fda.gov/Safety/Recalls/ucm492927.htm.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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 decisions. In the Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.* ■

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

Louisiana Reviewing Public Comment on Rule Revision Regarding Compounding for Office Use for Veterinarians

The Louisiana Board of Pharmacy reviewed the language for a proposed rule revision that will put pharmacists on notice as to the absence of clear federal authority for pharmacists to compound veterinary preparations for office use for veterinarians. The Board approved the proposed language for Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians at its meeting on February 24, 2016, and directed a public hearing to receive comments and testimony on that proposed revision. That public hearing took place April 19, 2016. The Board also canceled the previously issued emergency rule and issued a new emergency rule. The new emergency rule contains the proposed revision, and it was made effective immediately. Information on the progress of all the Board's rulemaking activities is available on the Board's website at *www.pharmacy.la.gov.*

Washington State Adopts New Secure and Responsible Drug Disposal Regulations

Washington State pharmacies no longer need to obtain Washington State Pharmacy Quality Assurance Commission approval to participate in a secure and responsible drug disposal program (commonly known as drug take-back). Washington Administrative Code 246-869-130(4) allows controlled substances (CS) to be returned to a pharmacy for destruction in accordance with Drug Enforcement Administration (DEA) regulations. DEA published its final ruling on the Secure and Responsible Drug Disposal Act on September 9, 2014. This rule is under Title 21 Code of Federal Regulations §1317. DEA permits ultimate users lawfully possessing household pharmaceutical non-CS and pharmaceutical CS to dispose of these drugs at authorized collection sites. A Secure and Responsible Drug Disposal Program Guidance Document was approved by the Commission and serves as a tool to assist pharmacists and to outline appropriate steps for the following Washington State entities to become DEA authorized collectors:

1. Retail pharmacies;
2. Hospitals and clinics with on-site pharmacies; and
3. Long-term care facilities that the retail or hospital and clinic pharmacies choose to register as collection sites.

The document may be found at *www.doh.wa.gov/portals/1/Documents/Pubs/690294.pdf.*

Each entity participating in a secure and responsible drug disposal program is responsible for ensuring that it fully complies with all DEA regulations.

New Mexico Amends PMP Reporting Rule, Announces Program Enhancements

The New Mexico Board of Pharmacy amended Regulation 16.19.29.8 NMAC, Mandatory Reporting of Prescription Information to the PMP to include a product identifier in the data set reported. Also, the rule was revised to make prescription monitoring program (PMP) regulation language uniform with national PMP and American Society for Automation in Pharmacy reporting. All information that should be submitted for each prescription, as well as the standards for how this information shall be formatted, is defined in the PMP Data Reporting Manual, available on the New Mexico PMP website at *http://nmpmp.org* under PMP Resources.

In addition, the Board has announced the implementation of the Board's Harold Rogers 2014 Grant enhancements for the PMP. More information about the enhancements can be found in the March 2016 issue of the *New Mexico Board of Pharmacy Newsletter*, available on the NABP website at *www.nabp.net* under Publications.

North Dakota Board Approves Rule Changes

The North Dakota State Board of Pharmacy approved changes to five rules. The following rules became effective on April 1, 2016.

- A new standard requiring that all pharmacies have a continuous quality improvement program in place to track and prevent quality-related events and/or errors;
- Updated terminology on procedures for transfer of pharmacists' licensure;
- Updated regulations on Clinical Laboratory Improvement Amendments-waived tests to the current practice standards, and also expanded lists of tests that a pharmacist may conduct to those applicable to current practice expectations;
- A new process for pharmacists to have prescriptive authority to distribute naloxone rescue kits to appropriate individuals to treat narcotic overdoses; and
- Revised collaborative agreement standards to be consistent with the legislative changes currently in effect.

The final version of each rule can be found on the Board's website at *www.nodakpharmacy.com* or can be obtained by calling the Board office for copies.

INNOVATIONS

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

UPCOMING EVENTS

August 4-6, 2016
NABP/AACP District 5 Meeting
Lincoln, NE

August 14-16, 2016
NABP/AACP District 3 Meeting
Point Clear, AL

September 11-14, 2016
NABP/AACP Districts 6, 7, & 8 Meeting
Portland, OR

September 13-24, 2016
PARE Administration

September 15-17, 2016
NABP/AACP Districts 1 & 2 Meeting
White Sulphur Springs, WV

October 4-5, 2016
NABP Interactive Executive Officer Forum
Rosemont, IL