I. Introduction

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...
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 historic 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 U.S. 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.

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 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.” 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 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 pharmacists 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 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 anti-competitive 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 of 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.

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 co-exist. 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.