Bloomberg BNA

Pharmaceutical Law & Industry Report®

Confounded in Compounding Apothecaries: The Critical Need for Confining State Pharmacy Boards to Self-Regulation

BY WILLIAM G. SCHIFFBAUER

Policy makers are all calling for greater federal regulation of the "compounding" activities of pharmacies after the New England Compounding Center's laboratory let loose contaminated injectable steroids. The most recent report notes that this pharmacy negligence has to date killed 44 people and sickened 678 people in 19 states. See, Centers for Disease Control, Multistate Fungal Meningitis Outbreak Current Case Count (January 14, 2013). This is the result of one small pharmacy among thousands of such pharmacies across the nation in all 50 states that engages in combining, mixing, or altering prescription drugs.

Greater federal regulation of the "compounding" activities of pharmacies does not address the fundamental flaw that has laid this danger on the nation's doorstep once again. The real question is just "who" is setting and enforcing the standards for these pharmacies? In nearly all cases it is state pharmacy boards consisting of the very same professionals who have committed compounding negligence. It took 25 deaths and 344 injuries at the hands of the New England Compounding Center to actually "move" the Massachusetts Board of Pharmacy, months after the fact and years after similar tragedies, to adopt "emergency regulations" for compounding pharmacies (10 PLIR 1438, 11/9/12).

This article reviews the make-up of these state boards, provides a very brief review of history of the "compounding" controversy, and offers some possible reforms for states to consider if they want to retain the state primacy of regulating the "practice of pharmacy."

William G. Schiffbauer is a health care attorney in private practice in Washington. He is a member of the Advisory Board for BNA's Health Insurance Report. *He can be contacted at wgslaw@erols.com.*

Pharmacists Are a Self-Regulated Profession

Pharmacies and pharmacists are "self-regulated" at the state level by legislatively created state boards of pharmacy. These state boards are comprised largely of pharmacists empowered to regulate the practice of pharmacy, admission to practice pharmacy, standards of pharmacy practice and licensure, and the discipline of pharmacists. The core premise of "self-regulation" is that the knowledge base, training and skills required to be a professional pharmacist would make regulation by non-professionals who are incapable of assessing quality difficult, and that the profession should be able to be trusted to carry out this necessary standard-setting and licensure.

The principal goal of "self-regulation" is to maintain the competence of professional pharmacists, to identify problem pharmacists and to discipline those problem pharmacists, and to address conflicts of interest in order to maintain the public's trust in the pharmacy profession through licensure and disciplinary activities. The proper exercise of "police power" by a pharmacy board must be adjudged in these terms. Indeed, as pharmacy boards expand their jurisdiction beyond the realm of "self-regulation" of their own "learned profession," the entire premise of functions beyond "self-regulation" is deserving of strict scrutiny and re-examination.

For example, pharmacy board oversight of the actual manufacture of prescription drugs or even the management of employer-provided drug benefit plans, are ac-

tivities that are beyond the realm of "self-regulation" of the competency and behavior of pharmacists.

The "mortar and pestle" is the iconic symbol of the pharmacy profession, and so it seems that its foundation is rooted in "compounding." In fact, the practice of compounding at one time was the practice of pharmacy. However, the emergence of the pharmaceutical manufacturing industry in the 1950's totally transformed the practice of pharmacy as a "local" apothecary into a mass production industry of interstate commerce. See Boodoo, Jesse M., *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDMA Circuit Split*, 36 Amer. Journal of Law & Medicine 221 at 223 (2010).

Exercising State Police Power

In general, state legislation enacting pharmacy boards is grounded in the traditional "police power" retained by the states under the Tenth Amendment of the U.S. Constitution. See, *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560 (1991) (authority to provide for the public health, safety, and morals). The core purpose of a pharmacy board is to ensure that only qualified persons be permitted to engage in the practice of pharmacy. The boards are also established to protect public health and safety through the effective control and regulation of the practice of pharmacy and the licensure and discipline of pharmacists. Accordingly, the "self-regulating" function of the pharmacy board must remain within the scope of ensuring pharmacist competency.

The U.S. Supreme Court has recognized a state's "strong interest" in maintaining and preserving a high degree of professionalism on the part of licensed pharmacists. The "practice of pharmacy" affects the public health, safety and welfare; and a state board of pharmacy is responsible for the integrity of, and public confidence in, the pharmacy profession as specialists in the potencies and dangers of drugs. See, *Virginia State Board of Pharmacy et al., v. Virginia Citizens Consumer Council, Inc.*, et al., 425 U.S. 748 (1976). So the state's "strong interest" is in preserving high professional standards for pharmacists, and not in the actual manufacture of prescription drugs or the management of employer-provided drug benefit plans.

Establishing State Boards of Pharmacy

All 50 States have enacted State Board of Pharmacy laws, and the composition of the boards varies from state-to-state. A state board of pharmacy is almost always comprised of a majority of pharmacists, along with some representatives of the public. A brief and general discussion of the composition of these boards is important in order to consider and evaluate whether or not these pharmacy boards are also competent to regulate the manufacture and distribution of pharmaceutical products in interstate commerce, or, as in the case of some boards, to regulate employer-provided prescription drug benefit programs.

A review of these state rules demonstrates that boards of pharmacy are established, and the qualifications of the board members are so designated, to be only professional competency panels and nothing more.

Composition in General. Typically the majority of state pharmacy boards consist of five (5) pharmacist members and two (2) public members. However, Alabama has five (5) pharmacist members and no public member, and Louisiana has sixteen (16) pharmacist members and one (1) public representative, and Mississippi's board is comprised of seven (7) pharmacist members and has no public members. By contrast, the State of California has seven (7) pharmacist members and six (6) public members, and Michigan has six (6) pharmacist members and five (5) public members. Massachusetts has five (5) pharmacist members, two (2) public members, and a physician and a nurse.

Appointment by Governor. Most states specify that the board members are "political" appointments by the Governor. Some states require that the appointments be made upon the advice and recommendation of the state pharmacist association. Several states establish that various pharmacy practice-setting interest groups directly submit nominees to the Governor for "assigned seats" on the pharmacy board. For example, Alabama provides that nominees are separately submitted by the hospital pharmacist's society, the chain pharmacists association, and the independent pharmacists. California authorizes one of the public members to be appointed by the State Senate, and one other by the General Assembly. South Carolina provides for one pharmacist from each Congressional District.

Public Member Qualifications. The qualifications for public members of pharmacy boards in those states that have public members vary from state-to-state. Most states require that a public member must be a resident of the State and have attained the age of majority. Some States provide that the public member be a "consumer" of pharmacy services. Many states require that a public member may not have been a pharmacist or the spouse of a pharmacist, or has not ever had a material financial interest in the provision of pharmacy services, or been engaged in any activity related to pharmacy, or connected with a school of pharmacy. Some states also specify that not more than a certain number may be from the same political party.

For example, Alaska requires that public members have no financial interest in the practice of pharmacy. Arizona only requires that the public members have been state residents for at least five (5) years immediately prior to their appointment. Arkansas requires that one of the two public members must be sixty (60) years of age or older and shall represent the elderly on the board. Connecticut requires that the public member have had no professional affiliation with any pharmacy industry, profession, occupation, trade, or institution for three (3) years prior to appointment. New Jersey has similar requirements to Connecticut but further requires the State Attorney General to ensure that no public member has a "conflict of interest."

Professional Pharmacist Qualifications. The qualifications for the professional members of pharmacy boards are more consistent across states but do have some variations. In general, state laws require that a pharmacist member of the board of pharmacy must: be a resident of the State for not less than six (6) months; be currently licensed and in good standing to engage in the practice of pharmacy in the state; be "actively engaged" in the practice of pharmacy in the state at the time of appointment to the board of pharmacy (most require five (5) years); and have a specified number of years of experience in the practice of pharmacy in the

  PLIR ISSN 1542-9547

State after having been licensed. A few States merely require that board members be only "licensed" without specifying a number of years of active pharmacy practice.

To be a "licensed" pharmacist, State laws generally require that applicants for licensure: have graduated and received a professional degree from a college or school of pharmacy that is a school or college approved by the State board of pharmacy; have completed a pharmacy practice experience program that is approved by the State board of pharmacy; have successfully passed an examination given by the State board of pharmacy; have undergone a fingerprint-based criminal background check specified by the State board of pharmacy, and have paid the fees specified by the State board of pharmacy for the examination and issuance of a license. Some states require continuing pharmacy education to maintain a "current" license.

Variation occurs mostly in the number of years of experience required to be a pharmacy board member. For example, Alabama provides that a pharmacist must have been actively engaged for at least five (5) years in pharmacy administration or the practice of pharmacy, and in various practice settings such as in a hospital, an independent pharmacy, or a chain pharmacy. Arizona requires that a pharmacist board member must have been engaged in the practice for at least ten (10) years but permits practice in another state to count. Connecticut requires that a pharmacist must have been engaged in the practice of pharmacy "on a full time basis." Illinois requires at least five (5) years of "practical experience" in the practice of pharmacy. Massachusetts requires at least ten (10) consecutive years of "practical experience in the compounding and dispensing" of prescriptions.

Practice of Pharmacy Defined. A key concern is how the State might define the "practice of pharmacy" so that the "practiced" activities remain clearly within the "police power" of the State under the Tenth Amendment.

For example, the National Association of Boards of Pharmacy ("NABP") has proposed a Model State Pharmacy Act that very broadly defines the "practice of pharmacy." The NABP "model" delineates as "practice" the following activities: the interpretation, evaluation, and implementation of medical prescription drug orders; the preparation and dispensing of prescription drug orders; labeling of drugs; patient records; drug utilization; drug and device selection; quality, research, and the science, effectiveness, and properties of drugs; and patient care and counseling to provide pharmacist care. The "model" also includes a provision for the licensing of pharmacy "facilities" involved in the storage, distribution, and sale of drugs or devices.

These activities are mostly consistent with the public's perception of the pharmacist's main function — to fill prescriptions written by medical doctors. However, the "model" also pursues a broader spectrum of activities in order to optimize the use of prescription drugs and the income of pharmacists and activities that arguably transverse into the realm of a physician's medical practice. Most of the activities outlined in Article I of the NABP "model" appear to have some relation to the "practice of pharmacy." However, Appendix B of the "model" includes a "Compounding Practices" model, and in November 2012, the association's pharmacist members approved amendments to the "model" that would include regulation of pharmacy benefit managers.

Beyond Self-Regulation of the Practice of Pharmacy

As discussed above, the principal function of pharmacist "self-regulation" seems obvious at first, namely to regulate the competence and activities of pharmacists engaged in the practice of their profession. The core function is to establish qualifications and ensure the quality of pharmacists and pharmacies in the interest of promoting, preserving, and protecting public health and safety through the effective control and regulation of the practice of pharmacy. Self-regulation is intended to maintain competency, identify and discipline unprofessional conduct, and address conflicts of interest. Self-regulation is a privilege entrusted to "professionals" to police themselves because they know better than the untrained public "customers" at large.

The focus on drug compounding as a matter of public policy concern began in earnest in 1992 with the Food and Drug Administration's issuance of a Compliance Policy Guide that attempted to reach "compounding" activities because these activities raised the kinds of concerns normally associated with the manufacture of drugs. This led to debate over modernization amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1997 that included "clarification" of pharmacy compounding that was challenged in court by the pharmacy industry. In 2002, the U.S. Supreme Court declared certain compounding provisions of the 1997 law unconstitutional on first amendment grounds in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

Nearly ten years ago, in 2003, the U.S. Senate Committee on Health, Education, Labor, and Pensions held hearings on the "Federal and State Role in Pharmacy Compounding and Reconstitution: Exploring the Right Mix To Protect Patients." See, *S. Hrg. 108-378* (October 23, 2003). The hearing was prompted by then-recent media coverage and significant adverse events caused by compounded drugs involving non-sterile eye drops causing blindness, *spinal injections contaminated with bacteria and fungus* that resulted in hospitalization and, in some cases death, and children poisoned as a result of pharmacy compounding errors. In testimony, the GAO observed that state pharmacy board resource limitations adversely affected inspections.

Regarding the recent expansion of the Mississippi Board of Pharmacy's authority to regulate service providers for employer-provided drug benefits, the U.S. Federal Trade Commission ("FTC") observed that pharmacists and PBMs have a competitive, and at times, adversarial relationship, and that giving a pharmacy board regulatory power over PBMs would create tensions and conflicts of interest for the pharmacy board. The FTC also noted that the antitrust laws recognize that there is a real danger that regulatory boards composed of market participants may pursue their own interests rather than those of the state. See, FTC, Letter to the Honorable Mark Formby, Mississippi House of Representatives, on Mississippi Senate Bill 2445 (March 22, 2011) (9 PLIR 374, 3/25/11).

As a final note, on January 4, 2013, Massachusetts Governor Deval Patrick submitted a legislative proposal

to the legislature following up on recommendations of a special Commission on Compounding Pharmacies. The proposal would require a special license, would authorize the assessment of fines, and would establish whistleblower protections for pharmacists and staff. Also, the proposal reforms the composition of the board to include one (1) quality improvement expert, one (1) pharmacy technician, and one (1) additional public member. These proposed changes, however, merely perpetuate the overreach of a state board whose core purpose and true expertise is to "police" the competence, quality, and behavior of professional pharmacists.

Conclusion: Pharmacy Boards Must Stick to Self-Regulation

The recurrent "compounding pharmacy" regulation problem is an example of overreaching by pharmacy boards that goes beyond the principal function of "self-regulation." It is an attempt to control businesses that have an impact on the income of pharmacists. The "compounding pharmacy" is a manufacturer, and such activity is not within the scope of the "policing" of the competency and behavior of pharmacists. Pharmacy boards unlawfully expand beyond "self-regulatory" authority in regulating PBMs, because the management of employer-provided drug benefit programs is not an activity of pharmacist "self-regulation." These are not "self-regulatory" activities concerned with maintaining the professional competence of pharmacists.

State pharmacy boards should be "reformed" to confine their authority solely to "self-regulating" the competency and behavior of pharmacists. The principal goal of "self-regulation" is to maintain the competence of professional pharmacists, to identify problem pharmacists and to discipline those problem pharmacists, and to address conflicts of interest in order to maintain the public's trust in the pharmacy profession through licensure and disciplinary activities. The proper exercise of "police power" by a pharmacy board must be adjudged in these terms, and any jurisdiction over activities or business beyond the realm of "self-regulation" of their own "learned profession" should be retracted.

PLIR ISSN 1542-9547