Mike Bertagnolli: Presentation to Economic Affairs Interim Com.

Good afternoon ladies and gentlemen of the committee, it is a pleasure to have the opportunity to speak to you today. I am here to provide a statement as well as to answer any questions pertaining to HB 525, specifically as to the Board of Pharmacy's serving a public purpose.

In short, the Board of Pharmacy ABSOLUTELY serves a public purpose by providing PUBLIC SAFETY to the citizens of Montana. The Board of Pharmacy is charged with regulating and licensing pharmacy professionals in our state-pharmacists, technicians, student interns-as well as regulating and licensing those involved in the PHARMACEUTICAL SUPPLY CHAIN (wholesalers, mail order pharmacies, on line pharmacies, and manufacturers). It is by regulation of the people and the product that the Board can ensure that safe, effective drug products are reaching our patients and being dispensed by licensed, competent professionals trained to do so.

The profession of pharmacy continues to grow and change as health care changes. Although pharmacists continue to be recognized for their expertise and knowledge to ensure the right product gets to the right patient, the role of the pharmacist has changed significantly: The insurers who cover Montana lives utilize pharmacists as consultants to review medication regimens of patients, develop a cost-effective yet treatment-effective drug formulary. In the hospital setting clinical pharmacists are involved in managing patients under the order of the physician. My own hospital is a perfect example: We are charged with dosing certain regimens of anticoagulants, antibiotics, and pain regimens based on protocols we have developed in conjunction with our physicians. We have data that demonstrates that we perform many of these clinical activities with greater efficacy and less cost that physicians.

Registered pharmacists have long been recognized for their expertise in medications and how medication therapy relates to disease states. Pharmacists have long been recognized as one of the most trusted professions in the United States. That said this trust and expertise does not come easily: Pharmacists must graduate from an accredited school of pharmacy in order to be eligible to take a national Board examination, and pass this examination in order to be eligible for licensure by the Board of Pharmacy.

The Montana Board of Pharmacy, as well as the other 49 Boards of Pharmacy in the United States, are member Boards of the National Association of Boards of Pharmacy (NABP). Since its inception in 1904, NABP has operated to support the Boards of Pharmacy as they develop, implement, and enforce uniform standards for the purpose of protecting the public health. This also allows the Board of Pharmacy to be very efficient, i.e., networking with NABP and other state Boards for guidance in rule making or changes to rules, therefore not having to "reinvent the wheel." In addition NABP provides member Boards a national clearinghouse of licensure information not only on pharmacists, but also pharmacies, student interns, pharmacy technicians, and wholesale distributors, which is extremely helpful when licensees from outside the state seek a license to practice or deliver product into Montana. In addition NABP has developed accreditation standards for wholesale distributors and internet pharmacies, to which the Montana Board of Pharmacy requires in order to be eligible for licensure.

In summary, the Montana Board of Pharmacy does indeed provide a public benefit to our citizens, and that public benefit is ensuring patient safety with respect to medication use and medication management. The board does this by regulating the profession of pharmacy as well as the pharmaceutical supply chain, which ensures safe, effective product is reaching our Montana patients, and the necessary information with respect to that product is being disseminated by trained, competent pharmacy professionals, all of which is done through our licensing process. Thank you for giving me the opportunity to address the committee.

ECONOMIC AFFAIRS COMMITTEE
PREPARED TESTIMONY
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What is the public health, safety, or welfare rationale for licensing and regulating your profession/occupation?

There is an unchallenged public policy in favor of licensing and regulation of the pharmacy profession and pharmaceutical industry. The responsibility of the Board of Pharmacy involves licensing the PRACTITIONER as well as the PHARMACEUTICAL SUPPLY CHAIN. Licensing of the pharmacist involves the culmination of background check, verification of graduation from accredited school of pharmacy, and successfully passing national licensing exam, all of which are regulated by the Board. In addition to registered pharmacists, the Board also oversees and licenses the PHARMACY TECHNICIAN. Montana was one of the first states in the country to require a national examination as a requirement of technicians to practice in our state, and many other states are adopting that requirement. Every state in the U.S. has a Board of Pharmacy to regulate the profession in their respective states, and all state Boards of Pharmacy belong to the National Association of Boards of Pharmacy (NABP), an international impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

Boards of Pharmacy are also responsible to license the pharmaceutical SUPPLY CHAIN. Our regulation and oversight of retail pharmacies, hospital pharmacies, home infusion pharmacies, mail order pharmacies (including those entities that are outside of MT but mail prescriptions to patients in Montana), as well as wholesalers and distributers ensure that integrity of the products that reach patients as well as the competency of those involved in the distribution of those products is maintained. NABP offers accreditation programs for drug wholesale distributors, as well as online pharmacies, and the MT Board of Pharmacy REQUIRES NABP accreditation before we will grant licensure to these entities. In addition, NABP operates and provides access to a national clearinghouse of licensure information on pharmacists, pharmacies, technicians, interns, and wholesale distributors that is provided to member Boards , as well as provides monthly reporting of disciplinary actions taken against licensees nationally.

If your profession is not licensed, what public protection would be lost?

The Board's response to the previous question addressed this question in some detail. The board provides oversight of practitioners that ensures only those qualified to practice are working in Montana providing pharmaceutical care to our public. As previously mentioned the Board provides oversight of out-of-state pharmacies and pharmacists that choose to do business within Montana. The board provides oversight of the SUPPLY CHAIN by licensing suppliers as well. Board licensing ensures integrity of practitioners, integrity of product.

If a license is necessary (for health, safety, or welfare), does the profession/occupation need a board for oversight? If yes, please explain why and describe the purpose of creating a board.

The Board of Pharmacy is responsible for writing, implementing, and interpreting rules that govern the pharmacy profession based on the intent and authority of the legislature and specific statutes enacted by the legislature. In order to effectively carry out this function a Board of its peers is necessary to effectively develop and administer these rules. As the profession of pharmacy changes the Board is often faced with revision of certain rules, new rules, or deletion of rules in order to regulate the profession responsibly, ethically, and efficiently. Without Board oversight of the rulemaking process undoubtedly this process would become ineffective and many challenges to proposed and existing rules, as well as possibility of need for emergency rules would result.

Does the board deal with unlicensed practice issues? If yes, what types of issues?

The board of pharmacy infrequently encounters unlicensed practice issues thanks in large part to the standardization of state boards with NABP and ability to share and exchange information, thus practicing unlicensed in Montana virtually impossible. Often the Board is confronted with out of state licensees that fail to license or renew before doing business in Montana as an example.

People who are not licensed but are qualified in an occupation or profession may feel that a licensing board is preventing them from earning a living. What is your response?

This question is not applicable to the practice of Pharmacy. Pharmacists, technicians, nor student interns can work and practice in a pharmacy unless they are licensed to do so, and they cannot become licensed until they meet the educational requirements to make them eligible for licensure.

How does your board monitor bias among board members toward a particular licensee, an applicant or a respondent (to unlicensed practice)? How does your board monitor bias toward a particular profession/occupation, if more than one profession or occupation is licensed by the board?

Montana is large geographically, but small in terms of the profession of pharmacy. No different than with physicians, nurses, or dentists, through professional affiliation board members know many of their colleagues in the state. That said, invariably the situation will arise where a licensee involved in case before the board will be known to one or more members. My first board meeting I was confronted with TWO pharmacists appearing before the Board on diversion issues that used to work for me. Since being assigned to the screening

panel of the Board another licensee has come before us on a diversion issue that used to work for me. In my specific situation, as a new member I sought advice from the Board counsel and executive director on this matter. Subsequently I attended new Board member training that provided guidance and direction on these potential issues, but quite honestly the structure of the Board provides a strong, objective body where bias or potential bias issues are infrequent.

Board members are unable to recall any conflict with any other profession because there is no professional overlap between pharmacists' professional boundaries and other professionals' boundaries. There may be, for instance, mutual overlap between the care afforded by an athletic trainer and a physical therapist, but there is no such overlap between pharmacists and other providers. Any potential overlap and possible bias with physicians dispensing medications is managed by law – §37-2-101 *et. seq.*

The board has no experience with internal conflicts or biases between licensed pharmacists and pharmacy technicians or between any of the various forms of licensed pharmacies. While conceivable, perhaps, such conflicts have not occurred.

Does the profession or occupation have one or more associations that could provide oversight without the need for a licensing board? Why not use the association as the oversight body?

The Montana Pharmacy Association is a pharmacists' advocacy organization geared toward promoting the profession and pharmacists' individual aims. Those goals are laudable, but an oversight body must be strictly focused on the interests of the public. The Montana Pharmacy Association could not divide its mission by both advocating for pharmacists and protecting the public interest. In addition many pharmacists choose to affiliate with other associations, e.g., American Society of Health-System Pharmacists, American Pharmacy Association, National Community Pharmacists Association, etc. My experience has shown that given the diverse practice settings many practitioners don't necessary agree on the same issues, so invariably MPA would be presented with many conflict of interest issues.It is impossible for MPA to perform the work of the Board, Executive director, two inspectors, and administrative staff.

Is a licensing board needed in order for the practitioner to bill to receive insurance (for example, health insurance)? If so, is there an alternate method for billing that may be recognized rather than having a license or being regulated by a licensing board?

Yes. Third party payers will only reimburse licensed pharmacies. In the case of clinical pharmacist practitioners, specially trained pharmacists may offer patients drug therapy management, but only licensed and certified practitioners are entitled to bill for this service. §37-7-306, MCA

No. Only licensed pharmacies may bill insurance carriers or government programs; any others would be rejected.

What are the benefits of a board being part of the licensing and discipline process instead of the department handling one or both?

The board offers the expertise and insight of practicing professionals representing a wide spectrum of pharmacy practice. That expertise and insight allows the board to better evaluate and judge an applicant's qualifications or the need for discipline in the case of a licensee's alleged misconduct. With rotating membership on the board, fresh ideas and novel approaches can be applied to recurrent issues. Additionally, a board offers the value of a number of individual's combined talent and experience, rather than that of a single department decision maker. A board of peers engenders the confidence of the profession through notions of self-governance by colleagues instead of rule by a distant bureaucracy. The rules governing the profession of pharmacy are complicated, and often the work of the Board involves extensive researching and discussion with respect to a potential issue as to specific violations of specific rules before any decision can be make with regard to discipline or further action. It is impossible and impractical for an agency that doesn't have the practice experience or expertise to exercise objective and appropriate decision making, another reason the Board is comprised of a quorum of practitioners from different practice settings.

Is there an optimum ratio between licensees, board size, or public representation?

Pharmacy practice is varied by type and by licensure level; representatives of which should act on the board together with representatives of the public the board serves. A cross-section of the practice should include pharmacists from institutional pharmacies such as hospitals or government operated pharmacies and community pharmacies whose practices face different challenges. Additionally, the board should include a representative of pharmacy technicians. Finally, the public should have significant voice. Considering these factors, the present board of seven with four pharmacists, one pharmacy technician and two public members is near optimal. The board is diverse enough to be inclusive, but not too large to be effective. The two public members give effective advocacy to the public's interest.

If a board's purpose includes protecting public welfare, would that consumer protection be handled better by the Attorney General's office than by a board? (In other words, is there a value in a disinterested third party? If yes, why? If not, why not?) Who should be responsible for monitoring fraud within the profession or occupation?

Although consumer protection is a mission of both the Board of Pharmacy and the Attorney General's office, the roles and functions of the Board and the Attorney's General office are very different. The Board possesses the licensing function which logistically could not be assumed by the AJ. In addition, the AJ office is not equipped with the Board's technical expertise to evaluate many cases, e.g., unprofessional conduct.

The board presently offers consumer protection by scrutinizing license applicants and disciplining licensee's misconduct. Since we do share a common goal of consumer protection

with the AJ however, there certainly is significant potential to align our two agencies to better serve the public, as evidenced in the newly enacted Prescription Drug Monitoring Program, a program that is equally important to both agencies share in efforts to curb prescription drug abuse. The Montana attorney general may have resources and legal tools available to it that are unavailable to the board of pharmacy, making it a useful ally to the board in promoting public safety. Indeed, the federal government, through the United States attorneys' offices, regularly pursues civil claims against pharmacies for significant violations of the Food, Drug and Cosmetic Act. The Montana attorney general may have resources and legal tools available to it that are unavailable to the board of pharmacy, making it a useful ally to the board in promoting public welfare. However, the attorney general could not undertake the board's licensing function which is a significant fraction of the board's duties. Additionally, the attorney general is not equipped with the board's technical expertise to evaluate cases of alleged substandard or unprofessional conduct – a properly trained pharmacist is indispensible in any case. The board presently offers consumer protection by scrutinizing license applicants and disciplining licensee's misconduct.

There is more than one type of "fraud" and properly there is more than one avenue to address it. The board of pharmacy enforces its administrative rule on unprofessional conduct that expressly addresses fraud in three particulars:

> 24.174.2301 UNPROFESSIONAL CONDUCT (1) The board defines "unprofessional conduct" as follows:
> * * *
> (g) Defrauding any persons or government agency receiving pharmacy services;
>
> * * *
> (l) fraud, misrepresentation, deception or concealment of a material fact in applying for or securing a license, or license renewal, or in taking an examination required for licensure; as used herein, "material" means any false or misleading statement or information;
> (m) Use of a false, fraudulent or deceptive statement in any document connected with the practice of pharmacy

The board's rules allow the board to discipline a licensee that defrauds a patient or government, the board itself, or anyone else impacted by a fraudulent statement. Local county attorneys have authority to criminally prosecute fraud as a particular form of theft. *See, e.g.,* §45-6-301(4), (5), (6), MCA. Presumably the attorney general's office has authority to take action through its consumer protection office if a consumer has been harmed by a pharmacist's fraud. With this tightly woven net, it is difficult to imagine fraud escaping detection and correction.

If boards have overlapping scopes of practice, should there be a third-party to determine whether there is intrusion into the others' practice? If so, who should be the judge? If not, why not? Should each be allowed to operate on the other's turf without repercussions?

As noted above, the board of pharmacy does not face instances of overlapping scopes of practice – the pharmacists' role in health care is unique.

The board agrees that it is vital to have a disinterested third party reviewing the board's proposed decisions. If any license applicant or licensee disputes a board's proposed decision on a matter – whatever its nature – it may be reviewed by an independent hearing examiner under the administrative procedures act.

Viewed as an academic question, if two professions truly have "overlapping scopes of practice" then each profession must be entitled to perform the act. Each board should be able to judge whether its licensees are working within their scope of practice or not. Generally it is unprofessional conduct to exceed one's scope of practice and the offending licensee would be disciplined by his or her own board. If a licensee improperly exceeds his or her scope of practice and encroaches on another's "turf" the second board could take action as well for unlicensed practice. In practice, however, it is more efficient to discipline a licensee than seek an injunction against a non-licensee. Regardless of the means of redress, an independent hearing examiner and an independent court of law checks the authority of the board.

Should the board have the ability to limit use of certain terminology to only a licensee?

Yes. The public has come to associate certain terms with licensed professions that have the endorsement and approval of government regulators. Over years of use, the term "pharmacy" has gained the public trust because of the skill and professionalism of licensed pharmacists. It would be a disservice to the public and to the profession to allow unqualified individuals to represent themselves in the same light as pharmacists operating a pharmacy. Allowing free use of the term would confuse consumers and erode public confidence in licensed pharmacists.