The Pharmacist Activist

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Editorial

Voters in North Dakota Should Oppose the Challenge to the Pharmacy Ownership Law!

North Dakota has a law regarding the ownership of pharmacies that is unique. The law was passed in 1963 and requires that the majority ownership of pharmacies must be held by licensed pharmacists. For more than 50 years the law has prevailed against numerous challenges (please see my editorial, "North Dakota has it Right! Challenges to its Pharmacy Ownership Law must be Rejected!" in the September, 2008 issue of *The Pharmacist Activist* at www.pharmacistactivist.com). The validity of the law was upheld by the U. S. Supreme Court in 1973, when it reversed by a 9-0 vote a state court decision that would have permitted a chain store to obtain a license to operate a pharmacy.

The current challenge to the law is designated the North Dakota Pharmacy Ownership Initiative, Measure 7, and is on the November 4, 2014 ballot. Support for Measure 7 is being led by North Dakotans for Lower Pharmacy Prices, as well as companies such as Walgreens, Walmart, and Kmart. The North Dakota Pharmacists Association is the primary opponent of the Measure. It is understandable that consumers are concerned about the cost of prescription medications. However, an expectation that Measure 7 will have any appreciable effect on prescription costs is misguided because a very large fraction of the cost of prescriptions is established/received by the companies that make the products, and differences in prescription costs at pharmacist-owned pharmacies and chain pharmacies such as Walgreens are very small. Both supporters and opponents of Measure 7 have examples and limited data to support their positions regarding drug costs, but this information falls short of convincing evidence or documentation. There are, however, other factors that will be strongly influenced by the outcome of the vote on Measure 7.

Who determines pharmacy policies?

Dedicated pharmacists with excellent skills are employed at both

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pharmacist-owned pharmacies and chain corporation-owned pharmacies. The pharmacist owner establishes the policies for her/his pharmacy, whereas the policies for the operation of chain pharmacies are made by executives who are usually not pharmacists working at corporate headquarters in another state. In some chain stores a non-pharmacist store manager has more authority for operations than the pharmacist manager.

One very important policy is the determinant of the number and schedules of the pharmacists, student pharmacists, and pharmacy technicians who work at the pharmacy. Chain pharmacies typically have metrics/quotas relating to the number of prescriptions dispensed that are used to determine whether additional pharmacist or technician hours can be added. The prescription quotas that must be met for a chain pharmacy to be provided with additional staffing are usually regarded as confidential information. However, the policies are often restrictive to the point that many chain pharmacists voice concerns about understaffing and a stressful work environment, and many consumers have complaints about long waits to obtain prescriptions. In contrast, pharmacists who own a pharmacy have made an investment in and are personally active in their community, and are much less likely to permit situations to exist that would result in employee or consumer concerns. The importance of the personal interest, service, and care of a pharmacist owner whose personal fulfillment and success is dependent upon the continued good will and patronage of her/his customers must not be underestimated.

During the U. S. Supreme Court deliberations regarding the North Dakota pharmacy ownership law, Justice William Douglas noted, "Those that control the purse strings control the policy." In my opinion, the interests of the residents of North Dakota are far better served by having local pharmacist owners establish policies rather than non-pharmacist executives of chain stores at corporate headquarters in another part of the country.

Errors and other drug-related problems

No other responsibility of a pharmacist is more important than exercising the knowledge, judgment, and care that will avoid prescription errors (e.g., dispensing the wrong medication) and avoid failure to identify other drug-related problems (e.g., drug interactions). To my knowledge, there are no studies or other available information that would provide a valid comparison between pharmacist-owned pharmacies and chain stores with respect to problems such as the number of prescription errors that have been made and the number of lawsuits in which the pharmacy and/or pharmacist has been named as a defendant.

In the absence of specific information, are there ways in which the degree of risk of such errors can be assessed? One approach might be to consider a question such as the following: Are errors more likely to occur in a pharmacy in which 100 prescriptions are dispensed by one pharmacist and one technician in an 8-hour period, or in a pharmacy in which 200 prescriptions are dispensed by one pharmacist and one technician in an 8-hour period? Most would respond that errors are more likely in the pharmacy in which 200 prescriptions are dispensed in an 8-hour period because there is less time to devote to each individual prescription/patient and the higher prescription volume could result in a more pressured/stressful work experience. However, others would contend that there are so many variables that there is not a valid answer to the question. Nevertheless, the relationship of the level of staffing and who determines policies as discussed earlier, can't be ignored.

Another approach would be to directly request the information regarding errors and lawsuits. For example, as a chain organization that wants to operate pharmacies in North Dakota, Walgreens should be asked to provide information regarding dispensing errors and lawsuits involving its pharmacies, at least in the states adjacent to North Dakota. They have this information. However, they will not provide it! Although the acknowledgement of errors or other problems is difficult for any individual or organization, the failure to provide such information should be reason to question why there is not transparency regarding a matter that is of such importance to the public. The same transparency would be expected of pharmacist owners of pharmacies.

Economic implications for the state

As noted earlier, I do not believe that a change in the pharmacy ownership law would result in a significant difference in the cost of prescriptions for individuals. However, I would expect losses for the economy of North Dakota. Currently, most, if not all, owners of pharmacies reside in North Dakota and the profits from their pharmacies are of benefit for the economy of the state. In contrast, if chain stores are permitted to operate pharmacies in North Dakota, the financial benefits would be derived by the corporate entity with its headquarters and priorities in other states.

North Dakota is a leader!

Some allege that North Dakota is behind the times because it is the only state that requires majority pharmacist ownership. However, it is my belief that the experience in other states sends a message

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New Drug Review

Empagliflozin
(Jardiance – Boehringer-Ingelheim; Lilly)

Antidiabetic Agent

New Drug Comparison Rating (NDCR) = 3
(no or minor advantages/ disadvantages) in a scale of 1 to 5 with 5 being the highest rating

Indication:
Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Comparable drugs:
Canagliflozin (Invokana), dapagliflozin (Farxiga).

Advantages:
- Recommendations for use in patients with impaired renal function are less restrictive (compared with dapagliflozin);
- May be used in patients with severe hepatic impairment (compared with canagliflozin that has not been studied in patients with severe hepatic impairment and use is not recommended);
- Has not been associated with reports of patients experiencing bladder cancer (compared with dapagliflozin).

Disadvantages:
- Additive benefit when used in combination regimens may be less pronounced (although agents have not been directly compared in clinical studies);
- Not available in a combination formulation with metformin (compared with canagliflozin).

Most important risks/adverse events:
Renal function impairment (contraindicated in patients with severe renal impairment; renal function should be monitored during therapy); hypersensitivity reactions (contraindicated in patients with a history of a serious reaction); hypotension (risk is increased in patients with impaired renal function or low systolic blood pressure, the elderly, and in patients treated with a diuretic); hypoglycemia (when used concomitantly with insulin or an insulin secretagogue [e.g., a sulfonylurea]); positive urine glucose test results (alternative methods to monitor glycemic control should be used).

Most common adverse events:
Urinary tract infection (9%), female genital mycotic infection (5%; e.g., vulvovaginal candidiasis), dyslipidemia (4%; e.g., increased LDL-C), increased urination (3%), male genital mycotic infection (3%; e.g., balanitis), upper respiratory tract infection (3%).

Usual dosage:
10 mg once a day in the morning; in patients who tolerate treatment and require additional glycemic control, dosage may be increased to 25 mg once a day; treatment should not be initiated in patients with an estimated glomerular filtration rate (eGFR) less than 45 mL/min/1.73 m2, and treatment should be discontinued if the eGFR is persistently below this value.

Products:
Film-coated tablets – 10 mg, 25 mg.

Comments:
Sodium-glucose cotransporter 2 (SGLT2) is expressed in the proximal renal tubules and is responsible for the reabsorption of the majority of glucose filtered by the kidneys. Empagliflozin is the third SGLT2 inhibitor, joining canagliflozin and dapagliflozin, and these agents reduce the reabsorption of filtered glucose, thereby increasing urinary glucose excretion and lowering blood glucose and glycosylated hemoglobin (hemoglobin A1c [HbA1c]) concentrations. Its effectiveness has been demonstrated in studies in which it has been used as monotherapy, or in combination regimens with metformin, glimepiride, pioglitazone, or insulin. The use of empagliflozin resulted in reductions in HbA1c and fasting plasma glucose (FPG) concentrations and, in many patients, weight reduction. In a placebo-controlled study, the percentage of patients achieving an HbA1c of less than 7% at Week 24 was 35% and 44% in patients receiving daily doses of 10 mg and 25 mg of empagliflozin, respectively, compared with 12% of those receiving placebo. Patients treated with empagliflozin lost an average of approximately 3 kg of body weight, compared with an average loss of 0.4 kg in those receiving placebo. The reductions in HbA1c and FPG in patients treated with combination regimens that included empagliflozin, as well as the percentage of patients achieving an HbA1c of less than 7%, were generally similar to those attained with empagliflozin monotherapy.

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that the advocates for this requirement have demonstrated vision and wisdom. Throughout the country, there are increasing concerns that government agencies, insurance companies, and corporations are acquiring excessive control over health care systems, as well as the responsibilities and decision-making capacities of health care professionals such as pharmacists and physicians. One very important consequence is that physicians, pharmacists, and other health professionals have less time that can be devoted to discussions and other communications with patients—a strong contradiction to the concept of "personalized" health care/medicine that is being promoted.

North Dakota has been a leader. Residents should vote against Measure 7!

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Chantix Should be Available Without a Prescription from a Pharmacist!

More than 480,000 Americans die each year of complications from smoking-related illnesses. Varenicline (Chantix) is more effective than any other medication/product in helping individuals stop smoking. However, it requires a prescription. For a variety of reasons, many individuals who smoke will not make an appointment to see a physician and, as a consequence, do not have access to this medication.

On October 16, 2014, a joint meeting of the FDA's Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will be held. The Committees will discuss safety data from observational studies and a meta-analysis of clinical trials that have been conducted since the original concerns regarding serious neuropsychiatric adverse events with Chantix emerged. They will also discuss whether any action needs to be taken with regard to how this risk is described in the product labeling.

The labeling (package insert) for Chantix has been revised this month (September) to include information from recent studies that indicate that the risk of neuropsychiatric adverse events is less than that suggested in previous reports and labeling. However, the boxed warning regarding this risk remains in the labeling. On the basis of the more recent information that suggests less risk, the manufacturer (Pfizer) plans to request that the FDA remove the boxed warning.

Some have contended that the FDA will not approve availability without a prescription of a medication that includes a boxed warning in the labeling for the prescription product. However, such situations already exist, and with the most widely used of all therapeutic agents—acetaminophen. For example, the prescription product Vicodin contains a combination of hydrocodone and acetaminophen, and its labeling includes a boxed warning. The boxed warning does not address a risk with hydrocodone, but rather a risk of hepatotoxicity with acetaminophen.

Pharmacists have the knowledge and judgment to recommend Chantix for appropriate patients, and to provide information and counseling to result in optimum use. We should no longer accept the paradox in which the toxins (cigarettes) are readily available requiring only proof of age to purchase, whereas the availability of the potential cure is restricted.

Chantix should be available without a prescription from a pharmacist!

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