The Pharmacist Activist

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Editorial

Chain Pharmacists of America (CPOA)

For many years (make that decades), I have been an advocate for a more effective organizational structure for the profession of pharmacy. The organizational model I envision is one in which our sometimes collegial but often competing national pharmacy associations, would establish and participate in a unified structure that would provide greater size, strength, and effectiveness in representing and being an advocate for the profession of pharmacy, as well as our constituencies based on type/location of practice, specialty, etc. My efforts in this direction have been an exercise in futility. If anything, our national professional associations have moved farther away from such a model, rather than closer to it. Pharmacists who have graduated during the last several decades will have difficulty even imagining earlier occasions when APhA, ASHP, NABP, and AACP actually convened together for annual meetings.

Considering my advocacy for a unified organizational structure, my recommendation in this editorial will be a surprise to many. I am recommending the establishment of a new national organization - Chain Pharmacists of America (CPOA).

More pharmacists are employed in chain pharmacies than in any other area of pharmacy. Most of them are not members of any national pharmacy association. There is no national pharmacy association that has an identity of providing programs for, and representing and promoting the interests of chain pharmacists. Although there is a National Association of Chain Drug Stores (NACDS), this is not an organization in which individual chain pharmacists are members, but rather its membership includes chain pharmacy corporations, and it is these corporate entities that NACDS represents.

I am not making this recommendation without first trying to work "within the system." I have met with the leaders of a national pharmacy organization and recommended an initiative to attract and engage chain pharmacists. However, no action was taken and, perhaps, that was for the best as I consider the current recommendation to have greater potential.

The need

Chain pharmacists, as other practicing pharmacists, give the highest priority to patient safety. However, compromised safety of patients is of great concern for many chain pharmacists who must contend with understaffing, metrics, a very busy and stressful workplace, and an apparent but unstated corporate philosophy that mistakes are a cost of doing business. A common refrain at the end of an 8-, 10-, 12, 14-hour shift is: "The day is a blur. I can only pray that whatever mistakes were made are not serious."

Concerns are frequently voiced regarding patient safety, working conditions, policies, schedules, adequacy of technicians (some of whom are paid minimum wage), and a lack of authority that is commensurate with responsibility. A pharmacist manager at a busy chain pharmacy shared with me that a new Wendys opened near the pharmacy. Five of the pharmacy technicians left to take a job at Wendys because of the better pay.

Some pharmacists who voice their concerns to management encounter indifference, if not hostility. In many parts of the country, the supply of pharmacists exceeds the number of positions available. Pharmacists who voice concerns to management are increasingly

receiving responses such as: "I have 10 applications on my desk from pharmacists who would love to work here. If you are not satisfied with your working conditions, perhaps it is time for you to work elsewhere." And this is the response to the pharmacists who have the courage to voice their concerns. Most suffer in silence. Many long-experienced pharmacists have the perception, if not the actual message, that management wants them to leave so that they can hire younger pharmacists at lower salaries. The need for advocacy for chain pharmacists is urgent, and there is no organization to which they can turn for support.

Are unions an option?

Two of my pharmacist friends have served as Presidents of unions of pharmacists. The care and safety of their patients are their highest priorities. One of these pharmacists observed to me: "No patient who brings a new prescription into the pharmacy when I am on duty leaves without my personally counseling them, regardless of how long the line of waiting patients becomes." However, notwithstanding their personal high standards, I also know that their experiences in dealing with management are far more frustrating than fulfilling. I highly commend them for persisting with their efforts to represent their pharmacist members.

For several reasons, I do not consider unions to be the best option. I do not have expertise in labor law or the structure of unions but my understanding is that a distinction is made between "management" and "staff" with respect to eligibility for membership in unions. Therefore, the pharmacist manager or two pharmacists who are co-managers in a chain pharmacy might be precluded from being members of a union. The association of chain pharmacists that I am recommending (CPOA) would welcome all pharmacists who are employed in chain pharmacies as members. This could include the small number of pharmacists who have risen to executive positions in chain pharmacy corporations and who most likely would have management "opinions" rather than the concerns of pharmacists working in the stores. However, in CPOA, the number and influence of this small number of individuals would be minimal in comparison with that of the much larger number of store pharmacists.

Another reason for my belief that unions do not provide the best option is that, fairly or unfairly, there is a common perception that unions are only interested in the economic welfare (e.g., salaries, benefits) of their members. An extension of this perception is that unions could go on strike if expectations/requests are not met. Although salaries and benefits are very important issues, they would not be a primary focus for CPOA. In addition, I anticipate that the size and influence that CPOA has the potential of developing will have sufficient strength that even the possibility of a strike will never have to be considered.

Priorities for CPOA

The priorities for CPOA will be the quality of care/services for patients, patient safety, avoidance of errors, and appropriate working conditions for pharmacists and pharmacy staff. These priorities do not preclude involvement with other services and benefits that many associations provide for their members.

Patient safety and avoidance of errors must receive the highest priority. The very busy and stressful practice environment in many chain pharmacies are primary factors in the frequent occurrence of errors and many harmful consequences and deaths. However, errors do not have to be reported and, even if serious consequences result in lawsuits, the chain pharmacy will typically settle them and insist on confidentiality regarding the incident and terms of the settlement. Therefore, there is little awareness on the part of the public, and even boards of pharmacy, of the actual frequency and consequences of pharmacy errors. If the public did know the frequency and harm of these errors, they would be outraged!

In my opinion, the executives of chain pharmacy corporations will *not* make the changes necessary to avoid errors, improve the quality of care/services for patients, or improve working conditions for pharmacists *until they are forced to do so* as a consequence of public outrage and large punitive damage awards in lawsuits that are not covered by their insurance. Therefore, it is not only in the interest of our patients, but also in the interest of chain pharmacists, to take actions in a direction that will result in positive changes.

An important role for CPOA will be to serve as a clearinghouse for information regarding pharmacy errors and workplace metrics and other issues that increase the risk for errors. This information may be submitted in a confidential and secure manner, and will not include the identity of the patient who experienced the error or the pharmacist or staff member who made the error. Any follow-up use of the information for constructive purposes will be done in a manner that does not permit identification of the source of the information. For example, information regarding errors can have great educational value in alerting pharmacists to the circumstances in which errors occur in a manner that will enable them to avoid the same problems. If information regarding an error is specific to the point that it might suggest a particular pharmacy as the site of occurrence, the error can be described in a general or modified way that will prevent recognition of the pharmacy or source of the information.

The potential for CPOA to have a very large membership will also result in many reports of errors and unacceptable workplace policies/conditions that will permit the development of aggregate data/information that will focus on the scope and extent of problems rather than the specifics of individual errors. This will provide additional protection of the confidentiality of the information and its source. An example of how CPOA might use aggregate information would be communication with a state board of pharmacy to identify a high frequency of reported errors at pharmacies in a particular chain in that state, that would include a recommendation that an investigation be initiated. There must be absolute assurance that CPOA would not use information in a manner that could result in action against an individual pharmacist.

(Continued on Page 4)

New Drug Review

Ertugliflozin L-pyroglutamic acid

(Steglatro – Merck) *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), empagliflozin (Jardiance).

Advantages:

- Warning in labeling regarding risk of lower limb amputation is not as definitive (compared with canagliflozin that has a boxed warning in its labeling regarding this risk);
- Has not been associated with reports of patients experiencing bladder cancer (compared with dapagliflozin).

Disadvantages:

- Labeled indications are more limited (compared with empagliflozin that is also indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease).

Most important risks/adverse events:

Renal function impairment (contraindicated in patients with severe renal impairment); 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); lower limb amputation (patients should be monitored for infections or ulcers of lower limbs); ketoacidosis; urinary tract infections; hypoglycemia (when used concomitantly with insulin or an insulin secretagogue [e.g., a sulfonylurea]); pregnancy (use is not recommended during the second and third trimesters); nursing mothers (use is not recommended); positive urine glucose test results (alternative methods to monitor glycemic control should be used).

Most common adverse events:

Female genital mycotic infection (12%), male genital mycotic infection (4%), urinary tract infection (4%), headache (3%), back pain (3%), increased LDL-C concentrations (5%).

Usual dosage:

Initially - 5 mg once a day in the morning; in patients who tolerate treatment and require additional glycemic control, dosage may be increased to 15 mg once a day; treatment should not be initiated in patients with an estimated glomerular filtration rate (eGFR) of 30 to <60 mL/minute/1.73m^2); in patients in whom the eGFR falls to and persists within this range during treatment, continued use of the drug is not recommended.

Products:

Film-coated tablets – 5 mg, 15 mg; combination formulations with metformin (Segluromet: 2.5 mg/500 mg, 2.5 mg/1,000 mg, 7.5 mg/500 mg, 7.5 mg/1,000 mg); combination formulations with sitagliptin (Steglujan; 5 mg/100 mg, 15 mg/100 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. Ertugliflozin is the fourth SGLT2 inhibitor, joining canagliflozin, dapagliflozin, and empagliflozin, and these agents reduce the reabsorption of filtered glucose, thereby increasing urinary glucose excretion and lowering blood glucose and glycosylated hemoglobin (A1C) concentrations. Its effectiveness has been demonstrated in studies in which it was used as monotherapy, or in combination with regimens with metformin and/or other antidiabetic agents. In the placebo-controlled study of ertugliflozin monotherapy (in doses of 5 mg and 15 mg once a day), the reduction in A1C at week 26 was -0.7% and -0.8%, respectively, compared with -0.2% in the patients receiving placebo. The percentage of patients achieving an A1C of less than 7% was 30% and 39%, respectively, for the two doses of ertugliflozin, compared with 17% of those receiving placebo. Similar reductions in A1C attributed to ertugliflozin were also reported in studies in which it was used in combination with metformin and/or sitagliptin (Januvia). In patients with type 2 diabetes and moderate renal impairment (eGFR 30 to <60 mL/minute/1.73m^2), reductions of A1C were not significantly different between the drug and placebo, and efficacy of the drug was not demonstrated in these patients. None of the SGLT2 inhibitors should be used in the treatment of patients with type 1 diabetes or diabetic ketoacidosis.

The labeled indications for empagliflozin have been expanded to include use to reduce the risk of cardiovascular death in patients with type 2 diabetes and established cardiovascular disease. However, this is not a labeled indication for ertugliflozin, canagliflozin, or dapagliflozin.

Daniel A. Hussar

CPOA leadership

It will be essential that chain pharmacists have complete trust in the leadership of CPOA. If chain pharmacists are being asked to provide sensitive information regarding errors and/or policies of a chain organization, confidentiality of the source of the information must be protected. Therefore, in addition to professional and management skills, individuals who serve in a leadership capacity, or otherwise have access to confidential information, must be those in whom chain pharmacists have complete trust and confidence. These qualities will also be critical in establishing the association and quickly recruiting a large membership. I welcome your suggestions of individuals who could serve CPOA in a leadership capacity.

CPOA membership

There is a saying that "there is safety in numbers," and this is applicable to the proposed CPOA association. If every chain pharmacist was a member, it would be very difficult for chain pharmacy executives to criticize or retaliate against individual pharmacists for joining the association. Indeed, if a chain pharmacy corporation was to take retaliatory or discriminatory action against individual pharmacists for their participation in an association that has patient safety as its highest priority, the chain pharmacy would be vulnerable to a challenge of the pharmacist who would have the support of CPOA.

Some will respond that it is not possible that every chain pharmacist, or even a majority, will join CPOA. But why would a chain pharmacist not join? In addition to advocating for the care and safety of their patients, they would have an opportunity that is not available otherwise, or on an individual basis, to improve their working conditions. They can be empowered by the strength and safety of the CPOA membership numbers, and have a voice through the association. The potential also exists for CPOA to increase the job security of individual pharmacists. For example, the increasing frequency of mergers and acquisitions involving chain pharmacies, and the resultant loss of positions, could be matters on which CPOA would take positions and/or actions.

CPOA has the potential to be the largest national association of pharmacists, and this would be accompanied by extensive accomplishments on behalf of patients, individual pharmacists, and the profession of pharmacy. The amount of association dues must not be a barrier to joining, and my initial thought is $100 a year which every pharmacist can afford.

Challenges

I anticipate that chain pharmacy corporations will be strongly opposed to the establishment and likely activities/programs of CPOA. They may actively discourage their pharmacists from joining, and attempt to identify their pharmacists who disclose information regarding errors, etc. to CPOA. This is the primary reason for which CPOA must have a system that assures the confidentiality and security of its information and its sources. However, chain pharmacy corporations would only make themselves more vulnerable by such actions, and any efforts to impose "gag clauses" on their pharmacists regarding matters that affect patient safety should be reason for state boards of pharmacy to take action against them.

The question of what chain pharmacy corporations are currently doing to support and encourage their pharmacists must also be asked. If chain pharmacists respond, "Nothing," or consider "Nothing" to be too positive a response, they certainly need the support and programs CPOA will provide.

About five years ago, I had a hallway discussion with two pharmacy leaders at an annual meeting of a national association. I asked them the following question for which I already knew the answer:

> "If chain pharmacy corporations could identify a way to legally dispense prescriptions without using pharmacists, would they do it?"

One individual immediately stated, "In a heartbeat," to which the other individual responded, "Faster than that."

Chain pharmacists need CPOA!

Next steps

The above discussion identifies a concept and outline of a plan. The ideas, opinions, and recommendations of chain pharmacists regarding this initiative are requested and valued, as are your recommendations of pharmacists to serve in leadership roles. Many chain pharmacists currently receive *The Pharmacist Activist*, and they often forward pertinent editorials to many of their coworkers and colleagues. I request that you forward this editorial to those for whom it could be important.

Daniel A. Hussar
d.hussar@usciences.edu

Author/Editor - Daniel A. Hussar, Ph.D.
Philadelphia College of Pharmacy, University of the Sciences in Philadelphia
Publisher - G. Patrick Polli III
Publications Director - Jeff Zajac

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The Pharmacist Activist, 515 Shoemaker Rd., King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

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