The Pharmacist Activist

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Editorial

Society, Patients, and our Profession Need Independent Pharmacists!

CHALLENGES AND STRATEGIES

Regular readers of *The Pharmacist Activist* know of my advocacy for independent pharmacists. They are the face and identity of our profession with the public. Most pharmacists in other areas of practice/employment, as important as their responsibilities might be, have no (e.g., mail-order pharmacists, pharmaceutical company employees) or little (e.g., hospital pharmacists, long-term care pharmacists) direct and personal (face-to-face) communication with patients. Even many chain pharmacists, whose practice sites position them for such opportunities, have very limited communication with patients because of management-imposed policies, staffing restrictions, and metrics.

The most important role/identity for our profession is the provision of medications on a timely basis with services and information that assure their appropriate, effective, and safe use, and positive therapeutic outcomes. But if this role is as important as we say it is, why are we not doing more to protect, support, and strengthen the independent pharmacists who are in the best position to accomplish these goals?

For several decades, some within pharmacy have been predicting the disappearance of independent pharmacies, usually without identifying that outcome as a reason for concern or practice alternatives of equal value. Although the disappearance of these pharmacies has not occurred, there is no question that many independent pharmacies have closed and the survival of many of those that remain is threatened.

I am of the belief that one of, if not *the* most important component of the services of healthcare professionals is their personal, competent, caring, and compassionate communication with patients. I consider the lack of such communication to be the most common reason for medication errors, as well as other drug-related problems such as adverse events, drug interactions, and noncompliance. Independent pharmacists are in the best position to provide such communication and, rather than accepting the predictions of their disappearance as inevitable, the profession of pharmacy must do much more to support, strengthen, and expand this role.

The challenges

Important challenges to the survival of independent pharmacies have been addressed in *The Pharmacist Activist* and elsewhere. These issues include excessively high drug prices, anticompetitive policies and schemes of health insurance companies and pharmacy benefit managers (PBMs), and inadequate compensation for prescription medications and services. Unfortunately, very little progress has been made in responding to these challenges, and many pharmacists have either not tried to respond or have given up trying with the rationalization that these issues are outside of our control. I view "silence" as an unacceptable response (or nonresponse). These issues are too important for society, our patients, and our profession to not respond with a strong commitment to resolve them.

There are also, however, other challenges facing independent pharmacists that can be considered within our control, *if* we choose to exercise it. These issues receive much less attention but

are also very important, and include the following:

1. Our profession and our associations (with the exception of those with a primary mission of advocacy for independent pharmacy) do not provide support for the role and autonomy of independent pharmacists at a level that corresponds to their importance for the entire profession.

2. Most colleges of pharmacy provide very little instruction, or even visibility/participation, related to independent pharmacy that would result in more students actively considering entrepreneurial/ownership opportunities.

3. Many independent pharmacists are apathetic (not that this characteristic is unique to this group), and do not take actions that would contribute to progress in addressing threatening challenges. Some may be satisfied with the status quo and do not feel that changes/threats will occur with a timing that will affect them personally. Many are not members of the National Community Pharmacists Association (NCPA) and regional/local associations that are advocates for their role and survival, have not written a single letter to their legislators or the employers, government agencies, and others who are paying for prescription benefit programs with inadequate services and compensation, and do not financially contribute to initiatives that offer hope for effectiveness in addressing the challenges.

4. There is too much competition among those who should be the strongest advocates for independent pharmacy. Yes, the decline in the number of independent pharmacies results in a situation in which they are seldom competing with each other. However, the professional associations, wholesalers with whom independent pharmacists affiliate, buying groups, and others are often in intense competition that precludes attainment of results and progress that would be possible with unified and strong collaboration. What might be accomplished if every independent pharmacist was a member of NCPA, and if wholesalers and buying groups functioned collaboratively, rather than competitively?

5. Some independent pharmacists have fallen into the trap of "filling more prescriptions faster" to respond to the challenges of metrics-driven chain pharmacies and the policies and inadequate compensation from PBMs. The consequences are a reduction in services for and communication with patients. But these are the very activities that distinguish independent pharmacies from mail-order and chain pharmacies, and provide the added value that is claimed. A "more prescriptions faster" response is self-destructive because, if services and counseling/communication are not provided at any of the pharmacies that patients use, they will conclude that it doesn't matter where they obtain their prescriptions.

Strategies

Although I can't do it at this stage in my pharmacy career, I have sometimes thought about opening my own independent pharmacy and the services I would provide. The following concepts seem attractive and viable. They are not original with me but are ideas that have been successfully implemented by others.

1. Prescription medications and services would be available for all patients. However, older adults are the patient population to whom the services of the pharmacy would be primarily promoted. These are the individuals who take more medications for chronic conditions and who have the greatest needs for which pharmacist counseling will be valuable.

2. The regular inventory of prescription medications would consist almost entirely of drugs that are available generically. Between 80% and 90% of prescriptions dispensed in community pharmacies are for medications for which generic equivalent formulations are available. Most, but not all, of these generic medications can be purchased at low cost. Many of these medications are ones that patients would be taking for many years for chronic conditions like hypertension and hypercholesterolemia. The focus on generic medications will permit low inventory costs.

3. The pharmacy would not participate in prescription benefit plans administered by PBMs and/or health insurance companies. Provision would be made for exceptions to include selected prescription plans that assure professional services for patients, and policies and equitable compensation that are consistent with the professional and financial operation of the pharmacy.

   The cost of a generic medication plus an equitable professional fee will often be less than what a patient would be charged as a co-pay for a prescription in current PBM prescription plans. Because many generic medications used for chronic conditions may be dispensed in 90-day supplies, the pharmacist would have increased flexibility to establish a professional fee that will support and build the financial viability of the pharmacy. This concept would be promoted to patients and local employers as one that would have lower costs than the programs provided by PBMs and health insurance companies. Patients/consumers would be encouraged to make an appointment for a free consultation to review their medications and costs, and the possibility of contacting their prescriber if

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New Drug Review

Elagolix sodium
(Orilissa – AbbVie)

Agent for Endometriosis

New Drug Comparison Rating (NDCR) = 4
(significant advantages)
in a scale of 1 to 5 with 5 being the highest rating

Indication:
Management of moderate to severe pain associated with endometriosis.

Comparable drugs:
Gonadotropin-releasing hormone (GnRH) receptor agonists (leuprolide [e.g., Lupron], nafarelin [Synarel]).

Advantages:
- Is administered orally (whereas leuprolide is administered intramuscularly and nafarelin is administered intranasally);
- Does not cause initial flare of symptoms;
- Labeled dosage recommendations permit use (150 mg once a day) for up to 24 months (whereas, when used for treating endometriosis, leuprolide should not be used for longer than 12 months and nafarelin should not be used for more than 6 months).

Disadvantages:
- Interacts with more medications;
- Has not been directly compared with other therapies in clinical studies;
- Labeled indications are more limited (leuprolide and nafarelin are indicated for use in children with central precocious puberty, and leuprolide is also indicated for the treatment of uterine fibroids and prostate cancer);
- Is administered once a day (compared with leuprolide depot 11.25 mg that is administered every 3 months).

Most important risks/adverse events:
Bone loss (causes dose- and duration-dependent decreases in bone mineral density [BMD]; contraindicated in women with osteoporosis; BMD should be assessed in women with additional risk factors for bone loss); contraindicated in pregnant women (risk of pregnancy loss may be increased; change in menstrual bleeding may reduce the ability to recognize the occurrence of pregnancy in a timely manner; women who are sexually active should use non-hormonal contraception during treatment and for one week following discontinuation of treatment; estrogen-containing contraceptives should not be used); suicidal ideation and mood disorders (patients with depressive symptoms should be promptly evaluated and appropriate actions taken); action may be increased in patients with hepatic impairment and is contraindicated in patients with severe hepatic impairment; may cause elevations of hepatic enzymes and blood lipids; action may be increased by organic anion transporting polypeptide (OATP) 1B1 inhibitors (concurrent use of strong OATP1B1 inhibitors such as cyclosporine and gemfibrozil is contraindicated), as well as by strong CYP3A inhibitors; action may be reduced by CYP3A inducers; may reduce the action of CYP3A substrates such as oral midazolam, and increase the action of digoxin and rosuvastatin.

Most common adverse events (and incidence with a dosage of 150 mg once a day):
hot flushes/night sweats (24%), headache (17%), nausea (11%), insomnia (6%), mood alteration/swings (6%), amenorrhea (4%), depression (3%).

Usual dosage:
150 mg once a day for up to 24 months; in patients with dyspareunia, treatment with a dosage of 200 mg twice a day for up to 6 months should be considered; product labeling should be consulted for recommended dosage adjustments in patients with moderate hepatic impairment or who are taking interacting drugs.

Products:
Tablets – 150 mg, 200 mg.

Comments:
Elagolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist that binds to GnRH receptors in the pituitary gland. It causes a dose-dependent suppression of luteinizing hormone and follicle-stimulating hormone, leading to decreased blood concentrations of the ovarian sex hormones, estradiol and progestin. The GnRH agonists also reduce estrogen concentrations with continued use, but only following an initial increase in estrogen concentrations that may be poorly tolerated. The effectiveness of elagolix was demonstrated in two placebo-controlled studies in which the new drug was significantly more effective than placebo in reducing dysmenorrhea and nonmenstrual pelvic pain. Patients with dyspareunia experienced improvement with a dosage of 200 mg twice a day but statistical significance was not achieved with a dosage of 150 mg once a day

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medications of equivalent benefit and risk can be provided at a lower cost.

4. Medications that are not included in inventory but may be obtained and provided at a cost (including professional fee) that patients are willing to pay, can be ordered and provided on a timely basis. For medications that are costly and would require the use of a prescription benefit plan, the pharmacy would identify another pharmacy to which the patient can be referred. As an alternative, the pharmacy could establish a working relationship with another pharmacy at which prescription plans are accepted, and the medication could be provided to the primary pharmacy for dispensing to the patient for an appropriate professional fee.

5. The pharmacist/pharmacy would assume the primary responsibility for maintaining records and for the review, monitoring, and recommendation for all medications used by its patients, including medications that are more expensive and are obtained from another pharmacy.

6. The pharmacist would coordinate/synchronize the provision of medications for chronic conditions in a manner that would permit convenient and time-efficient visits/consultations of patients with the pharmacist (e.g., once a month, once every 3 months for maintenance medications).

7. The visits of patients to the pharmacy to obtain refills of prescriptions would be on an appointment basis to enable greater convenience, time efficiencies, and schedule planning/staffing, as well as the avoidance of long waits for patients. Patients with new prescriptions for medications that do not have to be started immediately would also make appointments. Provision would be made for prompt dispensing and consultation for medications for which starting treatment quickly is necessary (e.g., antibiotics, analgesics).

   The schedule that is primarily appointment-based will permit hours of operation and staffing of the pharmacy to be established for the convenience of both patients and pharmacists. Procedures would be identified for obtaining medications needed for emergency, "after-hours" situations.

8. Depending on the scope and interests of the pharmacist and the patients, products and services could be extended, and might include immunizations, compounded prescriptions, medical supplies/equipment, and nonprescription medications and selected dietary supplements recommended by the pharmacist for common minor problems/symptoms.

9. The location of the pharmacy is important and should be convenient and readily accessible (e.g., parking) for patients. The needed real estate and the size of the pharmacy will be relatively small. Close proximity to a chain pharmacy could be advantageous because of its research regarding location and the likelihood that patients using the chain pharmacy may often experience waits/delays, have little or no discussion with the pharmacist, and be interested in changing pharmacies. Indeed, pharmacists currently working in a chain pharmacy might consider opening their own pharmacy in a nearby location in which they are already known to many members of the community.

10. In addition to the prescription department and area for nonprescription medications and healthcare products, the pharmacy would include an attractive reception area and an area for private consultation with the pharmacist.

11. Local physicians and senior citizen centers would be personally visited to acquaint them with the pharmacy and its services.

12. House calls would be made (for a fee, as appropriate) to patients who are unable to come to the pharmacy and would benefit from personal consultation.

I have more ideas but I have run out of space. I don't have the experience, expertise, or youth to move these strategies into plans and actions, but many readers of *The Pharmacist Activist* do. I am interested in your thoughts (danandsue3@verizon.net). And we need a great name for your pharmacy. The best name submitted will receive a free subscription to *The Pharmacist Activist*. Oh, wait – you are receiving it free already.

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