The Pharmacist Activist

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Editorial

Our Profession's Own Pharmacy Care Administrator (PCA): Part 5

This is the fifth (and final, for now) part of my series of editorials in which I have urged that the profession of pharmacy establish our own pharmacy care administrator (PCA). I wish that I could report that there has been strong and enthusiastic support for this action from the leadership of our professional organizations. There has not been any response from these individuals. I have received highly supportive comments from a number of other pharmacists, although some of these comments have been provided in the context of identifying the lack of success of previous efforts in this direction, the apathy of our profession, the difficulty of establishing a PCA that would assure professional services and positive therapeutic outcomes and also be competitive in the marketplace, and, in the opinions of some, skepticism that an initiative of the scope and size proposed could be accomplished. At the same time, I have not received or otherwise heard ideas or recommendations that I consider to offer as much positive potential for patients and our profession.

I recognize that there are numerous progressive professional initiatives that have been implemented by individual or local groups of pharmacists, and these efforts are to be commended and encouraged. Although compensation is being provided for the expanded services provided by pharmacists in some of these situations, certain of these initiatives have been implemented with grants or other funding that will not be sustained on a continuing basis.

In the last 5 years, the attainment of provider status for pharmacists has been the most prominent issue for which a number of the national pharmacy organizations have committed extensive staffing and financial resources and professional and legislative advocacy. I strongly support these efforts, although it should not escape our attention that some physicians view the word "provider" as demeaning to their role and urge their physician colleagues to reject its use. The hope of pharmacists is that, when provider status is attained, we will be able to submit bills and receive compensation for the services we provide. However, the attainment of provider status, without accompanying funding and mandates for compensation for such services, does not assure that funds will be available or that those with the authority to disburse funds that might be available will concur that compensation is warranted when pharmacists submit bills for payment.

As I attempt to sort through the maze of issues, problems, and opportunities that exist for our profession, I keep coming back to and give the highest priority to the following:

1. Pharmacists must actually provide the services of which we are capable and which we are promoting, that go far beyond the process of distributing medications.
2. Pharmacists must be paid for providing these services.

I can't expect that the payers for healthcare services, including the services of pharmacists, to be willing to pay for services that they do not observe to be provided on a consistent and widespread basis, and for which documentation of quality and value is very limited. Therefore, as individuals and a profession, we must initially commit our time and resources to the provision of such services without compensation, and document their quality and value in a manner that justifies and warrants payment. Many individual pharmacists and some of our professional organizations (e.g., through funding of pilot projects) have made the commitment of resources and abilities to accomplish these goals, and they are to be highly commended for doing so. However, these efforts require considerable time, are often localized and isolated, and may not be known to many within our own profession who might be inspired to pursue similar positive initiatives, let alone by the payers from which we need to seek compensation (with the Asheville project being a noteworthy exception).

Our profession does not have the luxury of time in the current economic and healthcare environment. We need a strategy that will integrate the priorities identified above and I am of the unwavering opinion that the establishment of our own PCA, notwithstanding the enormity of this effort, offers the best hope of achieving these goals.

Pertinent events

In the month that has elapsed since I wrote my August editorial (Part 4), there are additional examples of the continuing problems inherent in the current prescription programs, as well as other pertinent events and commentaries, including the following:

- A report from the U.S. Poison Control Centers indicates that medication errors outside of health care facilities more than doubled over the 13-year period of the study. The most common errors were taking the wrong dose, receiving or taking the wrong medication, and inadvertently receiving or taking medication twice.

- The huge health insurer Anthem is proposing a 35% rate increase for about 135,000 consumers in California, and justifies the proposal by forecasting a 30% increase in prescription drug costs in 2018.

- The charges and counter-charges between pharmaceutical companies and health insurance companies/PBMs continue to escalate. America's Health Insurance Plans (AHIP; the lobbying group for the insurance industry) claims that pharmaceutical companies are imposing excessive price increases, striking patent deals, and spending more on marketing than on research and development. The Pharmaceutical Research and Manufacturers of America (PhRMA; the lobbying group for the pharmaceutical companies) claims that insurance companies are making patients pay a higher share of drug costs and that PBMs are forcing them to provide larger rebates.

- The September 17 edition of *The New York Times* includes an article (K. Thomas and C. Ornstein) titled, "Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers." The explanation suggested for this situation is that opioid drugs are generally cheap whereas safer alternatives are often more expensive.

- Humira (AbbVie's adalimumab) is the world's top-selling prescription medicine with global sales for 2017 estimated to exceed $18 billion. Amgen has developed a less expensive biosimilar version of the drug. It has just been announced that AbbVie and Amgen have reached a settlement regarding patent challenges that will delay the U.S. launch of the biosimilar version until January 31, 2023.

- In an effort to head off generic competition for its ophthalmic product Restasis, Allergan has entered into an agreement with the Saint Regis Mohawk Tribe, agreeing to transfer patents for the product to the tribe and license them back for an up-front payment of $13.75 million, and up to $15 million per year. Because the Native American tribe is considered a sovereign nation, it can claim immunity from certain patent challenges. Some members of Congress are requesting an investigation of this "blatantly anticompetitive" deal.

- Walgreens and Rite Aid – Approximately two years after the planned acquisition of Rite Aid by Walgreens was announced, a "final" and much smaller deal appears to have been approved. Walgreens is acquiring 1,932 Rite Aid stores (42% of the total) for $4.38 billion and other considerations. Both companies claimed benefits for their respective organizations, while the value of the shares of both companies dropped on the news. This results in

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New Drug Review

Safinamide mesylate

(Xadago – Newron) *Antiparkinson Agent*

New Drug Comparison Rating (NDCR) = 2
(significant disadvantages)
in a scale of 1 to 5 with 5 being the highest rating

Indication:
Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.

Comparable drug:
Rasagiline (Azilect), selegilene (e.g., Eldepryl, Zelapar).

Advantages:
- May be used in patients with renal impairment (compared with selegilene that is not recommended in patients with severe renal impairment).

Disadvantages:
- Has not been directly compared in clinical trials with comparable drugs;
- Labeled indications are more limited (compared with rasagiline for which the labeled indications also include monotherapy and adjunctive treatment without levodopa);
- Is contraindicated in patients with severe hepatic impairment.

Most important risks/adverse events:
Hypertension (may cause or exacerbate hypertension; because of risk of severe hypertension/hypertensive crisis, concurrent use with another monoamine oxidase [MAO] inhibitor including linezolid is contraindicated; concurrent use with isoniazid should be closely monitored; concurrent use with amphetamine, methylphenidate, and derivatives is contraindicated; caution must be observed when used concurrently with other prescription or nonprescription sympathomimetic medications, including oral, nasal, or ophthalmic decongestants and cold remedies, and patients should be monitored for hypertension; patients should be advised to avoid foods containing a large amount of tyramine [e.g., aged cheeses]); serotonin syndrome (concurrent use with serotonin-norepinephrine reuptake inhibitors [e.g., duloxetine, venlafaxine], tricyclic, tetracyclic, or triazolopyridine antidepressants, cyclobenzaprine, or St. John's wort is contraindicated; concurrent use with a selective serotonin reuptake inhibitor [e.g., fluoxetine] is best avoided); concurrent use with an opioid analgesic or dextromethorphan is contraindicated; at least 14 days should elapse between discontinuation of safinamide and initiation of treatment with another MAO inhibitor, serotonergic drug, or opioid analgesic; may cause sleep attacks/sudden onset of sleep (patients should be advised of risk); may cause or exacerbate dyskinesia; may cause hallucinations, psychotic behaviors, and problems of impulse control/compulsive behaviors (e.g., intense urges to gamble, spend money, or binge eat; increased sexual urges); if used during pregnancy, may cause harm to the unborn child; use is contraindicated in patients with severe hepatic impairment; may increase action of breast cancer resistance protein substrates (e.g., methotrexate, rosuvastatin).

Most common adverse events:
Dyskinesia (17%), fall (6%), nausea (6%), insomnia (4%).

Usual dosage:
Initially, 50 mg once a day at the same time each day; after 2 weeks, the dosage may be increased to 100 mg once a day; in patients with moderate hepatic impairment the maximum recommended dosage is 50 mg once a day; if treatment is to be discontinued the dosage should be reduced to 50 mg daily for one week before stopping therapy to reduce the risk of hyperpyrexia and confusion.

Products:
Tablets – 50 mg, 100 mg.

Comments:
Safinamide is the third MAO type B inhibitor to be marketed for the treatment of patients with Parkinson's disease, joining rasagiline and selegilene. By inhibiting MAO-B activity, these agents reduce the catabolism of dopamine, resulting in increased dopamine concentrations and dopaminergic activity in the brain. The inhibition of MAO-B activity by safinamide is considered to be reversible, whereas selegilene and rasagiline irreversibly inhibit MAO-B activity. However, whether this distinction is of clinical importance is not known. The effectiveness of safinamide was demonstrated in two placebo-controlled studies. In both studies, safinamide significantly increased "on" time without troublesome dyskinesia compared to placebo, and this was accompanied by a similar significant reduction in "off" time, as well as a reduction in the United Parkinson's Disease Rating Scale Part III scores that were assessed during "on" time.

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Walgreens and CVS being the two huge retail pharmacy organizations with Rite Aid being much smaller and a distant third in size. The Federal Trade Commission has approved the deal although one commissioner voiced the concern that the deal "continues to raise significant competition issues." It is not likely that Rite Aid will use the $4.38 billion to increase pharmacist and technician staffing in its stores, as these funds will probably be used to reduce its huge debt.

- Amazon – Recent acquisitions by Amazon have sparked speculation that it could be considering participating in the drug supply chain. Rumors suggest that Amazon has been involved in discussions regarding this possibility, not with leaders of our professional associations, but with executives of PBMs. There has been increasing discussion that advances in technology, including the use of drones, may result in Amazon and other retailers being able to deliver products, including medications, to consumers faster, even on the same day of the requested purchase. What a remarkable idea! But, oh wait! Independent pharmacists have been doing this forever!

On a positive note, the American Medical Association has developed a program, "STEPS Forward," that encourages physicians to "Redesign your practice. Reignite your purpose." One of the modules (pharmacist H.M. Choe and physicians C.J. Standiford and M.T. Brown) is titled, "Embedding Pharmacists Into the Practice." This module "details six steps to collaborate with a pharmacist or pharmacy technician and evaluate impact, answers commonly asked questions about integrating pharmacists into your practice, provides tools and resources to guide you through the process, and outlines case studies describing different approaches to collaboration."

This is a very encouraging initiative that independent pharmacists, in particular, should carefully consider for the purpose of establishing/enhancing collaborative practice and team-based patient care services with physician practice groups. This concept should be included and encouraged in the new PCA to be established.

The new PCA

Many of the elements I envision being included in a new PCA are identified in the previous four parts of this series of editorials. However, the underwhelming response to these commentaries makes me pause, although briefly, to wonder whether what I am proposing can be accomplished. There are many very dedicated and highly motivated pharmacists who read *The Pharmacist Activist*. Are my recommendations not on target, or not possible? Are there other strategies that would be more effective in addressing the increasing concerns with which we are challenged? I welcome other ideas and will enthusiastically support better ones!

OK, that's a long enough pause! Unless better strategies are identified, I will work with the small group of individuals who are strongly supportive of participating in discussions regarding the development of a new PCA. The challenges are too important for our patients and our profession to stop fighting for progressive changes. There is no *status quo*! If we can't move forward, we are falling further behind.

And what if we don't establish a new PCA or embrace another progressive strategy? The insurance companies, PBMs, and government agencies have already squeezed so much of the financial resources out of the prescription distribution system for their own operations and profits, that there are hardly any funds left to be extracted. However, some pharmacies occupy valuable real estate that might be sold in favor of mail and drone delivery systems, and some feel that pharmacists earn high salaries for what many of them do. Are they vulnerable?

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