Events of the last month further confirm the importance of our profession establishing our own pharmacy care administrator (PCA), the topic of the editorials in the May and June issues of *The Pharmacist Activist*. Thus, this editorial becomes Part 3.

In just the short time since I wrote the June editorial, there have been many more examples of the continuing problems inherent in the current PBMs and their programs, including the following:

- In my June editorial I noted that Express Scripts is suing Kaleo for what it claims are unpaid rebates in the amount of $14.5 million. Kaleo has now filed a countersuit saying that it overpaid Express Scripts by $5.3 million. Kaleo states that it overpaid this amount because of “opaque and convoluted invoices” from Express Scripts.

- A class action lawsuit regarding the pricing of EpiPens has been filed against the manufacturer (Mylan), but also against CVS Health, Express Scripts, and Prime Therapeutics. The inclusion of the three PBMs as defendants is based on the allegation that they demand large rebates and discounts from the manufacturer that contribute to the high cost of the drugs. The spokesman for CVS notes that “…CVS Caremark passes along more than 90 percent of the price discounts it receives directly to its clients.” Even if that number is accurate, the remaining almost 10% retained by CVS Caremark is still a huge amount.

- A Bloomberg news article (Jared Hopkins, July 11) titled, “Pharmacy ‘Clawbacks’ Targeted in Latest State Law Aimed at PBMs,” reports on a new law in Connecticut that will permit pharmacists to inform patients about the least expensive way to obtain their prescription medications. This law addresses situations in which the co-pay for a medication determined by the PBM actually exceeds the cost of the medication, and pharmacists are prohibited under the terms of the contracts with the PBMs from informing patients of a less expensive option.

- The most important current challenge for pharmacists in Pennsylvania is to resist initiatives...
that would drastically reduce the professional fee for prescriptions obtained by patients participating in the Medicaid program and the state’s prescription program for the elderly (PACE). The budget initially proposed by the Governor would result in a reduction of $6 in the fee pharmacists would receive for a prescription dispensed in the PACE program.

- Walgreens and Rite Aid – Rite Aid has had serious financial challenges in recent years that have been primarily attributed by its CEO to “…the pharmacy reimbursement rate pressures that have had such a negative impact on our business.” Rite Aid’s “solution” to its dilemma was to agree in October 2015 to be acquired by Walgreens. However, many, including the Federal Trade Commission (FTC) that must evaluate whether such acquisitions will substantially reduce or eliminate competition, had strong concerns. When more than 18 months went by without an FTC opinion/action, Walgreens and Rite Aid executives anticipated that the FTC position would not be in their favor, and they terminated their agreement (with Walgreens paying Rite Aid a $325 million termination fee) and struck a smaller deal that they anticipate will address FTC concerns. The new deal will involve the sale of “only” 2,186 Rite Aid stores to Walgreens, and Rite Aid will keep 2,337 stores. As part of the new deal, Rite Aid will have an option to join Walgreens purchasing organization for certain products.

I commend the members of the FTC for recognizing and challenging the anticompetitive marketplace that would have resulted if Walgreens had acquired Rite Aid. They are also to be commended for recently not approving the planned mergers of Aetna and Humana, and Anthem and Cigna which would have reduced the number of the largest health insurance companies from five to three. However, the FTC should be urged to take further action with respect to the pharmacy marketplace. Although less problematic than the initial acquisition that was planned, Walgreens plan to now purchase more than 2,000 Rite Aid pharmacies should still be viewed as anticompetitive because it significantly increases the size of Walgreens to more than 10,000 pharmacies, while substantially diminishing any competition it would now have from Rite Aid. Walgreens and CVS would be the only two remaining large chain pharmacies that would dominate the marketplace to an even greater extent and greatly reduce competition. The FTC should reject the new deal between Walgreens and Rite Aid and, while they are studying the pharmacy marketplace, they should also address the most egregious and blatantly anticompetitive acquisition of all, and require CVS to divest Caremark.

Past experience

Each of the above situations could be the subject of an editorial of its own. However, individually and collectively, these issues and those described in my last two editorials should create alarm within our profession to a level that will result in bold and strong actions. In my opinion, the most important and strongest action our profession can take is to establish our own pharmacy care administrator that will assure optimal medication use and the provision of comprehensive pharmacist services in a cost-effective manner. This will effectively address many of the current challenges, and is the reason for which I continue to be an advocate for this action in multiple editorials.

The comments that I have received in response to the last two editorials have been very supportive, although some have questioned whether such an initiative is realistic in view of their experience in some previous programs with similar goals that were unsuccessful. It is essential that we learn from these experiences and from the pharmacists who were most involved. However, I would suggest that changes that have occurred in just the last five years provide a much more favorable environment for establishing our own PCA. There is a much greater awareness that the rate at which the costs of health care and drug therapy are increasing is not
New Drug Review

Crisaborole
(Eucrisa – Pfizer)  
Agent for Atopic Dermatitis

Indication:
Applied topically for the treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

Comparable drug:
Topical corticosteroids (e.g., hydrocortisone, triamcinolone).

Advantages:
• May be more effective in some patients;
• Has a unique mechanism of action (phosphodiesterase type 4 inhibition);
• May be less likely to cause systemic adverse events.

Disadvantages:
• Has not been directly compared with other drugs in clinical studies;
• Labeled indications are more limited (topical corticosteroids have numerous other dermatologic indications).

Most important risks/adverse events:
Hypersensitivity reactions (should be discontinued if such events occur).

Most common adverse events:
Application site pain (4%).

Usual dosage:
Applied topically twice a day to the affected areas.

Product:
Ointment – 2%.

Comments:
Atopic dermatitis is the most common type of eczema and is a chronic inflammatory skin disease that typically begins in childhood and can last through adulthood. It is caused by a combination of genetic, immune, and environmental factors, and may be characterized by red, scaly lesions, pruritus, inflammation, cracking, exudation, and, eventually, coarsening and thickening of the skin. Approximately 90% of patients have the mild to moderate form of the condition. The use of moisturizers (e.g., Aquaphor) and emollients may relieve the symptoms. For patients who do not experience adequate benefit from these nonpharmacologic products, a low-potency topical corticosteroid (e.g., hydrocortisone) is often effective in the treatment of mild atopic dermatitis, and a medium-potency (e.g., triamcinolone) or high potency (e.g., fluocinonide) topical corticosteroid is typically used in the treatment of patients with moderate to severe disease. The topical calcineurin inhibitors tacrolimus (Protopic) and pimecrolimus (Elidel) are indicated as second-line therapy for the treatment of atopic dermatitis in non-immunocompromised patients who have not responded adequately to other topical prescription treatments, or when those treatments are not advisable.

Crisaborole is a PDE4 inhibitor that, by increasing concentrations of cyclic adenosine monophosphate (cAMP), may suppress the production of proinflammatory cytokines. Its effectiveness was evaluated in two vehicle-controlled studies in which Investigator’s Static Global Assessment (ISGA), based on erythema, induration/papulation, and oozing/crusting on a severity scale of 0 to 4, was determined at baseline and on the day following completion of the 28-day course of twice-daily treatment. Success was defined as an ISGA grade of Clear (score of 0) or Almost Clear (score of 1) with a 2-grade or greater improvement from baseline. Patients treated with crisaborole achieved a greater response with successful results experienced in 33% and 31% of the patients in the two studies, compared with 25% and 18% of the patients treated with the vehicle.

Daniel A. Hussar

New Drug Comparison Rating (NDCR) = 3
(no or minor advantages/disadvantages)
in a scale of 1 to 5 with 5 being the highest rating
sustainable. There is a much greater awareness of drug pricing abuses/scandals by pharmaceutical companies and the deceptive and manipulative practices of PBMs and insurance companies. Our society is becoming much more adamant that greed, fraud, and waste, often at the expense of better health for patients, are not acceptable. As a profession, we are in a position to do something to improve the situation, notwithstanding the obstacles, and we must be adamant in our commitment to take positive action.

Ownership of the PCA

The PCA I envision would be owned by participating pharmacists and/or one or more of our national pharmacy associations. It would be nonprofit, and would commit sufficient funding for excellent leadership and management, effective, efficient, and transparent operations, and sufficient reserves to cover unanticipated circumstances. The structure of the PCA would be designed to assure ownership by pharmacists, and would prevent selling it to another company or investors.

The financial challenges involved in starting our own PCA, even initially at a local level, are formidable. However, I am confident that it can be financially successful. The most important reason for my optimism is that the PCA to be developed will be clearly superior to current prescription benefit programs in assuring increased pharmacist/patient communication, positive therapeutic outcomes, and a substantial reduction in medication errors and drug-related problems and the associated costs for managing these misadventures. Another important reason for anticipated success is the recognition that billions of dollars are currently extracted by PBMs and insurance companies as profits from the current prescription programs. Some of the funds that other companies would be budgeting as profit will be committed in the new PCA to provide comprehensive services for patients and equitable compensation for pharmacists. The new PCA will be financially competitive in recruiting clients.

The pharmacists who will be participating in the new PCA as owners and/or in the provision of medications and services will be expected to meet criteria and provide services associated with a high standard of professional practice. It must be recognized that, for many pharmacists, the status quo will not be sufficient to be a participant in the new PCA. This should not be cause for one concluding he/she should not be a participant, but rather should be viewed as an opportunity to strengthen expertise and services in a fulfilling and exciting initiative. I recognize that there are current pharmacist owners whose management responsibilities preclude them from maintaining and acquiring drug therapy expertise and in being engaged in services such as medication therapy management programs. However, if they do not presently have a partner or a staff pharmacist who can provide such, arrangements can be developed through which pharmacists or pharmacy students who are in a position to meet the established criteria can be retained on a part-time basis.

The criteria for participation in the new PCA, the options through which these criteria can be met, and other related issues will be considered in Part 4 of this series in the August issue of The Pharmacist Activist.

Daniel A. Hussar