The Pharmacist Activist

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Editorial

Merger Mania – Bigger Isn't Better!

In choosing topics on which to write editorials, there is usually a particular issue that I can identify quickly to be deserving of priority attention. In the January issue of *The Pharmacist Activist*, the topic was the proposed acquisition of Aetna by CVS. In the February issue, the topic was Independent Pharmacies and Their Fight for Survival. In just the last month, the number of new issues and updated commentaries to have emerged would almost require daily issues of *The Pharmacist Activist*. Therefore, this editorial will address more briefly what I consider to be the most important matters that require our attention, response, and action.

CVS-Aetna

In a recent nationally televised interview, the CEO of Aetna, in referring to the proposed acquisition and CVS's more than 10,000 pharmacies, stated, "Call it 10,000 new front doors to the health care system. And what we want to do is provide as many services as we can in the community . . . versus waiting for people to show up in the health care system broken and fix them." He further noted the health care industry currently works "backwards," conveniently overlooking the fact that both CVS and Aetna have separately had numerous opportunities to work 'forwards,' but have failed to do so. When asked whether the acquisition of Aetna by CVS would result in fewer options for some consumers, the Aetna CEO responded, "We can't force people into CVS," apparently being unaware of the CVS Caremark prescription "benefit" programs that try to do just that. When asked about a situation in which CVS might be the only drug store in town, he responded, "But there are plenty of drug stores in town. So there's Walgreens, and there are independent pharmacists, and there are a whole host of other pharmacists." Concerns have also been voiced about the statement of a former medical director of Aetna that he never looked at patients' medical records when deciding whether to approve or deny care, but rather relied on nurses' summaries of the records. This comment was made during a sworn deposition in a lawsuit against Aetna. Although Aetna has tried to explain away this statement by saying it was taken out of context and that the former medical director misunderstood the question, the recorded interview seems very clear and several states have initiated investigations of Aetna regarding this matter. On February 27, 2018, the American Medical Association (AMA) submitted a statement regarding the proposed acquisition of Aetna by CVS to a U.S. House of Representatives Committee addressing Regulatory Reform, Commercial and Antitrust Law. This statement includes the observation,

Contents

NEW DRUG REVIEW: Semaglutide (Ozempic – Novo Nordisk) ..... Page 3

"If CVS were to acquire Aetna and the latter were to require that patients use CVS-owned pharmacies, independent pharmacies may be foreclosed from the market and drug prices may rise." In support of this concern, the AMA statement cites the recent paper, "Abusing Drugs: How CVS Uses Its Market Power to Destroy Competing Independent Pharmacies," (David Dayen, *American Prospect*, January 23, 2018), and the following statement in this paper:

> "CVS's existing combination of a pharmacy (which dispenses drugs) and a pharmacy benefits manager (which reimburses other pharmacists for dispensing drugs) is a disaster for competition and access, particularly in underserved communities. Adding a health insurer like Aetna would further concentrate market power and narrow the networks people depend upon for medical care."

Meanwhile, I see CVS television advertisements showing smiling CVS pharmacists speaking with patients. However, the comments I hear from CVS pharmacists describe a very different experience. They don't have time to speak with patients. Numerous changes have been made at the district and regional levels that have resulted in managers who are not pharmacists establishing and enforcing policies that impose metrics and requirements that are even more onerous than the ones that have been in place. A long-term CVS pharmacist recently summarized his frustration to me with the statement, "I love pharmacy! I hate my job!" He is not alone.

Walgreens-Rite Aid

Rite Aid has experienced serious financial problems for many years. Although some of these problems were self-inflicted, the increasingly difficult economic challenges in successfully operating community pharmacies resulted in a situation in which Rite Aid's best hope was that it would be acquired by Walgreens. An acquisition agreement was reached but, following months of uncertainty based on the concerns that the Department of Justice/Federal Trade Commission would block the acquisition because of the expectation that it would have a negative impact on competition in the marketplace, the scope of the acquisition was significantly reduced. In the revised purchase agreement, Walgreens is buying 1,932 Rite Aid stores (less than one-half of the total number), three distribution centers, and related inventory for an all-cash purchase price of $4.4 billion (which Rite Aid will use to reduce its debt). As of March 2, 2018, Rite Aid had transferred 1,651 stores to Walgreens and expects to complete the store transfer process in the spring of 2018.Walgreens becomes even larger and, in conjunction with CVS, the two organizations have an increasingly dominant impact on competition in the community pharmacy marketplace. Several months after the initial announcement of the purchase of Rite Aid by Walgreens, I spoke with a long-term pharmacist manager of a Rite Aid store. She had been informed that her store was scheduled to be closed and that, although she would still have a pharmacist position, she would be rotating between several stores. However, she went on to observe that the long-standing concerns of many Rite Aid pharmacists would be even greater if the company was *not* sold to Walgreens.

Albertsons-Rite Aid

In late February it was announced that Albertsons Companies, one of the nation's largest grocery retailers (e.g., Acme, Albertsons, Jewel-Osco, Safeway, Vons) had agreed to acquire the rest of the Rite Aid organization/stores that had not been sold to Walgreens. It is anticipated that most Albertsons Companies pharmacies will be rebranded as Rite Aid, and that the company will continue to operate Rite Aid stand-alone pharmacies. With most acquisitions/mergers that result in a substantially larger combined company, it is expected that the success of the transaction will result from increased size-related operating efficiencies and, often, the elimination of positions. It is difficult to identify from my admittedly distant vantage point how efficiencies will occur, particularly with the added challenge of integrating two very different organizations with respect to priorities (i.e., groceries, medications), operations, location size, etc. However, if this acquisition is permitted to occur, it is clear that the much larger combined company will have the size and influence that could significantly reduce competition in many areas. In many communities the current close proximity of an Albertsons Companies supermarket and a Rite Aid store would result in one of the entities (presumably the Rite Aid store) being sold or closed, in the same manner in which either a Walgreens or Rite Aid store has been sold or closed in communities in which an excessively negative impact on competition was anticipated. Nevertheless, the net result of combining two large organizations with pharmacies into one larger retail organization, with the number of pharmacies exceeded only by Walgreens and CVS, will be a significant reduction in competition.

(Continued on Page 4)

New Drug Review

Semaglutide
(Ozempic – Novo Nordisk)

Antidiabetic Agent

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

Indication:
Administered subcutaneously as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Comparable drugs:
Exenatide (Byetta), exenatide extended-release (Bydureon), liraglutide (Victoza), lixisenatide (Adlyxin), dulaglutide (Trulicity); (albiglutide [Tanzeum] has also been available but marketing has been discontinued).

Advantages:
- Is administered less frequently (once a week compared with liraglutide and lixisenatide that are administered once a day and the Byetta formulation of exenatide that is administered twice a day);
- Is more effective in reducing hemoglobin A1C concentrations (compared with exenatide extended-release);
- May be associated with a greater loss of weight.

Disadvantages:
- Labeled indications are more limited (compared with liraglutide for which indications also include use to reduce the risk of major adverse cardiovascular events in patients with diabetes and established cardiovascular disease);
- Dosage titration requires an additional step (compared with dulaglutide).

Most important risks/adverse events:
Thyroid C-cell tumors (reported in studies in rodents but risk in humans is not known; boxed warning; contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2); pancreatitis (other antidiabetic agents should be considered in patients with a history of pancreatitis; treatment should be discontinued if pancreatitis is suspected); hypersensitivity reactions; acute kidney injury and worsening of chronic renal failure (risk is increased in patients who have experienced gastrointestinal adverse events [e.g., diarrhea, dehydration]); diabetic retinopathy complications (patients with a history of diabetic retinopathy should be monitored); hypoglycemia (when used concurrently with insulin or an insulin secretagogue (e.g., sulfonylureas); women should discontinue treatment at least 2 months before a planned pregnancy; delays gastric emptying and may alter the absorption of oral medications.

Most common adverse events:
Nausea (20%), vomiting (9%), diarrhea (9%), abdominal pain (6%).

Usual dosage:
Administered subcutaneously in the abdomen, thigh, or upper arm; initially, 0.25 mg once a week for 4 weeks (this dosage is subtherapeutic and is used only for treatment initiation); after 4 weeks, the dosage is increased to 0.5 mg once a week; if additional glycemic control is needed after at least 4 weeks on the 0.5 mg dose, dosage may be increased to 1 mg once a week.

Products:
Injection supplied in prefilled single-patient-use pens containing 2 mg/1.5 mL; pens deliver 0.25 mg, 0.5 mg, or 1 mg of the drug per injection (should be stored in a refrigerator prior to first use).

Comments:
Semaglutide is the sixth glucagon-like peptide-1 (GLP-1) receptor agonist to be approved in the United States. These agents have multiple actions that include suppression of glucagon secretion, stimulation of glucose-dependent insulin secretion, slowing gastric emptying, and promoting satiety. The effectiveness of semaglutide was demonstrated in studies in which it was used as monotherapy and in combination with metformin, metformin and sulfonylureas, metformin and/or a thiazolidinedione, and basal insulin. It reduced hemoglobin A1C and fasting plasma glucose concentrations, and the mean changes in weight from baseline were a weight loss of 4 to 5 kg. Semaglutide (in a dosage of 1 mg once a week) provided a greater reduction in A1C concentrations than sitagliptin (-1.5% vs. -0.7% at week 56), exenatide extended-release (-1.4% vs. -0.9% at week 56), and insulin glargine (-1.5% vs. -0.9% at week 30). Semaglutide has also been evaluated in a cardiovascular outcomes trial in patients with diabetes and a high risk of cardiovascular events. The primary composite endpoint was the time to first occurrence of a major adverse cardiovascular event. The number of these experiences was lower in patients treated with semaglutide compared with placebo (6.6% vs. 8.9%), suggesting an advantage for the medication. However, the design of the trial limits the conclusion to semaglutide being noninferior to placebo.

Daniel A. Hussar

Cigna-Express Scripts

On March 8, the health insurance giant Cigna announced that it had agreed to buy Express Scripts (for $67 billion including $15 billion of debt). In some respects this proposed acquisition has similarities to the CVS-Aetna deal, but there are also differences, the most notable of which is that Cigna-Express Scripts does not have, at least at present, the community pharmacy network represented by CVS. If the CVS-Aetna and Cigna-Express Scripts acquisitions are permitted to occur, the largest pharmacy benefit managers (PBMs) will be a part of the huge corporate structures that include the largest health insurance companies. In addition to these entities, OptumRx is owned by the largest health insurer UnitedHealth Group, and Anthem has had continuously evolving plans with respect to its prescription programs. Anthem has a 10-year agreement with Express Scripts that concludes in 2019, but the relationship between these companies has deteriorated to the point that Anthem has sued Express Scripts. Anthem has identified at least temporary plans to work with CVS/Caremark when its contract with Express Scripts concludes, but its longer-range plans are to have its own PBM.

Walgreens-AmerisourceBergen

Walgreens currently owns approximately 26% of AmerisourceBergen, one of the country's largest pharmaceutical wholesalers, and is its largest customer. There have been reports that high-level officials of both companies have spoken about the possibility of Walgreens purchasing the entire company. Although it appears that these discussions have concluded without an agreement, the resumption of consideration of this possibility can't be ruled out, nor can the potential for similar discussions between other large chain pharmacies and large pharmaceutical wholesalers. In addition to questions about the effect on competition, this type of acquisition has additional important implications. For example, if Walgreens was to own AmerisourceBergen, would other chain pharmacies and independent pharmacies that use AmerisourceBergen as a wholesaler continue to do so? The business and competition concerns also intersect with the very important concerns of addiction and overdosage with controlled substances, one of the results of which is that large pharmaceutical wholesalers have been sued for not identifying purchases of controlled substances by pharmacies that are so large that they should have been suspicious and reported. If a large chain pharmacy and a large pharmaceutical wholesaler are part of the same corporation, might there be less incentive to monitor the purchases of these pharmacies that might be excessive and suspicious?

Actions

The advocates for acquisitions/mergers of the type considered above claim that the larger corporate entities will be able to reduce the costs of health care products and services for consumers. Experience to date has not demonstrated this to occur, and I would contend that the opposite has occurred and costs have increased. Health insurance companies and PBMs are extracting huge profits from the resources available for health care but, in my opinion, they have contributed nothing to the scope and quality of health care. Just as I voiced opposition to the Walgreens-Rite Aid and CVS-Aetna mergers, I am opposed to the Albertsons-Rite Aid, Cigna-Express Scripts, Walgreens-AmerisourceBergen, and similar alliances that might subsequently be proposed. Previous experiences in this direction have demonstrated a reduction in competition and the ability of independent pharmacies and small (and even large) chain pharmacies to remain in business, and a reduction in the scope and quality of the services pharmacists can provide for patients. And the costs of medications and other health care products and services have just continued to increase. If there has been any encouragement in the last several years, it has been the intervention of the Department of Justice/Federal Trade Commission (DOJ/FTC) to block or reduce the scope of the proposed mergers of Cigna and Anthem, Aetna and Humana, and Walgreens-Rite Aid. Individual pharmacists and our professional association must continue to document and communicate the concerns about such mergers to the DOJ/FTC, and take other actions to prevent such anticompetitive initiatives from occurring.

Daniel A. Hussar

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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