



# The Pharmacist Activist

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Editorial

## “I Quit CVS Today”

**T**hese are the first words in an email message that I received recently from a pharmacist who became so disgusted with his experience as an employee at CVS that he took this precipitous action. His concerns include the safety of his patients, medication errors, inadequate staffing, pressure to fill more prescriptions faster, computer crashes, coercive/unauthorized refill practices, CMS sanctions, possible insurance fraud—and this is just a partial list of his concerns.

Very frankly, I don't want to write another editorial about CVS. I am also disgusted by the way in which the company and its management damage the respect for the profession of pharmacy through their policies and actions. When I have written editorials that are critical of CVS, I have received numerous responses. Many are from CVS pharmacists who confirm the validity of my criticisms and identify additional concerns of which I had not been aware. They also voice frustration that their concerns and requests (e.g., for additional staffing) are essentially ignored, and are appreciative when individuals outside their company are supportive of their efforts to provide better services for their patients and to improve their workplace environment. I recognize that my previous editorials have had no influence on the decisions and actions of CVS executives and managers. Indeed, the CVS

experience appears to have gone from bad to worse. However, I write this commentary with the anticipation that CVS pharmacists will feel supported by the recognition that there are others who share their concerns, and that their concerns that have important implications not only for CVS, but for the entire profession and the patients we serve, are being communicated to a much larger pharmacy audience.

The following are typical of the comments voiced by many CVS pharmacists regarding the company and its management:

“Our whole corporate philosophy is one of don't disagree, say everything is wonderful, and your numbers have to be good.”

“The more you do, and the faster, the better you are paid. Nothing mentioned about accuracy though.”

“They have numbers for everything except accuracy in filling prescriptions.”

“All corporate calls reference is capturing new business, increasing the volume, developing new business opportunities. The only thing I have never heard mentioned is patient care.”

“When the computer crashes and the store is in Offline, management's

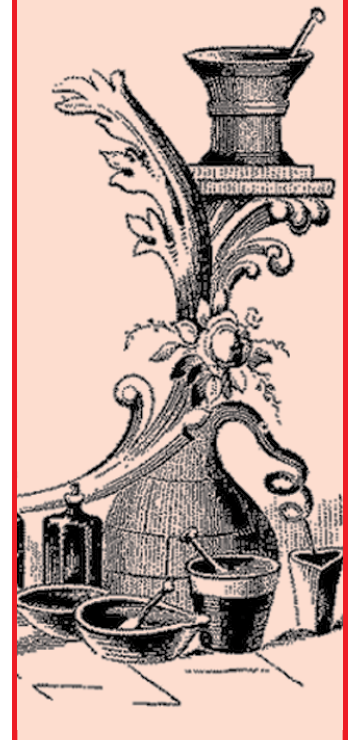
### Contents

#### New Drug Review

##### Linaclootide

(Linzess - Forest; Ironwood)

Page 3



‘expectation is that pharmacy teams *can* and *should* fill prescriptions’ (even without information that is needed for the safety of patients).”

In response to the concerns of pharmacists about patient safety, “management employs its HIT strategy – Harassment, Intimidation, and Termination.”

## CVS in the headlines

CVS has frequently been the subject of media headlines during the last several years, but for all the wrong reasons. It has been charged with penalties and fines in excess of \$100 million during this period of time. In late 2010 it was charged by the Drug Enforcement Administration (DEA) with unlawfully selling pseudoephedrine to criminals who made methamphetamine, and required to pay \$75 million in civil penalties (please see my editorial, “Strike 3 – CVS Should be OUT!” in the November 2010 issue of *The Pharmacist Activist* at [www.pharmacistactivist.com](http://www.pharmacistactivist.com)).

In February of 2012 the DEA moved to suspend two CVS pharmacies in Florida from selling controlled substances, noting that the two pharmacies purchased approximately 3 million oxycodone tablets in a year. The DEA further noted that the pharmacies are an “imminent danger” to the public (for a more detailed discussion, please see my editorial, “CVS—Criminal Charges are Needed!” in the February 2012 issue).

In March of 2012 it became known that a CVS pharmacy in New Jersey had mistakenly dispensed tamoxifen instead of chewable fluoride tablets to children in as many as 50 families over a period of several months (for a more detailed discussion, please see my editorial, “Is Patient Safety at Risk at CVS? There is a Whistleblower!” in the June 2012 issue). In early 2013 there were follow-up stories regarding this drug mix-up, with reports indicating that CVS was paying approximately \$650,000 to support programs in New Jersey to encourage the safe use of medications.

## The headlines continue

CVS Caremark owns the SilverScript Insurance Company (SSIC) that provides a Medicare Part D prescription drug plan to approximately 4 million members in the United States. During the first two weeks of 2013 (January 1 – 14), the Centers for Medicare and Medicaid Services (CMS) received more than 2,300 complaints regarding the SilverScript program, a figure that was four times the number for the sponsors of all other Part D programs combined. Many

members in the SilverScript plans were asked to pay more than was required under the terms of the benefit plan. Many of these individuals could not afford the higher-than-anticipated charge and left the pharmacy without their medication. Effective January 15 the CMS imposed intermediate sanctions on the SilverScript prescription plans based on the determination that “SSIC’s conduct poses a serious threat to the health and safety of Medicare beneficiaries.” These sanctions prevent SilverScript from marketing and enrolling any new beneficiaries in its plans, but do not affect current SilverScript members.

In the CVS Caremark statement in response to the CMS action, it is noted that “Issues with SilverScript enrollment processing resulted from an enrollment system conversion and brought about an increase in call volume and issues related to claims processing including, in some instances, not being able to have claims adjudicated at the pharmacy.” It is noteworthy that the CMS statement provides a clearer indication of the number of Medicare beneficiaries affected, through its observation that “SSIC has confirmed that tens of thousands of SSIC enrollees were affected by these system errors.”

The CVS Caremark statement includes several comments from one of its executives including, “We also want to commit to members who experienced enrollment issues that we will resolve these expeditiously,” (an explanation that will provide little consolation for the thousands of individuals who already have spent hours on multiple phone calls seeking resolution of the problems). I searched for some mention of an apology to members who had been greatly inconvenienced and at risk of health problems because they were unable to obtain needed medication on a timely basis. However, my search was in vain. What I did find, however, was further documentation of the priority of the CVS executives – not to its prescription plan members and other customers, not to its employees, but to its stockholders. The brief three-paragraph statement does include encouragement for its stockholders that “The company estimates that the sanctions should not have a material impact on its 2013 earnings.” To this observer the clear message is that the sanctions need to be much stronger.

## Employee “wellness program”

CVS has approximately 200,000 employees and it has recently informed those who use the company’s health insurance that they will be expected to have determinations of their weight, height, body fat, blood pressure, and glucose and lipid concentrations reported to its insurance program by May 1. Employees must sign a form saying that the screening is voluntary, and those who do not comply with the program

*(Continued on Page 4)*

# New Drug Review

## Linaclotide (Linzess – Forest; Ironwood) Agent for Constipation

**New Drug Comparison  
Rating (NDCR) = 4**

*(significant advantage[s])  
in a scale of 1 to 5 with 5  
being the highest rating*

### Indications:

For the treatment of adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC).

### Comparable drug:

Lubiprostone (Amitiza).

### Advantages:

- Has a unique mechanism of action (is a guanylate cyclase-C agonist);
- Labeled indication for IBS-C is not limited to use in women;
- Is administered once a day (whereas lubiprostone is administered twice a day);
- Does not require dosage adjustment in patients with moderate or severe hepatic impairment.

### Disadvantages:

- Has not been directly compared with lubiprostone in clinical studies;
- Risk of toxicity if used off-label in pediatric patients.

### Most important risks/adverse events:

Risk of toxicity in children (boxed warning; contraindicated in pediatric patients up to 6 years of age, and use should be avoided in pediatric patients 6 through 17 years of age); contraindicated in patients with known or suspected mechanical gastrointestinal obstruction; severe diarrhea (2%; suspension of treatment should be considered).

### Most common adverse events (and incidence, respectively, in patients with IBS-C treated with a dose of 290 mcg once a day, and patients with CIC treated with a dose of 145 mcg once a day):

Diarrhea (20%; 16%), abdominal pain (7%; 7%), flatulence (4%; 6%), abdominal distension (2%; 3%).

### Usual dosage:

Should be taken on an empty stomach at least 30 minutes prior to the first meal of the day; IBS-C – 290 mcg once a day; CIC – 145 mcg once a day.

### Products:

Capsules – 145 mcg, 290 mcg.

### Comments:

Linaclotide is a 14-amino acid peptide that is metabolized within the gastrointestinal tract to an active metabolite. It is a guanylate cyclase-C (GC-C) agonist and both it and its metabolite bind to GC-C and act locally on the luminal surface of the intestinal epithelium. It is the first drug with this mechanism of action to be approved for the treatment of constipation. Activation of GC-C results in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevation in intracellular cGMP stimulates secretion of chloride and bicarbonate into the intestinal lumen, resulting in increased intestinal fluid and accelerated transit. A change in stool consistency occurs and intestinal pain may be reduced. The drug and its metabolite are minimally absorbed and systemic availability is very limited.

The effectiveness of linaclotide was demonstrated in placebo-controlled studies. In patients with IBS-C, the drug was more effective than placebo in increasing the number of complete spontaneous bowel movements (CSBM) and in reducing abdominal pain. In patients with CIC, patients receiving linaclotide experienced more CSBM than those taking placebo. The higher dosage (290 mcg once a day) was not approved for the treatment of CIC because it was no more effective than the 145 mcg once a day dosage in the clinical studies.

Although the labeled indications for linaclotide are for use only in adult patients, there are a contraindication and a boxed warning regarding the risk of using it in pediatric patients. In studies in young juvenile mice, deaths occurred within 24 hours following administration of one or two daily oral doses. Although there were no deaths in older juvenile mice, the lack of safety data in pediatric patients contraindicates its use in children up to 6 years of age. The boxed warning also notes that its use should be avoided in pediatric patients 6 through 17 years.

Daniel A. Hussar

will be required to pay an additional \$50 per month for their health care coverage. A company spokesman has stated, "Our benefits program is evolving to help our colleagues take more responsibility for improving their health and managing health-associated costs."

Notwithstanding the potential benefits of wellness programs and the fact that some other organizations have also initiated such programs, there is concern and cynicism regarding both the motivation and specific requirements of the program CVS is implementing. Many employees and others believe that the single goal for the program is for CVS to reduce its costs for the health insurance programs for its employees. A rumor among company employees is that the company's goal is to reduce its cost for employee health benefits by more than one-half.

In my opinion, the statement that CVS has taken this action, in part, to help its employees improve their health is not credible. This is a company that continues to sell cigarettes that contain toxins that are responsible for more preventable deaths than any other cause. Any statement from CVS that it cares about the health of its employees or customers is blatant hypocrisy and has no credibility when it continues to sell tobacco products and denies so many of its pharmacies the level of staffing and related opportunities to provide services that will increase the effectiveness and safety of drug therapy for patients.

## CVS employees

CVS employs many excellent pharmacists. Unfortunately, their professional motivation and services are often undermined by the policies and actions of executives and other managers of their company who have a singular focus – MONEY! Pharmacists with continuing concerns regarding matters of patient safety, inadequate staffing levels, other company policies, and the workplace environment should consider the following actions:

1. Take the time that you need to assure that patient safety is not being compromised. The potential consequences of not doing this are harm to or death of a patient and loss of your license to practice pharmacy. For the executives of CVS, adverse events, deaths, and lawsuits are just costs of doing

business. For patients and pharmacists, the consequences are personal.

2. Concerns should be documented with appropriate details.
3. Concerns should be communicated to your supervisor.

If your concerns are ignored or otherwise not adequately addressed, the following can be considered:

4. You can resign from your position after identifying a professionally-fulfilling opportunity elsewhere. For many, however, resignation will not be an option. In these situations, you can confer with fellow employees who share your concerns and develop a strategy for bringing your concerns to the attention of management. If this initiative is not effective and the concerns are widespread among employees, the establishment of a recognized group of employees (e.g., a union) may be considered.
5. Pertinent concerns can be communicated to pharmacy organizations and publications who are likely to share the concerns and be supportive of your efforts to have them appropriately addressed.
6. Concerns that compromise the effectiveness of drug therapy and patient safety should be reported to the Board of Pharmacy. The failure of an organization to address certain types of inappropriate activities may be the basis for action as a whistleblower.

When an important concern exists, it is best that this concern be personally and directly communicated to the appropriate individual. However, I recognize that many pharmacists will not take this action because of concern that they will jeopardize their continued employment. In these situations consider communicating the concern anonymously to the appropriate manager/authority. It is better to have a concern that compromises patient safety communicated anonymously than not be communicated at all.

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