The Pharmacist Activist

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Independent Pharmacists The Front Line of our Profession

Within a 2-week period this month I have had the opportunity to participate in three events involving independent community pharmacists—the annual meeting of the pharmacist members of Value Drug based in Altoona, Pennsylvania, the annual banquet of the Philadelphia Association of Retail Druggists, and a symposium of the Mutual Wholesale Drug Company in Durham, North Carolina. There were approximately 350 independent pharmacists at this latter event which has to be one of the largest state or regional gatherings of independent pharmacists.

I am both encouraged and energized by what I observed and my discussions with individual pharmacists. Although all pharmacists have important responsibilities in the many different areas of opportunity within our profession, the responsibilities that many of us have are essentially invisible to the public. In my role as a professor, I am not one of the pharmacists people know of or think about when they respond to the surveys in which they give such high rankings to pharmacists for integrity and ethics year after year. Rather, it is the community pharmacists who are highly visible and known to the public who have earned these accolades for our profession from which all of us benefit.

There are many chain pharmacists who are very capable and are committed to serve their patients and advance our profession. However, as dedicated as these pharmacists may be, they often experience working conditions that preclude substantive discussions with individual patients, are subject to transfer to another pharmacy within the chain, and are more likely to accept a position with another employer. Independent pharmacy owners (and often their employee pharmacists) make personal, financial, and long-term investments in the community and usually reside there, often assuming leadership responsibilities.

Over the last several decades there has been a significant decline in the number of independent community pharmacies and a significant increase in the number of chain pharmacies. Although the number of independent pharmacies has remained fairly constant during the last several years and actually increased slightly in 2005 (from 24,345 in 2004 to 24,500 in 2005 according to preliminary data from the 2006 NCPA-Pfizer Digest), the survival of independent pharmacies is continually threatened on many fronts.

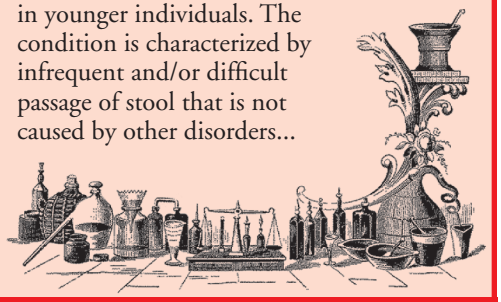
In my opinion, the recognition and respect for pharmacy as a health profession and the opportunities for our profession to advance are inextricably linked to the extent that independent community pharmacy practice not only survives, but thrives.

(Continued on Page 2)

Contents

Discussion

Chronic idiopathic constipation is a common disorder that is experienced over a period of more than six months, more often by women than men, and more often in those over 65 years of age than in younger individuals. The condition is characterized by infrequent and/or difficult passage of stool that is not caused by other disorders...



Distinguished Leadership

Gene Lutz and his wife Susan have an independent community pharmacy in Altoona, Iowa. At the annual meeting of the American Pharmacists Association (APhA) that was held in March in San Francisco, Gene concluded his term as President of the Association. He provided distinguished leadership for our profession during a challenging period of time (Medicare Part D—no other examples needed).

Gene's presidential address at the time of his installation at the APhA annual meeting in 2005 was "A Purpose-Driven Profession." Influenced to a large extent by the best-selling book, "The Purpose-Driven Life," written by Rick Warren, Gene very effectively applied concepts and observations regarding preparation, professionalism, leadership, collaboration, and mission to the responsibilities and issues that must be addressed by our profession of pharmacy. The concluding challenge in his address is noted below and is as important now as it was a year ago:

"If you are a student, seek out great teachers and mentors, pay attention to what they do and emulate them. If you are a pharmacist, think 'outside the counter.' Put purpose in your professional life, and demonstrate it to those you mentor and to your patients. Be a professional hero! If you are a teacher, teach your students to work for the benefit of patients and demonstrate your leadership by being actively involved in the profession outside of the classroom. If you are an association executive or elected leader, learn to cooperate with all segments of the profession and tear down the walls that separate and segregate us. Each of us can do something. I urge you to do what you can to help create and maintain a purpose-driven profession."

Thank you, Gene, for your purpose and your leadership!

- Daniel A. Hussar

(Front Line Cont.)

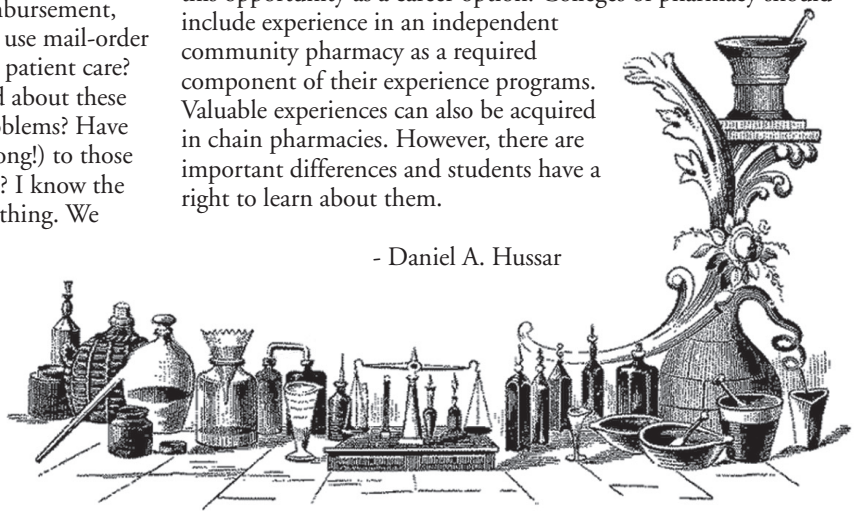
There are some within our profession who have been critical of community pharmacists for not more quickly implementing more comprehensive services for patients such as pharmacist care and medication therapy management. In some situations, such criticism is valid, particularly as it might apply to certain chain pharmacies in which management decisions are made by individuals who are not pharmacists. However, before any of us has a right to criticize what has occurred, or has not occurred, in community pharmacy practice, we must ask ourselves what we have done to help community pharmacists address the challenges they face.

How many of us who are not in community pharmacy practice can say we are even knowledgeable about the devastating impact Medicare Part D and the federal budget has on patients and community pharmacies? Do we really understand the threats presented by prescription drug benefit programs that provide inadequate dispensing fees, impose reductions in product cost reimbursement, provide mandates or financial incentives for patients to use mail-order pharmacies for maintenance medications and fragment patient care? Even for those of us who understand and are concerned about these situations, what have we done to help address these problems? Have we voiced our concerns (anger or outrage is not too strong!) to those who are responsible for these deficiencies and injustices? I know the answers to these questions–most of us have not done a thing. We must change that situation now!

Many of us work as pharmacists for organizations that provide prescription drug benefit programs that provide financial incentives to use mail-order pharmacies and prohibit community pharmacies from participating under the same terms that mail-order pharmacies do (e.g., only a 30-day supply of medication can be dispensed by a community pharmacy whereas a mail-order pharmacy can dispense a 90-day supply). By tolerating and participating in these programs, we are actually exacerbating the problems experienced by community pharmacists. However, they have probably been so occupied with even more urgent problems that they have seldom criticized us for failing to address this situation. We need to challenge and change these programs, starting with our own employers.

Many things can be done to support and expand independent community pharmacy practice and I will identify several in the area of my own professional responsibilities. Colleges of pharmacy and individual faculty members should do much more to make pharmacy students aware of opportunities in independent community pharmacy practice and to encourage them to actively consider this opportunity as a career option. Colleges of pharmacy should include experience in an independent community pharmacy as a required component of their experience programs. Valuable experiences can also be acquired in chain pharmacies. However, there are important differences and students have a right to learn about them.

- Daniel A. Hussar



New Drug Review

Lubiprostone (Amitiza)

New Drug Comparison Rating (NDCR) = 4
(Significant Advantage[s])
in a scale of 1 to 5, with 5 being the highest rating

Indications:

Treatment of chronic idiopathic constipation in adults.

Comparative drugs:

Tegaserod (Zelnorm)

Advantages:

- Has a unique mechanism of action
- Indication is not restricted to use in adults less than 65 years of age
- Effectiveness has been demonstrated over treatment periods of up to 12 months (compared with 12 weeks with tegaserod)
- Less likely to cause problems in patients with severe renal impairment or moderate or severe hepatic impairment (in whom tegaserod is contraindicated)
- May be less likely to cause complications associated with diarrhea
- Less expensive

Disadvantages:

- More likely to cause harm to a fetus (has stronger warnings against use during pregnancy)
- More likely to cause nausea

Conclusions:

In the treatment of chronic idiopathic constipation dietary fiber and laxatives should be initially used. However, for many individuals, these approaches are of limited benefit. Tegaserod and lubiprostone are the only medications that have been demonstrated to be effective in the treatment of chronic idiopathic constipation. The two agents have not been directly compared in clinical studies.

Lubiprostone should be the agent of first choice when choosing between these two medications. Its effectiveness has been demonstrated in adults including the elderly for treatment periods of up to 12 months. In contrast, the effectiveness of tegaserod has not been established in patients 65 years or older and the drug has not been formally studied for periods longer than 12 weeks. Lubiprostone has fewer contraindications to its use and is generally safer to use. However, it is more likely to cause nausea and should be administered with food to reduce symptoms of nausea. Lubiprostone should not be used during pregnancy.

Cost to the pharmacist for a 30-day supply:

(adapted from Medi-Span Price Alert, April 15, 2006)

Amitiza 24 mcg capsules–$182.40 (24 mcg twice a day–60 capsules)
Zelnorm 6 mg tablets–$202.45 (6 mg twice a day–)60 tablets)

Discussion

Chronic idiopathic constipation is a common disorder that is experienced over a period of more than six months, more often by women than men, and more often in those over 65 years of age than in younger individuals. The condition is characterized by infrequent and/or difficult passage of stool that is not caused by other disorders or by the use of medications and is typically associated with signs and symptoms such as abdominal pain or discomfort, bloating, straining, and hard stools. Dietary fiber and laxatives may be of benefit but these approaches are of limited value in many patients with chronic idiopathic constipation.

Tegaserod (Zelnorm) is a serotonin 5-HT4 receptor partial agonist that was initially approved for the treatment of women with irritable bowel syndrome associated with constipation, and subsequently as the first drug to be specifically approved for the treatment of chronic idiopathic constipation (in both women and men). However, the effectiveness of this agent in the treatment of elderly patients with chronic idiopathic constipation has not been established, and its indication for this disorder is for the treatment of patients less than 65 years of age.

Chronic idiopathic constipation may result from abnormal intestinal/colonic motility that can delay the transit of intestinal contents and inhibit the elimination of rectal contents. Lubiprostone (Amitiza-Sucampo; Takeda) is a chloride channel activator that acts locally to activate C1C-2, which is a normal constituent of the apical membrane of the intestinal epithelium. Its use provides a chloride-rich intestinal fluid secretion without altering sodium and potassium concentrations in the serum. By increasing intestinal fluid secretion, lubiprostone increases motility in the intestine, thereby facilitating the passage of stool and alleviating symptoms associated with the disorder.

Lubiprostone is indicated for the treatment of chronic idiopathic constipation in adults and, unlike tegaserod, its labeled indication for this condition is not limited to patients less than 65 years of age. The new drug was evaluated in patients who, on average, had less than 3 spontaneous bowel movements per week with symptoms of constipation for at least 6 months prior to entry into the

studies. Starting with the first week of treatment, patients receiving lubiprostone had a higher frequency of spontaneous bowel movements and also experienced an improvement in symptoms and constipation severity ratings. Long-term studies have demonstrated that lubiprostone decreases abdominal bloating, abdominal discomfort, and constipation severity over treatment periods of as long as 12 months. The effectiveness of tegaserod has not been studied beyond 12 weeks, and the two drugs have not been directly compared in clinical studies.

Lubiprostone is also being evaluated for the treatment of constipation-predominant irritable bowel syndrome. However, this is not a labeled indication at the present time.

The use of lubiprostone is contraindicated in patients with a history of mechanical gastrointestinal obstruction, and patients with symptoms suggestive of such obstruction should be evaluated before initiating treatment. Nausea (31%) is the most frequently reported adverse event although the incidence was substantially lower in men and in the elderly. Administration of the drug with food has been observed to decrease the occurrence of nausea. Diarrhea was experienced by 13% of the patients in the clinical studies, and lubiprostone should not be administered to patients who have severe diarrhea. Other commonly reported adverse events include headache (13%), abdominal distension (7%), abdominal pain (7%), and flatulence (6%).

Lubiprostone is classified in Pregnancy Category C. Its safety during pregnancy has not been evaluated in humans but reports from certain animal studies suggest a potential for causing fetal loss. It is recommended that women who could become pregnant should have a negative pregnancy test prior to initiating therapy, and should be capable of complying with effective contraceptive measures. Tegaserod is classified in Pregnancy Category B.

Following oral administration, lubiprostone has low systemic availability and its actions are primarily localized in the gastrointestinal tract. It is rapidly and extensively metabolized, presumably in the stomach and jejunum without appreciable systemic absorption. The drug has not been studied in patients with hepatic or renal impairment.

The recommended dosage of lubiprostone is 24 mcg twice a day with food. Capsules are supplied in a 24 mcg-potency. The need for continuing treatment with the drug should be periodically assessed.

- Daniel A. Hussar

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