The Pharmacist Activist

Volume 5, No. 4 • April 2010

Editorial

Pharmacy Must Develop Opportunities Now!

(Before Health Insurance "Reform" Limits our Role)

Even after the health insurance reform legislation has been approved by the Congress and President, vigorous debate continues. Very few have read the legislation and, considering some differences of opinion among these individuals, not even all of them understand it. Dozens, if not hundreds, of important questions exist, and answers for some of them will not be known for many years when certain provisions of the law are eventually implemented.

Who won and who lost? There have been declarations that the legislation is a positive step for the country and the public, and some claims of "victories" on the part of some stakeholders. Others are highly critical and predicting failure of the new "reforms." To the extent I understand the provisions and anticipated implementation of the legislation, it is my opinion that the insurance companies and the pharmaceutical companies are the winners, and the losers are the health professionals, most of the patients/public who presently have health insurance (because many will experience a reduction in access and quality of care), and the country (when the actual cost of the program becomes known).

I strongly support a system that provides access to health care services for everyone in the United States. It is unconscionable in a country of our wealth for individuals to unnecessarily experience serious symptoms and premature death because of the lack of access to health care services. The advocates for the new law state that this is the single most important goal and that the law is a successful effort that represents an important step forward for millions of individuals who do not have health insurance now. However, in my opinion, the legislation that has been approved is seriously flawed, will not accomplish intended goals, and will incur a huge cost. I wish I could focus on the question of "What went well?" but this has been obscured by the question of "What went wrong?"

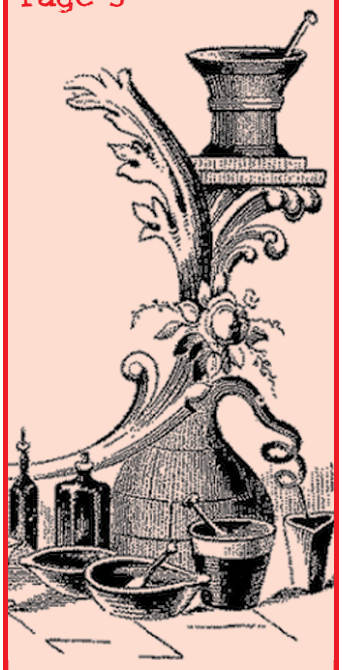
What went wrong?

A long list of problems could be developed but I have identified those that I consider the most important.

1. There is a pervasive lack of trust. If a concept/proposal was developed by Democrats, Republicans view it as partisan and self-serving, and vice versa.

2. Artificial deadlines were established that resulted in the highest priority being given to "getting it done" rather than "doing it well."

Contents



3. The legislative process became secretive, involving only Democrats, thereby creating even greater distrust and resentment on the part of Republicans.

4. There is the appearance of deception. Shortly before Congress approved the legislation, new budgetary projections suggested that the cost would be lower than initially anticipated. Shortly after the legislation was approved, budgetary projections indicated that the cost would be substantially higher.

5. Most important of all, very little concern, attention, and discussion were directed to the *quality* of health care services.

Implications for pharmacy

Some pharmacists and pharmacy organizations have spoken positively about the law that has been approved, primarily because of its recognition of the value of medication therapy management (MTM). Pharmacists have the expertise and are well-positioned to provide MTM. However, questions remain regarding the implementation of the provisions pertaining to MTM, and it is my understanding that assurance is not provided in the law that it will be *pharmacists* who will be providing the MTM. Is this a role that pharmacy benefit managers (PBMs) or insurance companies will attempt to assume to a greater extent? Another possibility is that MTM would be an expanding role for nurse practitioners and physician assistants.

Actions that pharmacy should take

Although some pharmacy organizations have had some noteworthy successes, it has been my observation that pharmacy has not been highly successful in developing and influencing legislation that effectively addresses concerns and issues of our patients and our profession. We must be highly active in the political process, but this process is too often unpredictable and/or unresponsive on a timely basis. We must also pursue other initiatives over which we have more influence and control. As examples, I will provide one recommendation that will require the participation of a network of thousands of pharmacists, and one recommendation that can be implemented in individual pharmacies.

A new prescription benefit program

Most community pharmacists are highly critical of the PBMs and consider the terms of their programs to be a disservice to patients and unfair to pharmacists. Our profession should actively pursue the development of a new prescription benefit program. Given the shortcomings and concerns about the existing programs of PBMs, I am fully confident that a far better program can be designed that will provide greater effectiveness and safety of drug therapy for patients, equitable terms and compensation for pharmacists, incentives for pharmacists to provide comprehensive services, and be competitive with respect to costs. The National Community Pharmacists Association (NCPA) has collaborated in an initiative in this direction but a more extensive program must be developed.

The program to be developed should be national in scope that could be provided by a network of thousands of independent pharmacies that would assure adequate geographical distribution and personalized services for patients. Additional benefits would accrue to the participating pharmacists as a result of involvement in a large network of pharmacies.

Personal Service Program

The March 2010 issue of NCPA's *America's Pharmacist* includes a story titled, "Synchronized Success" (written by Chris Linville), that describes the Personal Service Program (PSP) established by pharmacist John Sykora and his colleagues at Abrams & Clark Pharmacy in Long Beach, California. This provides an excellent example with multiple benefits of what an individual pharmacist can do. A primary feature of the PSP is the organization and synchronization of the refills of medications that patients take on a long-term maintenance basis. Obtaining these medications is organized in a manner in which patients receive all of their refills on the same day once a month. Patients are called approximately one week before the anticipated need for the refills so that the use of the medications may be discussed and the need for any adjustments can be identified.

The implementation of the PSP has resulted in better understanding and compliance of patients with respect to their use of medications, as well as increased communication and collaboration with physicians to whom summaries of the monthly discussions with their patients are forwarded. Additional benefits for the patients include fewer phone calls and pharmacy visits that previously would have been made many times a month. There are also benefits and efficiencies for the pharmacy. John Sykora reports that, since implementation of the PSP, pharmacy hours have been cut by 10%, payroll has been reduced by

(Continued on Page 4)

New Drug Review

Liraglutide
(Victoza – 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 drug:
Exenatide (Byetta).

Advantages:
- Provides a greater reduction in glycosylated hemoglobin (A1C) and fasting plasma glucose;
- Is administered once a day (whereas exenatide is administered twice a day).

Disadvantages:
- Provides a smaller reduction in postprandial glucose after breakfast and dinner;
- Labeled indication is more limited (i.e., is not recommended for first-line therapy whereas the labeling for exenatide does not include this limitation);
- Has caused thyroid C-cell tumors in rodents and is contraindicated in patients with risk factors.

Most important risks/adverse events:
Thyroid C-cell tumors have been reported in rodents (boxed warning; contraindicated in patients with a personal or family history of medullary thyroid carcinoma and in patients with Multiple Endocrine Neoplasia syndrome type 2); pancreatitis (should be used with caution in patients with a history of pancreatitis; if pancreatitis is suspected, treatment should be discontinued); hypoglycemia (risk exists when used concurrently with an insulin secretagogue [e.g., sulfonylureas], and a reduction in dosage of the insulin secretagogue should be considered).

Most common adverse events:
Nausea (28%), diarrhea (17%), vomiting (11%), constipation (10%), upper respiratory tract infection (10%), headache (9%).

Usual dosage:
Administered subcutaneously in the abdomen, thigh, or upper arm; treatment is initiated with a dosage of 0.6 mg once a day for 1 week; after 1 week, the dosage should be increased to 1.2 mg once a day; if this dosage does not provide the anticipated glycemic control, the dosage may be increased to 1.8 mg once a day.

Products:
Prefilled multidose pens that deliver 0.6 mg, 1.2 mg, or 1.8 mg (should be stored in a refrigerator); after initial use, may be stored for 30 days at controlled room temperature.

Comments:
Liraglutide is an analog of glucagon-like peptide-1 (GLP-1) and acts as a GLP-1 receptor agonist. Its properties are most similar to those of exenatide, and both agents are administered subcutaneously. Liraglutide may be used as monotherapy or in combination with one or more oral antidiabetic drugs such as metformin, glimepiride, or a thiazolidinedione. However, it is not recommended as first-line therapy for

50%, inventory has been significantly reduced because expensive drugs are not ordered until several days before the anticipated need, and gross margin is about 5 points above the national average. Not surprisingly, he and his colleagues experience a high level of professional fulfillment as a consequence of their more comprehensive and effective communication with their patients, and the enthusiastic response of his patients to the PSPs.

This initiative is an excellent example of what can be accomplished in an individual pharmacy, and also provides encouragement for other pharmacists that they can be similarly successful. However, it is very important that pharmacists be proactive in developing these opportunities. Individually and collectively, we need to take action now!

Daniel A. Hussar

Author/Editor
Daniel A. Hussar, Ph.D.
Philadelphia College of Pharmacy
University of the Sciences in Philadelphia

Publishers
Christopher J. Polli • G. Patrick Polli II

Assistant Editor
John Buck

Publications Director
Jeff Zajac

Graphic Artist/Designer
Joe Monte

The opinions and recommendations are those of the author and do not necessarily represent those of his full-time employer or the publisher.

The Pharmacist Activist
661 Moore Rd., Suite 100
King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

News, Information and Career Opportunities
NEWS - Line PUBLISHING

New Drug Review (cont.)

patients inadequately controlled on diet and exercise, whereas the labeling for exenatide does not include this limitation. In a study in which liraglutide monotherapy was compared with glimepiride monotherapy, the new drug provided significantly greater reductions in glycosylated hemoglobin after 52 weeks. In one study, either liraglutide (1.8 mg once a day) or exenatide (10 mcg twice a day) was added to metformin and/or glimepiride. After 26 weeks, patients receiving liraglutide achieved a significantly greater reduction in A1C from baseline (-1.2%) compared with -0.79% in patients receiving exenatide. Liraglutide also provided significantly greater reductions in fasting plasma glucose, but patients treated with exenatide experienced a greater reduction in postprandial glucose after breakfast and dinner. As with exenatide, many patients treated with liraglutide lose weight (approximately 3 kg on average).

Liraglutide has been reported to cause malignant thyroid C-cell tumors in rodents. The labeling for exenatide does not address this problem, but recent observations suggest the possibility of an increased cancer risk with its use. The once-a-day dosage regimen for liraglutide is an advantage over exenatide that is administered twice a day. However, this advantage is likely to be short-lived as it is anticipated that a longer-acting formulation of exenatide that is administered once a week will soon be approved.

Daniel A. Hussar