The Pharmacist Activist

Volume 8, No. 10 • October 2013

Editorial

Obtaining Health Insurance that Isn't Understood Using a System that Isn't Working – And the Situation Will Get Worse if there is not Compromise!

The "old" health care system had serious deficiencies. Almost every participant (e.g., pharmaceutical companies, hospitals, physicians, pharmacists) could determine the prices to be charged for products and services and expect to be compensated in the amounts requested. However, there were valid questions as to whether this health-care model was financially sustainable. In addition, there was little or no attention given to assessing the quality of health care provided and the outcomes for patients.

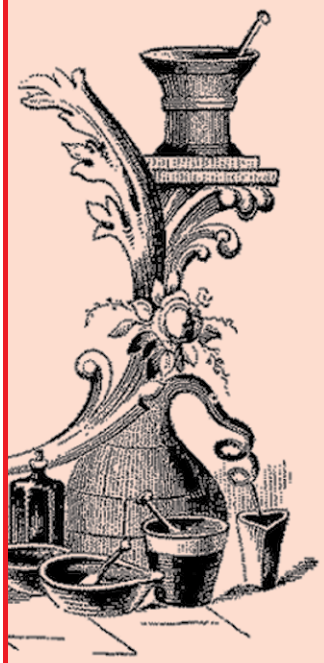
The "new" health care system (i.e., the Affordable Care Act [Obamacare]) that is being implemented has serious deficiencies. The health-care providers who provide services, care, and products for patients have little participation or influence in the determination of the scope and terms of the program or the compensation they will be provided. Instead, government agencies, insurance companies, and organizations such as pharmacy benefit managers are making these decisions. The scope and services of the new system raise valid questions as to whether this health-care model is financially sustainable. In addition, there is inadequate attention given to assuring the quality of health care provided and the outcomes for patients.

The old and new systems are markedly different, yet many of the questions and concerns are very similar. Is progress really being made or have we just replaced one set of problems with other problems of equal or greater importance? I do not defend or advocate the return of the old system. However, the new system is seriously flawed and will collapse as a consequence of the problems and concerns with which it is burdened unless major changes are made. We can and must do better!

Continuing concerns

The current problems that individuals have encountered in attempting to learn

Contents



more about the health-care benefit options and to choose a particular type of coverage are just the latest of a long series of concerns regarding the parameters and implementation of Obamacare. Indeed, the secrecy surrounding the development and approval of the legislation that has enabled the changes in the health care system was an early indicator of the problems ahead (Please see my editorial, "Health Care Reform – Let's Start Over and Do It Right!" in the January 2010 issue of *The Pharmacist Activist* at www.pharmacistactivist.com).

The current problems have, however, greatly increased the awareness of the public of the challenges that exist. These challenges include, but are not limited to, employers reducing the number of full-time positions and increasing the number of part-time positions; decisions of employers to change health benefit programs for employees and retirees; insurance companies canceling policies; the President making changes in the terms and implementation of the program without accompanying legislative authority; whether individuals can continue to use the same physicians and pharmacies; other terms of the health coverage options; access to needed information using the online network; and the cost of the coverage options.

Positives of Obamacare

The sharp differences of opinion that exist regarding certain provisions of Obamacare have polarized discussions and precluded consideration of areas of agreement and constructive change. I would identify the following as components of the legislation for which I feel there is strong support:

1. The opportunity for many individuals who do not currently have health insurance to obtain such coverage at an affordable cost or, if necessary, have the coverage subsidized.

2. The provision that individuals with pre-existing conditions would be able to obtain health insurance at an affordable cost.

3. The increased age at which young adults are permitted to be included in their parents' health insurance coverage.

I would like to think that a focus on these areas of general agreement could be a starting point for constructive discussion of the issues on which there is disagreement. However, the acrimony and polarization that have resulted from the differing philosophical, ideological, and political positions on these issues, make it difficult to be optimistic that agreement regarding a health care system can be reached.

Is compromise possible?

To date, it has not been possible to reconcile the two markedly different positions regarding Obamacare. Advocates extol the benefits and claim the authority of the legislation that established it. Opponents have such strong concerns that they strive to defund the program and/or repeal the legislation. There is seemingly no hope for compromise. However, this impasse is a "lose-lose" situation for both advocates and opponents, Democrats and Republicans.

Advocates for Obamacare have the position of strength and some feel there is no need for any compromise. But hardly a day goes by without an announcement that a large employer is making substantial changes in its health-care benefits or that an insurance company is canceling thousands of policies. Does anyone really think that these changes will be of greater benefit for employees and/or individual policy holders? Of course not! The employers and insurance companies are making these changes to protect their own interests.

The implementation of the early phases of Obamacare has revealed serious conceptual and operational flaws and limitations. And consumers are not yet even close to learning the options regarding health care providers and services and the cost of the insurance coverage. In my opinion, there will be additional problems that

(Continued on Page 4)

New Drug Review

Ospemifene
(Osphena – Shionogi)

Agent for Dyspareunia

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/ disadvantages) in a scale of 1 to 5 with 5 being the highest rating

Indication:
Treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

Comparable drugs:
Estradiol (administered vaginally; e.g., Estrace, Estring, Vagifem).

Advantages:
- Has both estrogen agonist and antagonist actions (whereas estradiol has estrogen agonist activity);
- Is administered orally.

Disadvantages:
- Is more likely to cause systemic adverse events;
- Is more likely to interact with other medications.

Most important risks/adverse events:
Contraindicated in women with known or suspected estrogen-dependent neoplasia (boxed warning regarding risk of endometrial cancer; when prescribed for a postmenopausal woman with a uterus, the use of a progestin should be considered to reduce the risk of endometrial cancer); contraindicated in women with active deep vein thrombosis, pulmonary embolism, or active arterial thromboembolic disease (e.g., stroke, myocardial infarction), or a history of these conditions (boxed warning; if feasible, use should be discontinued at least 4 weeks before surgery that may be associated with an increased risk of thromboembolism or during prolonged periods of immobilization); contraindicated in women with undiagnosed abnormal genital bleeding; contraindicated in women who are or may become pregnant (Pregnancy Category X); should not be used in women with severe hepatic impairment; should not be used concurrently with estrogens or an estrogen agonist/antagonist; action may be increased by fluconazole and decreased by rifampin, and concurrent use with either agent should be avoided.

Most common adverse events:
Hot flush (8%), vaginal discharge (4%), muscle spasms (3%), hyperhidrosis (2%), genital discharge (1%).

Usual dosage:
60 mg once daily with food; treatment should be for the shortest duration consistent with treatment goals and risks.

Product:
Film-coated tablets – 60 mg.

Comments:
The reduction in estrogen concentration associated with menopause may make vaginal tissues thinner, drier, and more fragile, resulting in dyspareunia (pain during sexual intercourse). Vaginal moisturizers (e.g., Replens) and lubricants and vaginally administered estrogen (e.g., estradiol) formulations have been used most often to treat these symptoms. As an estrogen agonist/antagonist, ospemifene activates estrogenic pathways in some tissues and causes antagonism of estrogenic pathways in some other tissues. It acts like estrogen on vaginal tissues, making them thicker and less fragile. Also designated as a selective estrogen receptor modulator, ospemifene has properties that are generally similar to those of raloxifene (Evista) although the latter agent is used primarily for the treatment and prevention of osteoporosis in postmenopausal women.

Ospemifene is the first orally-administered agent with estrogenic activity to be approved for the treatment of dyspareunia due to menopause. Its effectiveness was demonstrated in two 12-week placebo-controlled studies in which statistically significant improvement in dyspareunia occurred in the women treated with ospemifene compared with those receiving placebo. A third study that was conducted over 52 weeks demonstrated the safety of the new drug.

Daniel A. Hussar

will be worse than the ones that are recognized now. The problems and challenges may be of a magnitude that the program will fail. Advocates for the program must be willing to compromise.

Opponents of Obamacare must also be willing to compromise. Their criticisms of the program have not been accompanied by suggested revisions or recommendations of viable alternatives. Their position would maintain the present system, and that should no longer be considered acceptable. There is an important need for progressive changes in the provision of health care services and insurance, and compromise will be essential for the attainment of this goal.

I would like to think that there are legislators who have the personal character to rise above partisan politics and provide bipartisan leadership for the Congress and Administration in forging a compromise on these issues. To not do so risks the failure of Obamacare and the possible development of alternative health care systems and insurance coverage that are even more problematic and divisive.

Where are the health care providers?

Health care services and insurance coverage for such are of the greatest importance for the recipients of these services. But these issues are also of great importance for the providers of health care services (e.g., pharmacists, physicians, nurses). To what extent have health care providers and our professional organizations been involved in the development and implementation of Obamacare, as well as active participants in the discussion/debate regarding the benefits and deficiencies of the program? Our involvement and influence have been limited at best. Some would suggest nonexistent or ineffective.

Our organizations of health professionals must do more! We are in the best position to identify the parameters of a program that would assure the effectiveness, safety, and quality of health care. We can work effectively with those with administrative and financial expertise in developing those components of the program. However, experience has demonstrated that when health professionals are not involved and/or effective in the development of health care benefit programs, important decisions are made by others and we must cope with the consequences.

If the current impasse among our legislators continues and a compromise is not reached, there could be an even greater opportunity for our organizations of health professionals to fill the void with progressive recommendations.

Even if the legislators do reach a compromise, it is essential that our organizations become more involved, both independently and in collaboration. To address just one of the important issues, I recommend that the American Pharmacists Association and the American Medical Association work together to introduce and seek support for a provision that patients have freedom of choice in selecting their physicians and pharmacies in health care programs that are funded by the government. I am certain that there would be strong public support for this recommendation.

Daniel A. Hussar

Author/Editor - Daniel A. Hussar, Ph.D.
Philadelphia College of Pharmacy, University of the Sciences in Philadelphia
Publisher - G. Patrick Polli II
Assistant Editor - John Buck • **Publications Director -** Jeff Zajac

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., Ste. 100, King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

NEWS-Line PUBLISHING