The Pharmacist Activist

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Editorial

Health Care Reform – Let's Start Over and Do It Right!

The voters of Massachusetts have done our country a great service. And just in time! They exercised their anger, frustration, and right to vote in sending a strong message rejecting a broken political system that was on the verge of pushing our health care system into further chaos. Does our health system need to be reformed? Absolutely! However, both the direction and the process of the recent, and continuing, "reform" debacle have threatened to make the system worse. Let's terminate the current process, identify what can be learned from the experience, and start again.

What have we learned?

Reform must benefit individuals and society – Let's agree that the initial intention of health care reform was valid and honorable. There are individuals in this country who cannot afford or, for other reasons, do not have access to health care but need such services. However, the term "health care reform" quickly became a misnomer as the "care" for the people to be served disappeared in an avalanche of political, corporate, and personal interests. Indeed, a more accurate designation for the distorted emphasis would be "health insurance reform."

The quality of health care was ignored or compromised – Access to health care is of limited value unless the quality of that care is assured. Yet this critical dimension of a health system has been rarely mentioned.

Very limited involvement of health professionals – If any health system is going to be effective, it is essential that the health professionals who provide the patient care and services are involved in designing and implementing the system. The American Medical Association (AMA) had a role in the "negotiations," but many of its own members were angered by some of the positions taken by their leadership, and the AMA support (some say "deal") was quickly politicized by the administration.

Although leaders of national pharmacy associations publicized meetings with high-level officials and legislators, pharmacy did not have "a seat at the table." In fact, other than support for the inclusion of recognition of medication therapy management (MTM), the national pharmacy associations have not appeared to take a position supporting or opposing the proposed legislation that has been evolving. Although I disagree with the position that the AMA took, at least I know where it stands and can respond accordingly.

The inclusion of recognition of MTM could actually be an illusion for the pharmacists who are directly involved in providing care and services for patients if there is not funding to support this service and/or if pharmacy

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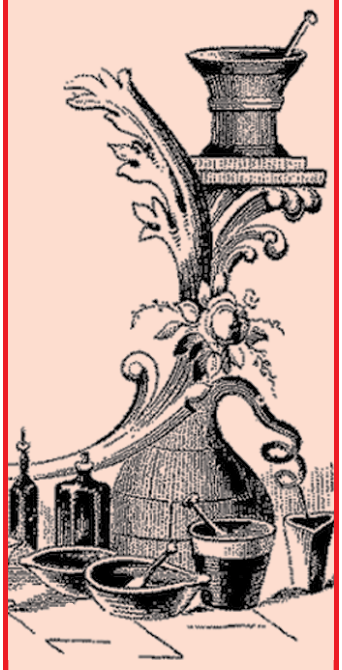

benefit managers (PBMs) and insurance companies attempt to provide MTM from a distance via mail or phone.

No more deals! – From the beginning of this initiative to reform health care, deals were made with pharmaceutical companies, insurance companies, hospitals, unions, the AMA, and others who might be in a position to mount formidable opposition to the Administration's plans. To consider just one of these deals, the pharmaceutical companies outsmarted the Administration and the Congress and they still do not realize they have been outsmarted. The pharmaceutical companies made a commitment of $80 billion over 10 years to develop and promote the proposed health care plan. However, there will be many millions more patients covered by this plan who will be prescribed medications made by these companies in a program that favors use of brand-name drugs rather than generics, there will be no importation of drugs from countries such as Canada in which these same brand-name medications are available at much lower prices, and there are no restrictions/limitations on the prices these companies can charge for their medications and how often and by how much they can increase these prices. The pharmaceutical companies will experience increased revenues that far exceed the $80 billion it has committed to support health care "reform." And this is just one example of the flaws in the "reform" that has been proposed.

In recent months, the deals went from bad to worse to unconscionable as exemplified by the efforts/bribes to obtain support from legislators in Louisiana and Nebraska, as well as union leadership.

Insurance companies have excessive influence – Insurance companies contribute little or nothing to the quality of health care but their policies often place inappropriate restrictions/limitations on the scope and quality of health care. Some of these companies have been discontinuing programs that they deem to be no longer in their best financial interest, leaving thousands of subscribers in a situation in which they must purchase more expensive policies on short notice. And yet we have still come very close to approving "reform" that would serve the interest of the insurance companies but not the interests of patients.

No more unrealistic deadlines – To accomplish needed reform of the health care system in an effective and progressive manner is a huge challenge that cannot be accomplished within the politically motivated deadlines that were established. The request for a bill on the President's desk before Christmas was a clear signal that adequate time was not being provided for the importance and scope of the task to be accomplished.

No more secrecy – Once the Senate passed its bill, continuing discussions involved the leadership of only one political party and were held under a cloak of secrecy. This occurred even though the President of the same political party made a commitment during his campaign to not just have open discussions but to have them televised. Secrecy results in suspicion and distrust.

Bipartisan support is necessary – The domination of one political party has resulted in a position that support from the other party is not needed, and placed the country on the precipice of a gross abuse of power. Perhaps the most important lesson from this experience is that our country is not well served if either major political party has such a majority that it can conclude that it does not need to work with the other party.

We need to start over

The problems inherent in the proposals developed by the Senate and the House are too important and numerous to fix. We need to start over and the following actions should be given priority:

1. There must be trust and cooperation. In view of the acrimony and polarization in recent months, it may be impossible to establish trust among our elected officials. If this is the case it will probably be necessary to reform our political system before it will be possible to accomplish meaningful reform of the health system.

2. The health care needs and interests of the people must be the central focus of reform and given the highest priority.

3. Many individuals have urgent health care needs now. These situations should be addressed immediately through the establishment of an interim program that can be provided during the time that the components of comprehensive health care reform are being determined.

4. A coalition of patients and health professionals should have the initial responsibility for identifying a system that will provide the care, and the scope and quality of services, that will best meet the health needs of patients, and provide professional fulfillment and equitable compensation for health professionals. Pharmacists have the drug therapy expertise and a strategic position to have an important role in designing and implementing this system.

5. The health care system must place a strong emphasis on health education, wellness, and disease prevention.

6. The health care system must emphasize the attainment of quality indicators and positive health outcomes, and provide incentives for meeting these goals. An investment in these parameters will result in substantial financial

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New Drug Review

Asenapine
(Saphris – Schering)

Antipsychotic Agent

New Drug Comparison Rating (NDCR) = 2

(significant disadvantages) in a scale of 1 to 5, with 5 being the highest rating

Indications:
For use in adults for the acute treatment of schizophrenia and for the acute treatment of manic or mixed episodes associated with bipolar I disorder with or without psychotic features.

Comparable drug:
Olanzapine (Zyprexa).

Advantages:
- Less likely to cause weight gain;
- May interact with fewer medications.

Disadvantages:
- Has appeared to be less effective in some studies;
- Labeled indications are more limited (e.g., olanzapine has labeled indications for maintenance treatment as well as acute treatment);
- May cause QT interval prolongation (should be avoided in patients with risk factors for this response);
- Administered twice a day (whereas olanzapine is administered once a day);
- Administered sublingually;
- May cause hypoesthesia;
- Effectiveness and safety have not been established in pediatric patients (whereas olanzapine has indications for use in adolescents aged 13 to 17 years);
- Fewer formulation options (e.g., olanzapine is also available in a parenteral formulation for acute agitation and in an extended-release parenteral formulation).

Most important risks/adverse events:
Increased mortality in elderly patients with dementia-related psychosis (boxed warning; is not approved for the treatment of dementia-related psychosis); cerebrovascular adverse events; neuroleptic malignant syndrome; tardive dyskinesia; hyperglycemia and diabetes mellitus; orthostatic hypotension and syncope; QT interval prolongation (should not be used in patients at risk including those who are taking other medications that are known to cause QT prolongation [e.g., certain antiarrhythmic agents, moxifloxacin (Avelox)]); leukopenia, neutropenia, and agranulocytosis; hyperprolactinemia; disruption of body temperature regulation; dysphagia; seizures; potential for cognitive and motor impairment (patients should be cautioned about engaging in activities requiring mental alertness); suicide (risk is inherent in psychiatric illness); exposure is markedly increased in patients with severe hepatic impairment and use is not recommended in these patients; is a substrate for CYP1A2 and concurrent use with fluvoxamine (Luvox), a CYP1A2 inhibitor, should be closely monitored; may increase the action of central nervous system depressants and certain antihypertensive medications.

Most common adverse events:
Patients with schizophrenia: somnolence (13%), akathisia (6%), oral hypoesthesia (5%); Patients with bipolar disorder: somnolence (24%), dizziness (11%), extrapyramidal symptoms (excluding akathisia – 7%); increased weight (5%).

Usual dosage:
Administered sublingually; tablet should be placed under the tongue and left to dissolve completely; tablet will dissolve in saliva within seconds; patients should avoid eating and drinking for 10 minutes after administration; in patients with schizophrenia, the recommended starting and target dose is 5 mg twice a day; in patients with bipolar disorder, the recommended starting and target dose is 10 mg twice a day; the dosage may be decreased to 5 mg twice a day if there are adverse events; although a labeled indication for maintenance treatment has not yet been approved, treatment in patients who respond well to treatment may be continued beyond the acute response.

Product:
Sublingual tablets: 5 mg, 10 mg.

Comments:
Asenapine is an atypical antipsychotic agent that is classified as a dibenzo-oxepino pyrrole. Its properties are most similar to those of olanzapine, quetiapine (Seroquel),

savings by reducing inadequate care, errors, and drug-related problems that currently cost billions of dollars a year to address.

7. Efficiencies and areas for cost containment must be identified. This is an extremely difficult challenge that will necessitate the determination of the roles and the extent of the influence and profits that are appropriate for the entities that are not the direct and personal providers of health care (e.g., government, insurance companies, pharmaceutical companies).

8. Fraud must not be tolerated. One of the travesties of the recent discussions of "reform" is the observation that billions of dollars are wasted each year as a result of fraud and abuse in the system, and that seemingly we need comprehensive health care reform before we can address this situation. If enough is known about the fraud to determine that billions are being lost, there should be enough information to take action now to stop those who are perpetrating the fraud.

9. Discussions, decisions, and actions must be transparent and receptive to consideration of diverse recommendations and opinions.

10. Bipartisan legislative support must be attained.

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

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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

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New Drug Review (cont.)

and clozapine (e.g., Clozaril). Other atypical antipsychotic agents include aripiprazole (Abilify), risperidone (e.g., Risperdal), paliperidone (Invega), and ziprasidone (Geodon). The efficacy of these agents is thought to be mediated through a combination of antagonist activity at dopamine type 2 (D2) receptors and serotonin type 2 (5-HT2) receptors. The effectiveness of asenapine in the treatment of schizophrenia was evaluated in three six-week studies in which placebo and active controls were used. In two of the three studies asenapine demonstrated superior efficacy to placebo. However, in the third study, asenapine could not be distinguished from placebo, whereas a statistically significant difference was observed with olanzapine, the active control, although the study was not designed to directly compare the new drug with an active control. In a 52-week study, the effectiveness of asenapine was generally similar to that of olanzapine.

The effectiveness of asenapine in the treatment of bipolar disorder was evaluated in two three-week studies in which placebo and an active control (olanzapine) were used. In one study both asenapine and olanzapine exhibited significantly greater response and remission rates compared with placebo. In the other study, the response and remission rates with asenapine were higher than those with placebo but were not considered to be significantly different, whereas the response and remission rates with olanzapine were superior to those with placebo.

In the studies in which olanzapine was used as an active control, asenapine was less likely to cause dry mouth and weight gain, but more likely to cause dizziness, nausea, akathisia, and oral hypoesthesia. In the 52-week study with asenapine, 15% of patients experienced at least a 7% increase in body weight. The effects of asenapine on the QT interval were evaluated with the use of doses up to twice the recommended dosage. The drug was associated with increases in the QTc interval ranging from 2 to 5 msec compared to placebo, but no patients experienced a QTc as high as 500 msec.

If it is administered in a conventional tablet formulation that is swallowed, the bioavailability of asenapine is very low (less than 2%). However, when administered sublingually, the bioavailability of a dose of 5 mg is 35%. Water or food may reduce asenapine exposure, and eating or drinking should be avoided for 10 minutes after administration.

Daniel A. Hussar