The Pharmacist Activist

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Editorial

HEALTH INSURANCE Threatens the Quality of Health Care!

Much of the rhetoric of the political debates and campaigning has pertained to health insurance. That many millions of Americans do not have health insurance is a common refrain. However, through ignorance or oversight, the political candidates appear to be equating health insurance with health care. These two concepts must not be confused or blended. Indeed, there are reasons to conclude that health insurance threatens the quality of health care for much of our society.

Pharmacists, physicians, and other health professionals must accept some of the blame for the problems encountered with health insurance programs and the impact they have on the scope and quality of health care. Early on we did not have enough vision to anticipate the problems evident now in many of the health insurance programs and we defaulted on opportunities to insist on being active participants in determining the terms of these programs in a manner that would not only protect, but also enhance, the quality of health care services provided to patients in these programs. We have now reached the point at which health professionals have no or little influence on the terms of health insurance programs, and we and/or our professional associations would be at risk of violating antitrust laws if we attempt to work together in challenging these programs.

An opinion column titled, "The Health Insurance Mafia," was published in a recent issue of *The Wall Street Journal* (April 14, 2008; page A15). Written by Jonathan Kellerman, clinical professor of pediatrics and psychology at the Keck School of Medicine at the University of Southern California, the column includes many cogent observations and perspectives...

Dr. Kellerman notes:

> "...any middleman interposed between seller and buyer raises the price of a given service or product. Some intermediaries justify this by providing benefits, such as salesmanship, advertising or transport. Others offer physical facilities, such as warehouses. A third group, organized crime, utilizes fear and intimidation to muscle its way into the provider-consumer chain, raking in hefty profits and bloating costs, without providing any benefit at all."

He goes on to make the following observations:

> "The health insurance model is closest to the parasitic relationship imposed by the Mafia and the like. Insurance companies provide nothing other than an ambiguous, shifty notion of 'protection.'"
>
> "When insurance companies insinuate themselves into the system, their first step is

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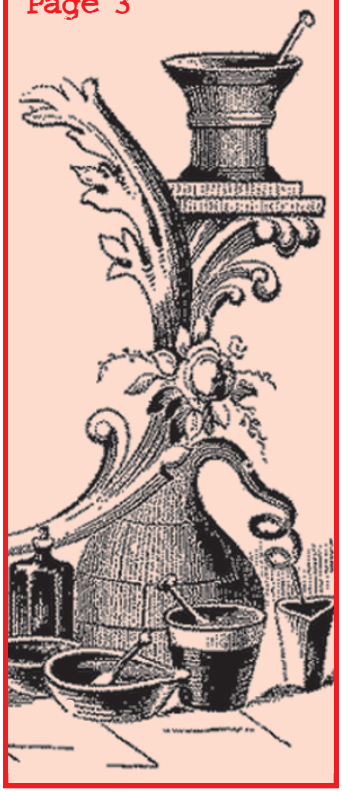

figuring out how to increase the skim by harming the people they are allegedly protecting through reduced service."

"There will be progressively draconian rationing using denial of authorization and steadily rising co-payments on the patient end; massive paperwork and other bureaucratic hurdles, and steadily diminishing fee recovery on the doctor end."

Although Dr. Kellerman's column addresses the influence of health insurance programs on physicians, pharmacists will also quickly relate to his perspectives. In considering the terms and restrictions that are characteristic of current health insurance programs, the most basic of questions must be asked: "Is there anything that health insurance programs do that contributes to the quality of health care for individual patients?" Many would quickly respond to this question with a resounding "No," and follow this response by identifying the ways in which these programs actually reduce the quality of health care. Even when some would contend that the purpose of insurance is to provide protection against expenses that many would not be able to afford, this must be accomplished without compromising the quality of health care.

The second very important issue regarding health insurance programs is their huge cost, totaling many billions of dollars a year without even counting the reimbursement for the product costs of prescription medications. This issue is of such concern that many employers are reducing health care benefits, and candidates for President and other political offices give it a high priority but, regrettably, offer "solutions" that will most likely exacerbate the current problems and introduce additional costs.

Almost all would agree that our society has a responsibility to help individuals with serious financial need and/or who incur extraordinary costs for needed health care. However, the current (and continually growing) problems associated with health insurance programs mandate that we address the following questions: Can we justify the continuation of costly insurance programs that may compromise the quality of health care for patients? What could be accomplished to improve the quality of health care if a large fraction of the money currently spent on health insurance programs could be committed to the provision of health care?

Actions for pharmacists

The issues associated with health care and health insurance programs are so numerous and complex that few, if any, have the ability, willingness, and/or political courage to address them. However, we must not be inactive and risk a further worsening of these problems! At the least, pharmacists and our professional associations must be aggressive in addressing the part of the health insurance programs that has the greatest impact on our profession, namely the prescription drug benefit programs. We are already well aware of the formidable challenges in making changes in these programs that represent just one part of the comprehensive health insurance programs (see also the editorial in the March 2008 issue of *The Pharmacist Activist*). There are actions that should be taken now.

1. Pharmacists should decline to participate in programs that threaten the quality of health/pharmaceutical care for patients and/or for which pharmacists are not provided equitable compensation.

2. Pharmacists must obtain relief from the antitrust laws that currently preclude their working together or within their professional organizations to negotiate the policies, terms, and restrictions of the prescription programs offered by insurance companies and their agents. The National Community Pharmacists Association is promoting legislative initiatives in this direction but needs much more support and action from the entire profession. Other health professions also face these antitrust challenges and should be engaged in collaborative initiatives to eliminate the existing restrictions.

3. Pharmaceutical companies must be held accountable for establishing more responsible policies for pricing their medications. Their programs for needy patients, many of which are inadequate and/or encumbered with red tape, can not be accepted as justification for the sometimes outrageous prices they charge for medications that bear no relationship to the actual cost of the drug.

4. The profession of pharmacy should identify strategies and alternatives to existing prescription programs that will optimize drug therapy for patients, enhance the professional services of pharmacists, and provide equitable compensation for pharmacists. An early step in this initiative should be to convene a group of individuals who have the expertise and vision with respect to health care and benefit programs, as well as a commitment to improve the quality of health care, the use of medications, and the services provided by pharmacists.

5. With the collaboration of selected employers, employee groups, and/or unions, the profession of pharmacy should establish pilot programs in which the strategies and alternatives to existing prescription programs may be evaluated.

Daniel A. Hussar

New Drug Review

Desvenlafaxine succinate (Pristiq – Wyeth)

Antidepressant

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 patients with major depressive disorder.

Comparable drugs:

Venlafaxine extended-release capsules (Effexor XR).

Advantages:

- Dosage titration usually not necessary;
- Less risk of interactions with CYP2D6 inducers or inhibitors;
- Dosage reduction is not necessary in patients with hepatic impairment.

Disadvantages:

- Has not been directly compared with venlafaxine in clinical studies;
- Fewer labeled indications (venlafaxine extended-release also has indications for generalized anxiety disorder, panic disorder, and social anxiety disorder).

Most important risks/adverse events:

Risk of suicidal thinking and behavior in children, adolescents, and young adults (boxed warning [is not indicated for use in pediatric patients]); serotonin syndrome (risk is greater in patients who are also treated with other drugs that may affect serotonergic systems [e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), triptans], or drugs that impair metabolism of serotonin [monoamine oxidase inhibitors (MAOIs)]); activation of mania/hypomania; seizures; hyponatremia; interstitial lung disease and eosinophilic pneumonia; elevated blood pressure (pre-existing hypertension should be controlled before initiating treatment; blood pressure should be regularly monitored); elevated cholesterol and triglyceride concentrations; mydriasis (patients with increased intraocular pressure should be monitored); bleeding events (e.g., ecchymosis, epistaxis; risk is increased by the concurrent use of anticoagulants, aspirin, and nonsteroidal anti-inflammatory drugs); Pregnancy Category C (risk of complications has been reported to be increased if used during the third trimester); contraindicated in patients being treated with an MAOI or within 14 days of discontinuing treatment with an MAOI; treatment with an MAOI should not be initiated for at least 7 days following discontinuation of desvenlafaxine; caution should be exercised when used concurrently with other central nervous system-active drugs; patients should be advised to avoid consuming alcoholic beverages; action may be increased by the concurrent use of a potent CYP3A4 inhibitor (e.g., clarithromycin [e.g., Biaxin]); concurrent use with tryptophan supplements should be avoided.

Most common adverse events:

Nausea (22%), dizziness (13%), dry mouth (11%), hyperhidrosis (10%), constipation (9%), insomnia (9%), fatigue (7%), decreased appetite (5%), somnolence (4%), male sexual function disorders (e.g., decreased libido; 4%).

Usual dosage:

50 mg once a day; patients should be advised that the tablets should be swallowed whole and that the tablet should not be divided, crushed, chewed, or dissolved; patients should also be informed that they may observe the inert matrix tablet in the stool but that the active medication has already been absorbed; a dosage higher than 100 mg once a day should not be exceeded in patients with hepatic impairment; a dosage of 50 mg once a day is recommended in patients with moderate renal impairment, and a dosage of 50 mg every other day is recommended in patients with severe renal impairment (creatinine clearance less than 30 mL/minute); when treatment is to be discontinued, the dosage should be gradually reduced by administering 50 mg of the drug less frequently rather than abruptly stopping therapy.

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New Drug Review (cont.)

Product:

Extended-release tablets – 50 mg, 100 mg.

Comments:

Desvenlafaxine is the major active metabolite of venlafaxine that is pharmacologically approximately equiactive and equipotent to its parent compound. Like venlafaxine, as well as duloxetine (Cymbalta), desvenlafaxine is a serotonin and norepinephrine reuptake inhibitor. The effectiveness of desvenlafaxine in the treatment of patients with major depressive disorder has been demonstrated in four 8-week, placebo-controlled studies in adult patients. However, it has not been directly compared with venlafaxine in clinical studies and there is no reason to consider it to be more effective than venlafaxine. Venlafaxine also has labeled indications for the treatment of generalized anxiety, social anxiety, and panic disorders, and duloxetine also has labeled indications for generalized anxiety disorder and pain associated with diabetic peripheral neuropathy. However, these are not labeled indications for desvenlafaxine at the present time, although the new agent is being studied for the treatment of other conditions.

The drug-related problems associated with the use of desvenlafaxine are generally similar to those for venlafaxine and duloxetine, as well as the selective serotonin reuptake inhibitors (SSRIs; e.g., fluoxetine [e.g., Prozac]). The labeling for each of these agents includes a boxed warning regarding an increased risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24). Like venlafaxine, desvenlafaxine may increase blood pressure and pre-existing hypertension should be controlled before initiating treatment. The CYP2D6 metabolic pathway is the most important pathway through which venlafaxine is converted to desvenlafaxine. However, this pathway is not involved in the metabolism of desvenlafaxine and it is not likely to interact with other medications that are inhibitors or inducers of the CYP2D6 pathway.

Like venlafaxine extended-release capsules (Effexor XR), desvenlafaxine extended-release tablets are administered once a day. The recommended dosage is 50 mg once a day. Although dosages as high as 400 mg a day have been effective, no additional clinical benefit has been demonstrated with dosages higher than 50 mg a day.

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