The Pharmacist Activist

Volume 5, No. 9 • September 2010

Editorial

# CARE is Missing in Health Insurance Reform!

## Independent Pharmacists are Well Positioned to Provide It!

My greatest concern regarding the health care reform legislation that has been passed is that I expect that the quality of the health care provided for individual patients is being jeopardized. It would be more accurate to identify the legislation as health insurance reform rather than health care reform. During the extensive debate and publicity regarding this legislation, does anyone recall discussion that addressed the quality of the health care to be provided? Yes, we will be able to say that millions of Americans who did not previously have health insurance will now have it, and that the expanded use of sophisticated technology will provide certain advantages. However, the proponents of this legislation have also claimed that the overall cost of health care will be reduced. How will it be possible to reduce costs when health care will be provided to millions more patients and other costly changes will be implemented?

Some will respond that waste and fraud in the health care system has a cost of billions of dollars a year and that this will be eliminated. Fraud and waste must not be tolerated and this is certainly a laudable goal. But if fraud and waste are recognized to the point that we can estimate their cost, why is not more being done already to eliminate them? We did not need legislation to take action! And can we be any more confident that the passage of legislation will result in more effective reduction of fraud and waste than the current system (or non-system) that is in place now?

Some have suggested that a reduction in fees for physicians and pharmacists will result in savings in the provision of health care. In recent years the Congress has been playing games with a reduction in physician fees for providing services to patients in the Medicare program. Although physicians have been in strong opposition, a substantial cut in fees was to have been implemented earlier this year. However, the legislators delayed action on this fee cut, and will not consider this matter again until after the election. This delay does nothing more than demonstrate the cowardice of the Congress in failing to address an issue because of its political implications.

At the same time the politicians seem to think that reducing fees for health professionals will reduce the cost of health care, they enable insurance companies, pharmacy benefit managers (PBMs), and government agencies to dictate the conditions and compensation offered to health professionals on a take it or leave it basis. They permit this, as one example, by refusing to approve legislation that will allow pharmacists to work together in negotiating the terms of prescription benefit programs. As a consequence, health professionals and, therefore, patients are at the mercy of insurance companies and PBMs whose highest priority is profit, and also legislators, many of whom do not have expertise regarding health care and/or the courage to make the best decisions.

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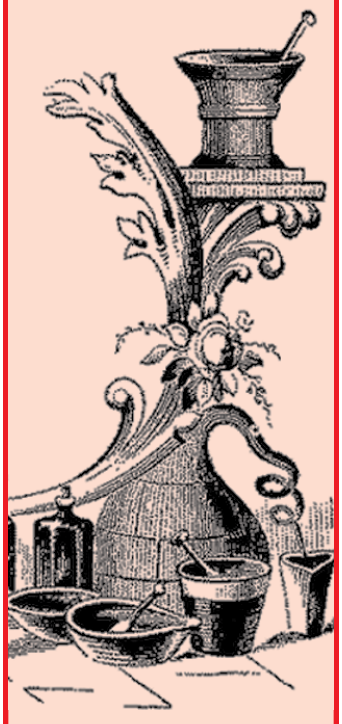

The health care system(s) that have been in place over the years have serious flaws, and health professionals must accept our significant share of the responsibility for our failure to develop a higher-quality and more financially responsible system. However, we are now moving toward the other extreme in which the scope and quality of health care for individual patients may be significantly compromised. As much as pharmacists and our organizations have been encouraged by the inclusion of medication therapy management (MTM) in the legislation, I am concerned that our focus has been too narrow and that there has not been sufficient attention to important questions such as who will be providing MTM (i.e., pharmacists, PBMs, other health professionals?) and how will such initiatives be funded?

## Where is the care?

Even at the present time some health benefit programs are requiring physicians to see more patients and are requiring patients to obtain prescriptions from mail-order pharmacies. These situations, combined with patients waiting in lines at many understaffed local pharmacies, result in a significant reduction in the amount of time committed to face-to-face discussion between patients with their physicians and pharmacists. To this point the consideration of the "reform" of health care has essentially been limited to insurance, economics, and politics. In my opinion, the reforms that have been proposed will result in the further reduction of communication with and care for patients.

We are very familiar with the remarkable, and even life-saving, benefits that can be attained with the appropriate use of medications. We are also well aware that drug-related problems occur very often - problems such as prescribing and dispensing errors, adverse events, drug interactions, and patient noncompliance. Most of these drug-related problems are preventable! So why do they still occur so frequently?

I would contend that most preventable drug-related problems could be avoided if physicians and pharmacists would spend more time in face-to-face discussions with their patients. This would provide greater opportunity for discussing important information about the patient's illness and medications, and encouraging the patient to ask questions. Also extremely important, but far too often overlooked, is the recognition by the patient of the care that physicians and pharmacists have demonstrated in these discussions. This reflects a personal touch, the value of which can not be overstated. I am convinced that patients who experience caring on the part of their health professionals, and also understand the reasons for which their medications have been prescribed as well as their appropriate use, will be much more compliant in using their medications and more alert to symptoms or other warning signs that will enable early identification and prevention of potential drug-related problems. Drug-related problems can be, and must be, greatly reduced. Numerous patients can be spared the harmful, and even fatal, consequences of such problems and, in addition, the substantial reduction in the cost to manage drug-related problems will be of great value in balancing the increased financial commitment necessary to support the additional time being devoted to patient care by physicians and pharmacists.

## Which pharmacists will provide the care?

I consider the demonstration of care, and the commitment and information that accompany it, to be the most important responsibility that pharmacists must fulfill if our role as health professionals is to be strengthened, better recognized, and financially supported. But which pharmacists have the personal commitment and are best positioned to provide this care, as well as their expertise?

Hospital pharmacists? Many progressive advances in health care and the practice of pharmacy have been initiated by hospital pharmacists. However, many pharmacists in the hospital setting have limited, if any, direct communication with patients. In addition, at any given time, the number of patients receiving the benefits of the services of hospital pharmacists is only a very small fraction of the population.

Mail-order pharmacists? Although pharmacists practicing in the mail-order setting may be very capable, their employers have made a decision that face-to-face discussion of a pharmacist with a patient does not have value and is not necessary. It is essentially impossible for a mail-order pharmacist to demonstrate personal care for a patient.

Chain pharmacists? There are many capable and caring pharmacists who practice in the chain pharmacy setting, and there are some chain pharmacies that value and promote the professional role of their pharmacists. However, the executives of most chain pharmacies, including the largest ones, focus only on money, profit, and stock value, and do not care about the profession of pharmacy or the health of their customers. It is extremely difficult, if not impossible, for even the most dedicated chain pharmacist, to counsel patients and demonstrate caring in an understaffed pharmacy with long lines of patients waiting for prescriptions that company policy promises within 15 minutes.

Independent pharmacists? Many independent pharmacists are highly respected by their patients and communities because of their caring for those they serve and the scope and quality of their services. There are also some independent pharmacists who do not demonstrate this commitment. However, it is the independent pharmacists who are primarily responsible for the high level of respect and trust accorded the profession of pharmacy by the public. All pharmacists benefit as a result of how well they represent our profession. Independent pharmacists are in the best position to provide caring and services for a very large number of patients, and our entire profession should support them.

*(Continued on Page 4)*

# New Drug Review

## Dienogest/estradiol valerate (Natazia – Bayer)

*Contraceptive*

**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:

For use by women to prevent pregnancy; efficacy in women with a mass body index (BMI) of greater than 30 kg/m$^2$ has not been evaluated.

### Comparable drugs:

Combination hormonal oral contraceptives (e.g., drospirenone/ethinyl estradiol [Yaz]).

### Advantages:

- Four-phase dosage regimen may reduce the occurrence of breakthrough bleeding;
- Does not cause hyperkalemia (compared with the drospirenone component of Yaz).

### Disadvantages:

- Labeled indication is more limited (i.e., efficacy has not been evaluated in women with a BMI greater than 30 kg/m$^2$);
- Has fewer labeled indications (e.g., compared with drospirenone/ethinyl estradiol that is also indicated for the treatment of symptoms of premenstrual dysphoric disorder [PMDD] and the treatment of acne vulgaris);
- May interact with more medications;
- Backup nonhormonal contraception should be used during the first 9 days of use.

### Most important risks/adverse events:

Thrombotic and other vascular events, and use is contraindicated in women who have deep vein thrombosis or pulmonary embolism, cerebrovascular disease, coronary artery disease, thrombogenic valvular or thrombogenic rhythm diseases of the heart, inherited or acquired hypercoagulopathies, uncontrolled hypertension, diabetes with vascular disease, headaches with focal neurological symptoms, or migraine headaches if over age 35; also contraindicated in women over age 35 who smoke (boxed warning); contraindicated in women with undiagnosed abnormal genital bleeding, breast cancer or other estrogen - or progestin-sensitive cancer, liver tumors or liver disease, or who are pregnant (Pregnancy Category X); action may be reduced by the concurrent use of CYP3A4 inducers (women taking a strong CYP3A4 inducer [e.g., carbamazepine, phenytoin, St. John's wort] should not use dienogest/ estradiol valerate as their contraceptive or for at least 28 days following the discontinuation of the inducer; women who are using a moderate or weak inducer should use an alternative method of contraception or a back-up method to the oral contraceptive); women receiving thyroid hormone replacement therapy may require increased doses of thyroid hormone; may decrease plasma concentrations and activity of lamotrigine (e.g., Lamictal).

### Most common adverse events:

Headache (13%), metorrhagia and irregular menstruation (8%), breast pain, discomfort, or tenderness (7%), nausea or vomiting (7%), acne (4%), increased weight (3%).

### Usual dosage:

One tablet once a day in the following sequence:

- 2 dark-yellow tablets each containing 3 mg estradiol valerate;
- 5 medium-red tablets each containing 2 mg estradiol valerate and 2 mg dienogest;
- 17 light-yellow tablets each containing 2 mg estradiol valerate and 3 mg dienogest;
- 2 dark-red tablets each containing 1 mg estradiol valerate;
- 2 white tablets (inert).

Use should be started on day 1 of the menstrual cycle (i.e., the first day of menstrual bleeding); one tablet should be taken at the same time every day; a nonhormonal contraceptive should be used as backup during the first 9 days of use; if severe vomiting or diarrhea is experienced, additional contraceptive measures should be used; if vomiting or diarrhea occurs within 4 hours after taking a colored tablet, this should be considered as a missed tablet.

### Product:

Blister pack containing 28 tablets to be used in the potencies and sequence identified above.

## Challenges and opportunities

It has become increasingly difficult to own an independent pharmacy. There are numerous challenges such as prescription benefit programs that include mandates or incentives for patients to use a mail-order pharmacy, and restrictions that limit the participation of local pharmacies. However, many independent pharmacists have responded to the challenges in a manner that has enabled them to continue to be professionally and financially successful. But much more needs to be done to increase the number and influence of these pharmacists. We should start by increasing the awareness of pharmacy students and young pharmacists of the opportunities for owning their own pharmacy. Colleges of pharmacy, pharmacy associations, and wholesalers have important roles in providing encouragement, expertise, and financial planning to support those having this interest.

The profession is currently experiencing a significant tightening in the job market. Chain pharmacies have been the largest employer of pharmacists in recent years but they now have a much smaller number of positions available. If positions are not available with the traditional employers of pharmacists, more pharmacy graduates will seriously consider owning their own pharmacy. An increasing number of chain pharmacists who have become disillusioned as a result of a stressful work environment and inadequate staffing will consider starting their own pharmacy. I am convinced that a pharmacist who cares for and effectively serves her/his patients and community can open a pharmacy right next door to most chain pharmacies and have a well-respected and successful practice.

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# New Drug Review (cont.)

## Comments:

Dienogest is a new progestin that also exhibits antiandrogenic activity that is similar to that of drospirenone. However, unlike drospirenone, dienogest does not cause hyperkalemia. The new combination oral contraceptive formulation is the first to use estradiol valerate as the estrogen component (most use ethinyl estradiol), although estradiol valerate has been used alone in other formulations for other indications. Estradiol valerate is a prodrug that is converted during absorption and its first pass through the liver to 17-beta estradiol, an endogenous estrogen that is biotransformed to estradiol and subsequently to other metabolites (e.g., estrone).

The dienogest/estradiol valerate product is the first combination oral contraceptive to be used in a four-phase dosage regimen, in which the dosage of the estrogen is decreased and the dosage of the progestin is increased during the cycle in an effort to avoid breakthrough bleeding. The new product is highly effective in preventing pregnancy but no data suggest that it is more or less effective than comparable products.

The contraindications and precautions associated with the use of dienogest/estradiol valerate are generally similar to those for the other combination oral contraceptives. Both dienogest and estradiol valerate are extensively metabolized via the CYP3A4 pathway and their action may be decreased or increased by the concurrent use of other agents that induce or inhibit, respectively, this metabolic pathway. It is recommended that women who are using a strong CYP3A4 inducer (e.g., carbamazepine, phenytoin, rifampin, St. John's wort) not use dienogest/estradiol valerate as their contraceptive while using these inducers and for at least 28 days following the discontinuation of the inducer. This represents a stronger restriction to such concurrent use than is provided with other combination oral contraceptives.

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