The Pharmacist Activist

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Editorial

Save the Independent PHARMACISTS!

Editor's note: This commentary begins with a reprise of an editorial that I wrote almost 10 years ago (*Pharmacy Today*, June 1998). I have not run out of important topics that I have not yet considered. However, I consider this to be a topic that our profession must urgently and effectively address.

1998

I grew up in a Philadelphia neighborhood that had seven independent pharmacies and seven independent grocery stores within a mile of my home. Now there are none. The grocery stores closed first, as supermarket chains came into the area. And, one by one, for a variety of reasons, the independent pharmacies also closed.

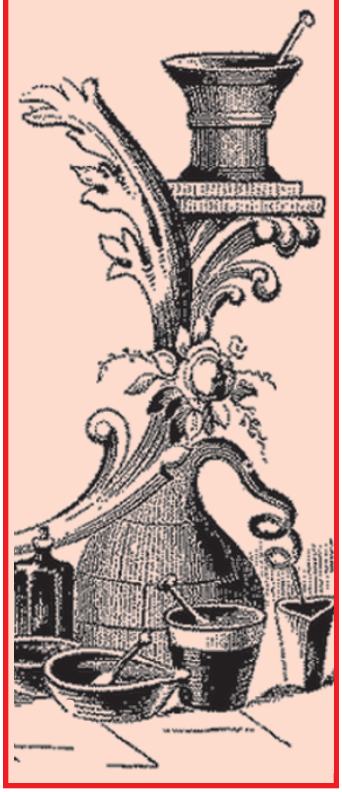
An endangered species?

This editorial is not intended to predict the disappearance of independent pharmacies. Indeed, many have not only survived, they have thrived in the face of the many changes that have occurred in healthcare and the business community in recent years. However, the number of independent pharmacies has unquestionably decreased markedly, and the rate at which they have closed or been sold to chain pharmacies within the past two years is unprecedented. Given this rapid decline in numbers, independent pharmacies should qualify as an "endangered species."

The concept of endangered species and programs such as "Save the Whales" are familiar to us because of concerns that certain animals and birds will become extinct if steps are not taken to protect them. Actions to save the whales, and even the snail darters, are noble purposes worthy of people's attention. But I find it ironic that our society has essentially been silent regarding the risk of the disappearance of many small businesses, including independent pharmacies. It is no exaggeration to suggest that the vitality of a community may be severely compromised by the closing of independent pharmacies and other small businesses. In many cities, as well as smaller towns, boarded-up buildings now stand where once were thriving business communities.

Some say that the increase in the number of chain pharmacies compensates for the loss of these independent pharmacies. But they are not the same. Independent pharmacy owners make personal, financial, and long-term investments in the community and usually reside there, often assuming leadership responsibilities and becoming well known and highly respected. As dedicated as chain pharmacists may be, they rarely have a personal financial investment in the community. And they often experience working conditions that preclude substantive

Contents



discussions with individual patients, are subject to transfer to other pharmacies within the chain, and are more likely to accept a position with another employer.

Why are independents at risk?

Plenty of blame for the closing of independent pharmacies can be spread around, but let's start with ourselves:

- Too satisfied with the status quo, many independent pharmacists have been unwilling to update themselves and their pharmacies to stay competitive in a changing healthcare and business environment.
- Pharmacists are not making their patients aware of the challenges being faced and are not providing patients with the information they need to recognize that these issues affect the quality of their own healthcare.
- Pharmacy schools and associations have not done enough to prepare students and pharmacists to respond to the changes, problems, and opportunities they encounter.
- Some chains have been predatory in intimidating independent pharmacy owners to sell immediately, indicating that the independents are unlikely to survive and that no one will buy their pharmacies later.
- Some pharmaceutical companies have pricing policies that are unfair to community pharmacies, and they have opposed legislation that would expand pharmacists' practice responsibilities and increase the value of their services.
- The programs of some insurance and managed care organizations exclude the participation of certain pharmacies, or permit participation only if the patient assumes added costs. The "take it or leave it" reimbursement programs dictated by many of them present a dilemma for pharmacists: they cannot afford to participate under such programs' financial terms, but they also cannot afford to decline to participate in programs to which many of their patients belong.
- Legislators and government agencies permit the continuance of outdated laws and systems that allow other entities to dictate levels of pharmacist reimbursement and stop pharmacists from collectively negotiating the terms of such programs. Isn't the Small Business Administration supposed to advocate for and protect the interests of small businesses?
- Our patients are not protecting their freedom to choose a pharmacy and other healthcare providers, and they are not doing enough to be advocates for the independent pharmacies in their communities.

Is it too late? No! But we must act quickly and aggressively to address these issues. Save the independent pharmacists!

2007

How much have the challenges for independent pharmacists changed since 1998? The problems have not changed and my 1998 editorial could be written almost verbatim today and supplemented with current examples of challenges such as the Medicare prescription program and AMP. However, if there was a need to act quickly and aggressively in 1998, the highest level of urgency exists now. Although the number of independent pharmacies in the country remained fairly constant over a period of several years and even increased slightly in 2005, the number declined by 1,152 (a reduction of approximately 5%) in 2006. Many of these closures were attributable to the problems associated with the Medicare prescription program.

For many pharmacists, including myself, who do not practice in an independent pharmacy, it is easy to become preoccupied with the issues pertaining to our own areas of professional responsibility and to be unaware and uninvolved in issues that do not directly affect our personal responsibilities. However, I would contend that threats to the survival of the independent practice of pharmacy have major implications for the entire profession of pharmacy and each of us as individual pharmacists.

The identity of pharmacists with the public and the respect the public has for the profession of pharmacy result primarily from their interaction with independent pharmacists. The extent to which legislators are aware of the issues facing the profession of pharmacy and are supportive of our concerns is highly dependent on their discussions with independent pharmacists. For many years pharmacists have ranked at or near the top in opinion surveys of the public with respect to the integrity and ethics of those in a large number of professions/vocations. Although I consider myself to be very active within the profession of pharmacy, I must acknowledge that my employment and other pharmacy responsibilities are essentially invisible to the public (as are the responsibilities and practices of many other pharmacists). Therefore, the benefit that I derive from being a member of a profession that enjoys such a positive reputation is a result of the favorable interaction with the pharmacists whom the public personally meets. The least I can do to demonstrate my appreciation for this is to be active in efforts that support and advance the independent practice of pharmacy. I haven't done enough. Have you?

There are some reasons for encouragement such as the involvement of a growing number of pharmacists in medication therapy management. However, the implementation of such initiatives must move more quickly and involve a much larger number of pharmacists.

In my opinion, the recognition and respect for pharmacy as a health profession and the opportunities for our profession to advance are inextricably linked to the extent that independent community pharmacy practice not only survives, but thrives. Is it too late? No! But moral and verbal support is not enough. Participation and action are urgently needed! If we do not know them already, we should get to know the independent pharmacists in our communities and ask how we can support them in their efforts. If we are not members of the professional associations such as the National Community Pharmacists Association that are advocates for independent pharmacists, we should take steps to learn about and take action on the issues that they identify as threatening to these practices. We should meet or otherwise communicate with our legislators to urge their support in addressing the concerns we have identified. We should participate in activities (e.g., column or letter in a local newspaper) to better inform the public regarding the professional roles of pharmacists and the challenges being faced.

Save the independent pharmacists!

Daniel A. Hussar

New Drug Review

Maraviroc
(Selzentry – Pfizer)
Antiviral Agent

New Drug Comparison Rating (NDCR) = 4
(significant advantages) in a scale of 1 to 5, with 5 being the highest rating

Indications:
In combination with other antiretroviral agents, for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.

Most important risks/adverse events:
Hepatotoxicity (boxed warning), which may be preceded by evidence of a systemic allergic reaction (e.g., pruritic rash); caution should be exercised in patients with pre-existing liver dysfunction or who are co-infected with viral hepatitis B or C; immune reconstitution syndrome; increased risk of infection; use with caution in patients at increased risk for cardiovascular events; risk of adverse events is increased in patients with impaired renal function; is a substrate for CYP3A and concentration may be increased by the concurrent use of CYP3A inhibitors such as HIV protease inhibitors (except tipranavir/ritonavir), delavirdine (Rescriptor), clarithromycin (e.g., Biaxin), telithromycin (Ketek), and itraconazole (e.g., Sporanox); concentration may be decreased by the concurrent use of CYP3A inducers such as efavirenz (Sustiva), rifampin (e.g., Rifadin), carbamazepine (e.g., Tegretol), and phenytoin (e.g., Dilantin); should not be used concurrently with St. John's wort.

Most common adverse events:
Upper respiratory tract infection (20%), cough (13%), pyrexia (12%), rash (10%), musculoskeletal symptoms (9%), abdominal pain (8%), dizziness (8%).

Usual dosage:
300 mg twice a day; dosage of 150 mg twice a day is recommended in patients also being treated with a CYP3A inhibitor (with or without a CYP3A inducer); dosage of 600 mg twice a day is recommended in patients also being treated with a CYP3A inducer (without a strong CYP3A inhibitor).

Products:
Tablets – 150 mg, 300 mg.

Comparable drug:
Enfuvirtide (Fuzeon).

Advantages:
- Has a unique mechanism of action (inhibits entry of CCR5-tropic HIV-1 into cells);
- Is effective in some patients who have become resistant to previous regimens;
- Is administered orally (enfuvirtide is administered subcutaneously).

Disadvantages:
- Does not inhibit the entry of CXCR4-tropic and dual tropic HIV-1 into cells;
- Greater risk of causing hepatic adverse events;
- Interacts with more medications.

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New Drug Review (cont.)

Comments:

Maraviroc (Selzentry – Pfizer) is the twenty-third antiretroviral agent to be marketed for the treatment of HIV infection/AIDS in the United States. With only one exception (enfuvirtide [Fuzeon]), the previously marketed antiretroviral agents inhibit HIV replication within white cells. Enfuvirtide interferes with the entry of HIV into cells by inhibiting fusion of viral and cellular membranes, and is designated as a fusion inhibitor. CCR5 is a chemokine receptor protein that is present on the surface of some immune cells and is the primary route by which HIV-1 enters uninfected cells. Maraviroc has a unique mechanism of action and is classified as a CCR5 co-receptor antagonist. It selectively binds to CCR5 that is necessary for CCR5-tropic HIV-1 to enter cells, thereby inhibiting the entry of the virus into cells. Approximately 60% of patients who have already received antiretroviral medications have circulating CCR5-tropic HIV-1. The new drug does not appear to inhibit cell entry via the other HIV-1 co-receptor CXCR4 or dual-entry-tropic HIV-1.

Maraviroc is specifically indicated for use, in combination with other antiretroviral agents, in treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. Its effectiveness in reducing HIV-1 RNA concentrations was demonstrated in two controlled studies in patients who had already been treated with three classes of antiretroviral agents who had evidence of HIV-1 replication despite ongoing treatment. Patients received either maraviroc or placebo in addition to an optimized background regimen consisting of three to six antiretroviral agents. The action of maraviroc is additive/synergistic with enfuvirtide. Maraviroc has been reported to be as effective as efavirenz when these agents were used in combination with lamivudine (Epivir) and zidovudine (e.g., Retrovir) in treatment-naïve patients. However, this is not a labeled indication at the present time. The identification of patients for whom maraviroc treatment is appropriate should be guided by tropism testing (i.e., Trofile HIV coreceptor tropism assay).

The most important concern with the use of maraviroc is the risk of hepatotoxicity, and the occurrence of hepatic adverse events may be preceded by a systemic allergic response (e.g., pruritic rash). Patients who experience symptoms of hepatitis or an allergic reaction should be evaluated immediately. Patients in the clinical studies who received maraviroc had a higher incidence of cardiovascular events (1.3%), and the drug should be used with caution in patients at increased risk of such events. Maraviroc is a substrate for CYP3A and its concentration and action may be increased by the concurrent use of CYP3A inhibitors, and decreased by the concurrent use of CYP3A inducers. Because many of the antiretroviral agents that will be used in combination regimens with maraviroc alter CYP3A activity, the guidelines for concurrent use and the dosage regimens identified in the product labeling should be closely observed.

Maraviroc is administered twice a day without regard to food. Its unique mechanism of action makes it a valuable addition to the group of antiretroviral agents, and it offers the hope for effective treatment in patients who have become resistant to previous regimens.

Daniel A. Hussar