The Pharmacist Activist

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Editorial

A NEW YEAR, an OLD THEME

Pharmacy Must Have a More Effective National Organizational Structure!

The first part of the title for this editorial is not new. This is the sixth editorial I have written regarding what I consider to be the extremely important need for our profession to have a much more effective organizational structure at all levels, but particularly at the national level. In the January, 1996 editorial, I voiced the opinion:

> "It is essential that we develop an organizational system with the size and strength to effectively address the challenges and threats to our professional roles and responsibilities and the issue of compensation for our services… The ideal would be to have a single national pharmacy organization with the size and strength provided by a large membership base, as well as a network of divisions or academies to provide strong, effective services and representation for each pharmacy practice area."

Fifteen years later, I hold the same opinion. However, I now consider the need for action to be even more urgent! I have received many responses supporting the position I have taken in these editorials. However, for practical purposes, nothing has changed. There has been very little response from the leaders of our national professional organizations who are in the best position to consider progressive changes that would be in the best interest of the profession of pharmacy and extend beyond the interest of the particular association in which he/she has a leadership position. Indeed, the CEO of one of the largest national pharmacy organizations made a point of telling me that his Board evaluates him based on the membership, programs, and success of that organization. That is not surprising but it does raise the question, "Are there any national organizations whose highest priority is to support and advance the profession of pharmacy?" The answer is "No."

The last 15 years

During the last 15 years, many county or other local pharmacy associations have become less active, and some no longer exist. Many state pharmacy associations have experienced reduced membership (even during a time when there has been an increase in the number of pharmacy graduates), as well as a corresponding reduction in programs and services. Can we honestly say that there are more than 10 (more than five?) state pharmacy associations that can be considered to be thriving and that have highly effective professional and legislative influence in their states?

During most of this 15-year period, many of the national pharmacy associations could be considered to be doing well. Membership was growing, or at least stable, and they were providing increased services and programs for their members. Leaders of these associations have been periodically meeting with each other in forums like the Joint Commission of Pharmacy Practitioners (JCPP) that is comprised of 11 national pharmacy organizations, and has articulated a progressive vision for the profession. Important progress has also been made in areas such as pharmacist-provided immunizations and medication therapy management (MTM) services. However, during the last several years most, if not all, of our national associations have encountered financial challenges that have necessitated reductions in staff. Although some would explain this as a consequence of the

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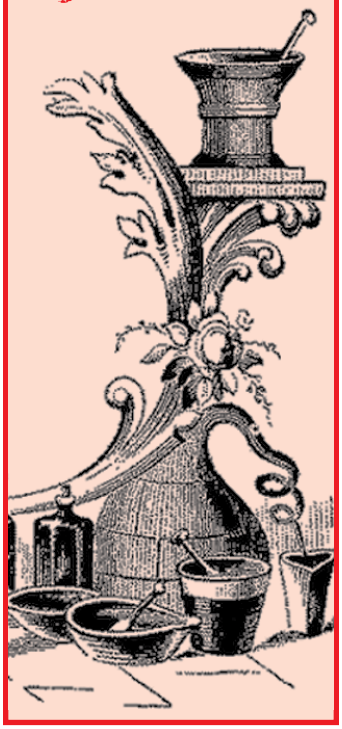

economic problems that are national in scope, I would contend that these economic challenges for our profession and our pharmacy organizations are occurring at the same time that we need our greatest resources and strength.

Many changes have occurred in the provision of health care during the last 15 years. Among these changes is the marked increase in the involvement of physician assistants and nurse practitioners in providing health care services to patients. Notwithstanding the increased patient care services provided by numerous pharmacists, the acceptance and compensation for expanded roles of pharmacists has not advanced to a degree that is even close to the advancement of the roles of physician assistants and nurse practitioners. Indeed, some would suggest that the role of pharmacists in providing patient care is regressing when recognition is taken of the rapid growth in the number of prescriptions dispensed by mail-order pharmacies in which there is no personal interaction of patients with a pharmacist. This is not an issue that only involves ambulatory patients and community pharmacies, as there are many hospitals and long-term care facilities in which there is little or no personal communication between pharmacists and patients.

In my opinion, the failure of our profession to establish a more effective and accepted role for pharmacists as providers of personalized drug therapy expertise and services is in large part due to the lack of an organizational structure that best serves the interest of the entire profession, as well as its individual constituencies. I am not aware of current attempts on the part of our organizations and leadership to address this matter, so I am identifying the following options with the hope that positive discussion and action will result.

National organizational structure options

1. **No changes** – It is my belief that our profession is losing ground at a faster rate than it is gaining ground. Therefore, to make no organizational changes in response to the continuing challenges and opportunities being faced should not be an acceptable option.

2. **Affiliated membership structure** – The American Pharmacists Association (APhA) is the national organization that comes closest to representing pharmacists in all areas of practice/employment. A policy could be established that would require every pharmacist who joins one of the national pharmacy practitioner organizations to also join APhA. Conversely, pharmacists who join APhA would be required to also join the national practitioner organization that best corresponds to her/his responsibilities. Some pharmacists will recall affiliation agreements between national associations, and national associations with state associations, that were in existence some years ago. However, the fact that these arrangements were discontinued should not be reason to conclude that they should not be considered now.

3. **Mergers of organizations** – Every national pharmacy organization can legitimately claim that it provides unique and valuable services for its members. However, the large number of these organizations also has the potential for communicating mixed messages to legislators and others, the effectiveness of which may also be compromised by a limited membership and financial base to support the messages. Although each organization has some unique programs, other activities and initiatives overlap, thereby creating competition for increasingly scarce resources. Some would suggest that our national organizations compete with each other more than they work with each other. Is it necessary for so many of our national associations to have their own Foundations, Political Action Committees, publishing and educational enterprises, etc? It is difficult to escape the conclusion that, at the least, scarce resources are not being used as efficiently as they could be. For these and other reasons, we have reached the point at which mergers of at least some of the national organizations should be considered. The elected leaders of these organizations are the individuals who must have the vision for our profession, as well as for their specific organization, and who must demonstrate the leadership and initiative in pursuing these opportunities.

4. **A new national organization** – The perpetuation of an organizational status quo has been the basis for some to suggest that the profession should start from the beginning and develop what might be considered an "ideal" structure to represent and advance the profession. Such an organization might have a policy-making body with representation from the various areas of practice corresponding to the number of members having a particular responsibility. The structure would include academies, special interest groups, and other groups which members would choose based on practice responsibilities, professional interests, ethnic/cultural background, religious affiliation, etc. Although such a step would add yet another organization to a number that many feel is already too large, the strategy is sufficiently different that it might attract many of the thousands of pharmacists who are not members of even one national organization now.

5. **A national pharmacy union** – The increasing concerns about stressful working conditions for many employee pharmacists has resulted in growing interest in membership in a union of pharmacists. Although some view unions as being involved only with economic issues, they are also in a position to address patient care and professional issues. The pharmacist union leaders whom I know best have as strong a commitment to the care of their patients and to the advancement of our profession as any pharmacist I know.

Our responsibility

Most of this editorial commentary has been directed toward the leaders of our national organizations, individuals who have already committed extensive time and personal resources on behalf of our profession. Their accomplishments and service are very much appreciated. Perhaps it is unfair to ask them to make an even greater commitment, but they are in the best position to promote effective change that our profession greatly needs. At the same time, every pharmacist has a responsibility to participate in and contribute back to the profession that has provided us with excellent opportunities.

Daniel A. Hussar

New Drug Review

Fingolimod hydrochloride (Gilenya – Novartis)

Agent for multiple sclerosis

New Drug Comparison Rating (NDCR) = 4

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

Indication:

Treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Comparable drugs:

Interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron).

Advantages:

- More effective in reducing frequency of relapses (compared with interferon beta-1a);
- Is administered orally (whereas comparable drugs are administered parenterally);
- Labeled indication includes delaying accumulation of physical disability (compared with interferon beta-1b);
- Has a unique mechanism of action;
- Appears less likely to be associated with the occurrence of depression.

Disadvantages:

- More likely to cause cardiovascular adverse events (bradyarrhythmias and atrioventricular blocks);
- Interacts with a greater number of medications;
- More likely to cause ocular adverse events (macular edema).

Most important risks/adverse events:

Bradyarrhythmias and atrioventricular blocks (patients should be observed for six hours after the first dose; risk factors include existing cardiovascular disorders [e.g., congestive heart failure] and use of a beta-blocker, calcium channel blocker, and/or Class Ia or Class III antiarrhythmic agent); infection (treatment should not be initiated in patients with active acute or chronic infections; risk is increased in patients taking other agents that suppress immune function); macular edema (patients with diabetes or a history of uveitis are at increased risk); elevations in liver transaminases; baseline or recent electrocardiogram, ophthalmologic exam, liver function tests, and blood pressure should be evaluated prior to starting treatment and during treatment as clinically indicated; decrease in certain pulmonary function tests (forced expiratory volume over one second [FEV1]); administration of live attenuated vaccines should be avoided during treatment and for two months after stopping treatment; patients who have never had chickenpox or have not been vaccinated against varicella zoster virus (VZV) should be tested for antibodies to VZV (vaccination should be considered for patients who are antibody-negative, prior to initiating treatment with fingolimod); exposure is increased in patients with severe hepatic impairment and treatment must be closely monitored; exposure is increased by the concurrent use of ketoconazole; may cause fetal harm (Pregnancy Category C) and women of childbearing potential should use contraception during and for two months after stopping treatment.

Most common adverse events:

Headache (25%), influenza (13%), back pain (12%), diarrhea (12%), cough (10%), hypertension (5%), liver transaminase (ALT/AST) elevations (14%).

Usual dosage:

0.5 mg once a day; patients should be observed for six hours after the first dose to monitor for bradycardia.

New Drug Review (cont.)

Product:
Capsules – 0.5 mg.

Comments:
Fingolimod is metabolized by sphingosine kinase to its active metabolite, fingolimod phosphate. It is designated as a sphingosine 1-phosphate receptor modulator and binds with high affinity to sphingosine 1-phosphate receptors 1, 3, 4, and 5. Fingolimod phosphate blocks the capacity of lymphocytes to egress from lymph nodes, thereby reducing the number of lymphocytes in peripheral blood that are available for migration into the central nervous system. Its unique mechanism of action and effectiveness following oral administration are advantages over the interferon beta and glatiramer acetate (Copaxone) products that must be administered parenterally.

In a placebo-controlled study, the annualized relapse rates for patients treated with fingolimod and placebo were 0.18 and 0.40, respectively, and the percentages of patients without relapse were 70% and 46%, respectively. In a study in which fingolimod was compared against interferon beta-1a, the annualized relapse rates were 0.16 and 0.33 and the percentages of patients without relapse were 83% and 70%, respectively. In MRI evaluations, the mean number of new or newly enlarging T2 lesions was lower in patients treated with fingolimod in both studies.

Following the administration of the first dose, a decrease in heart rate starts within an hour and is maximal (a mean decrease of approximately 13 beats per minute) at approximately six hours. All patients should be observed for a period of six hours following the first dose. With continuing use the heart rate returns to baseline within a month. Because the action of fingolimod results in a reversible sequestration of lymphocytes in lymphoid tissues, there is a dose-dependent reduction in the peripheral lymphocyte count to 20-30% of baseline values, resulting in an increased risk of infection.

When treatment with fingolimod is discontinued, some of the drug persists in the system and its action continues for up to two months following the last dose, including decreased blood lymphocyte counts.

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