The Pharmacist Activist

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Editorial

Who are Pharmacy's Leaders?

If we were asked to identify individuals in our country whom we considered to be leaders, we would probably think first of certain elected officials or high-ranking military personnel, certain CEOs of successful organizations, prominent religious figures, and/or certain celebrities and others who are advocates in addressing certain needs and injustices.

In the July issue of *The Pharmacist Activist*, the topic of my editorial was, "We Have Too Many Colleges of Pharmacy!" I received many comments in response to this editorial, almost all of which were in strong agreement with the observations and concerns I voiced (selected comments that are representative of those received are included on page 2). There were several recurrent themes in many of these comments. One was that there are many pharmacists speaking among themselves about the implications of the rapid growth in the number of colleges of pharmacy and the existence/potential for a surplus of pharmacists, but that the pharmacy organizations and the profession of pharmacy in general have essentially been silent regarding these matters. Another observation that was often strongly stated is that some individuals and organizations within pharmacy should be doing something to address these issues. These observations invite the question: Who are the leaders in pharmacy who should be addressing these issues that many within the profession consider to be very important?

Who are our leaders?

Some would suggest that the executives and elected officers of our pharmacy organizations are our leaders. These are dedicated and highly respected individuals, and many are leaders in the profession of pharmacy, as well as in the particular organization(s) in which they serve. However, how would these individuals respond to an issue in which the position/action that would be best for the profession would not be considered the best for the particular organization they serve? This is not a theoretical question. There are many such issues, and pharmacists who have been appointed or elected in a particular organization would find it very difficult to place the interests of the profession above those of their organization.

There are other pharmacists who might be considered as leaders because of their exceptional accomplishments in their practice or other responsibilities. They have certainly provided leadership through their example and may also provide broader leadership for the profession. However, extensive accomplishments as an individual do not assure effectiveness in leadership of an organization or the profession.

(Continued on Page 4)

Contents

SELECTED RESPONSES TO THE EDITORIAL, "WE HAVE TOO MANY COLLEGES OF PHARMACY"
Page 2

New Drug Review
Tocilizumab (Actemra – Genentech)
Page 3

SELECTED RESPONSES TO THE EDITORIAL, *"WE HAVE TOO MANY COLLEGES OF PHARMACY"*

Included below are comments from responses to the editorial in the July issue of *The Pharmacist Activist* that are representative of those received. I appreciate the thoughtful comments of those who have taken the time to respond but, to "protect the innocent," I have not identified those who have provided these observations.

"The editorial expresses what a lot are thinking but many are hesitant to say."

"The surplus has become acute in the area where I live…..The solution from the chain store vantage point is to begin to eliminate those pharmacists over the age of 50. I expect salaries to be attacked in the near future."

"In my experience, the university officials have not received realistic appraisals of the current manpower needs that exist in the profession, and have, in fact, been encouraged to move forward with their plans to establish a new pharmacy school…..The national and state associations appear to be relatively silent on this issue."

"Is anyone pointing out potential workforce excess to our incoming students?....Few of the new schools even attempt to hide their rush after professional school tuition dollars."

"Hopefully, we will not make the same mistakes of the past of no decisions or wrong decisions…..Unfortunately, I am not very hopeful due to the chain domination, hospital pharmacy and benchmarking systems and lack of vision for clinical services, and academia more and more pushed for research and less for clinical teaching."

"The most viable alternative (for employing a larger number of pharmacists) seems to be to get some of the surplus pharmacists absorbed into the growing number of physician groups that are being formed because of health care reform initiatives and incentives. They would still be staff pharmacists, but performing non-product based functions as parts of Accountable Care Organizations or Medical Homes."

"Pharmacy leaders must make it a top priority to prove that pharmacists are really both saving dollars and assuring more effective use of medications…..We need to take a lesson from the nurses. Look how they have positioned themselves to become physician adjuncts…..Adding more years of education is not the answer. We must clearly define and make effective the role of pharmacists in assuring quality and cost effective pharmaceutical care."

"It is up to each of us, individually and collectively, to stand up and say, "We are not going to take this any longer!!!!"

New Drug Review

Tocilizumab
(Actemra – Genentech)

Antiarthritic Agent

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

Indication:
Administered intravenously for the treatment of adult patients with moderately-to severely-active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

Comparable drugs:
TNF antagonists that are indicated for the treatment of rheumatoid arthritis: etanercept (Enbrel), adalimumab (Humira), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade).

Advantages:
- Is effective in some patients who have failed treatment with TNF antagonists;
- Has a unique mechanism of action (is an interleukin-6 [IL-6] antagonist);
- May have a lesser risk of congestive heart failure;
- Less frequent administration – once every 4 weeks (compared with etanercept that is administered every week, adalimumab that is administered every 2 weeks, and certolizumab that is used, at least initially, every 2 weeks);
- Indication is not limited to use in combination with methotrexate (compared with infliximab).

Disadvantages:
- Is not indicated for first-line use;
- Indication is more limited; indication does not include inducing major clinical response, inhibiting progression of structural damage, and/or improving physical function (compared with etanercept, adalimumab, and infliximab);
- Has not been directly compared with other agents in clinical studies;
- Fewer labeled indications (compared with etanercept, adalimumab, and infliximab);
- May have a greater risk of gastrointestinal perforation;
- Is administered intravenously (compared with etanercept, adalimumab, certolizumab, and golimumab that are administered subcutaneously);
- Is not indicated for use in patients less than 18 years of age (compared with etanercept and adalimumab for which the indications include juvenile idiopathic arthritis).

Most important risks/adverse events:
Serious infections (boxed warning; e.g., tuberculosis [TB], invasive fungal infections, and other opportunistic infections [patients should be evaluated for TB risk factors and be tested for latent TB infection; treatment should not be initiated in patients with active infection, including localized infection; treatment should be interrupted if a patient develops a serious infection; should not be used concurrently with a TNF antagonist, abatacept {Orencia}, anakinra {Kineret}, or rituximab {Rituxan} because of the increased risk of infection]); gastrointestinal perforation (must be used with caution in patients with risk factors); serious hypersensitivity reactions, including anaphylaxis; malignancies (possible increased risk because of immunosuppressive action); exacerbation of demyelinating disorders (e.g., multiple sclerosis); use is not recommended in patients with active hepatic disease or hepatic impairment; neutrophils, platelets, ALT, AST, and lipids should be monitored every 4 to 8 weeks; live vaccines should not be given concurrently.

Most common adverse events:
Infusion reactions (7%), upper respiratory tract infection (7%), nasopharyngitis (7%), headache (7%), hypertension (6%), elevated ALT (6%).

Usual dosage:
Used as monotherapy or concomitantly with methotrexate or other nonbiological disease-modifying antirheumatic drugs (DMARDs); treatment should not be initiated in patients with an absolute neutrophil count below 2000/mm^3, platelet count below 100,000/mm^3, or who have ALT or AST above 1.5 times the upper limit of normal; administered once every 4 weeks as a 60-minute single intravenous drip infusion; recommended initial dose is 4 mg/kg followed by an increase to 8 mg/kg based on clinical response; a reduction in dosage to 4 mg/kg, or discontinuation of treatment, is recommended for the management of certain dose-related laboratory changes.

Products:
Single-use vials – 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL (should be refrigerated); the volume of solution needed to provide the appropriate dose should be diluted to 100 mL with 0.9% Sodium Chloride Injection.

The need is urgent

The number of colleges of pharmacy and the number of pharmacists in the workplace have an extremely important influence on issues such as the current and future responsibilities of pharmacists, the number of positions available, salaries, compensation for pharmacists' services, and the extent to which we have any influence over the destiny of our profession. A potential exists for a "perfect storm" of factors that will irreversibly damage our profession. However, the current situation also provides great opportunity! If the expertise and skills of pharmacists could be optimally utilized in new models of health care, our profession could be challenged to provide enough pharmacists to meet the demand. I want to be optimistic that this situation is attainable, but it will not occur without much greater leadership and activism than I feel is evident in our profession now.

We can't afford to just observe how changes in pharmacy and health care unfold. To the extent that we are able, we must establish, promote, and, indeed, force the changes and roles that can be of such great value for patients, as well as for our profession.

We must start by identifying those who should provide the leadership. I would ask you to identify pharmacists whom you consider to be best prepared to provide effective leadership for the profession of pharmacy (and do not hesitate to suggest yourself). I would also value your recommendations regarding a forum and/or platform that will best facilitate leadership and accomplishment.

Daniel A. Hussar

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New Drug Review (cont.)

Comments:

Interleukin-6 (IL-6) is a naturally occurring proinflammatory cytokine that is produced by synovial and endothelial cells and contributes to the local inflammation experienced by individuals with rheumatoid arthritis. Tocilizumab is a recombinant humanized monoclonal antibody that binds to soluble and membrane-bound IL-6. Its mechanism of action is unique among the antiarthritic agents, and it has been effective in some patients who have had an inadequate response to one or more TNF antagonists. Its effectiveness has been demonstrated in studies in which it was used as monotherapy, in combination with methotrexate, in combination with other DMARDs, and in combination with methotrexate in patients who failed TNF antagonist therapy.

The risks and adverse events associated with tocilizumab are generally similar to those of other biological therapies for rheumatoid arthritis. As with the TNF antagonists, the labeling for tocilizumab includes a boxed warning regarding the risk of serious infections.

Like infliximab, abatacept, and rituximab, tocilizumab is administered intravenously, whereas the other biologicals used for the treatment of rheumatoid arthritis are administered subcutaneously.

Daniel A. Hussar

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