The Pharmacist Activist

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Editorial

Pharmacy Must Establish its Own Prescription Benefit Program

The primary reason for which I can be optimistic about the future of our profession of pharmacy is that there is such a great need for the expertise regarding drug therapy that pharmacists are better prepared than anyone else to provide. The elderly use more medications than any other age group, and the elderly are the fastest growing segment of the population. There is an increasing number of medications whose use and risks are sufficiently complex that additional expertise and monitoring are necessary to assure optimum effectiveness and safety. The literature and the news are replete with accounts of drug-related problems – adverse events, drug interactions, patient noncompliance, medication errors, drug abuse/misuse, drug overdoses. The need for more effective and safer use of medications is great, as are the opportunities for the profession of pharmacy to address this need. However, to what extent is pharmacy positively responding to this need, or are we defaulting on a responsibility for which we are uniquely prepared to contribute?

In recent years some pharmacists have taken impressive steps in areas such as medication therapy management (MTM) that provide excellent examples of the scope and quality of services that pharmacists are capable of providing. However, most of these accomplishments have resulted from the efforts of individual pharmacists, rather than representing profession-wide or community-wide initiatives. Yes, we need to start with what might be considered pilot projects, and I certainly do not wish to detract from the commitment and leadership of those who are leading the way in a positive direction. But I am concerned by what I consider to be the very slow pace in implementing progressive change from which patients, society, and our profession will greatly benefit. Indeed, in my opinion, the profession of pharmacy has lost ground during the last several years, and many of the legislative, economic, and health care system changes do not bode well for an expanded role for our profession.

The obstacles

There are numerous obstacles that hinder the further development of the professional role and services of pharmacists. Some obstacles originate within our profession, whereas others are imposed by government prescription programs, insurance companies, and pharmacy benefit managers. Of this latter group of obstacles, I would identify the design and compensation of prescription benefit programs as having the greatest negative impact with respect to both the quality of care for patients and the role of pharmacists.

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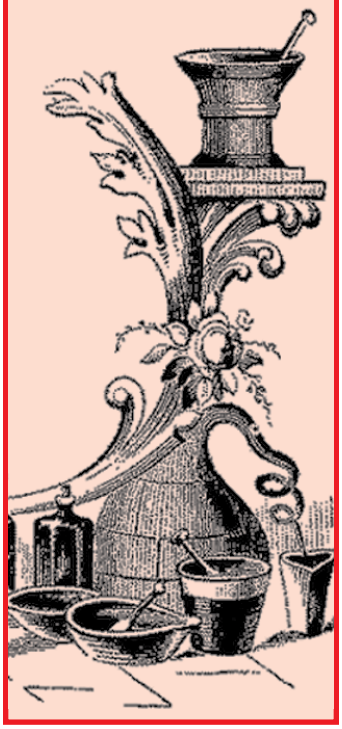

The deficiencies and inequities of prescription benefit programs are well known to community pharmacists. There is no opportunity for pharmacists to have input into or negotiate the terms of the programs that are imposed on a take-it-or-leave-it basis. Pharmacists who challenge the pharmacy benefit managers (PBMs) that develop the programs do so with the concern that there may be retaliation through responses such as abusive audits. Efforts to seek legislative or other relief are met with deceptive and arrogant responses from the PBMs and insurance companies having resources that pharmacists are in no position to match. When they are caught being engaged in inappropriate activities, they negotiate settlements, often in the tens of millions of dollars, so that they are not required to acknowledge any wrongdoing.

It is very important that pharmacists continue to challenge the inequities of prescription benefit programs through legislative and other strategies. However, progress in these efforts has been slow and we run the risk of having even more patients mandated or incentivized to participate in these programs during the time it takes to try to gain more support for current strategies. These circumstances lead me to conclude that the profession of pharmacy must develop our own prescription benefit program.

Pharmacy's prescription program

I believe that the profession of pharmacy can develop a prescription benefit program that, when compared to current programs, will 1) provide more comprehensive and higher-quality personalized services for patients, 2) provide better therapeutic outcomes and greater safety of therapy, 3) provide more equitable compensation for pharmacists, and 4) be less costly for those who fund the benefit programs.

I propose that the National Community Pharmacists Association (NCPA) and the American Pharmacists Association (APhA) share the responsibility and initial cost for the development of the program. An early step would be to convene a group of NCPA and APhA members who have the highest level of expertise and experience regarding prescription benefit programs. As needed, this group could also retain outside consultants with expertise in related areas.

The specific professional services to be provided for the patients served in the program will be identified, as will the responsibilities of the participating pharmacists. The primary focus will be on the quality of pharmaceutical care provided for patients and the services needed to provide this level of care. However, there can also be additional levels of service provided by pharmacists, with corresponding increases in compensation. I do not anticipate that all community pharmacies will be interested in making the commitment to meet the professional criteria for participation to be established. However, I fully expect that the number of highly-motivated pharmacists who are enthusiastic about the merits of the program will be sufficient to establish a national network of participating pharmacies.

The program to be designed will provide access to all prescription medications and selected nonprescription medications, with patient co-payments to be identified based on the type of medications and their cost. This is the area of the program in which the options will offer the greatest flexibility with respect to meeting the budgetary expectations of prospective clients. However, there will be no alteration of the commitment regarding the scope and quality of professional services.

The costs for more comprehensive services for patients and higher compensation for pharmacists will be higher than those in current programs. However, I anticipate that there will be significant efficiencies with respect to administrative, auditing, and selected other costs that will result in a lower net cost to provide the program.

Once established, the program should be financially self-sustaining. Several strategies can be considered relative to the costs of establishing the program. One approach would be for NCPA and APhA to serve in the role of sponsors/investors. Another strategy would be for the participating pharmacies to be investors/owners. This approach offers the intriguing possibility of whether a financial "partnership" of the participating pharmacies would qualify them to negotiate as a network of pharmacies relative to participation in other prescription benefit programs. Another approach would be to seek "outside" funding for the program. However, this would have to be done in such a way that outside investors would not be able to subsequently sell their shares to individuals who do not have a commitment to the principles regarding the scope and quality of pharmaceutical services on which the program was established.

The current prescription benefit programs are beset with problems and are a disservice to both patients and pharmacists. We can and must do better!

Daniel A. Hussar

New Drug Review

Belimumab
(Benlysta – Human Genome Sciences; GlaxoSmithKline)

Agent for Systemic Lupus Erythematosus

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 active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Comparable drugs:
Corticosteroids (e.g., prednisone).

Advantages:
- Increases effectiveness of treatment in some patients when used with standard therapy;
- Has a unique mechanism of action (inhibits binding of B lymphocyte stimulator protein to its receptors on B cells).

Disadvantages:
- Must be administered intravenously;
- Effectiveness in black/African-American patients has not been demonstrated;
- Has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus.

Most important risks/adverse events:
Hypersensitivity reactions, including anaphylaxis (premedication for prophylaxis against hypersensitivity reactions and infusion reactions should be considered; patients should be monitored during and for an appropriate period of time after administration; use is contraindicated in patients who previously experienced anaphylaxis to the drug); serious infections (treatment should not be started in patients receiving treatment for a chronic infection; interruption of belimumab therapy should be considered in patients who develop a new infection while undergoing treatment); live vaccines should not be given for 30 days before or during the period of treatment; depression; suicidality; Pregnancy Category C – patients who are pregnant should be enrolled in the designated Pregnancy Registry; use in nursing mothers is not recommended; concurrent use with biologic therapies or intravenous cyclophosphamide is not recommended.

Most common adverse events:
Nausea (15%), diarrhea (12%), pyrexia (10%), nasopharyngitis (9%), bronchitis (9%), insomnia (7%), pain in extremity (6%), depression (5%), migraine (5%), pharyngitis (5%).

Usual dosage:
Administered as an intravenous infusion over a period of 1 hour; 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter; infusion rate may be slowed or interrupted if the patient develops an infusion reaction.

Products:
Single-use vials – 120 mg, 400 mg (should be stored in a refrigerator); powder in vials should be reconstituted with 1.5 mL and 4.8 mL, respectively, with Sterile Water for Injection to provide a drug concentration of 80 mg/mL; vial should be gently swirled (but must not be shaken) for 60 seconds

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New Drug Review (cont.)

every 5 minutes until the powder is dissolved (reconstitution is usually complete within 10-15 minutes but may take up to 30 minutes); reconstituted solution should be diluted to 250 mL in 0.9% Sodium Chloride Injection (dextrose solutions are incompatible and must not be used); solutions should be protected from sunlight; product labeling should be consulted for specific instructions for dilution and administration.

Comments:

Belimumab is the first drug to be approved for the treatment of systemic lupus erythematosus (SLE) since 1955. It is a human monoclonal antibody specific for soluble human B lymphocyte stimulator protein (BLyS), and is produced by recombinant DNA technology. The drug does not bind B cells directly but, by binding BLyS, it inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

Standard therapy for SLE has included corticosteroids (e.g., prednisone), immunosuppressives (e.g., azathioprine, methotrexate, mycophenolate), antimalarials (hydroxychloroquine), and nonsteroidal anti-inflammatory drugs. The patients in the clinical studies had active SLE and were treated with belimumab plus standard therapy or placebo plus standard therapy. Patients who had received prior B-cell targeted therapy or intravenous cyclophosphamide, or who had active SLE involving the kidneys or central nervous system, were not included in the studies. Patients who were treated with belimumab experienced less disease activity than those who received placebo. Study results also suggest that some patients had a reduced likelihood of severe flares, and some could use a lower corticosteroid dosage. Black/African-American patients participating in the studies did not appear to respond to treatment although data are insufficient to reach a definite conclusion.

The use of belimumab is associated with important risks and, during the controlled periods of the clinical trials (52 weeks and 76 weeks), there were more serious infections and deaths reported in the patients treated with the new drug than in those receiving placebo.

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