The Pharmacist Activist

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Editorial

A New Year, an Old Theme

The title for this editorial is not new. From 1995 to 2000, I served as the Chief Pharmacy Editor of *Pharmacy Today*, published by the American Pharmacists Association. In my editorial in the September 1995 issue, I raised the question of whether our pharmacy associations should consider alliances, mergers, and other initiatives to create a more effective and efficient organizational structure to meet the needs of our profession.

It did not take me long to realize that I had been too timid in approaching this issue in the form of a question so, in the January 1996 issue in an editorial having the same title as this one, 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."

Two years later in the January 1998 editorial with the same title, I noted that there had been some positive and unifying initiatives in certain states. For example, the pharmacists in several states united around the theme, "One voice - one vision." Some excellent programs and services developed by the national associations were recognized in this editorial but a question was raised "as to whether our national associations collaborate with each other as much as they compete (e.g., in recruitment of pharmacist members, development of credentialing programs, seeking financial support for programs)." A further observation was made that "there is no evidence that the leaders of our national organizations have had any substantive discussions of this topic" (i.e., an organizational structure that could merge the membership and programmatic strengths of the individual associations). I urged "a goal of making substantial advances in establishing a unified organizational structure for pharmacy that will best serve the profession. What better way to begin the new millennium!"

The title of my November, 1999 editorial was slightly different: "A new millennium, an old theme." It included the observations: "No one is more aware than our national associations of the importance of having strong and effective organizations and, for the most part, they are advancing their individual interests very well. However, there are some state and local pharmacy associations that are struggling, both financially and professionally, and some of them will not survive. Some would suggest that this could also become the fate of some of the national associations if we do not take steps now that will strengthen the organizational structure and our profession." I recommended that "a meeting be convened for the specific purpose of discussing the development of an organizational structure that would be most effective in addressing the needs and opportunities of our profession." I further recommended that the participants in this meeting be the executive vice

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presidents/directors of the national practitioner organizations, and that the meeting be called and moderated by the executive who had the most seniority in his position. I later learned that, at another meeting in which some of these individuals participated, this topic was identified, there were some smiles, and they moved to the next topic.

Well, it is now 2007, and I have not addressed this topic in more than six years, nor, to my knowledge, has anyone else. Let's consider two questions:

- Is our profession in a better position now than it was in 2000?

Notwithstanding some excellent initiatives on the part of certain associations and individual pharmacists in areas such as immunization and medication therapy management, my impression is that most pharmacists would answer "no" to this question. The greatly increased intrusion of government agencies, insurance companies, and pharmacy benefit managers into the practice of our profession and their denial of opportunities to discuss fair compensation for pharmacist services have markedly eroded our autonomy as a profession and severely compromised our ability to control our professional destiny.

- Are our pharmacy associations more effective now than they were in 2000?

At the county, state, and regional levels, although there are some encouraging noteworthy exceptions, the answer is clearly "no." Some once-thriving county pharmaceutical associations are only marginally active now or exist in name only. Many state associations do not have sufficient participation and resources to be effective. Most of the national associations have maintained a "status quo" and some have increased in members and programs. However, although there are occasional alliances or coalitions to address selected issues, the primary goal of these associations is to protect and advance their individual association and members. This goal is understandable but may be compromised if the organizational structure at the local and state level weakens and dissolves. This goal also leaves unanswered the question, "Who has the responsibility to protect and advance the profession of pharmacy?"

The easy answer is "We all do!" But our efforts as individuals must be coordinated and mobilized through our professional associations. I feel strongly that every pharmacist has a responsibility to join and support our professional associations. Part of that responsibility is to assure that our associations are accountable not only in addressing the issues that pertain to our specific practice area and professional interests, but also in addressing the issues that are important for our profession. If our profession cannot thrive, our associations will not either.

I would submit the following recommendations as to how we should proceed. The executive vice president/director and elected president of the American Pharmacists Association (John Gans; Bruce Canaday), American Society of Health-System Pharmacists (Henri Manasse, Jr.; Cynthia Brennan), and the National Community Pharmacists Association (Bruce Roberts; John Tilley) should meet for the purpose of addressing the question – What organizational structure will most effectively meet the needs, interests, and opportunities for the profession of pharmacy?

I recommend that John Gans, the longest-serving association executive in this group, convene and serve as moderator for the first meeting. I have confidence that this group of leaders can move our profession forward!

Daniel A. Hussar

New Drug Review

Paliperidone (Invega – Janssen)

Antipsychotic Agent

New Drug Comparison Rating (NDCR) = 2

(significant disadvantages)

in a scale of 1 to 5, with 5 being the highest rating

Indication:

Treatment of patients with schizophrenia

Most important risks/adverse events:

Increased mortality in elderly patients with dementia-related psychosis (boxed warning; is not approved for the treatment of patients with dementia-related psychosis); prolongation of the QT interval of the electrocardiogram (should not be used in patients at risk, including those taking other medications that are known to cause QT prolongation [e.g., quinidine, amiodarone, thioridazine (e.g., Mellaril), moxifloxacin (Avelox)]); neuroleptic malignant syndrome; tardive dyskinesia; hyperglycemia/diabetes mellitus; cerebrovascular adverse events; gastrointestinal (GI) obstructive symptoms (extended-release tablet formulation is swallowed whole and the tablet shell remains intact during GI transit; should not be used in patients with pre-existing severe GI narrowing or other conditions that would restrict/limit transit of the tablet); cognitive and motor impairment; orthostatic hypotension/syncope; seizures; hyperprolactinemia; dysphagia; priapism; thrombotic thrombocytopenic purpura; disruption of body temperature regulation; suicide (risk inherent in psychotic illnesses); may reduce the action of levodopa and other dopamine agonists.

Most common adverse events (and the incidence reported with the usual dosage of 6 mg once a day):

tachycardia (12%), headache (12%), somnolence (9%), weight gain (6%), QT interval prolongation (4%), akathisia (3%), extrapyramidal disorder (2%); frequency of adverse events increases as the dosage is increased.

Usual dosage:

6 mg once a day in the morning with the aid of liquids; dosage may be increased in increments of 3 mg/day at intervals of more than five days to the maximum recommended dosage of 12 mg once a day; dosage should be reduced in patients with renal impairment.

Products:

Extended-release tablets – 3 mg, 6 mg, 9 mg

Comparable drug:

Risperidone (Risperdal)

Advantages:

- Dosage titration usually not necessary;
- Less risk of interactions with CYP2D6 inducers (e.g., carbamazepine [e.g., Tegretol]);
- Less potential for variation in response in patients with low CYP2D6 activity ("poor metabolizers");
- First drug for schizophrenia for which information regarding the Personal and Social Performance (PSP) evaluation is included in the labeling.

(cont. page 4)

New Drug Review *(cont.)*

Disadvantages:

- Has not been directly compared with risperidone in clinical studies;
- Indication for schizophrenia is more limited (risperidone has also been demonstrated to prevent relapses);
- Fewer labeled indications (risperidone is also indicated for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder, and for the treatment of irritability associated with autistic disorder in children and adolescents (ages 5 to 18);
- May prolong the QT interval (use with other medications having this potential should be avoided);
- Restrictions regarding use in patients with GI disorders that may impede GI transit of tablet formulation;
- No/limited experience in pediatric patients;
- Fewer formulation options (risperidone is also available as an oral solution, orally disintegrating tablets, and in a long-acting parenteral formulation for intramuscular administration).

Comments:

Paliperidone is the major active metabolite of risperidone but has not been directly compared with its parent compound in clinical trials. They are thought to exhibit their antipsychotic activity through a combination of central dopamine type 2 (D2) and serotonin type 2 (5-HT2A) receptor antagonism. The new drug joins the group of atypical antipsychotic agents which, in addition to risperidone, includes aripiprazole (Abilify), clozapine (e.g., Clozaril), olanzapine (Zyprexa), quetiapine (Seroquel), and ziprasidone (Geodon).

The labeled indications for, and available formulations of, paliperidone are much more limited than those for risperidone. The labeling for paliperidone, but not for risperidone, includes a warning regarding prolongation of the QT interval and associated risks and precautions. Patients should be advised that paliperidone tablets must be swallowed whole and that they should not be concerned by the appearance of the tablet shell (from which the medication has been released) in the stool.

When compared with risperidone, the type and number of disadvantages of paliperidone outweigh its advantages. When one of these agents is to be considered for the treatment of patients with schizophrenia, risperidone is the best choice.

Daniel A. Hussar

Editor's Note

The completion of the first year of publication represents a milestone for *The Pharmacist Activist*. The response has been very gratifying and indicates that we are on target in identifying issues for editorials that you consider important for our profession. I appreciate the many supportive comments and recommendations that you have forwarded but regret that I have not had the time to personally respond to many of them. Even the critical comments have had value in confirming my decisions to address certain issues that some would prefer to ignore. As we progress into our second year, the issues for which we need more activism on the part of more pharmacists will continue to receive priority attention.

Monthly issues of *The Pharmacist Activist* will also continue to include a "New Drug Review." However, I have modified the format to facilitate the provision of the information that is most important and practical, and that provides the basis for comparing the new drug with related agents. The enthusiasm of readers for the "New Drug Comparison Rating" system has been very encouraging. As space permits, in some of the 2007 issues I also plan to include reviews of selected therapeutic classes of drugs that will compare the properties, advantages, and disadvantages of the individual agents.

We have been very pleased by the large number of pharmacists and pharmacy students who have signed up to receive the monthly issues of *The Pharmacist Activist* via email. This has been accomplished almost entirely by "word of mouth" recommendations that we very much appreciate. However, we wish to further increase the circulation and request that you encourage the pharmacists and pharmacy students with whom you are in contact to sign up (www.pharmacistactivist.com) to receive this publication free of charge. Those wishing to read back issues may access them on this website; an index of the topics addressed in the 12 issues of 2006 is included in the December issue.

I wish to express my personal appreciation to Chris Polli, Patrick Polli, and Jeff Zajac of NEWS-Line Publishing for their very capable production of *The Pharmacist Activist* at their cost, and to the benefactor who is committed to the provision of editorial commentary that will stimulate discussion/debate and objective information on new drugs/drug therapy, and who has provided the financial support to cover the publishing costs.

Daniel A. Hussar