The Pharmacist Activist

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Editorial

The APhA and ASHP Should Merge!

This is the seventh 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 in *Pharmacy Today*, as well as in the January 2007, January 2009, and January 2011 editorials in *The Pharmacist Activist*, 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 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."

I began attending meetings of the national pharmacy associations in the late 1960s. Even then, and perhaps long before then, many pharmacists voiced strong concerns regarding the lack of "unity" within our profession. Some pharmacists urged their colleagues to place their dues to the national associations in an escrow account, and only release these funds when the associations would actively consider and make substantive progress toward the establishment of a more unified and effective national organizational structure. However, the concerns of these pharmacists were ignored by the national associations and, in the last several decades, there has been very little discussion about the organizational structure of pharmacy at the national level. Indeed, rather than moving toward a consolidation/reduction in the number of national pharmacy organizations, additional national pharmacy organizations have been established.

As an alternative to addressing the organizational structure of the profession, the national associations choose to act as coalitions of associations in communicating positions on important issues, and/or participate in the Joint Commission of Pharmacy Practitioners (JCPP) that is comprised of 11 national pharmacy organizations. Quick question—How recently have you learned of a recommendation or action taken by the JCPP, and what was the issue addressed? My expectation is that most pharmacists will not have a response to this question, even though there has certainly been no lack of important issues faced by the profession of pharmacy in recent years. If those of us within the profession of pharmacy have such difficulty recalling the issues that our national associations consider important enough to discuss as a "joint commission," can we realistically expect that our legislators and others outside our profession will have a current awareness of our concerns?

The successes

It is not the purpose of this commentary to be critical of our national associations. Hundreds of dedicated and capable pharmacists have

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provided leadership and service from which our associations and profession have greatly benefited. It has been remarkable what our associations have accomplished with resources that are very limited. There have been numerous successes including pharmacist-based immunization programs, medication therapy management initiatives, and advances in patient safety, residency, fellowship, and specialty programs, to name just several. There is no question that substantial progress has been made. However, we are falling far short of our potential!

The challenges

Most, if not all, of our national pharmacy associations have experienced economic challenges in recent years and have had to reduce staff and implement other efficiencies. This situation is being experienced at a time when I would contend there is an unprecedented need to greatly increase financial and personnel resources to address the challenges facing pharmacy and to advance our profession. The challenges include, but are certainly not limited to, the need to greatly reduce the number of drug-related problems and errors, and greatly increase positive drug therapy outcomes for patients; integrating the role and services of pharmacists with those of physicians, physician assistants, and nurse practitioners; obtaining recognition and equitable compensation for the value of our services; contending with excessive and abusive policies and restrictions of insurance companies, PBMs, and government agencies; and recapturing our autonomy to function as health professionals.

We should be encouraged by our successes but I must reluctantly conclude that we are losing our professional role and influence at a faster rate than we are making progress. However, I would hasten to say that my optimism regarding the future of our profession is sustained by the recognition that those who have the greatest need (i.e., the elderly) for the expertise and services that pharmacists are prepared to provide are the fastest growing segment of our population. Nevertheless, our profession must take bold and urgent actions to convert opportunity to reality.

Strategies

Several options exist for the development of a stronger national organizational structure for our profession including:

1. An affiliated membership structure (in which a member of any national association would also be a member of the American Pharmacists Association (APhA)
2. Mergers of associations
3. A new national organization
4. A national pharmacy union

In my opinion, mergers of our existing national pharmacy associations offer the best hope for our profession's need to attain the strength and influence necessary to effectively address the challenges with which we are confronted (please also see my editorial in the January 2011 issue of *The Pharmacist Activist* at www.pharmacistactivist.com). Although each of our national associations has some unique programs, other activities and initiatives overlap, thereby creating competition for increasingly scarce resources. Some would suggest that our national associations compete with each other more than they work with each other. Is it really necessary for so many of our national associations to have their own publishing and educational divisions, political action committees, etc? At the least, are there not substantial efficiencies to be attained that would result in more resources that can be used to respond to challenges and opportunities?

In general, I am not an advocate for "bigger is better." However, my decades of experience as an active member of our profession and multiple organizations lead me to conclude that the present structure of our national associations does not give us the strength, influence, and programs that will best serve our profession and our patients. We must make progressive change!

To move in the direction of merging the national pharmacy associations, my first thought was to initially encourage the smaller national associations that had some overlapping goals and programs to actively consider merging their associations. However, while certainly not wanting to discourage such discussions, I recommend that we start this initiative with our largest associations, specifically APhA and the American Society of Health-System Pharmacists (ASHP). The APhA and ASHP have an excellent opportunity to provide leadership that will strengthen the structure and effectiveness of our profession through organizational change in a manner that would make it attractive for the other national pharmacy associations to also want to be a part of this process.

As one pharmacist who has been a member of both APhA and ASHP for many years, I can think of nothing else that would give me as much encouragement and optimism for the future of our profession than if APhA and ASHP would merge and attain the greater strength and influence that are so important for our profession to advance. There are thousands of pharmacists who presently do not belong to even one national pharmacy association, and I believe that the enthusiasm surrounding the initiative to create a more effective national organizational structure would result in many of these pharmacists supporting this effort with their membership and participation.

We should encourage the leaders of both APhA and ASHP to begin discussions regarding the national organizational structure for pharmacy and the potential to merge APhA and ASHP. I do not underestimate the scope and implications of this effort, and the loyalties and passions that support each of these associations. Others may have better recommendations but, at present, the alternative appears to be maintaining the *status quo*. That is not sufficient. Bold action is needed now!

Daniel A. Hussar

New Drug Review

Aclidinium bromide
(Tudorza Pressair – Almirall; Forest)

Bronchodilator

New Drug Comparison Rating (NDCR) = 4

(significant advantage[s]) in a scale of 1 to 5 with 5 being the highest rating

Indication:
For oral inhalation for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Comparable drug:
Tiotropium (Spiriva HandiHaler).

Advantages:
- More convenient administration and lesser likelihood of problems associated with administration;
- May provide more effective symptom control at night (although data are not conclusive);
- Lesser risk in patients with renal impairment (whereas tiotropium may cause anticholinergic adverse events in patients with moderate or severe renal impairment).

Disadvantages:
- Administered more frequently (twice a day whereas tiotropium is administered once a day);
- Has not been demonstrated to reduce exacerbations of COPD (whereas the labeled indication for tiotropium includes use to reduce exacerbations).

Most important risks/adverse events:
Immediate hypersensitivity reactions (must be used with caution in patients with severe hypersensitivity to milk proteins); paradoxical bronchospasm (treatment should be discontinued); new or worsening narrow-angle glaucoma; new or worsening urinary retention; must not be used for acute episodes of bronchospasm (i.e., rescue therapy); action may be increased by other agents with anticholinergic activity and concurrent use should be avoided.

Most common adverse events:
Headache (7%), nasopharyngitis (6%), cough (3%), diarrhea (3%).

Usual dosage:
400 mcg twice a day via oral inhalation; each actuation of the inhaler unit provides a metered dose that delivers 375 mcg of aclidinium bromide from the mouthpiece; if a dose is missed, that dose should be skipped and the next dose administered at the usual time; product labeling should be consulted for specific instructions for use.

Product:
Inhaler unit (Tudorza Pressair) containing 60 doses; drug is provided in a dry powder formulation in a breath-actuated multi-dose inhaler.

Comments:
Aclidinium bromide is the third synthetic quaternary ammonium compound with anticholinergic activity to be approved for use by oral inhalation in the treatment of COPD, joining ipratropium (e.g., Atrovent) and tiotropium. The new drug is most similar structurally to clidinium, an anticholinergic agent that at one time was available for oral use as a single agent (e.g., Quarzan) and in combination (e.g., Librax) with chlordiazepoxide. However, the use and route of administration of aclidinium are most similar to those of ipratropium and tiotropium.

The effectiveness of aclidinium was demonstrated in placebo-controlled studies in which the drug provided significantly greater bronchodilation. The primary efficacy endpoint was the increase from baseline in morning pre-dose FEV_1 (forced expiratory volume in the first second of expiration) at 12 weeks. There have been limited studies of aclidinium in which some patients were treated with tiotropium, and the efficacy of the two drugs was generally similar. Although some results suggest that aclidinium provided improved symptom control at night, there are insufficient data to conclude that there is a difference in the effectiveness of the two drugs. The labeled indication for tiotropium goes beyond the one for aclidinium by including use for reducing COPD exacerbations.

Only approximately 0.1% of a dose of aclidinium is excreted in the urine, compared with 14% of a dose of tiotropium, primarily in unchanged form. Thus, in patients with moderate to severe renal impairment, tiotropium is more likely than aclidinium to cause anticholinergic adverse events.

The administration of doses of aclidinium is more convenient than with tiotropium that is supplied in capsules that are placed in the inhalation device and pierced to release the medication.

Daniel A. Hussar

New Therapeutic Agents Marketed in the United States in 2012

Generic name	Trade name	Manufacturer	Therapeutic classification	Route of administration	FDA classification[a]	New Drug Comparison Rating[b]
Aclidinium bromide	Tudorza Pressair	Almirall; Forest	Bronchodilator	Oral inhalation	1-S	4
Axitinib	Inlyta	Pfizer	Antineoplastic agent	Oral	1-S	3
Bosutinib	Bosulif	Pfizer	Antineoplastic agent	Oral	1-S	4
Carfilzomib	Kyprolis	Onyx	Antineoplastic agent	Intravenous	1-S	4
Clobazam	Onfi	Lundbeck	Antiepileptic drug	Oral	1-S	4
Elvitegravir/Cobicistat	Stribild[d]	Gilead	Antiviral agent	Oral	1-S	4
Enzalutamide	Xtandi	Astellas; Medivation	Antineoplastic agent	Oral	1-P	4
Ezogabine	Potiga	GlaxoSmithKline; Valeant	Antiepileptic drug	Oral	1-S	3
Glucarpidase	Voraxaze	BTG	Antidote	Intravenous	P[c]	5
Indacaterol maleate	Arcapta	Novartis	Bronchodilator	Oral inhalation	1-S	3
Ingenol mebutate	Picato	LEO	Agent for actinic keratosis	Topical	1-S	4
Ivacaftor	Kalydeco	Vertex	Agent for cystic fibrosis	Oral	1-P	5
Linaclotide	Linzess	Forest; Ironwood	Agent for constipation	Oral	1-S	4
Mirabegron	Myrbetriq	Astellas	Agent for overactive bladder	Oral	1-S	4
Omacetaxine mepesuccinate	Synribo	Teva	Antineoplastic agent	Subcutaneous	1-S	2
Peginesatide acetate	Omontys	Affymax; Takeda	Erythropoiesis-stimulating agent	Intravenous; subcutaneous	1-S	4
Pertuzumab	Perjeta	Genentech	Antineoplastic agent	Intravenous	P[c]	4
Ponatinib	Iclusig	Ariad	Antineoplastic agent	Oral	1-P	4
Regorafenib	Stivarga	Bayer; Onyx	Antineoplastic agent	Oral	1-P	4
Sodium picosulfate	Prepopik[e]	Ferring	Laxative	Oral	1-S	4
Tafluprost	Zioptan	Merck	Agent for glaucoma	Ophthalmic	1-S	3
Taliglucerase alfa	Elelyso	Pfizer; Protalix	Agent for Gaucher disease	Intravenous	S[c]	3
Teriflunomide	Aubagio	Sanofi	Agent for multiple sclerosis	Oral	1-S	4
Tofacitinib citrate	Xeljanz	Pfizer	Antiarthritic agent	Oral	1-S	4
Vismodegib	Erivedge	Genentech	Antineoplastic agent	Oral	1-P	5

[a]FDA classification of new drugs: 1 = new molecular entity; P = priority review; S = standard review.
[b]New Drug Comparison Rating (NDCR):
5 = importance advance; 4 = significant advantage(s); 3 = no or minor advantage(s)/disadvantage(s); 2 = significant disadvantage(s); 1 = important disadvantage(s).
[c]A biological approved through an FDA procedure that does not assign a numerical classification.
[d]Product also contains emtricitabine and tenofovir disoproxil fumarate.
[e]Product also contains magnesium oxide and anhydrous citric acid.

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