The Pharmacist Activist

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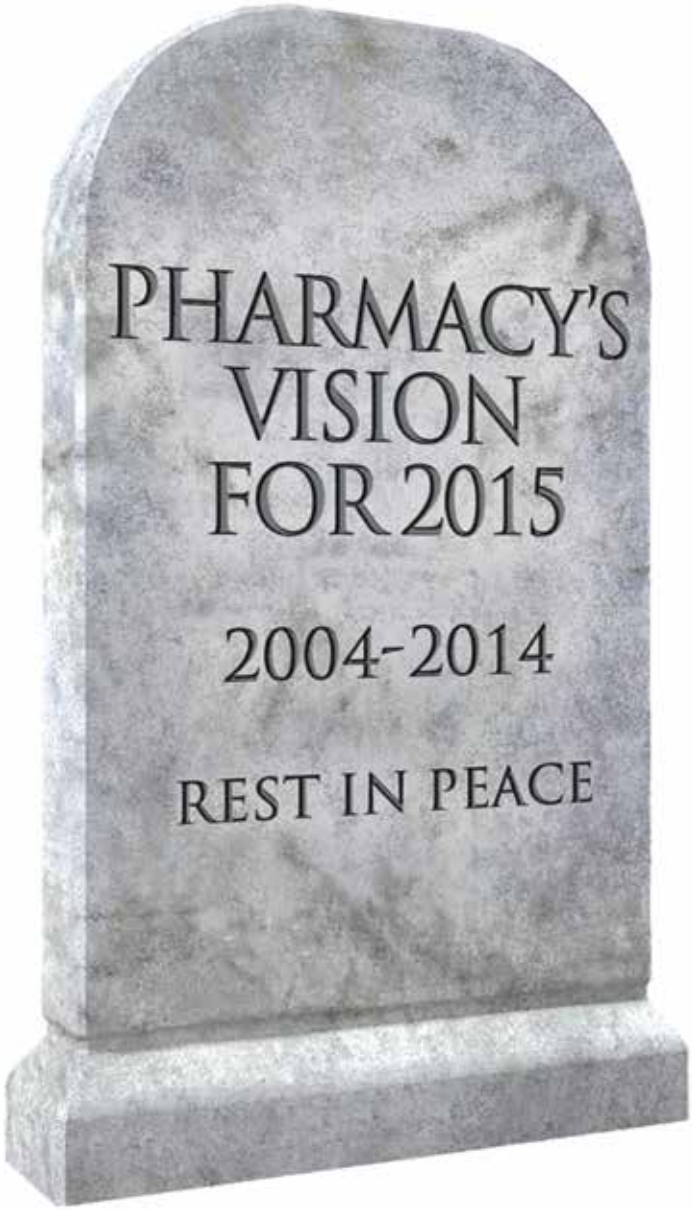
Editorial



The Joint Commission of Pharmacy Practitioners (JCPP) provides a forum in which the chief executive officers and chief elected officers of the national pharmacy organizations meet to discuss issues that are of importance to the profession. In late 2004 officers of 15 organizational members of JCPP developed the following vision statement that was endorsed the following year by all of the major pharmacy practitioner organizations:

> "Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."

This vision statement is followed by a discussion titled, "Pharmacy Practice in 2015," that addresses "The Foundations of Pharmacy Practice," "How Pharmacists Will Practice," and "How Pharmacy Practice will Benefit Society." The vision statement and the supporting discussion are both bold and progressive, and provided a platform from which the JCPP and its member organizations could have developed and implemented strategies and plans that would result in the vision becoming a reality. If you have not read the supporting discussion for the vision statement recently, I would encourage you to locate it on one of the association's websites and review it. In addition to the association leaders who developed the vision statement, I and others within the profession lauded the importance and clarity

Contents

of the direction it articulated (please see my editorials, "Pharmacy's Vision for 2015 OR a Large Surplus of Pharmacists?" and "We Will Try Resolutions Again but Pharmacy May Need a Revolution!" in the June 2011 and January 2014 issues of *The Pharmacist Activist*).

Ten years have gone by since the establishment of this vision statement and 2015 has arrived. It is an appropriate time to assess our profession's progress, or lack thereof, in attaining our vision. The following questions are among those that are pertinent to this assessment:

> How many pharmacists are even aware that the national pharmacy organizations established a vision for 2015?
>
> What are the most important actions that the national pharmacy associations have taken in the last 10 years to establish plans and actions to attain this vision?
>
> To what extent are patients currently (i.e., in 2015) being provided with care that ensures optimal medication therapy outcomes?
>
> To what extent are pharmacists recognized as the health care professionals responsible for optimal medication therapy outcomes?
>
> How many pharmacists can be encouraged and optimistic by their answers to these questions?

I commend the important and progressive initiatives that many pharmacists have implemented in their individual practice responsibilities. They have provided positive examples for others within our profession. Also, some of the national associations have supported and conducted pilot projects and practice-based research initiatives. Regrettably, however, these situations are "the exception rather than the rule," and the positive actions are essentially invisible and unknown to much of society. In stark contrast, however, hardly a week goes by when there is not a horror story in the national news about a preventable death resulting from a medication error or some other serious drug-related problem. Very clearly, pharmacists and other health professionals have not made the progress that is necessary to "ensure optimal medication therapy outcomes."

What happenened to our vision?

In the more than 10 years since "Pharmacy's Vision for 2015" was established by 15 national pharmacy associations, I have heard nothing but positive comments regarding the vision and supportive statements, and the potential provided for attaining optimal medication therapy outcomes and expanding the professional role of pharmacists. This strong support was also encouraged by the commitment of 15 pharmacy organizations which suggested a unity and strength from the profession in support of the vision.

Pharmacy has NOT attained its vision for 2015. Although many of the factors that influence the provision of health care and the roles of pharmacists are outside of the control of our profession, we must first evaluate what our 15 pharmacy organizations have done, or not done. Are there reasons for which these organizations did not follow their collaborative decision in establishing the vision with collaborative efforts to develop the strategies and plans needed to implement it? I have heard several leaders of the national associations make the observation that there has never been a previous time in our profession when there has been better communication among our associations than there is now. If this is accurate, it is all the more reason for our profession's failure to attain our vision for 2015, and the lack of accountability of our associations, individually and collectively, to be considered unacceptable? What have you heard recently from any of our national associations about the vision for 2015? In my opinion, they are hoping that this visionary statement that looked so promising 10 years ago, will quietly disappear.

A moment of silence

I was one of the speakers at a breakfast meeting held as part of the annual meeting of the American Pharmacists Association in late March. I started my comments by requesting a moment of silence for Pharmacy's Vision for 2015, and voiced regret that it had not

(Continued on Page 4)

New Drug Review

Vorapaxar sulfate
(Zontivity – Merck)

Antiplatelet Agent

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

Indication:
For the reduction of thrombotic cardiovascular events in patients with a history of a myocardial infarction (MI) or with peripheral arterial disease.

Comparable drug:
Clopidogrel (e.g., Plavix).

Advantages:
- Has a unique mechanism of action (is a protease-activated receptor-1 [PAR-1] antagonist);
- When used in addition to aspirin and/or clopidogrel, may increase the effectiveness of the regimen in some patients;
- Does not interact with CYP2C19 inhibitors (e.g., omeprazole).

Disadvantages:
- Labeled indications are more limited (clopidogrel is also indicated for the treatment of patients with acute coronary syndrome);
- Interacts with strong CYP3A inhibitors and inducers.

Most important risks/adverse events:
Contraindicated in patients with a history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage, or in patients with active pathologic bleeding (boxed warning); increased risk of bleeding (boxed warning; risk is increased by the concurrent use of anticoagulants, nonsteroidal anti-inflammatory drugs, selective serotonin reuptake inhibitors, and serotonin norepinephrine reuptake inhibitors); use is not recommended in patients with severe hepatic impairment; is a substrate for the CYP3A4 pathway and the concurrent use of a strong CYP3A inhibitor (e.g., clarithromycin) or strong CYP3A inducer (e.g., carbamazepine) should be avoided.

Most common adverse events:
Bleeding (25% in those treated with the vorapaxar regimen, compared with 18% of patients treated with aspirin and/or clopidogrel).

Usual dosage:
2.5 mg once a day.

Product:
Film-coated tablets – 2.5 mg of the sulfate salt, representing 2.08 mg of vorapaxar.

Comments:
Protease-activated receptors (PARs), particularly PAR-1, are thought to facilitate the action of thrombin in the formation of thrombi. PAR-1 has a high affinity for thrombin and is found primarily on platelets, smooth muscle cells, and endothelial cells. Vorapaxar is a selective, reversible antagonist of the PAR-1 expressed on platelets, but its long half-life makes it effectively irreversible. It inhibits thrombin-induced and thrombin receptor agonist peptide (TRAP)-induced platelet aggregation, and is the first drug with this mechanism of action. Vorapaxar has been studied only in regimens that also include aspirin and/or clopidogrel, and experience with its use as a single agent, or with

(Continued on Page 4)

(PHARMACY'S VISION - continued from Page 2)

survived. I commended the organizations that had established the vision, but faulted them for failing to provide the subsequent communication, collaboration, and resources that would provide the best opportunity for attainment of the vision.

The speaker who followed me is a leader of one of our national pharmacy associations, and immediately challenged my comments by noting that the Vision for 2015 has not been abandoned, but rather has been revised to place greater emphasis on patients. As this was not the topic that either of us was asked to address, continued debate will await another forum.

Following this meeting and the comment of the pharmacy leader, I set out to locate a revision to the JCPP vision statement and found the following that was apparently adopted in 2014:

> "Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare."

Like its predecessor (or the original version if this is to be considered a revision), this is a fine statement which presumably all pharmacists would support. However, I have not been able to locate revised supportive statements such as accompanied the earlier vision statement. We could debate whether one of the statements is better, worse, stronger, or weaker than the other, but clearly it has become more important to insist that JCPP and its associations support their "talk" with appropriate "action," and being more accountable in their communications with their members.

Daniel A. Hussar

New Drug Review - *continued*

antiplatelet agents other than aspirin and clopidogrel is very limited.

The effectiveness of vorapaxar was demonstrated in a placebo-controlled (i.e., vorapaxar or placebo in addition to aspirin and/or clopidogrel) study involving more than 26,000 patients. The primary endpoint was the composite of cardiovascular death, MI, stroke, and urgent coronary revascularization (UCR). A key secondary endpoint was these same events but not including UCR. In patients without a history of stroke or TIA, the 3-year event rate for the primary efficacy endpoint was 10.1% in the patients treated with vorapaxar, compared to 11.8% in the placebo group. With respect to the secondary efficacy endpoint, the 3-year event rate was 7.9% in patients treated with vorapaxar, compared to 9.5% in the placebo group.

If a severe bleeding event occurs during treatment with vorapaxar, the drug should be discontinued. Withholding the drug for a short time will not be useful in managing an acute bleeding event because of the drug's long half-life (3-4 days). Significant inhibition of platelet aggregation remains for approximately 4 weeks following discontinuation of the drug. There is no antidote/treatment available to reverse the antiplatelet effect of the drug.

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