

Boards of Pharmacy Should Discontinue Issuing Licenses to Pharmacies that Sell Tobacco Products and to Pharmacies that are in Facilities that Sell Tobacco Products

ou have heard the number before, perhaps to the point that it is no longer shocking to the extent that it must continue to be. More than 440,000 Americans die each year as a consequence of the medical problems resulting from smoking cigarettes. I do not have sales statistics but I have to think that CVS, Rite Aid, Walgreens, and Walmart sell more cigarettes than other retail organizations and, therefore, have facilitated the occurrence of early deaths of many of their customers. What hypocrisy for organizations who want consumers to view them as providers of health care! And what an embarrassment for the profession of pharmacy that organizations that call themselves pharmacies persist in selling products that have such deadly consequences! To their credit, the vast majority of independent pharmacies, as well as large retailers like Target and Wegmans, do not sell tobacco products.

I and others have sent communications to the CEOs of CVS, Rite Aid,

Walgreens, and Walmart to urge them to discontinue the sale of tobacco products. Early communications were respectful requests, but these were ignored or rejected. More recent commentaries have been stronger (please access the website www.pharmacistactivist.com for my editorials, "Pharmacy-Assisted Suicide – at CVS, Rite Aid, Walgreens, Walmart, etc." [November, 2012] and "Merchants of Death – Chain Pharmacy CEOs Must Stop the Sale of Cigarettes!" [November, 2011]). These efforts have been an exercise in futility. The CEOs of these companies are obsessed with just one thing – MONEY – (which must include the revenue from cigarette sales) and do not care about the health of their customers! Other strategies are needed.

Boards of Pharmacy

State boards of pharmacy have a responsibility to the citizens of their states to protect their interests and safety with respect to the licensure and operations of pharmacies, and the licensure and

Contents New Drug Review Vilanterol trifenatate/ fluticasone furoate (Breo Ellipta GlaxoSmithKline) Page 3

Volume 8, No. 9 • September 2013 2

practices of pharmacists. Consumers have a right to expect that pharmacies are health care facilities in which there is a commitment to promote and improve the public health, as well as to assure the most effective and safest use of medications that is possible. I would contend that the sale of cigarettes in pharmacies is contradictory to the role, products, and services of a facility expected to have a commitment to health care. I would also contend that the sale of cigarettes is not consistent with the responsibility of a board of pharmacy to protect the interests and safety of citizens with respect to products sold in facilities that it licenses.

On August 20, 2013, I attended the meeting of the Pennsylvania State Board of Pharmacy for the purpose of submitting the following recommendation (with pertinent background information):

"It is recommended that the Board of Pharmacy take action to 1) discontinue issuing and renewing licenses to pharmacies that sell tobacco products and to pharmacies that are in facilities that sell tobacco products and, 2) establish the rules and regulations that will enable implementation of this action."

In my opinion, the Pennsylvania Pharmacy Act currently provides the authority for the State Board of Pharmacy to take this action by revising regulations. However, a question exists that such an action might be challenged if it is not specifically enabled by legislation. This will take longer but I and others will review this further and propose appropriate new legislation if considered necessary.

The Pennsylvania Board initiative

The National Association of Boards of Pharmacy (NABP) and the American Association of Colleges of Pharmacy (AACP) facilitate regional joint meetings of their members by dividing the country into eight districts. NABP/AACP Districts 1 & 2 (comprised of boards and colleges of pharmacy in the New England and Mid-Atlantic states) will be holding their annual meeting in mid-October.

Ed Bechtel owns a community pharmacy in Slatington, Pennsylvania and is the Chairman of the Pennsylvania State Board of Pharmacy. He developed the following resolution that was approved by the Pennsylvania Board at its meeting on September 17 and has been submitted to NABP/AACP Districts 1 & 2 for consideration and action at its upcoming meeting:

"Whereas, in the United States, tobacco use is responsible for nearly 1 in 5 deaths; this equals about 443,000 early deaths each year (Source: *Cancer Facts & Figures* 2013), and

Whereas, state boards of pharmacy are charged with protecting the public health, safety and welfare as related to services provided by pharmacies and pharmacists; and

Whereas, it is an inherent conflict of interest for pharmacies to dispense the medications that treat heart disease, lung disease, and cancer – and then also sell tobacco, and

Whereas, San Francisco, Boston and other municipalities have enacted ordinances making the sale of tobacco products illegal in their jurisdictions, and

Whereas, in 1988 the National Association of Boards of Pharmacy adopted a resolution encouraging pharmacies to stop selling tobacco products and work toward a Smoke Free Society, and

Whereas, in 2008 the National Community Pharmacists Association adopted a resolution which states that any law or regulation prohibiting the sale of tobacco products apply to all entities operating a pharmacy, and

Whereas, the American Pharmacists Association adopted a policy in 2010 urging "State Boards of Pharmacy to discontinue issuing and renewing licenses to pharmacies that sell tobacco products

(Continued on Page 4)

Volume 8, No. 9 ● September 2013

New Drug Review

Vilanterol trifenatate/ fluticasone furoate (Breo Ellipta - GlaxoSmithKline)

Bronchodilator

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/disadvantages)
in a scale of 1 to 5 with 5
being the highest rating

Indications:

For oral inhalation for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis or emphysema; is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

Comparable drugs:

Combinations of a long-acting, beta2-adrenergic receptor agonist (LABA) and a corticosteroid: salmeterol/fluticasone propionate (Advair), formeterol fumarate/budesonide (Symbicort).

Advantages:

- Is administered once a day (whereas comparable products are administered twice a day);
- Indications also include reduction of exacerbations of COPD (whereas this is not a labeled indication for formeterol/budesonide).

Disadvantages:

- Has not been directly compared with comparable drugs in clinical studies;
- Labeled indications are more limited (comparable combination products are also indicated for the treatment of patients with asthma);
- Vilanterol is not available as a single agent (whereas salmeterol and formoterol are also available as single agents);
- More limited dosage flexibility (whereas comparable combination products provide the corticosteroid in multiple potencies).

Most important risks/adverse events:

Contraindicated in patients with severe hypersensitivity to milk proteins; increased risk of asthma-related death (attributable to vilanterol; boxed warning; not indicated for the treatment of asthma); should not be used for the relief of acute bronchospasm, or initiated as treatment in acutely deteriorating COPD; paradoxical bronchospasm (treatment should be discontinued); must be used with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation; risk of hypokalemia and hyperglycemia; may increase the risk of exacerbations of seizure disorders, diabetes, and thyrotoxicosis; the inclusion of the corticosteroid (fluticasone) is associated with additional risks such as Candida infection of the mouth and pharynx, increased risk of pneumonia and potential worsening of existing infections, glaucoma, and cataracts; should not be used in combination with another LABA; action of vilanterol may be reduced by the concurrent use of a beta-blocker; cardiovascular actions of vilanterol may be increased by the concurrent use of a monoamine oxidase inhibitor, tricyclic antidepressant, or drugs that prolong the QT interval; concurrent use with a loop or thiazide diuretic may increase the risk of hypokalemia and cardiovascular adverse events; action may be increased by the concurrent use of a CYP3A4 inhibitor (e.g., clarithromycin).

Most common adverse events:

Nasopharyngitis (9%), upper respiratory tract infection (7%), headache (7%), oropharyngeal candidiasis (5%).

(Continued on Page 4)

Volume 8, No. 9 ● September 2013

and to pharmacies that are in facilities that sell tobacco products',

Therefore be it Resolved, that the National Association of Boards of Pharmacy revise the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy to include language which would prohibit the licensure of pharmacies that sell tobacco products and pharmacies that are located in facilities that sell tobacco products."

Congratulations to Ed Bechtel and his colleagues on the Pennsylvania Board of Pharmacy for this excellent initiative. We should encourage the members of the boards and colleges of pharmacy of Districts 1 & 2 to strongly support this resolution with the anticipation that it will then be forwarded for consideration and action at the NABP annual meeting next year.

The Great American Smokeout

More than 40 years ago pharmacist Fred Mayer of California started the Great American Smokeout. To expand the impact of this initiative, he transferred the responsibility for this event to the American Cancer Society, and it is held on the third Thursday of November (i.e., November 21, 2013). To this day, Fred is a tireless advocate and leader for smoking cessation and other public health programs. Plan to honor his efforts and help your family members, friends, and others who currently smoke by being proactive in assisting them in stopping smoking, at least on November 21 and, hopefully, forever after.

Daniel A. Hussar

New Drug Review (cont.)

Usual dosage:

One oral inhalation of vilanterol (25 mcg) and fluticasone (100 mcg) once a day; after inhalation, the patient should rinse his mouth with water without swallowing to reduce the risk of oropharyngeal candidiasis.

Product:

Inhaler containing 2 blister strips of powder for oral inhalation; one strip contains 25 mcg of vilanterol in each blister and the other contains 100 mcg of fluticasone in each blister.

Comments:

Vilanterol joins salmeterol (Serevent), formoterol (Foradil, Perforomist), arformoterol (Brovana), and indacaterol (Arcapta) in the class of LABA bronchodilators that are administered by oral inhalation. Unlike the other LABA, vilanterol is not available as a single agent but is only provided in a combination formulation with fluticasone. The effectiveness of vilanterol/fluticasone was evaluated in studies that included 7,700 patients with COPD. Patients treated with the new combination formulation showed improved lung function and reduced exacerbations compared to placebo.

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