



The Pharmacist Activist

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Editorial

Commendation for CVS!

On February 5, CVS announced that it will stop selling cigarettes and other tobacco products at its more than 7,600 stores in the United States by October 1, 2014. CVS President and CEO Larry Merlo stated, “Ending the sale of cigarettes and tobacco products at CVS/pharmacy is the right thing for us to do for our customers and our company to help people on their path to better health.... Put simply, the sale of tobacco products is inconsistent with our purpose.”

Larry Merlo and CVS have made an excellent decision and are to be commended! They have provided important leadership for chain pharmacies in addressing the issue of selling tobacco products. Among those who are the most pleased by the decision are CVS’s own pharmacists.

Commendation for the Pharmacies that Never Sold or have Discontinued the Sale of Tobacco Products!

It is understandable that an organization as large as CVS would receive extensive media coverage of its decision to discontinue the sale of tobacco products. It is also important to recognize that thousands of other pharmacy owners have either never sold or have discontinued the sale of tobacco products. These individuals have provided a very positive example and leadership for the profession of pharmacy and their communities. **Their decisions are to be commended!**

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The Tipping Point Should Become a Domino Effect!

The CVS decision will be the tipping point that will result in other chain pharmacies also making decisions to stop the sale of tobacco products. CVS, Walgreens, and Rite Aid are so competitive with each other that Walgreens and Rite Aid can't be satisfied to be perceived as having less concern for the health of their customers than CVS has for its customers. I anticipate that Walgreens, Rite Aid, and other chain pharmacies will also make decisions to stop the sale of tobacco products, and that this will happen sooner rather than later. Indeed, my expectation is that Walgreens and Rite Aid will stop the sale of tobacco products by the end of 2014. I and others will be continuing to urge them to do this. However, these companies have already considered this action and their CEOs will have the wisdom to recognize the importance of making this decision on a timely basis. If CVS can make the decision to stop the sale of tobacco products, there is no valid reason for which Walgreens, Rite Aid, and other chain pharmacies can't make the same decision!

What about the large retail organizations (i.e., "big box"/department stores, grocery stores) that have pharmacies that only occupy a small percentage of the space in their facilities and that account for a small percentage of their overall business? If they choose to have pharmacies in their facilities and derive the accompanying benefit of a positive reputation for improving the health of their customers, they must not sell products that are recognized to cause harmful/fatal consequences. Target does not sell tobacco products. If Target can make a decision to stop the sale of tobacco products, there is no valid reason for which Wal-Mart and other "big box"/department stores with pharmacies can't make the same decision! Wegmans is a regional organization of grocery stores with pharmacies that does not sell tobacco products. If Wegmans can make a decision to stop the sale of tobacco products, there is no valid reason for which other grocery store organizations with pharmacies can't make the same decision!

The blatant contradiction of selling tobacco products in pharmacies and facilities that include pharmacies has persisted far too long. There must be no more excuses! CVS's decision has provided the tipping point. However, the momentum associated with a tipping point may vary in rate and intensity. A domino effect occurs very quickly. We have seen television stories or videos of long chains of hundreds or thousands of dominoes standing in close proximity to each other. When the first domino is tipped, it starts a rapid cascade of falling dominoes. With respect to the decisions still to be made to discontinue the sale of tobacco products in pharmacies and facilities that include pharmacies, we should accelerate the momentum of the tipping point into a domino effect.

Many pharmacists employed in chain pharmacies or other large corporations have been reluctant to recommend that their company stop selling tobacco products because of concern that their suggestion would not be positively received or that their job might even be in jeopardy if their well-intended recommendation is perceived as being critical of the company. However, things are different now. For example, pharmacists at Walgreens and Rite Aid should encourage their pharmacy supervisors to convey a recommendation to upper management that their company should stop selling tobacco products, rather than having to respond to continuing negative comparisons in the context of the CVS decision. Similarly, state boards of pharmacy have been reluctant to consider recommendations that they discontinue issuing/renewing licenses to pharmacies that sell tobacco products. The CVS decision provides reason to reconsider this matter (please see my editorial, "Boards of Pharmacy Should Discontinue Issuing Licenses to Pharmacies that Sell Tobacco Products..." in the September 2013 issue of *The Pharmacist Activist* at www.pharmacistactivist.com). There are also other strategies that can be used but they may not be necessary after the domino response.

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NEWS-Line
PUBLISHING

Chantix Should be Available Without a Prescription from a Pharmacist!

Most individuals who smoke have attempted on multiple occasions to stop smoking, but without success. An important barrier to the success of these efforts is that certain of the products that are the most effective in helping people stop smoking are available only with a prescription. In stark contrast is the fact that cigarettes, a far more dangerous product, is available only by providing proof of age.

Although nicotine gum, lozenges, and patches are available without a prescription, products like nicotine nasal spray, nicotine inhalation system, and varenicline (Chantix) require a prescription. Chantix is more effective than any other medication/product in helping individuals stop smoking.

However, for a variety of reasons, many individuals who smoke will not make an appointment to see a physician and, as a consequence, do not have access to this medication. A paradox is perpetuated in which the toxin is readily available whereas the availability of the potential cure is restricted.

Chantix and the nicotine nasal spray and inhalation system should be available without a prescription from a pharmacist. In this discussion, we will focus consideration on Chantix. The labeling/package insert for Chantix contains important warnings, including a boxed warning regarding serious neuropsychiatric events. The abbreviated version of this boxed warning that is included in the Highlights of Prescribing Information in the package insert is provided below. The complete text of this warning is included in the Full Prescribing Information for the drug.

This warning must be taken very seriously. However, the third part of this boxed warning begins to establish a context of risks compared with benefits. Let's extend this context further and imagine that obtaining cigarettes required a prescription. The labeling/package insert for cigarettes would include multiple contraindications and I will not even begin to contemplate how

many risks would be included in boxed warnings. However, they would no doubt continue over many pages.

Some contend that the FDA will never permit a medication for which there is a boxed warning to be available without a prescription. However, such a situation already exists, and with the most widely used of all therapeutic agents – acetaminophen. The prescription product Vicodin contains a combination of hydrocodone and acetaminophen, and its labeling/package insert includes a boxed warning. The boxed warning does not address a risk with hydrocodone, but rather a risk with acetaminophen, and it reads as follows:

Hepatotoxicity: Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

Chantix from a pharmacist

Pharmacists have the knowledge needed to assure the use of Chantix in an effective and safe manner as possible. They are also readily available to those who wish to stop smoking, and strategically positioned to provide the appropriate assessment, recommendations, and monitoring. The FDA should take prompt

action to approve the availability of Chantix without a prescription from a pharmacist.

More than 480,000 individuals die each year in the United States as a consequence of complications from smoking-related illnesses. The most effective medication to help people stop smoking must no longer be excessively restricted in its availability!

Daniel A. Hussar

WARNING: SERIOUS NEUROPSYCHIATRIC EVENTS

See full prescribing information for complete boxed warning.

- Serious neuropsychiatric events have been reported in patients taking CHANTIX.
- Advise patients and caregivers that the patient should stop taking CHANTIX and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior while taking CHANTIX or shortly after discontinuing CHANTIX.
- Weigh the risks of CHANTIX against benefits of its use. CHANTIX has been demonstrated to increase the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. The health benefits of quitting smoking are immediate and substantial.

New Drug Review

Sofosbuvir (Sovaldi – Gilead)

Antiviral Agent

**New Drug Comparison
Rating (NDCR) = 5**

*(important advance)
in a scale of 1 to 5 with
5 being the highest rating*

Indication:

Treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen (efficacy has been established in patients with hepatitis C virus (HCV) genotype 1, 2, 3, or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection).

Comparable drugs:

Boceprevir (Victrelis), telaprevir (Incivek), simeprevir (Olysio).

Advantages:

- Has a unique mechanism of action (is a HCV nucleotide analog NS5B polymerase inhibitor);
- Is effective in some patients in combination antiviral regimens that do not include interferon;
- Is effective in some patients with HCV genotypes 2 and 3 infection;
- Is effective in some patients awaiting liver transplantation, and in some patients with HCV/HIV-1 co-infection;
- Activity has not been reported to be reduced in patients with HCV genotype 1a with an NS3 Q80K polymorphism (compared with simeprevir);
- Is less likely to cause serious skin reactions (compared with telaprevir), hypersensitivity reactions (compared with boceprevir), and photosensitivity (compared with simeprevir);
- Interacts with fewer medications;
- Is administered once a day (compared with telaprevir that is administered twice a day and boceprevir that is administered three times a day);
- Used in shorter treatment regimens (12 weeks) for many patients.

Disadvantages:

- May be more likely to cause fatigue and nausea;
- Safety and dosage recommendations have not been established for patients with severe renal impairment.

Most important risks/adverse events:

Contraindicated in women who are pregnant and in men whose female partners are pregnant (because the ribavirin component of the regimen may cause birth defects and fetal death; negative pregnancy test must be obtained; two non-hormonal methods of contraception should be used during treatment and for 6 months

after completion of treatment); action may be reduced by potent intestinal P-glycoprotein inducers (e.g., rifampin, St. John's wort), and concurrent use should be avoided; action may also be reduced by the concurrent use of other transporter and/or enzyme inducers (e.g., carbamazepine).

Most common adverse events:

When used in combination with ribavirin – fatigue (38%), headache (24%); when used in combination with ribavirin and peginterferon alfa – fatigue (59%), headache (36%), nausea (34%), insomnia (25%), anemia (21%).

Usual dosage:

400 mg once a day with ribavirin for 12 weeks in patients with genotype 2 CHC, and for 24 weeks in patients with genotype 3 CHC; 400 mg once a day with ribavirin and peginterferon alfa for 12 weeks in patients with genotype 1 or 4 CHC; use with ribavirin for 24 weeks is an option for patients with genotype 1 infection who are ineligible to receive an interferon-based regimen; in patients with hepatocellular carcinoma awaiting liver transplantation, is used in combination with ribavirin for up to 48 weeks or until the time of liver transplantation.

Product:

Tablets – 400 mg.

Comments:

Sofosbuvir is a direct-acting antiviral agent against the hepatitis C virus (HCV) and has a unique mechanism of action as a nucleotide analog inhibitor of HCV NS5B polymerase, a protein needed for the virus to replicate. It is extensively metabolized in the liver to form an active derivative. It is the first drug to be approved for the treatment of certain types of HCV infection in a regimen that does not include interferon, and the FDA has designated it as a breakthrough therapy. Treatment for 12 weeks with regimens that include sofosbuvir have achieved a sustained virologic response (SVR) of 90% in some studies, and treatment has been effective in many patients with HCV infection who have not experienced an adequate response with other treatment regimens.

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