



## Rx Focus

### The Economic Costs of Cigarette Smoking and Overview of Smoking Cessation Products

Cigarette smoking is the leading cause of death that can be prevented in the United States and produces substantially high health-related economic costs and productivity losses to society. Smokers not only spend money on their cigarettes, they also cost society more due to their medical expenses, and the medical expenses of second hand smokers. In addition, smoking causes productivity losses, including the value of lost work time from smoking related disability, absenteeism, and excessive work breaks.

Many diseases and deaths are related to cigarette smoking. Cigarette smoking can cause respiratory diseases, such as bronchitis, pneumonia, and chronic obstructive pulmonary disease (COPD). It can also increase the risk of cancer, especially in the lungs, oral cavity, esophagus, and colon. Cigarette smoking can worsen cardiovascular diseases. It damages blood vessels and causes blood vessel narrowing, which leads to hypertension, heart attack, and stroke. Some disease states such as GERD, or heartburn, as well as sexual dysfunction, can become worse when people smoke. Smoking during pregnancy contributes to an elevated risk of miscarriages, premature delivery, and having a low birth weight infant. It can also cause fires and consequently cause burn wounds and even death.

Cigarette smoking among adults has declined substantially since 1964. However, by 2003, still roughly one out of every four adult males and one out of every five adult females were smokers. For each pack sold in the U.S. in 1999, \$3.45 was spent on medical care attributable to smoking, and \$3.73 in productivity losses were incurred, for a total cost of \$7.18 per pack. If this number is not alarming enough, for an average smoker who smokes one pack per day, the cumulative annual cost will be \$2,621. Often times, the economic cost of smoking is even higher, the total cost can be \$3,391 per smoker per year. Implementation of comprehensive tobacco control programs could greatly reduce the economic costs of smoking.

Not only do employers benefit from the cost savings of encouraging smoking cessation among those employees who smoke, but also many smokers learn of the high economic and personal health costs. However, sustained elevated level of nicotine in the body from long-term tobacco use produces a cascade of physiologic and behavioral effects that lead to the nicotine dependence disorder. Most smokers will say that smoking helps them concentrate, keeps them from being bored, and helps reduce the perceived level of tension in their lives. In addition, smoking helps them cope with an over-stimulating environment, gives them positive pleasure, helps them relax, reduces their feelings of distress, helplessness, and loneliness, helps them keep their weight down, and makes them feel more at ease in social situations. Smoking can even provide a burst of energy

when feeling tired, and help a smoker concentrate more effectively. In fact, smoking helps a smoker control his moods. Understandably, these substantial benefits would be difficult to give up. Once smokers try to quit, they can experience withdrawal symptoms, including craving for nicotine, irritability, frustration or anger, anxiety, tension, difficulty concentrating, restlessness, sleep disturbances, decreased heart rate, and increased appetite or weight gain. Although not all symptoms necessarily occur in any one individual, these unpleasant symptoms further prevent smokers from quitting.

Preventing the initiation of tobacco use among individuals is the most cost-effective way to control tobacco use. Providing adequate education programs about the health damage and individual economic cost of tobacco use among employees, can benefit employers in saving money on additional health care costs. Employers can also encourage the employees who are current smokers to seek pharmacotherapy and to participate in smoking cessation programs; for example, group counseling programs. Currently, nicotine replacement therapy (NRT) and the antidepressant bupropion are recommended by the FDA as the first line pharmacotherapies.

Nicotine replacement therapy is the most widely used treatment for managing nicotine dependence and withdrawal syndromes. These nicotine containing medications can help smokers to function while they learn to live without cigarettes, since these medications can provide some effects for which the patients previously relied on cigarettes, such as sustaining desirable mood and attention states, making it easier to handle stressful or boring situations, and managing hunger and body weight gain.

Listed below are the products for smoking cessation, with their advantages and disadvantages.

#### Transdermal nicotine patches (OTC)

- Apply once daily, better compliance than other NRT products.
- Longer duration delivery system, 21mg/24-hour, vs. 15/16-hour, yields better control of cravings, and greater reduction in anxiety, irritability and restlessness.
- Provides general (baseline) craving relief, however, it may not adequately protect against breakthrough craving provoked by smoking-related stimuli for all smokers.

#### Nicotine gums (OTC)

- Patients can actively titrate up the dose by themselves.
- Provides better sense of control for the patients.
- Better protection for the breakthrough cravings than patches.
- Taste of these gums is the number one factor for noncompliance.
- Acidic beverages can interfere with buccal absorption of nicotine; therefore, patients should avoid acidic beverages (eg, soda, coffee, beer) for 15 minutes before and during chewing gum.

#### Nicotine lozenges (OTC)

- Very similar products to nicotine gums.
- Provides alternative choice for patients who don't like to chew gums.
- May have better taste than gums.

### Nicotine vapor inhaler (Rx only)

- Designed to satisfy the hand-to-mouth behavioral aspects of smoking.
- Many patients prefer the frequent puffing and sensory stimuli to manage their tobacco cravings.
- Amount of nicotine absorbed from the inhaler is temperature dependent, with higher ambient air temperatures delivering larger amounts of nicotine and lower temperatures delivering smaller amounts.

### Nicotine nasal spray (Rx only)

- Provides the most rapid absorption than any other NRT product; therefore it can deliver acute craving relief.
- Dose of nasal spray should be individualized for each patient, with maximum of 40 doses per day.
- May cause nasal irritation, though this effect dissipates with repeated use for most patients.

### Bupropion (Rx only)

- Recommended as one of the first line agents to treat smoking cessation by FDA.
- Can alleviate some nicotine withdrawal symptoms, including depression, difficulty concentrating, and irritability.
- No effects on craving, anxiety, restlessness, or hunger.
- Dry mouth and insomnia are the most common side effects reported. There is a very small increased risk of seizure.

Many smokers attempt to quit several times before they are successful, even with the help of pharmacotherapy. However, under supervision of clinicians and specialists, it is proven to be more effective to use combinations of different NRT products, as well as NRT products and bupropion. Although smoking cessation is considered the most difficult thing to do by many smokers, it is a well achievable goal.

Tobacco uses can cause severe damages to an individual's health, and very high economic costs to both the individual and society, smoking cessation should be encouraged for all smokers. Many patients will benefit from group counseling, NRT products and bupropion. Much more research is being conducted and many more products are under development.

### References:

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2. CDC: Best Practice for Comprehensive Tobacco Control Programs—August 1999. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC, 1999.
3. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 1997-2001, *MMWR*, 2005; 54:625-628.
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5. Smoking, Insurance, and Social Cost, Regulation, Summer, 1997



## Industry Focus

### Xenical® may Go Over-The-Counter

Monday, Jan. 23, 2006, an FDA advisory panel voted 11-to-3 in favor of making orlistat, the active ingredient in Xenical®, available without a prescription under the trade name Alli™. The OTC application was made by GlaxoSmithKline with dose of 60mg per capsule to be taken three times daily. Roche is the manufacturer is the prescription version of this medication with dose of 120mg/capsule also taken three times daily. FDA usually follows the recommendations of its advisory panel, however, its final decision could take months. If approved,

orlistat would be the first weight-loss drug sanctioned for over-the-counter sales.

Orlistat is used to help obese people who fit certain weight and height requirements lose weight and maintain weight loss. It works in the intestines by blocking the digestion and absorption of fat. The undigested fat is then eliminated in the stools.

The most common side effects are abdominal discomfort and pain, oily or fatty stools, and increased frequency of bowel movements. Patients who are taking orlistat are advised to take multivitamin supplement daily, specifically vitamins A, D, E, and K. People should take multivitamin supplements at least two hours before or two hours after taking orlistat. Diabetic patients may need monitoring and treatment adjustments when taking orlistat because it may affect blood sugar control. Pregnant women, breast-feeding women, and patients who have kidney problems or gallbladder problems should not take orlistat. Patients should consult with their health care providers, including pharmacists, before taking orlistat.

If FDA approves the move, it will provide an additional option of treatment for many overweight and obese patients who do not like to address the body weight issue with their health care providers. However, life-style changes are still recommended and considered the most effective treatment for obesity by the experts. Exercise and diet, or specifically control of calorie uptake, are the best way to lose weight and maintain the weight loss. Patients, who completely rely on weight loss medications, including orlistat, may not be fully satisfied with the result. The common side effects of orlistat may further deter its compliance of usage by many patients. CBCA Rx does not anticipate adding this medication to the OTC Assist program.



## Recipe X-Change

### Banana Bars - A Healthy Treat

- ¾ cup margarine or butter
- 1 cup packed brown sugar
- 1 egg
- ½ teaspoon salt
- 1½ cups mashed bananas (approximately 4-6)
- 4 cups Oats
- 1 cup raisins

Cream butter and sugar; beat in egg, salt, and bananas (add one banana at a time for best results). Stir in remaining ingredients until well blended.

Bake in greased 9 X 13 pan at 350 degrees for 50 minutes. Cool and cut into bars. Refrigerate.



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