Nicotine Lollipops Could Help If FDA Let Them

By ACSH Staff — April 24, 2002

The U.S. Food and Drug Administration (FDA) recently warned pharmacies selling "nicotine lollipops" and "nicotine lip balm" to stop, calling them illegal. According to the FDA, these products are being promoted as smoking cessation treatments or therapeutic drugs and therefore must gain FDA approval before public consumption. The lollipops and lip balm also contain a specific form of nicotine, nicotine salicylate, which has not been approved for smoking cessation. Current FDA-approved smoking cessation products, such as the patch, gum, inhaler, and nasal spray contain other forms of approved nicotine replacements. Further, the FDA worried that because this was a form of candy, and because the lollipops did not have adequate warning labels, children could be enticed to use them. The FDA threatened harsh sanctions against pharmacies if they did not cease sales immediately. What will now happen to the creative concept of the nicotine lollipop or lip balm, items conceived by smokers themselves and created by drug developers due to a consumer demand for such a product? These products might help smokers quit, if FDA doesn't stand in the way.

While nicotine lollipops may sound childish, they (and the lip balm) could be much-needed additions to the world of nicotine replacement therapy (NRT), which plays a fundamental role in smoking cessation treatment. The nicotine lollipop may have several advantages over other products. When smokers stop smoking or attempt to stop they are often afflicted by nicotine withdrawal symptoms, which can include anxiety, depression, irritability, and intense nicotine cravings. NRTs deliver nicotine to the body in a way that is safer than cigarettes.

The lollipop and lip balm products that were offered through the online pharmacies in question contained nicotine in .5 mg, 1 mg, 2 mg, and 4 mg dosages, which is similar to yet slightly less than the nicotine content in other smoking cessation aids. Products such as the patch and gum also contain nicotine in various doses so that the user can monitor and taper doses as addiction wanes, a strategy used by many smokers to avoid the "cold turkey" method. The lollipops could function in a similar fashion. It's the same concept, just an alternative form of nicotine delivery. The gum can provide a slight oral "fix," but gum users often complain that the taste of the gum is poor and that they must "chew" multiple (at times up to twenty) pieces per day, which can cause the jaw to ache. The nicotine lollipops have tasty
natural sweeteners and fruit flavorings in addition to the nicotine. You can also use the same lollipop intermittently throughout the day. The nicotine inhaler is really the only product on the market that closely mimics the practice of smoking, since users can inhale the nicotine and hold the devices between their fingers. However, a commonly reported side effect is irritation of the lining of the mouth. The lollipop at least gives the user something to hold. Some may argue that in order to truly “kick” the habit, the behavioral addiction needs to be broken along with the nicotine addiction, and promoting products that foster any behavior associated with smoking may prove counterproductive. But like the nicotine addiction, the behavioral addiction is not easily broken, and a gradual decrease may work for some.

Pharmacies were selling the lollipops at prices ranging from $2-2.50 apiece. No one knows exactly how many lollipops a user would need per day, and this is sure to vary among individuals. However, the cost would similar to, possibly even less than, other smoking cessation aids. The gum averages $4.00 per day (up to $50-60.00 for a week's supply), the patch averages $3.75 per day ($45-60.00 for a two-week supply), the inhaler is $5.70 per day ($80.00 for a two-week supply), and the nasal spray is $5.00 per day ($70.00 for a two-week supply).

One of the major reasons cited by the FDA for the ban is the fear that children would either mistake the nicotine lollipops for regular lollipops or become addicted to them, with potential adverse effects unknown. Some of the pharmacies were selling the lollipops only with a doctor's prescription, but they also sold some lollipops over-the-counter (OTC). Because of their candy-like nature, if nicotine lollipops were ever to come to legal fruition, their distribution would most likely need to be monitored closely. Currently, the gum and patch are available OTC, while the inhaler and nasal spray are prescription only.

Smoking cessation is an intricate and difficult process, and nicotine lollipops alone may not prove to be effective for large numbers of smokers. However, studies show that combining more than one NRT can increase quit rates. Combining the non-nicotine prescription medication bupropion (an antidepressant) with NRTs has been shown to increase quit rates. Further, combining pharmacotherapies with behavioral and supportive therapies can increase a smoker’s chance of quitting permanently.

Quitting smoking is the single most important thing that an individual can do to enhance and preserve health. Cigarette smoking causes an estimated 430,000 deaths per year. Aside from reducing your risk of lung cancer and heart disease in the long term, stopping smoking has more immediate, short-term health benefits such as reduction in fatigue, shortness of breath, and cough. Each year approximately 46% of smokers try to quit, and only a small number about 1-2% are successful. The more varied and diverse products that exist to help a diverse smoking population quit, the more likely smokers are to succeed. As long as the products are safe, approved, and regulated, there is no reason to let go of the nicotine lollipop concept. Nor should we discourage other creative approaches to this very difficult problem.

Ashlee Dunston is Assistant Director of Public Health for the American Council on Science and Health.
Responses:

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To me it is the most ludicrous thing I have ever heard that the FDA is banning the sale of nicotine lollipops. These are precisely what helped me the most during the seventy-two-hour physical withdrawal period.

Of course, there is the behavioral aspect of it as well, but for the government to ban the sales is one of the most ridiculous things I have ever heard in my life. If they are worried about the children, I am sure the pharmacies would be more than willing to put up a warning sign stating what the nicotine lollipops are.

I guess the FDA would rather have people die from cigarette smoking than allow something helpful to stay on the market.

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