

# New Tobacco and Nicotine Products: Snake Oil or Harm Reduction

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Since FDA lost its regulatory authority over tobacco in 2000, new tobacco and non-medicinal nicotine products have been appearing in the conventional and electronic marketplace every 3-4 months with no sign of letting up. It is like the 19<sup>th</sup> century days of snake-oil peddlers before FDA regulation of medicinal products. New products include nicotine delivery devices "heated" by carbon fuel and electronic ignition systems, a candy-like tobacco lozenge, and smokeless tobacco products marketed to help smokers remain smokers by using slogans such as "Any Time Any Where"<sup>TM</sup> and for "When You can't smoke."<sup>TM</sup> There are cigarettes implying safety with claims of "reduced carcinogens," "the next best thing to quitting," "80 percent less secondhand smoke," and one with a misleading claim of "nicotine free" that is marketed for quitting by imitating the three-step program of nicotine patches. By Internet, there are nicotine lollipops (complete with "lollipop luggage"), nicotine water, and most recently, nicotine wafers.

None of these products have clinically tested and approved protocols for dosing, guidance for use to achieve health benefits (even where health benefits are implied), or guidance to minimize unintended consequences or dangerous forms of use (such as dual use to perpetuate smoking). Yet, it is theoretically possible that some of these products are useful advances towards less deadly tobacco products for those who are unable to quit tobacco altogether. Some might even be useful as smoking cessation approaches.

Presently there is no way for the consumers or public health officials to know, because there is no meaningful system of regulatory oversight. Yet, there is a rather straightforward path to this end. It is the path of scientific study and FDA regulation built around the key principle of pre-market evaluation of the products and the claims. It is a proven path toward products that are less harmful and possibly even helpful. The focus of this presentation will be on the issues and challenges raised by new tobacco and nicotine products, and how science-based regulation could be applied to assess and control their public health impact.