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Point of View

FDA will rule none too soon on e-cigarette regulations

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By Michael Hufford and Scott Ballin

Over the past few years, innovations in nicotine delivery have enabled smokers to obtain their nicotine without the carcinogens found in cigarette smoke. Today, we stand on the cusp of an FDA ruling on these novel nicotine devices that could set the stage to permanently extinguish the combustible cigarette.

At stake is an industry with over \$35 billion in annual profits, deep political clout and a product that, when used as directed, kills 50 percent of its users.

The health risks associated with smoking are not in dispute. Each year, 430,000 Americans die of smoking-related illnesses, more than all American deaths in wars in the 20th century combined; around the world, 5 million people die each year.

A common misperception is that nicotine is a carcinogen; it is not. Rather, the 7,000 other chemicals in combustible cigarettes, at least 70 of which are known carcinogens, are responsible for tobacco-related death and disease. At its core, the cigarette continues to use the same 5,000-year-old technology – fire – to deliver nicotine as well as a host of cancer-causing compounds. Innovation is long overdue when a drug-delivery platform has the wheel as one of its technological peers.

E-cigarettes create an aerosol by heating a solution of nicotine and other chemicals (often propylene glycol or vegetable glycerin). These devices are confronting public health advocates with a difficult moral calculus: More lives may be saved by advocating widespread use of safer forms of nicotine delivery than by encouraging nicotine abstinence.

This is at the heart of a public health policy called harm reduction. It is a greatest-good-for-the-greatest-number moral argument as a quiet public health catastrophe plays out every day as over 1,200 smokers die in the U.S. A harm-reduction approach, emphasizing not abstinence but safer forms of nicotine delivery, would mark a philosophical change from the tobacco control wars of the past, with important implications for one of the largest and most profitable industries in the world.

In June 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act, which gave the FDA's Center for Tobacco Products the authority to regulate the manufacture, labeling, distribution and marketing of tobacco products. However, it does not encompass electronic nicotine-delivery devices, including e-cigarettes.

The FDA's forthcoming ruling, known as the "deeming rule," is the sort of regulatory brick-laying that might escape notice. The ruling will determine what regulatory requirements will be placed on these nicotine-delivery devices. At stake is whether innovative forms of nicotine delivery will be left unregulated, lightly regulated or forced down a development path akin to new drugs, where hundreds of millions of dollars and many years are spent researching and documenting the safety and efficacy of new medicines.

We stand at an intersection of regulation, innovation and public health policy. Cigarettes continue to be available at every corner store for a few dollars. A rational, science-based approach to the comprehensive regulation of all tobacco and nicotine-containing products is needed to characterize the risks, relative risks and intended uses of these products.

U.S. regulators have both challenges but, more important, opportunities in front of them that could have a significant effect on reducing disease and death caused by cigarettes. Erring on the side of caution by enacting strict drug-development-like regulations could crush a nascent industry and, with it, an opportunity to transform the tobacco-control landscape. Erring on the side of laxity could put adult customers at risk of products that deliver inconsistent or contaminated doses and enable broader nicotine exposure among children.

If the FDA embraces harm reduction and enacts balanced regulations that encourage the efficient development of safer forms of nicotine delivery, then it can both protect public health and enable free market forces, driven by innovation, to help permanently extinguish the combustible cigarette and, with it, a man-made public health disaster without parallel.

Dr. Michael Hufford is the chief medical officer for e-Nicotine Technology, a Chapel Hill company developing an electronic nicotine delivery device. Scott Ballin is a health policy consultant.

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