Could FDA e-cigarette regulations help more people quit smoking?

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Credit: AI-generated image (disclaimer)

E-cigarettes are smoking hot. They are the most popular nicotine-delivery products used by kids and the majority of adult smokers have tried them. E-cigarettes are a multi-billion dollar industry, with the website Yelp tallying more than 10,000 vape shops across the country. Wall Street analysts are predicting that revenue from e-cigarettes will

surpass traditional cigarettes in a decade.

Given the size of the enterprise, you would think there would be policies and rules in place that would assure e-cigarettes' safe use and promote them as a tool to quit smoking. After all, the vast majority of long-time adult smokers desperately want to quit the habit. While vaping is not risk-free, nearly everyone agrees that e-cigarettes are almost certainly better than smoking, if for no other reason than the fact that smoking is *so* harmful due to the tars and toxins in smoke that are created from burning the tobacco in traditional cigarettes.

Surprisingly, despite the size of the market and the millions of smokers (and some nonsmoking kids and former smokers) who have tried e-cigarettes, there are virtually no federal rules or regulations that govern any aspect of the industry.

That could change soon. Federal officials are expected to come out with a decision any day now that could give the Food and Drug Administration (FDA) authority to develop regulations. But figuring out how to regulate e-cigarettes to maximize their benefits and minimize their risks is harder than it looks.

What's at stake for cigarette smokers

Cigarette smoking is the leading preventable cause of death in the world, killing nearly 500,000 Americans and six million people around the world each year. The causes of death and chronic illness include, of course, lung cancer, but also heart disease, diabetes mellitus, colorectal and pancreatic cancer and a range of medical conditions that fall under the umbrella of chronic obstructive pulmonary disease (COPD).

Most adult smokers took their first puff of a cigarette as a teenager. And most wish they had never started, and consider it one of the worst

decisions they have ever made.

More than half of middle-age smokers have quit. Quitting can be extraordinarily hard. The average 40-year-old smoker who started in his teens will have made more than 20 failed attempts to quit. While there are aids to help people quit smoking, such as Nicotine Replacement Therapy (NRT) and prescription medications Chantix and Zyban, they vary widely in how well they work. There is certainly room for a more effective method. But it's unclear whether e-cigarettes are the answer.

Some research suggests that e-cigarettes are as effective as other smoking cessation approaches. But the research is limited, and the major health and medical organizations currently do not recommend e-cigarettes for cessation. A noteworthy exception is the United Kingdom, where an e-cigarette became part of the National Health Service smoking cessation program in January.

Meanwhile, U.S. smokers are being barraged by mixed messages. Vaping advocates promote e-cigarettes as a potentially life-saving product, but the industry can't make health claims without going through an FDA review process. (And the FDA doesn't currently have the authority to conduct such a review.) Right now we are waiting for Office of Management and Budget to approve FDA's request to extend their current authority to cover e-cigs and other novel products.

For the first time in generations, there are glamorous ads on TV for what appears to be smoking (but is actually vaping). One e-cigarette company even ran a "Welcome Back" marketing campaign that appeared designed to entice former smokers to start vaping, a move that could get them readdicted to nicotine and possibly on the road to smoking traditional cigarettes again.

How are e-cigarettes regulated right now?

The federal government has been slow to regulate the fast-evolving e-cigarette industry, but it has been trying. In 2009 the FDA attempted to have e-cigarettes regulated as a drug-device combination, which would require FDA oversight. But the courts didn't see it that way, and in 2010 ruled that e-cigarettes were tobacco products and had to be regulated as such. When President Obama signed the Family Smoking Prevention and Tobacco Control Act, it complicated things in that it allowed the FDA to regulate some tobacco products, but it did not explicitly include e-cigarettes (or hookah, cigars and cigarillos and other novel tobacco products).

That meant that for the FDA to regulate e-cigarettes, they had to extend or "deem" their authority to include these novel products. FDA indicated their intent to do so in early 2014 and received over 100,000 public comments on their proposed rules, which today are awaiting final action from the Office of Management and Budget.

The net effect is that there are currently no federal rules, and the e-cigarette industry is basically unfettered. The one exception is a new law signed by President Obama in January to require childproof caps for the containers of liquid nicotine used in e-cigs. The containers had been blamed for more than 3,700 calls to poison control centers in 2014, with more than half of the cases involving children under 6.

Some state and local jurisdictions have stepped in to pass laws and policies within their authority. For example, most states have passed minimum age of purchase laws, many jurisdictions call for e-cigarettes to follow the same restrictions as tobacco products in terms of where they can be used, and some states are imposing excise taxes on e-cigarettes as well.

Are e-cigarettes tobacco products or not?

The burning question (pun intended) is whether e-cigarettes should be treated the same as tobacco products (as the courts have ruled and as the e-cig industry fears) or if they should benefit from preferential policies because they are less harmful than traditional cigarettes.

Creating a regulatory framework that varies by the risk of the product makes sense, but is fraught with challenges, mainly because e-cigarettes are relatively new and the science is mixed. Decisions will need to be made about whether e-cigarettes should benefit from differential tax policy, marketing regulations and, perhaps most knotty, where they can be used. Rep. Duncan Hunter, a Republican from California, tried to argue that vaping should be allowed on airplanes, dramatically blowing a cloud of vapor while speaking at a Congressional hearing last week. (He lost that debate.)

Some argue that e-cigarettes should be used to nudge smokers away from traditional cigarettes, and that this could be achieved by having public policies differ based on the harm caused by the product. For example, e-cigarettes and other noncombustible tobacco products could be taxed at a lower level and be allowed to advertise commensurate with the harm they cause. Advertising for combustible cigarettes would still be severely restricted, but e-cigarettes could be marketed like nicotine replacement therapy.

Some have even made the dubious suggestion that rather than increasing the minimum age of buying tobacco products to 21 (as many jurisdictions are doing), having a different minimum age of e-cigarette sales of 16 years of age so that young people who crave nicotine can start with a less "harmful" product.

We don't know all the answers, but we do know that smokers urgently need (and want) to quit smoking. The policy challenge for FDA is to have the wisdom to put in place the rules and regulations that will

achieve the greatest population health benefit and result in the beginning of the end of smoking as we know it.

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