

POLICY FOCUS

E-Cigarettes: When Regulatory Overkill Actually Kills

RECIPES FOR RATIONAL GOVERNMENT FROM INDEPENDENT WOMEN'S FORUM

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WHAT YOU NEED TO KNOW

Each year, nearly half a million Americans die of smoking-related diseases. Smoking-related healthcare costs exceed \$300 billion a year. Convincing people to stop smoking is both a public health and economic priority.

Electronic cigarettes, more commonly called e-cigarettes, have helped in that effort. In Europe, **6.1 million people** have switched from traditional cigarettes to far less harmful vaping products. In the United States, **new government data** reveals nine million adults now use e-cigarette products—the vast majority of whom were former traditional cigarette smokers.

Unlike traditional cigarettes, e-cigarettes do not contain tobacco and, crucially, do not burn or smoke. With traditional cigarettes, harm comes from the toxins released (tar) when a cigarette burns. As **Professor Michael Russell remarked in his landmark 1976 study** on harm reduction, “People smoke for nicotine but they die from the tar.”

E-cigarettes do not burn but instead contain a liquid solution made up of glycol and flavorings, and in some cases, nicotine. Vaping (the term for smoking an e-cigarette) closely mimics smoking yet is **95 percent less harmful than smoking** and has helped **millions of smokers quit traditional cigarettes**.

Yet access to these products is in danger thanks to new FDA regulations that require all vaping products to undergo a retroactive FDA pre-approval process at a cost of \$400,000 and over 500 man-hours *per vaping product*.

Because the vast majority of vape shops are small businesses, and most produce multiple vaping flavors (each of which will be required to go through a separate approval), it's estimated that 99 percent of all vaping businesses will close, robbing consumers and, tragically, those who are trying to quit traditional cigarettes of these vital, safe, and useful products.

WHY YOU SHOULD CARE

Government efforts to limit product choices often backfire. In particular, this new regulation on the vaping industry:

- **Will Result in Less Vaping, More Smoking:**

Fewer companies and individual vape shops means that more people will return to or keep using traditional cigarettes. Prices for vaping products are likely to rise as the costs of the approval process are passed on to consumers, and consumers will have fewer products to choose from as providers must prioritize which products to select for the lengthy approval process.

- **Will Kill Small Business:** FDA's regulation will put thousands of small, independently-owned vaping shops out of business, as many of these vape shops don't have the resources to comply with these federal regulations.

- **Will Lead to Job Loss:** Estimates vary, but most agree that the vaping industry employs tens of thousands of people, mostly working in small shops. These regulations will result in the closing of these shops and the loss of these jobs.

- **Will Foster Crony Capitalism:** The larger tobacco companies—all of which produce vaping products—will be able to comply with these regulations. The smaller, one- and two-person shops won't. This is yet another case of big government helping out big business at the cost of small business, consumer choice and lower prices.

MORE INFORMATION

If Americans only pay attention to the official unemployment rate, they may not know that our labor market has a problem. Our official unemployment rate today is a low **4.6 percent**.

In the United States, the number of people who smoke traditional, combustible cigarettes continues to decline. From 1964 to 2014, the proportion of adult smokers declined from 42 percent of the population to 18 percent. Yet, as noted by the **U.S. Department of Health and Human Services (HHS)**, smoking is still a public health concern. **HHS estimates** that more than 3,200 people under 18 smoke their first cigarette, with roughly two-thirds of that going on to become daily smokers.

To quit, the FDA recommends the following options:

1. Willpower
2. Use of any of the FDA-approved smoking cessation products, including:
 - a. Prescription medicines, which the **FDA warns** carry serious health risks such as “changes in behavior, depressed mood, hostility, aggression, and suicidal thoughts or actions.”
 - b. Over-the-counter products such as skin patches and gum, which **studies show are minimally effective** in helping people to quit smoking long term.

These are the only options currently recommended by the FDA. Fortunately for thousands of people who want to quit traditional

cigarettes, there's another option for smokers: e-cigarettes.

Yet the FDA is working to discourage the use of these products and has created a regulatory scheme that will result in most e-cigarette companies and vape shops closing their doors. The FDA also misinforms consumers by claiming that e-cigarettes haven't undergone enough safety testing (despite multiple safety tests) and are too risky. Their strategy of employing fear and alarmism will result in only one thing: more people smoking traditional, cancer-causing cigarettes.

Emergence of E-Cigarettes

In 2007, Americans began to see the first vaping products enter the marketplace. By 2009, these products were widely available to consumers. Vaping is very different than smoking in these important ways:

- No Tobacco: E-cigarettes contain no tobacco.
- No Burning: Vaping does not involve combustion—or burning. Instead e-cigarettes use water vapor to deliver nicotine.
- No Risk of Second Hand Smoke: E-cigarettes don't produce smoke so there's no risk to non-smokers from second hand smoke. The vapor produced by e-cigarettes contains no dangerous chemicals or carcinogens.

Since 2007, the e-cigarette industry has grown significantly. Today, it is a \$2 billion industry with around 15,000 vape shops nationwide—many of them small, individually owned stores.

While much has been written about how e-cigarettes help people quit smoking, this thriving industry is bringing other benefits to communities: new low-skilled jobs, additional tax revenues for local governments, the development of vaping enthusiasts and community groups that help and encourage others to quit smoking, and greater competition and better prices for consumers who use smoking cessation products.

E-Cigarettes: Are They Safe?

Smoking is a tremendously difficult habit to quit, and people often need to use nicotine replacement therapies to kick the habit altogether. Some products, such as nicotine patches and gum, offer some aid, yet **studies** show that the efficacy of these products is low and most people who use these products exclusively eventually return to traditional cigarettes.

While nothing is risk-free, those looking to quit smoking should know that e-cigarettes have a **far higher success rate** in helping people permanently quit traditional cigarettes, and they are **95 percent less harmful than cigarettes**. Consider a few of the studies on e-cigarettes:

- A **2008 study by Health New Zealand** found that e-cigarettes are “several orders of magnitude (100 to 1000 times) less dangerous than smoking tobacco cigarettes” and that these products are a “safe alternative to smoking.”
- A **2011 study published in the journal *Addiction*** found that smokers are

successfully quitting or significantly reducing the number of cigarettes they smoke, and that e-cigarettes are being used by many ex-smokers to maintain abstinence.

- In 2011, a clinical trial published in the journal [BioMed Central](#) found that e-cigarettes are a more effective treatment to quit smoking than traditional nicotine replacement therapy and crucially “...may be particularly effective in smokers who are not motivated to quit.”
- In 2015, an [independent review by Public Health England](#) found e-cigarettes are significantly less harmful to human health than smoking traditional, combustible cigarettes and that e-cigarettes can help smokers quit.
- In a 2016, a [200-page report by the Royal College of Physicians](#) on the effectiveness of e-cigarettes found that “smokers can . . . be reassured and **encouraged to use them**, and the public can be reassured that e-cigarettes are much safer than smoking.”

Vaping Under Threat: The Tobacco Control Act and the Deeming Rule

In 2009, Congress passed and President Obama signed the Family Smoking Prevention and Tobacco Control Act (known now as the Tobacco Control Act or TCA), which gave the FDA authority to regulate the manufacture, distribution, and marketing of tobacco products.

Under this new authority, the FDA was given broad authority over the marketing and sales of

tobacco products, the types of warning labels and “reduced harm” claims that could be used by manufacturers, and how companies disclosed ingredients in tobacco products. The law also allowed annual FDA inspections of tobacco facilities.

As the law’s name suggests, the TCA was intended to control tobacco products and to prevent the introduction of new tobacco products into the market. The TCA “grandfathered” in older tobacco products that were already on the market at the time of the TCA (so, in other words, traditional combustible cigarettes would not be subject to new approval regulations).

Yet, soon after the TCA passed, it became clear that the FDA planned to extend its legislative authority to non-tobacco products like e-cigarettes. In fact, within months of TCA’s passage, the FDA declared its opposition to the sale of e-cigarettes, stating incorrectly that e-cigarettes are filled with harmful “toxins” and “carcinogens.” The FDA also objects to people using nicotine—a drug that can be addictive but is not known to be harmful itself. In fact, nicotine is similar to coffee.

Yet, nicotine has become a great concern to public health advocates who don’t seem to separate the established high risk of smoking traditional cigarettes as a way to get nicotine from the lower risk of smoking e-cigarettes to get nicotine. Ann McNeill, a Professor of Tobacco Addiction at King’s College London, [explained in a 2016 interview](#) the need to “de-demonize nicotine” adding:

...the risks are nuanced - that potential harms lie on a curve with smoking at one end, and

nicotine at the other. People who don't see that may hesitate to seek help stopping smoking, or try to restrain their intake of nicotine replacement therapy (NRT). That can make it harder to quit.

In order to circumvent TCA's legislative limits so that they could begin regulating the vaping industry, in 2016, the FDA passed the "deeming rule" whereby all products designed to provide a nicotine delivery system (including vaping) would be "deemed" tobacco products. Under this new rule, all vaping products—the thousands of different flavors and types—not on the market before the passage of TCA (2007) would be subject to a retroactive premarket approval process. Since vaping products weren't fully available until 2009, this new rule captures nearly every vaping product.

This incredibly complex premarket approval process will cost manufacturers roughly \$400,000 per product (and manufacturers often produce hundreds of products) and more than 500 hours of manpower per product just to fill out the paperwork. Rather than face these costs and crushing additional workload, many shops will simply close, leaving smokers without these innovate and life-saving products.

Let the Market Work

When it comes to helping people kick the smoking habit, it's clear the market is working. Private technological innovation has done what the government and public health advocates haven't been able to do: give smokers effective tools that can help them quit smoking. The FDA

needs to recognize these products as separate from traditional combustible cigarettes and other tobacco products and create a regulatory framework that allows e-cigarette makers to continue to offer e-cigarettes to consumers while continuing to study the safety of these innovative products.

To understand how important vaping products are to those trying to quit smoking, consider [these testimonials](#) :

"I smoked for 36 years. I tried so many ways to quit...Drugs, patches, cold turkey, nicotine gum, self hypnosis didn't work. I felt like a failure...I smoked my last cigarette the day that I bought my first personal vaporizer. That was four years ago. Vaping saved my life!"

"I started smoking at age 12 and I enjoyed it even though I could hardly breathe and sounded like a train whistle while sleeping. On Jan. 15th 2015 I bought my first pen style Vape and after 48 years of smoking, have not touched a cigarette since. I can now walk without stopping to get my breath..."

"I am 62. Smoked for 45 years. Found a vape shop with trained people. I have not smoked tobacco in 3 months. Free at last."

"Was a pack a day smoker for 8 years, with severe asthma. When my daughter was born I switched, it's been almost a year now. I can breathe wonderfully now..."

WHAT YOU CAN DO

- **Get Informed:** Learn more about e-cigarettes.

Visit:

- **Smoke Free Alternatives Trade Association**
 - **Reason Foundation**
 - **The Competitive Enterprise Institute**
- **Talk to Your Friends:** Help your friends and family understand these important issues. Tell them about what's going on and encourage them to join you in getting involved.

- **Become a Leader in the Community:** Get a group together each month to talk about a political/policy issue (it will be fun!). Write a letter to the editor. Show up at local government meetings and make your opinions known. Go to rallies. Better yet, organize rallies! A few motivated people can change the world.
- **Remain Engaged Politically:** Too many good citizens see election time as the only time they need to pay attention to politics. We need everyone to pay attention and hold elected officials accountable. Let your Representatives know your opinions. After all, they are supposed to work for you!

ABOUT INDEPENDENT WOMEN'S FORUM

Independent Women's Forum (IWF) is dedicated to building support for free markets, limited government, and individual responsibility.

IWF, a non-partisan, 501(c)(3) research and educational institution, seeks to combat the too-common presumption that women want and benefit from big government, and build awareness of the ways that women are better served by greater economic freedom. By aggressively seeking earned media, providing easy-to-read, timely publications and commentary, and reaching out to the public, we seek to cultivate support for these important principles and encourage women to join us in working to return the country to limited, Constitutional government.

We rely on the support of people like you! Please visit us on our website www.iwf.org to get more information and consider making a donation to IWF.

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