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The U.S. Court of Appeals for the D.C. Circuit ruled that the FDA could not regulate e-cigarettes as drug delivery devices and could only regulate e-cigarettes as tobacco products under the Family Smoking Prevention and Tobacco Control Act because the products were derived from tobacco and were *not* being marketed with claims of therapeutic benefit.<sup>1</sup> In addition, the District Court decision in the *Soterra* case, Judge Leon stated: "To the extent those products are marketed as providing the same experience as traditional cigarettes but without the negative health consequences associated with tar and smoke, they fall within the plain meaning of 'modified risk tobacco product,' which the Tobacco Act defines as any tobacco product 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'" (680 F. Supp. 2d 62 at 75 (D.D.C. 2010), *affd*, 627 F. 3d 891 (U.S. App. DC 2010)).

In the absence of FDA regulation, the companies have been marketing e-cigarette products with both claims of reduced health risks and harms compared to tobacco cigarettes and with therapeutic smoking cessation claims. Several e-cigarette retail websites feature explicit or implicit health claims, often in comparison to the health risks and harms posed by tobacco cigarettes (Figure 1) and with claims the products do not produce secondhand smoke, (e.g., "Contains no tar, second-hand smoke, or burning substances." [www.myluci.com](http://www.myluci.com), April 19, 2013). Overt health claims are further exemplified by pictures and videos of doctors touting the health benefits of using the products (Figure 2). Websites also feature claims that overtly stated or implied the products could be used in smoking cessation (e.g., "How can Altimoff e-cigarette help you quit smoking?" [www.usaecigarette.com](http://www.usaecigarette.com); Figure 3) and contain language such as "E cigarette helps you to slowly decrease your nicotine addiction without the stress of giving up the behavioural pleasures of smoking" ([usaecigarette.com](http://usaecigarette.com); Figure 3).

In addition, e-cigarette websites also feature testimonials from customers about how e-cigarettes help them quit smoking (Figure 4). For example, on [www.vapornine.com](http://www.vapornine.com) (January 14, 2013):

"I just wanted to let you know that you have changed my life! I LOVE my vapornine supplies and I was able to completely quit the same week I started vaping. I am now sickened by the smell of cigarettes, which never happened before, not even during any of the other brief periods of time during which I was able to temporarily quit..."

Featuring these claims and publishing these testimonials on websites controlled by e-cigarette companies represents promotion of e-cigarettes as risk and harm-reducing products and therapeutic devices, despite the fact that many of the websites also contain disclaimers in tiny print stating that the products are not intended for smoking cessation (example in Figure 5).

A national survey (Pearson et al., 2012) and studies with convenience samples of e-cigarettes users demonstrate that people perceive e-cigarette products as less harmful than tobacco cigarette smoking and that the products could help (or have helped) with quitting smoking (Etter and Bullen, 2011; Goniewicz et al., 2012). Adkison and colleagues (2013),

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<sup>1</sup>680 F. Supp. 2d 62 (D.D.C. 2010)

using ITC data from four countries, found that users report using e-cigarettes because they consider them less harmful than traditional cigarettes, to help them reduce their smoking, and to help them quit smoking (Adkison et al., 2013).

The companies' marketing practices indicate that they regard their products as harm reducing or therapeutic and public opinion, especially among e-cigarette users, appears to reflect the marketing claims. Therefore, it seems likely that e-cigarette companies may attempt to submit applications to gain approval for their products as modified risk tobacco products (MRTP). It is important to note that the Tobacco Control Act, and the MRTP section in particular, states that in addition to evaluating individual risks and harms, FDA is required to assess whether the product will "***benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.***" Their current marketing practices should be monitored and potentially halted until (and if) they can be substantiated by adequate science and proven not to negatively impact the public's health as required by section 911(g) of the Tobacco Control Act.

#### References:

Adkison, S. E., O'Connor, R. J., Bansal-Travers, M., Hyland, A., Borland, R., Yong, H. H., Cummings, K.M., McNeill, A., Thrasher, J.F., Hammond, D. & Fong, G. T. (2013). Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey. *American Journal of Preventive Medicine*, 44(3), 207-215.

Etter, J. F., & Bullen, C. (2011). Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction*, 106(11), 2017-2028.

Goniewicz, M. L., Lingas, E. O., & Hajek, P. (2012). Patterns of electronic cigarette use and user beliefs about their safety and benefits: An Internet survey. *Drug and Alcohol Review*. 32(2), 133-140.

Pearson, J.L., Richardson, A., Niaura, R.S., Vallone, D.M., & Abrams, D.A. (2011) e-Cigarette Awareness, Use, and Harm Perceptions in US Adults. *American Journal of Public Health*. 102(9), 1758-1766.

**WHY SWITCH**

**Why Should You Put Down Your Traditional Cigarettes And Pick Up VaporNine?  
27 Benefits & Advantages To Using VaporNine ...**

<p><b>1.</b>  VaporNine E-Cigs don't contain 4,000+ nasty, harmful chemicals.</p>	<p><b>2.</b>  You're able to smoke anywhere, anytime (avoid the smoking ban!)</p>
<p><b>3.</b>  You're NOT hurting the ones you love ... friends, family.</p>	<p><b>4.</b>  By not smoking you're increasing your health dramatically.</p>
<p><b>5.</b>  That means more energy and less fatigue throughout the day.</p>	<p><b>6.</b>  Plus increased lung functionality over time.</p>
<p><b>7.</b>  Not to mention being able to breathe through your nose.</p>	<p><b>8.</b>  Getting rid of that morning phlegm cough routine.</p>
<p><b>9.</b>  Not damaging your lungs.</p>	<p><b>10.</b>  No more smelling like an ashtray.</p>

Figure 1. www.vapornineecigs.com on January 14, 2013 - section of the site called "Why Switch"

**Videos**

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**Dr. David Baron M.D.**  
Chief of Staff, UCLA Santa Monica Hospital



**Dr. Matthew Huebner, M.D.**

**Compare V2 Cigs Vapor vs. Cigarette Smoke**

Figure 2. Doctors featured in videos on websites on January 14, 2013 for www.smokestik.com (left) and the homepage of V2cigs (right).

Altimoff



Alternative to smoking cig

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CATEGORIES:	HOME	PRODUCTS	PRODUCT INFO	CIGARETTE DANGERS
	FAQ	ABOUT US	CONTACT US	LOGIN

- ▶ E Cigarette Starter Kit
- ▶ E Cigar
- ▶ E Cigarette Cartridges
- ▶ E Cigarette Car Charger
- ▶ E Cigarette Atomizer
- ▶ E Cigarette Battery
- ▶ E Cigarette Charger

*Welcome to Altimoff*

*E Cigarettes* by USAE Cigarette is an innovative new smoking alternative. We offer [e cigarette starter kit](#), [e cigar](#) and e smoking accessories in USA. Altimoff [E Cigarette](#) brand name stands for quality and innovation. [Electronic Cigarette](#) is a new smoking alternative that LOOKS, FEELS and SMOKES like a real cigarette. It is battery operated device with replaceable cartridges– that does not need to be lit. When [Electronic Cigarette](#) is in use the indicator light starts glowing in red and virtually odourless vapour is emitted which looks like real smoke. [E Cigarette](#) helps you to slowly decrease your nicotine addiction without the stress of giving up behavioural pleasures of smoking.

STARTER + FREE CAR CHA

*Faq*

**How can Altimoff E Cigarette help you quit smoking?**

With all other alternative smoking products that are available on the market you receive your dose of nicotine but they do not relieve your cravings for the actual process of smoking. After years of smoking the continuous use of cigarettes in different places it becomes a habit. If you smoked for 20 years while driving – imagine every day, multiple times a day for 20 years – then driving without smoking is extremely difficult – it's a habit, a way of life. You are not only addicted to nicotine and other added chemicals you are addicted to the actual process of smoking. With Altimoff [E Cigarette](#) quitting smoking is easier and less stressful than with any other product available on the market today.

**What is the best method to quit smoking with Altimoff E Cigarette?**

Best method is the one that works for you. Each person is different and the same method does not apply to all. You can try one of the 3 possible [e cigarette](#) methods outlined below:

1. Four step method – with specific time period guidelines for each nicotine content level e cigarette cartridge. Full description is available in the User's Manual that comes with each [e cigarette starter kit](#).
- 2.General method – no specific guidelines - quit smoking with [e cigarette](#) at your own pace.
- 3.Slow substitute method – first start by substituting ordinary cigarettes with Altimoff [E Cigarette](#). Cut down on smoking traditional cigarettes. Decide which nicotine level is best for you. Then as you see that you do not use e cigarette as much as you did before then start with lower nicotine content e cigarette cartridges. Then when you are ready move on to NO nicotine e cigarette cartridges.

**Is there a possibility of a relapse?**

www.apolloecigs.com/What-is-an-Electronic-cigarette-s/67.htm

ited Getting Started New Bookmark

to visit. You can also work as our reseller or sales consultant and earn sales commission!  
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**Sign up for our mailing list!**

Join to receive exclusive news on sales, new products, and more!

Email \*

Name

\* = Required Field



## HOW DO PEOPLE USE E-CIGARETTES TO QUIT SMOKING?

In a recent study, about 80% of smokers were able to completely replace cigarettes with electronic cigarettes in under 6 months. The majority of our customers have successfully quit smoking using electronic cigarettes instead of tobacco cigarettes. The most successful method we've found is to start using an e-cigarette whenever you crave a tobacco cigarette. After 1-2 weeks, you should notice your senses of taste and smell coming back, and you should be able to completely stop smoking cigarettes.

We offer 5 nicotine strengths to make sure you can quit smoking comfortably. Each level can correspond with a particular style of cigarette:

- Extra High (24mg) - unfiltered cigarettes
- High (16mg) - Regular, full-flavored cigarettes
- Medium (12mg) - Regular, full flavored cigarettes
- Low (8mg) - Light or ultralight cigarettes
- Zero (0mg) - Ultralight cigarettes to non-smoker; best for completely quitting nicotine (will be most successful after going down in strength)

**Figure 3.** Presence of therapeutic claims on e-cigarette websites.

Information about using an e-cigarette to "slowly decrease your nicotine addiction without the stress of giving up the behavioural pleasures of smoking" on the homepage of [www.usaecigarette.com](http://www.usaecigarette.com) (top) and information about how Altimoff e-cigarettes can be used to quit smoking in the FAQ section of [www.usaecigarette.com](http://www.usaecigarette.com) (middle), January 15, 2013. Information on Apollo Ecigs website: "How do people use e-cigarettes to quit smoking" <http://www.apolloecigs.com/What-is-an-Electronic-cigarette-s/67.htm> (bottom), January 15, 2013

Katie - Alexandria, VA

"I just wanted to let you know that you have changed my life! I LOVE my vapornine supplies and I was able to completely quit smoking the same week I started vaping. I am now sickened by the smell of cigarettes, which never happened before, not even during any of the other brief periods of time during which I was able to temporarily quit... I used all my business cards (as several friends have ordered too). When you print more, I will be happy to hand some out. I will ask for them in my next order."

Testimonial about quitting smoking with the e-cigarette on [www.vapornine.com](http://www.vapornine.com)

**Figure 4.** Testimonial on an e-cigarette website regarding using the e-cigarette to quit smoking, [www.vapornine.com](http://www.vapornine.com) (bottom) January 14, 2013

The screenshot shows the V2 Cigs website homepage. At the top, there are five promotional banners: "30 DAY Money Back Guarantee", "LIFETIME Warranty", "Smoke For FREE", "Worldwide Shipping", and "Superior Quality". Below these is a paragraph stating: "V2 Cigs is known for providing e-cigs with the thickest vapor in the electronic cigarette industry. E-cigarettes from V2 Cigs are tested daily for safety and quality. Even long term smokers love V2 Cigs e-cigarettes." Below this is a "NEWSLETTER" sign-up section with an email input field and a "FOLLOW V2CIGS" section with icons for Facebook, Twitter, Pinterest, and YouTube. To the right is a "V2PROFIT AFFILIATE NETWORK" section with a large dollar sign icon and text: "OVER \$20 MILLION PAID IN COMMISSIONS" and "EARN \$25.00 JUST FOR SIGNING UP!". At the bottom, there is a disclaimer section with the following text: "YOU MUST BE OF LEGAL SMOKING AGE TO BUY AND/OR USE ANY V2 CIGS PRODUCT." followed by a "WARNING:" paragraph, a paragraph about product safety, a "CALIFORNIA PROPOSITION 65 Warning:" paragraph, and a final line: "V2 Cigs products are not marketed for use as a smoking cessation product. Just like traditional tobacco cigarettes, V2 Electronic Cigarettes are not approved by the American FDA."

**Figure 5.** Disclaimer on the bottom of the [www.v2cigs.com](http://www.v2cigs.com) homepage. The last line read: "V2Cigs products are not marketed for use as a smoking cessation product. Just like traditional tobacco cigarettes, V2 Electronic Cigarettes are not approved by the American FDA."