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Docket No. FDA-2014-N-0189

I am resubmitting the following public comment, submitted to an earlier docket:

Grana, R., Ling, P.M., Barnes, R.L., Lempert, L., Glantz, S.A. (2013). Comment submitted regarding Feed and Drug Administration actions related to Nicotine Replacement Therapies and smoking-cessation products; report to Congress on innovative products and treatments for tobacco dependence; public hearing; extension of comment period. tracking # 1jx-835b-n9ph.

This comment is referenced in the following comment, which was just submitted to the current docket: FDA Should Prohibit E-cigarette Marketing that Promotes False Health Claims, tracking number 1jy-8cgs-11sq

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Professor of Medicine

Comment Submitted Regarding
Food and Drug Administration Actions Related to Nicotine Replacement Therapies and Smoking-Cessation Products;
Report to Congress on Innovative Products and Treatments for Tobacco Dependence; Public Hearing; Extension of
Comment Period
FDA-2012-N-1148-0011

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January 16, 2013

The FDA attempted to block the import of e-cigarettes into the U.S. as unregulated medical (drug [nicotine] delivery) devices under the Food, Drug and Cosmetics Act until such time that they were submitted to and approved by the FDA as drug delivery devices. Sottera Inc., the company that promotes NJOY e-cigarettes, sued the FDA for an injunction against the FDA's detention of their product in part on the basis that their e-cigarette products were *not* therapeutic drug delivery devices, but intended for and marketed as recreational products.¹ Sottera, Inc. prevailed at both the trial court and the Court of Appeals, which rejected the FDA's position that e-cigarettes were unapproved drug devices and agreed with Sottera, Inc. The ruling stated 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.² On the other hand, the Court of Appeals in *Sottera Inc. v. Food & Drug Administration*³ ruled that the FDA has express authority to regulate e-cigarettes when e-cigarette products are "therapeutically marketed," like nicotine gums and transdermal patches, since then they would fall under the jurisdiction of the drug/device provisions of the Federal Food, Drug, and Cosmetic Act (FDCA)⁴.

Given the position the e-cigarette company took in the litigation against the FDA, we were surprised to find that Sottera, Inc., which promotes the e-cigarette brand NJOY, as well as VMR Products LLC, which promotes the e-cigarette brand V2Cigs, as well as the e-cigarette industry's trade association, Smokefree Alternatives Trade Association (SFATA) have been directing their consumers to provide public comment to this docket regarding a "Report to Congress on Innovative Products and Treatments for Tobacco Dependence" in their direct e-mail (Figure 1) and on their websites (Figure 2). This action indicates that these companies are concerned about how the FDA could characterize the use of these products in its report to Congress on "products and treatments for tobacco dependence."

In addition to urging their customers to comment on this docket regarding products and treatments for nicotine dependence, e-cigarette companies have explicitly and implicitly made therapeutic claims about their products in their online marketing and promotional materials. E-cigarette websites provide information and feature testimonials from customers about how e-cigarettes help smokers curb and eventually quit smoking (Figures 3 and 4). Specifically, sites 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" (Figure 3).

The e-cigarette companies' websites also contain sections of sites that explain how an e-cigarette could be used to quit smoking, as seen on www.usaecigarette.com and www.apollo.com (Figure 3). The testimonials on the websites often imply that their e-cigarette products will help their customers quit smoking (Figure 4). For example, on www.vapornine.com (January 14, 2013):

¹ Note 1, *supra*

² 680 F. Supp. 2d 62 (D.D.C. 2010)

³ 627 F. 3d 891 (U.S. App. DC 2010)

⁴ 21 U.S.C. section 351 *et seq.*

"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..."

Likewise, a testimonial posted on www.smokestik.com (January 14, 2013) explicitly compared e-cigarettes to FDA regulated therapeutic products used for smoking cessation treatments:

"Just wanted to let you know how much I love your product. I have smoked for over 30 years and thanks to Smoke Stik I have quit. I know that this product was not meant to be a quitting type of product but it worked for me. I tried the patches, gum, mints and Chantix...none of them worked. I now use the non nicotine flavor and just the thoughts of having it in my hand and the "smoke" coming out, I quit thanks to your product." (Figure 4)

Publishing these testimonials on websites controlled by e-cigarette companies represents promotion of e-cigarettes as 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).

Whether the tobacco product is marketed for therapeutic use is gleaned from the universe of the product's marketing. For FDA regulatory purposes, the "intended use" of a product is determined by "the objective intent of the persons legally responsible" for labeling the product. 21 C.F.R. § 201.128. Objective intent may be shown, for example, "by labeling claims, advertising matter, or oral or written statements" by the labeler. *Id.* It may also be shown "by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." *Id.* By posting customer comments and testimonials on websites controlled by the e-cigarette marketers, they clearly have knowledge that their products are "used" by those customers as either a smoking cessation therapeutic device. Furthermore, the fact that these companies and their trade association, SFATA, have been encouraging their consumers to submit public comments to a docket about smoking cessation products can be read no other way than they are promoting their products as having therapeutic benefit.

At least one site, <https://rivosisig.com>, explicitly acknowledges that the company, RivoSig, should not be making smoking cessation claims on their site (Figure 6). In a blog post RivoSig states: "Now legally we can't say that RivoSig e-cigarettes are a smoking cessation product, nor can we tell you they are better for you (those legal pencil-pushers at the FDA would get their panties ruffled if we did). However, what we can offer is unbiased knowledge and research that comes from reputable sources"(Figure 6). It is unclear to the reader to which reputable sources they refer, as no evidence of the knowledge or research is actually offered with this statement (Figure 6).

In the *Sottera* decision, Judge Williams wrote: "Still, the district court noted that the factual record on NJOY is meager and that the FDA may establish that NJOY does in fact make therapeutic claims regarding its electronic cigarettes. Mem. Op. at 25 n.17. Until such time, the definitional line laid down in *Brown & Williamson* (as we understand it) leaves the FDA without jurisdiction over these products under the FDCA's drug/device provisions." The *Sottera* decision holds that the FDA could and should regulate e-cigarettes as drugs/devices under the FDCA if they are found to be "therapeutically marketed."

The e-cigarette companies cannot have it both ways. They cannot claim they are regular tobacco products that, as "customarily marketed," may only be regulated as a tobacco product under the Family Smoking Prevention and Tobacco Control Act⁵, thus avoiding regulation as medical devices and the burden of proving safety and therapeutic benefit, and then create the impression through their marketing and direct consumer communication they have submitted therapeutic claims to the FDA and won approval for them.

The FDA should take the following actions as a result of the information presented in this comment:

⁵ Pub. L. 111-31, June 22, 2009

1. Make note of the therapeutic and health claims made and promoted by e-cigarette companies in its Report to Congress on Innovative Products and Treatments for Tobacco Dependence, comment on the lack of evidence to support such claims, and inform Congress that the FDA is taking actions now to stop such claims from being made until such time as the companies submit scientific evidence to substantiate these therapeutic claims.⁶
2. Immediately order the companies to stop making claims (direct and implied) that e-cigarettes are effective cessation devices, including ordering the companies to remove and not post further testimonials to this effect.
3. Work with the Federal Trade Commission to prohibit such claims as false advertising until such time that they have been scientifically substantiated and approved by the FDA.

⁶ As a separate issue from the promotion of e-cigarettes as a smoking cessation therapy, the e-cigarette companies also promote their products as healthier alternatives to conventional cigarettes. In 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)). E-cigarettes have not been approved as modified risk tobacco products as required by section 911 of the Tobacco Control Act and cannot lawfully be promoted as such. The FDA could take immediate action to halt this unlawful promotion activity.

From: NJOY.com <news@njoy.com>
Date: January 11, 2013 6:00:05 AM PST
To: [REDACTED]
Subject: The FDA seeks your opinion on Electronic Cigarettes
Reply To: NJOY.com <news@njoy.com>

If NJOY's electronic cigarettes have had a positive impact on your life, we encourage you to share your story with the FDA. [View it in your browser.](#)

NJOY

FIND SHOP
A STORE NOW

The FDA Seeks Your Opinion on Electronic Cigarettes

The FDA has announced its intention to issue regulations deeming electronic cigarettes to be within the scope of FDA jurisdiction under the Tobacco Control Act. These regulations may affect the manner in which electronic cigarettes are sold and could have the effect of making these products more expensive and/or less accessible.

You have the opportunity to have your opinion heard regarding this matter.

The FDA is accepting public submissions via the Internet through **next Wednesday (January 16th, 2013)**.

If NJOY's electronic cigarettes have had a positive impact on your life, we encourage you to share your story with the FDA and to urge the FDA not to take any action that would make these products more difficult or expensive to obtain than they are currently.

All you need to do is follow the link below to have your voice heard on this important topic.

To submit a comment electronically:

Go to <http://www.regulations.gov/#submitComment;D=FDA-2012-N-1148-0011>.

Comments are limited to 2,000 characters. If your comment is longer, you can upload a file to fully share your story.

----- Forwarded message -----
From: V2 Cigs <newsletter@v2cigs.com>
Date: Mon, Jan 14, 2013 at 2:21 PM
Subject: The Future of E-Cigs - Important Notice to V2 Cigs Customers...
To: [REDACTED]

Email not displaying correctly? [View it in your browser.](#)

Submit Your Comments to FDA

Help Us Tell the FDA "NO!" to Added Regulations- Action Requested by Wednesday, 1/16/2013

The FDA announced it will regulate electronic cigarettes under the Tobacco Control Act. [See announcement here.](#) This added regulation could have a negative impact on the availability, accessibility and cost of V2 Cigs and other e-cig brands' products.

But you can make sure that your opinion is heard!

If V2 Cigs electronic cigarettes have made a positive difference in your life, please share your story with the FDA. Ask them not to implement additional regulations which would limit your ability to obtain V2 Cigs. [Read the notice of public hearing on the FDA website.](#) You can click on the blue Comment Now button in the upper right corner of the FDA's site to **submit your comments through Wednesday, January 16, 2013**.

Your opinion matters! This is your chance to make a difference for the entire electronic cigarette industry. Visit the FDA Website today and encourage your friends to do the same. Together, we will be heard!

Thank you for your continued support.

Sincerely,
V2 Cigs Team

SFATA Please visit The Smoke Free Alternatives Trade Association, or SFATA's, website for the latest news affecting the electronic cigarette industry. From pending legislation to scientific studies, SFATA org provides you with up-to-date information where it matters most. SFATA is also urging customers to

Figure 1. Emails to consumers from e-cigarette companies encouraging submission to docket FDA-2012-N-1148-0011 on a report to Congress about smoking cessation therapies from NJOY, January 11, 2013 (top) and V2Cigs, January 14, 2013 (bottom). The links in these emails were:
FOR NJOY: http://www.regulations.gov/?utm_source=NJOY+Customer+List&utm_campaign=f15e166e79-FDA_email_11jan2013_customerlist&utm_medium=email#!submitComment;D=FDA-2012-N-1148-0011
FOR V2: http://www.regulations.gov/?utm_source=V2Cigs.com+Newsletter&utm_campaign=4a5a75101e-V2_Cigs_FDA1_14_2013&utm_medium=email#!documentDetail;D=FDA-2012-N-1148-0011

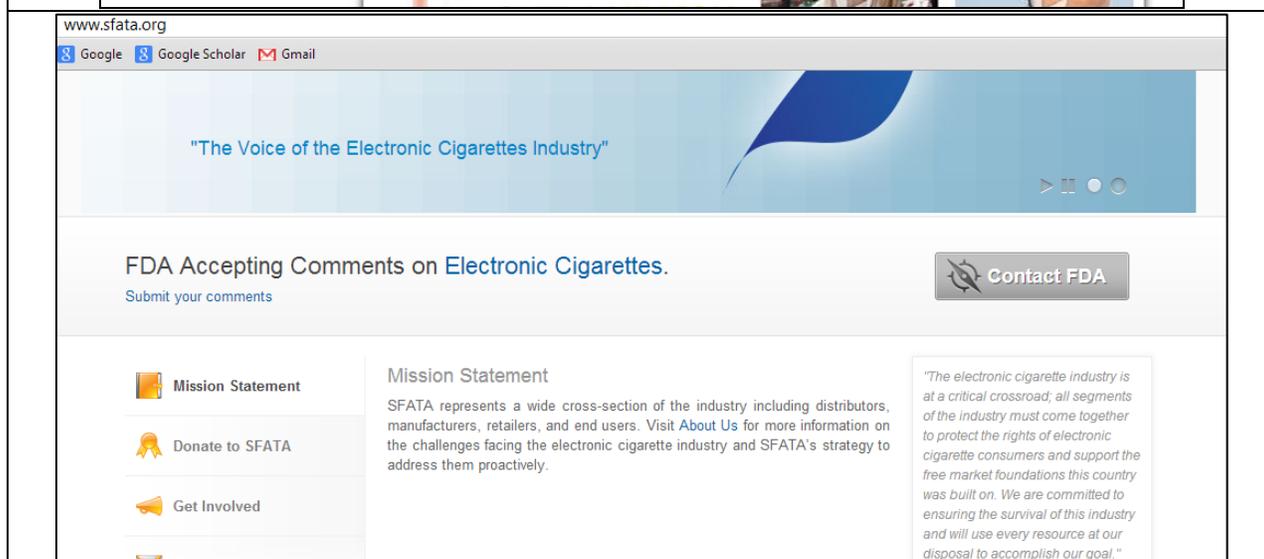
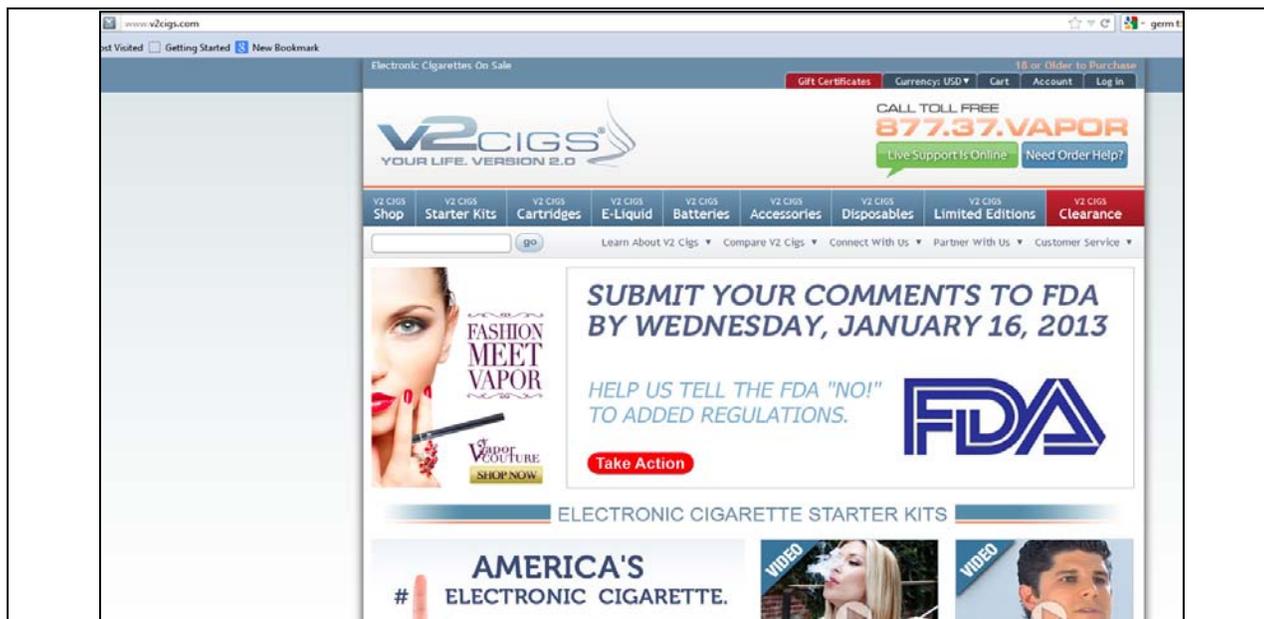


Figure 2. Homepage of V2Cigs and the Smoke Free Alternatives Trade Association encouraging submissions to docket FDA-2012-N-1148-0011 on a report to Congress about smoking cessation therapies . The links in these pages were:
 FOR V2: <http://www.v2cigs.com/blog/2013/01/help-us-tell-the-fda-not-to-further-regulate-electronic-cigarettes/> and
 FOR SFATA: Went to another page: <http://www.sfata.org/call-to-action/> On that page if you clicked the link at the bottom it went here: <http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1148-0011>

Altimoff



Alternative to smoking cig

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CATEGORIES:

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

- ⋮ HOME
 - ⋮ PRODUCTS
 - ⋮ PRODUCT INFO
 - ⋮ CIGARETTE DANGERS
- ⋮ FAQ
 - ⋮ ABOUT US
 - ⋮ CONTACT US
 - ⋮ LOGIN

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
+ FRE
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 work, you can also work as our reseller or sales consultant and earn sales commission!
[Click here to learn more >](#)

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 (top) and information about how Altimoff e-cigarettes can be used to quit smoking in the FAQ section of 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

Just wanted to let you know how much I love your product. I have smoked for over 30 years and thanks to Smoke Stik I have quit. I know that this product was not meant to be a quitting type of product but it worked for me. I tried the patches, gum, mints and Chantix....none of them worked. I now use the non nicotine flavor and just the thoughts of having it in my hand and the "smoke" coming out, I quit thanks to your product.

Deborah

Testimonial about quitting with the e-cigarette in contrast to approved smoking cessation therapies on www.smokestik.com

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

Figure 4. Testimonials on e-cigarette websites regarding using the e-cigarette to quit smoking, www.smokestik.com (top) and www.vapornine.com (bottom) January 14, 2013

<p>30 DAY Money Back Guarantee No Risk. No Obligation. Learn More ></p>	<p>LIFETIME Warranty Worry Free Protection Learn More ></p>	<p>Smoke For FREE Earn Credits for Referrals Learn More ></p>	<p>Worldwide Shipping Daily International Shipments Learn More ></p>	<p>Superior Quality Tasted. Proven. Performance Learn More ></p>
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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.

NEWSLETTER

SIGN UP TO RECEIVE SPECIAL OFFERS AND PROMOTIONS FROM V2CIGS.

Enter Email Address

FOLLOW V2CIGS



V2PROFIT AFFILIATE NETWORK

- OVER \$20 MILLION PAID IN COMMISSIONS
- EARN \$25.00 JUST FOR SIGNING UP!

[JOIN NOW >](#)

YOU MUST BE OF LEGAL SMOKING AGE TO BUY AND/OR USE ANY V2 CIGS PRODUCT.

WARNING: This product is not intended for use by persons under legal smoking age, nonsmokers, women who are pregnant or breastfeeding, or persons with or at risk of heart disease, high blood pressure, diabetes, or taking medicine for depression or asthma. This product contains nicotine. If you are allergic to nicotine, propylene glycol, or any combination of inhalants, if you are pregnant or breast-feeding, or if you have a heart condition, diabetes, high blood pressure or asthma, consult your physician before using any V2 Cigs products. Discontinue use and consult a physician if you experience nicotine misuse symptoms such as nausea, vomiting, dizziness, diarrhea, weakness and rapid heartbeat.

Our products do not treat, diagnose, or cure any disease, physical ailment, or condition. Keep out of the reach of children and pets as ingestion of certain pieces can present a choking hazard. Nicotine can be toxic if inhaled or ingested in large doses, and may cause irritation to eyes and skin if exposed. Wash immediately with soap and water upon contact. Nicotine is highly addictive and habit forming.

CALIFORNIA PROPOSITION 65 Warning: This product contains nicotine, a chemical known to the state of California to cause birth defects or other reproductive harm.

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 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."

Posted in [RivoSig Blog](#) and tagged with [assistance](#), [contribute](#), [tragedy](#), [donate](#), [support](#), [help](#), [donation](#), [shooting](#), [school](#), [elementary](#), [sandy hook](#), [rivosig](#) by [RivoSig®](#).

Shape Magazine on Electronic Cigarettes

Posted on December 3, 2012

I think we can all agree that cigarettes are not found neatly under the "Health Concious Things To-Do" category. If it's not the graphic television advertising, online media, or the public service announcements you can probably figure that out from the warnings plastered on every single pack. Cigarettes are indeed horrible for you. They are littered with over 4,000 toxic chemicals, they cause lung disease and emphysema and the heavy-hitter...cancer. So many people have tried to quit smoking. Some choose the gum, the patch, or even cold turkey (hats-off to those who succeed on that one).

I suppose when you break it down simplistically, when you smoke a traditional cigarette your intent is to obtain nicotine into your bloodstream to ...well...take the edge off, relax a bit, etc. Whatever the reason it IS fact that the nicotine you are putting into your lungs is riding the coat-tails of several disgusting toxic, and deadly chemicals. It's kind of like someone incasing your favorite food in rat poison and despite the obvious death wish, you just chew right through the poison to get to the tasty morsels that are held within. Well cigarettes are no different. You want the nicotine right? Why get it into your lungs with the schmorgesborg of toxins when all you really want is the nicotine?

Electronic cigarettes offer that gateway. Oh yea, and instead of the toxins paving the way to your lungs, it's distilled water vapor, glycerin (a sugar product), flavoring and nicotine purely extracted from tobacco leaves. Basically, you're sucking in steam and some ingredients to give the e-cig a nice flavor along with the nicotine. Sounds a bit better than putting your mouth on an exhaust pipe right?

Now legally we can't say that RivoSig e-cigarettes are a smoking cessation product, nor can we tell you they are better for you (those legal pencil-pushers at the FDA would get there panties ruffled if we did). However, what we can offer is unbiased knowledge and research that comes from reputable sources.

In this series of our blog posts we are going to dig up the research goodies for you. Why should you have to search?

This weeks post features an article from Shape Magazine. Yes, Shape Magazine. You know, the health-conscious magazine that would probably spontaneously combust if you even put it next to a pack of cigarettes.

Take a look...we'll let their editors do the talking for us:

Live Healthy SOLUTIONS

KICK BUTTS—FOR GOOD

Yes, giving up cigarettes is tough. But there's more help available than ever before—and no better time to win at quitting. BY JOAN RAYMOND

Click here to read the PDF

THE TRUTH ABOUT E-CIGARETTES
You're not even there yet. But can they help you quit? Although electronic cigarettes look like the real thing and contain nicotine, they lack the toxic tars and other additives found in a typical pack of cigarettes. That's because has led the American Association of Public Health Physicians to say that if all current smokers switched to e-cigs, tobacco-related deaths might be slashed by 50 percent over the next 20 years. The catch is that they won't break your nicotine addiction—only your reliance on regular cigarettes. Plus, some research shows they may cause breathing difficulties in some people. Soit says Michael Siegel, M.D., a professor at Boston University School of Public Health. "E-cigarettes may be worth considering if other methods have failed you."

92 SHAPE.MAGAZINE.2012@SHAPE.COM

Figure 6. Full text of the blog entry on the RivoSig site with accompanying image on January 14, 2013: <https://rivosig.com/blog/#.UPCFhdXCnWB>. Where it says "Click here to read the PDF" is a link to <https://rivosig.com/media/wysiwyg/rivosig-electronic-cigarettes-shape-magazine.pdf>