

Comment on

FDA’s Proposed Regulations: Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”

Docket No. FDA-2015-N-2002

UCSF TCORS¹

November 18, 2015

Cessation and “satisfaction” claims cause confusion for consumers, so any products making such claims should be regulated under FDA’s drug/device authorities.

FDA’s proposed rule attempting to clarify when products made or derived from tobacco should be regulated as drugs, tobacco products, or modified risk tobacco products is a necessary and positive step towards minimizing confusion for consumers and thereby protecting the public health. Currently, many non-cigarette products that are made or derived from tobacco (such as e-cigarettes, cigars, smokeless tobacco/chew, and snus) make marketing claims (either explicit *or implicit*) that communicate that they are frequently used, are intended to be used, or can be used to help quit smoking, to alleviate nicotine cravings, or to provide the same nicotine hit or “satisfaction” as conventional cigarettes. Some alternative products make other unsubstantiated therapeutic claims that they deliver vitamins, boost energy, cure sleeplessness, and aid weight loss. These claims confuse consumers and lead them to think that these products, like other FDA-approved cessation products such as nicotine gum or patches, or other drugs and supplements such as sleeping pills and multi-vitamins, are effective for cessation, treating nicotine addiction and withdrawal, or managing vitamin deficiencies, and are harmless or less harmful than cigarettes. That manufacturers sometimes accompany these obvious therapeutic or modified risk claims with legalese disclaimers to evade regulation does not cure the problem.

FDA’s final rule should clearly and directly provide that any and all claims made about products – including claims distributed in both conventional and new social media formats – that either explicitly or implicitly suggest that the product can or might be used for smoking cessation, to cure or treat nicotine addiction, to provide the same “satisfaction,” “nicotine fix,” and other pleasures of smoking, or for other therapeutic uses, shall be regulated under FDA’s drug/device authority

The proposed rule’s reliance on the basic statutory definitions of “drugs” and “devices” and the two-prong test that would treat a product made or derived from tobacco as a drug or device if it is either: (1) intended for use in diagnosing, curing, mitigating, treating, or preventing a disease (the “disease prong”); or (2) intended to affect the

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structure or function of the body in any way that is different from effects of nicotine that were “customarily” claimed in marketing prior to the March 2000 *Brown & Williamson* decision (the “structure/function prong”) is appropriate. However, any marketing claims made prior to March 2000 would necessarily have been made prior to the August 2006 legal decision in *United States v. Philip Morris*,² which uncovered the tobacco industry’s fifty-year history of defrauding the public about the physiological and addictive effects of nicotine. ***Therefore, FDA’s proposal does not go far enough; FDA should also consider claims suggesting that a tobacco product will provide the same “satisfaction” or nicotine hit as conventional cigarettes and/or provides an alternative way to get the same “pleasures of smoking” to fall within its drug and device authority.***

In two previous comments to the FDA,^{3,4} incorporated herein, we presented evidence of cessation claims made by companies selling and manufacturing e-cigarettes and other tobacco products. Here we provide additional scientific evidence and examples of cessation and other therapeutic claims made by manufacturers of e-cigarettes and other non-cigarette products made or derived from tobacco. Moreover, we demonstrate that consumers are confused by these claims, and we show that these claims fall within FDA’s drug and device authority because:

1. The manufacturers make explicit and implicit claims in advertisements that these products are smoking cessation aids and have other therapeutic uses;
2. Confusing cessation and therapeutic claims are made in both mainstream media as well as in blogs, testimonials, and social media formats that are especially attractive to youth and young adults;
3. The placement of e-cigarettes and other alternative tobacco products near smoking cessation devices in retail stores confuses consumers;
4. Cessation and therapeutic claims influence adult, older adult, and adolescent smokers’ misperceptions about the supposed benefits and relative harms, risks, and addictive properties of e-cigarettes and other non-cigarette products. These claims confuse consumers, lead them to believe that these products are safe and effective like FDA-approved nicotine replacement therapies and other therapeutic purposes, and encourage initiation and ongoing use of non-cigarette tobacco products. Therefore, products made or derived from tobacco that make these claims should be subject to regulation by FDA as a drug, device, or a combination product; and

² *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff’d in part & vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam), *cert. denied*, 561 U.S. ___, 130 S. Ct. 3501 (2010).

³ Grana R., Ling PM, Barnes RL, Lempert L, Glantz SA. (2013). 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. Tracking # 1jx-835b-n9ph.

⁴ Dutra LM, Grana RA, Lempert L, Cataldo JK, Glantz SA, Halpern-Felsher BL, Ling PM, Popova L, Walsh M. (2014). FDA should prohibit e-cigarette marketing that promotes false health claims. Docket No. FDA-2014-N-0189. June 3, 2014. Tracking # 1jy-8cgs-11sq

5. Claims suggesting that a tobacco product provides “satisfaction,” a “nicotine fix,” or other “pleasures of smoking” are claims about the pharmacological affects of nicotine, and therefore should be regulated under FDA’s drug/device authority.

Further, we show that:

6. Many claims made by manufacturers that non-cigarette tobacco products are less harmful than conventional cigarettes should be regulated as modified risk tobacco claims;
7. FDA’s economic impact analysis does not appropriately analyze the costs and benefits of the proposed rule; and
8. FDA’s proposed rule should be modified to strengthen FDA’s ability to protect the public health.

Companies should not be permitted to market the physically identical or similar tobacco products as both medicinal and recreational. In such cases, FDA should regulate both products under its drug/device authority to prevent confusion for consumers. FDA must be vigilant in monitoring the market to ensure that companies do not try to introduce and market physically identical or similar tobacco products that differ only in name and/or packaging or nearly identical products under both its Center for Drug Evaluation and Research (CDER) and its Center for Tobacco Products’ (CTP) by making cessation or therapeutic claims about one of the products (causing it to be regulated as a drug/device) and making recreational claims about the other product (causing it to be regulated as a tobacco product). Additionally, no tobacco product should be permitted to use CTP’s substantial equivalence pathway if the predicate product to which it is being compared entered the market through CDER. ***Any product that is substantially equivalent to a product regulated by CDER must also be regulated by CDER.***

The manufacturers of e-cigarettes and other alternative tobacco products make explicit and implicit claims that these products are smoking cessation aids and have other therapeutic uses. Products that make such claims should be regulated as drugs.

A proliferation of ads and other messages made by e-cigarette companies, including those owned by the top cigarette manufacturers, either implicitly or explicitly claim that e-cigarettes will aid conventional smoking cessation.⁵ A systematic content analysis of e-cigarette web marketing found that 95% of the websites studied between June and July 2011 made explicit or implicit health-related claims, and 64% made explicit smoking cessation claims. A September 2015 Truth in Advertising analysis found that, of the 159 sites they surveyed, 31% made cessation claims through testimonials,

⁵ Grana R, Ling P. Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*. 2014;46(4):395-403. Truth Initiative (formerly American Legacy Foundation). *Vaporized: E-Cigarettes, Advertising, and Youth*, available at http://truthinitiative.org/sites/default/files/LEG-Vaporized-E-cig_Report-May2014.pdf (accessed November 17, 2015)

studies, or statements in the advertising.⁶ Reacting to this analysis, five major health groups wrote the FDA on October 14, 2015 urging it to take immediate action to investigate therapeutic smoking cessation claims found on e-cigarette sites and to take prompt and appropriate enforcement action against those found to be violating the law.⁷

An October 29, 2015 review of the Stanford Research into the Impact of Tobacco Advertising website⁸ yielded over 300 examples of e-cigarette ads claiming cessation. Some of the ads make explicit claims that e-cigarettes help users stop smoking (Figure 1); others make more subtle or implicit claims, such as suggesting that users should switch from conventional cigarettes to e-cigarettes (Figure 2).

In addition to cessation claims, many e-cigarette companies claim that their products are “natural” or “organic,” implying that they are healthier. For example, Velvet Cloud markets its “organic, all natural e-liquid” that is “hand-brewed in micro-batches”⁹ and NutriCigs promotes its “fortified electronic cigarettes” that “utilize nanograms of proven, all-natural, USA made synthetic-free ingredients, in the advanced delivery method of vapor technology.”¹⁰ Examples of such e-cigarettes on the company’s website include “all natural energy booster” (Figure 3), and “all-natural sleep aid” (Figure 4).

E-cigarettes are frequently advertised using doctors as models or spokespersons to imply health benefits. For example, the content analysis of e-cigarette retail websites found that 22% depicted doctors in their ads¹¹ (Figure 5). This strategy has been used successfully in cigarette advertising since the 1930s to deceive consumers into believing that doctors endorse smoking because it is not only not harmful, but also has potential health benefits¹² (Figure 6).

E-cigarette advertisements also make other therapeutic claims, including that e-cigarettes can help users lose weight¹³ (Figure 7), boost energy¹⁴ (Figure 3), sleep better¹⁵

⁶ Truth in advertising.org. Smoking out e-cigarette ad claims. <https://www.truthinadvertising.org/smoking-out-e-cigarette-ad-claims/#cessation>. Accessed 10/30/2015.

⁷ Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Truth Initiative. FDA urged to move quickly on e-cigarette cessation claims. Available at <https://www.truthinadvertising.org/wp-content/uploads/2015/10/Letter-to-FDA-re-cessation-claims-10-14-15.pdf> (accessed November 1, 2015)

⁸ SRITA; http://tobacco.stanford.edu/tobacco_main/subtheme_ecigs.php?token=fm_ecigs_mt043.php (accessed on October 30, 2015)

⁹ Velvet Cloud. <http://www.velvetcloud.com/> (accessed November 1, 2015)

¹⁰ NutriCigs. <http://www.nutricigs.com/> (accessed November 1, 2015)

¹¹ Grana R, Ling P. Smoking Revolution? A content analysis of electronic cigarette retail websites. *American Journal of Preventive Medicine*. 2014;46(4):395-403.

¹² SRITA, http://tobacco.stanford.edu/tobacco_main/images-comp.php?token2=fm_tn_st300.php&token1=fm_tn_img9821.php&theme_file=fm_tn_mt035.php&theme_name=Cigs%20vs.%20eCigs&subtheme_name=Cigs%20vs%20eCigs%20Doctors (accessed October 30, 2015)

¹³ SRITA, http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st510.php&token1=fm_ecigs_img21954.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Lose%20Weight (accessed October 31, 2015)

¹⁴ SRITA, http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st542.php&token1=fm_ecigs_img23975.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Energy%20Boost (accessed October 31, 2015)

¹⁵ SRITA, http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st508.php&token1=fm_ecigs_img21920.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Calming (accessed October 31, 2015)

(Figure 4), get nutritional and vitamin supplementation¹⁶ (Figure 8), and stimulate sex¹⁷ (Figure 9). Some e-cigarette companies have even unlawfully placed a FDA logo on their products¹⁸ (Figure 10).

Despite FDA-issued warnings that cessation or health claims must not be made,¹⁹ manufacturers and sellers of other non-cigarette tobacco products such as snus and moist snuff continue to make such misleading cessation claims. For example, snus advertising has made claims that these products may facilitate reduction or cessation of cigarette use.²⁰ Instead of reducing cigarette use, these claims might encourage dual use of these products and cigarettes²¹ (Figure 11). Other ads state that snus and moist snuff contain “natural” or “organic” ingredients, implying that they are therefore more healthful. For example, Copenhagen snus comes in “Natural pouches,”²² cans of General snus advertise “Naturally grown tobacco”²³ and Grizzly advertises “Premium natural”²⁴ moist snuff.

Confusing cessation and therapeutic claims are made in blogs and social media formats that are especially attractive to youth and young adults and easily evade regulation.

Cessation and therapeutic claims about tobacco products come in many forms in addition to traditional print or mainstream media including blogs, social media, testimonials, and links to studies or media reports on websites. Some claims are blatant, while other cleverly crafted claims are subtle or veiled.²⁵ Manufacturers of e-cigarettes or e-liquids often use online blogs as a way to make implicit or explicit cessation claims, and in some cases such assertions run counter to disclaimers posted on the same website that hosts the blog. For example, the e-liquid retailer Tasty Vapor (Oakland, CA) includes the following message at the bottom of its commercial website home page (Figure 12): *“The use of PV’s (personal vaporizers) are an alternative to smoking traditional cigarettes. Tasty Vapor makes products exclusively for use in PV’s. We make no claim that our products are for smoking cessation, nor a cure for smoking/nicotine addiction. If you wish to quit smoking or discontinue the use of nicotine related products, we strongly advise you to consult your personal physician.”*²⁶

¹⁶ SRITA,

http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st509.php&token1=fm_ecigs_img21953.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Nutritional (accessed October 31, 2015)

¹⁷ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/medicinal/large/med_1.jpg (accessed October 31, 2015)

¹⁸ <https://www.fasttech.com/products/3009/10004171/1310900-dekang-e-liquid-for-electronic-cigarettes-50ml> (Accessed November 9, 2015)

¹⁹ See for example, FDA warning letters to Vaperz Ltd, Knoxville Vapor, and Dr. K, issued April 2, 2015, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm441314.htm>;

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm441310.htm>;

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm441302.htm> (accessed November 17, 2015)

²⁰ Mejia AB, Ling PM. Tobacco industry consumer research on smokeless tobacco users and product development. *Am J Public Health*. 2010 Jan;100(1):78-87.

²¹ Popova L, Ling, PM. Alternative tobacco product use and smoking cessation: A national study. *American Journal of Public Health*. 2013; 103(5): 923-930.

²² Snubie.com, Snus news, reviews and information. <http://chadizy1.blogspot.com/2014/03/copenhagen-snus-wintergreen-mint-and.html> (accessed November 3, 2015)

²³ General Green Harvest. <http://blog.northerner.com/reviews/snus-reviews/general-green-harvest/> (accessed November 3, 2015)

²⁴ Trinkets and Trash. <https://trinketsandtrash.org/detail.php?artifactid=7056&page=1> and

<https://trinketsandtrash.org/detail.php?artifactid=7732&page=1> (accessed November 3, 2015)

²⁵ Truth in Advertising. <https://www.truthinadvertising.org/smoking-out-e-cigarette-ad-claims/> (accessed October 30, 2015)

²⁶ Tasty Vapor. “www.tastyvapor.us/” Accessed: October 23, 2015.

On the same website,²⁷ Tasty Vapor posts periodic blog entries. A post dated October 15, 2015 (Figure 13), titled, “Tips on How to Make the Switch” made clear to consumers that vaping products can be used to quit cigarette smoking. This manufacturer-attributed blog post included numerous implicit claims that vaping can be used to enhance smoking cessation, including, “*you’ve finally decided to do something about your smoking habit;*” and, “*When making the switch from cigarettes to vaping, it is extremely important to enlist the help of a friend or family member, especially if one of your main goals is to quit smoking.*”²⁸ Despite the presence of an explicit disclaimer on the website home page, the message conveyed from this blog entry clearly constitutes a therapeutic claim regarding e-liquid and e-cigarette products. The content of this blog posting is an example of a claim that would require FDA product regulation as a drug.

The placement of e-cigarettes and other alternative tobacco products near smoking cessation devices in retail stores also confuses consumers.

Another claim related to use of electronic cigarettes as smoking cessation devices comes from the location where these products are sold. E-cigarettes are sometimes sold in the “smoking cessation” section (Figure 14). Selling these products in convenience stores or in pharmacies under the title “smoking cessation” sends the message to consumers that these products are effective smoking cessation devices.²⁹

Cessation and therapeutic claims influence adolescent, adult, and older adult smokers’ misperceptions about the supposed benefits and relative harms, risks, and addictive properties of e-cigarettes and other non-cigarette products.

As stated by the proposed rule,³⁰ “The FD&C Act defines ‘drug’ (in relevant part) as an article intended either: (1) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” Alternative tobacco products’ implicit and explicit claims that these devices can be used as smoking cessation devices sends the message that they can cure or treat cigarette addiction or cigarette use and thereby prevent smoking-related diseases. “Accordingly, FDA has long considered claims related to smoking cessation in the context of curing or treating nicotine addiction and its symptoms to be within FDA’s ‘disease prong’ jurisdiction.” Smoking cessation would be the “intended use” of alternative tobacco products and therefore it should “be regulated as a medical product, not as a tobacco product.”

As requested in the draft FDA rule, we looked “to ‘any . . . relevant source,’ including but not limited to the product’s labeling, promotional claims, and advertising”

²⁷ Tasty Vapor. Tips on How to Make the Switch (online blog). “<http://www.tastyvapor.us/blog/tips-on-how-to-make-the-switch/>” Accessed: October 23, 2015.

²⁸ Tasty Vapor. Tips on How to Make the Switch (online blog). “<http://www.tastyvapor.us/blog/tips-on-how-to-make-the-switch/>” Accessed: October 23, 2015.

²⁹ UCSF TCORS Investigators. Adopted from Responses to FDA Questions on E-Cigarettes and Public Health; Docket Number FDA-2014-N-1936.

³⁰ Food and Drug Agency. Clarification of when products made or derived from tobacco are regulated as drugs, devices, or combination products; amendments to regulations regarding “intended uses”. FR Doc. 2015-24313. Filed 9/24/15. <http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-2002-0001>. Accessed 10/26/15.

to guide this comment, keeping in mind that the “FDA is not bound by the manufacturer or distributor's subjective claims of intent.” Product claims outlined in this comment are consistent with the claims that the FDA has stated would classify products under the “disease prong” and therefore make them subject to regulation as drugs or devices (e.g., “treatment of tobacco dependence,” “wean yourself off of nicotine,” “for people who wish to quit smoking,” “stop smoking aid,” “prevent relapse,” or “stay quit”).

Claims that e-cigarettes can be used as smoking cessation tools directly influence consumer opinions about such products and their use. As correctly noted in the proposed rule, “smoking cessation claims on any product generally create a strong suggestion of therapeutic benefit to the user that generally will be difficult to overcome absent clear context indicating that the product is not intended for use to cure or treat nicotine addiction or its symptoms, or for another therapeutic purpose... Where products making claims related to quitting smoking also attempt to disclaim that use in some way, FDA intends to view such disclaimers skeptically because of the likelihood of consumer confusion. In most cases, FDA does not believe that disclaimers will sufficiently mitigate consumer confusion related to the intended therapeutic use of the product.”³¹

The rest of this section summarizes results from several studies that demonstrate that users consider e-cigarettes and smokeless tobacco products effective cessation interventions.

Influenced by manufacturers’ and sellers’ unsubstantiated marketing messages that make cessation and therapeutic claims about e-cigarettes and other non-cigarette tobacco products, many people use these products to try to stop smoking.^{32,33,34,35} In a nationally representative sample of 1,836 current or recently former smokers collected in November 2011, 36% of smokers reported trying an alternative tobacco product (loose leaf chewing tobacco, moist snuff, snus, dissolvable tobacco, or e-cigarettes), and those who intended to quit smoking were more likely to have used these products.³⁶ However, despite claims that these products may aid smoking cessation, the smokers were not more likely to report successful quit attempts. A qualitative study of smokers who tried snus found that although some tried snus thinking of it as a way to reduce or quit smoking, some smokers actually found that the product reinforced their preference for smoking, and they did not actually find it to be an acceptable cessation aid.³⁷ Similarly, data from

³¹ Food and Drug Agency. Clarification of when products made or derived from tobacco are regulated as drugs, devices, or combination products; amendments to regulations regarding “intended uses”. FR Doc. 2015-24313. Filed 9/24/15. <http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-2002-0001>. Accessed 10/26/15.

³² Etter JF. Electronic cigarettes: a survey of users. *BMC Public Health*. 2010; 10: 231.

³³ Pearson JL, Richardson A, Niaura RS, Vallone DM, Abrams DB. e-Cigarette Awareness, Use, and Harm Perceptions in US Adults. *American Journal of Public Health*, 2012; 102 (9): 1758-1766.

³⁴ Pokhrel P, Fagan P, Kawamoto CT, Herzog TA. Smokers who try e-cigarettes to quit smoking: Findings from a multiethnic study in Hawaii. *American Journal of Public Health*, 2013; 103(9): e57-e62.

³⁵ Vickerman KA, Carpenter KM, Altman T, Nash CM, Zbikowski SM. Use of electronic cigarettes among state tobacco cessation quitline callers. *Nicotine Tob Res*. 2013; 15 (10): 1787-1791.

³⁶ Popova L, Ling, PM. Alternative tobacco product use and smoking cessation: A national study. *American Journal of Public Health*. 2013; 103(5): 923-930.

³⁷ Bahreinifar S, Sheon NM, Ling PM. Is snus the same as dip? Smokers' perceptions of new smokeless tobacco advertising. *Tob Control*. 2013 Mar;22(2):84-90.

two clinical trials did not find any evidence of higher smoking cessation rates among smokeless tobacco (such as snus) users (compared to nonusers).^{38,39}

The same November 2011 nationally representative sample of smokers showed that cessation and therapeutic claims shape perceptions about tobacco products and influence purchasing decisions. For example, smokers expressed more interest in trying alternative tobacco products, such as e-cigarettes, snus, dissolvables, and moist snuff, when questions about these products referenced specific reasons to use, such as in situations when they cannot smoke, if these products were described as something to help them quit or reduce smoking.^{40,41} These themes perfectly match the messages used to promote Camel snus. Camel snus ads urge smokers to use snus in smoke-free environments to “break free” and “boldly go anywhere,” and proclaim snus to be “bar-friendly,” “concert-friendly,” “endless meeting-friendly,” and even “date-friendly.”⁴² Snus has also been promoted for cessation in the Camel snus “Smoke-free resolution” campaign, which encouraged smokers to switch to Camel snus around the New Year, a time when many smokers make a resolution to quit smoking.⁴³ In contrast, when smokers were asked about interest in trying these products without including wording on a specific cessation benefit, smokers were overwhelmingly not interested in smokeless tobacco products (snus, moist snuff, and dissolvables) and only somewhat interested in trying e-cigarettes.⁴⁴

A focus group study conducted October 2013 through January 2014 with 90 older smokers (≥ 45 yrs) revealed that older smokers are using e-cigarettes in increasing numbers. Those exposed to e-cigarette advertisements were more likely to perceive e-cigarettes as 1) an effective cessation aid, 2) having less risk than cigarettes, and 3) a way to “deal with no smoking laws.”⁴⁵

In a 2014 cross-sectional national online survey of 555 older smokers (mean age 57), the participants reported exposure to tobacco ads online, in print, on TV and radio, and at point-of-sale.⁴⁶ The majority of the anti-tobacco messages seen were about the risks of cigarette use and the majority of pro-tobacco messages were advertisements for e-cigarettes.⁴⁶ In this sample of older smokers, prevalence of last 30-day dual use of e-

³⁸ Tønnesen P, Mikkelsen K, Bremann L. Smoking cessation with smokeless tobacco and group therapy: an open, randomized, controlled trial. *Nicotine Tob Res.* 2008; 10 (8):1365-1372.

³⁹ Lund KE, Scheffels J, McNeill A. The association between use of snus and quit rates for smoking: results from seven Norwegian cross-sectional studies. *Addiction.* 2011; 106 (1):162-167.

⁴⁰ Popova, L. (2014). Scaring the snus out of smokers: Testing effects of fear, threat, and efficacy on smokers' acceptance of novel smokeless tobacco products. *Health communication*, 29(9), 924-936.

⁴¹ Popova L, Ling, PM. Alternative tobacco product use and smoking cessation: A national study. *American Journal of Public Health.* 2013; 103(5): 923-930.

⁴² Trinkets & Trash, Artifacts of the Tobacco Epidemic. <https://trinketsandtrash.org/detail.php?artifactid=5937&page=3> (accessed November 1, 2015)

⁴³ Trinkets & Trash, Artifacts of the Tobacco Epidemic. https://trinketsandtrash.org/detail.php?item_number=214003 (accessed November 1, 2015)

⁴⁴ Popova L, Ling PM. Alternative tobacco product use and smoking cessation: A national study. *American Journal of Public Health.* 2013; 103(5): 923-930.

⁴⁵ Cataldo JK, Petersen AB, Hunter M, Wang J, Sheon N. E-cigarette marketing and older smokers: road to renormalization. *A J Health Behav.* 2015;39(3):361-71.

⁴⁶ Wang J, and Cataldo JK. Preliminary Findings on Flavored Tobacco Products and E-Cigarette Use in Older Adult Smokers. NIH Tobacco Centers of Regulatory Science 2014 Annual Fall Meeting; November 2014; Bethesda Maryland.

cigarettes and cigarettes was 24.3% and prevalence of last 7-day dual use was 16.6%.⁴⁶ This sample believed that e-cigarettes are *not* a tobacco product (41.2%), have no tar (55.5 %), are safer than cigarettes (61.9%), are not addictive (25.1%), and are helpful for people quitting cigarettes (63.7%).⁴⁶ To prevent these misconceptions caused by advertising that promotes e-cigarettes as harm reduction and smoking cessation aids, e-cigarettes should be regulated as drugs.

In a 2015 national survey in which adult (≥ 45 years old) current and former smokers (quit less than 5 years ago) were asked how likely they were to try an e-cigarette for the first time in the next six months, one in ten agreed that it was likely that they would try an e-cigarette with flavor and with or without nicotine.⁴⁷ Of the 555 current smokers, 187 (33.7%) used e-cigarettes to try and quit cigarettes; of the 187, 67 (35.8%) were able to fully quit cigarettes but continued to use e-cigarettes; and they continued to use e-cigarettes for a mean of 4.7 months after quitting cigarettes ($SD=2.3$). Of those 187, only six (3.2%) reported being “cigarette free now” and only two out of 187 (1.1%) reported being both “cigarette and e-cigarette free now.”³

Because of the tendency for consumers to rely on manufacturers’ unsubstantiated claims and use e-cigarettes as a smoking cessation product (often unsuccessfully), these products should be regulated as drugs to combat these misperceptions.

Adolescent smokers are especially vulnerable to cessation and therapeutic claims in tobacco product marketing, and misperceive the supposed benefits and underestimate the relative harms, risks, and addictive properties of e-cigarettes and other non-cigarette products.

Adolescents may be particularly vulnerable to unsubstantiated health claims in tobacco product marketing. Adolescents are exposed to both professional advertisements and peer-to-peer messaging about e-cigarettes. They report being exposed to tobacco ads both online and in print as well as on TV, radio and at point-of-sale. Further, they report mostly seeing ads for the risks of cigarette use, whereas they are exposed more to advertisements regarding the benefits of using e-cigarettes. Similarly, adolescents are more likely to report or forward messages they see regarding the risks of cigarettes than e-cigarettes, but post the benefits of e-cigarettes more than cigarettes. This section describes several studies of adolescents that demonstrate how cessation and therapeutic claims in marketing targeted at adolescents cause adolescents to be confused about the addictive properties and risks of e-cigarettes and other non-cigarette products.

In a study of almost 700 9th and 12th grade adolescents, it was found that adolescents rated the various tobacco products as conferring significantly different levels of risks and benefits.⁴⁸ Generally, adolescents’ rated cigarettes as most risky, followed by cigars and chew, with hookah and e-cigarettes rated as least risky. Adolescents rated

⁴⁷ Cataldo JK and Delucchi K. Older Smokers’ Perceptions of Tobacco-Related Risks, Benefits and Acceptability of Use for Cigarettes and Alternative Tobacco Products. NIH Tobacco Centers of Regulatory Science 2015 Annual Fall Meeting; October 2015; Bethesda Maryland

⁴⁸ Halpern-Felsher B, Roditis R, and Cash D. Assessing adolescents’ perceptions of health risks, social risks and benefits across tobacco products. American Public Health Conference; November 4, 2015; Chicago, IL.

hookah followed by cigarettes and e-cigarettes as most likely to make them look cool or fit in, and cigars and chew as least likely to confer these benefits. Older adolescents and those who had used tobacco previously held the lowest perceptions of risk.

Unsubstantiated cessation claims in marketing of e-cigarettes and other non-cigarette tobacco products that reach adolescents is confusing and lead teens to believe that these products are useful quitting aids. For example, a teenager in a recent qualitative study said, “I heard that the only reason they were made is to help people get off from cigarettes for people that want to quit. You would use an e-cigarette to help you quit supposedly. It was on the news.”⁴⁹

Many dual-users of smokeless tobacco with cigarettes believe that smokeless tobacco can be used for cigarette cessation. In the 2008 Consumer Styles survey of more than 10,000 Americans, 25% of smokeless tobacco and cigarette dual-users selected smokeless tobacco products as a modality that can be used to help quit smoking from a list that also included evidence-based modalities such as nicotine replacement therapy and anti-depressant medications.⁵⁰

In a nationally representative sample of current and recently former US smokers, 7.8% of the respondents reported that they tried to quit smoking by switching to chewing tobacco, snuff, or snus and an additional 5.8% considered it but never tried.⁵¹ These numbers were higher among those who ever tried moist snuff, snus, dissolvables, or e-cigarettes (n = 632). Among them, 21.0% reported trying to quit smoking by switching to smokeless tobacco, and 9.9% considered it.

These claims confuse consumers, lead them to believe that these products are safe and effective like FDA-approved drugs and devices used for cessation and other therapeutic purposes, and encourage initiation and ongoing use of non-cigarette tobacco products. Products made or derived from tobacco that make these claims should be subject to FDA’s drug/device regulatory authority.

The Family Smoking Prevention and Tobacco Control Act (FSPTCA),⁵² final Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,⁵³ and the Master Settlement Agreement²¹ already impose restrictions on advertising (especially advertising targeted at youth) for cigarettes and smokeless tobacco. Section 903 of the FSPTCA provides that a tobacco product shall be considered misbranded if its labeling is false or misleading in any way, and section 911 prohibits the sale or distribution of tobacco products for which the labeling or advertising represents either *explicitly or implicitly* that the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially

⁴⁹ Roditis, M.L., & Halpern-Felsher, B. Adolescents’ perceptions of risks and benefits of conventional cigarettes, e-cigarettes and marijuana: A Qualitative Analysis. *Journal of Adolescent Health*. 57(2); 179-85, 2015.

⁵⁰ McClave-Regan AK, Berkowitz J. Smokers who are also using smokeless tobacco products in the US: a national assessment of characteristics, behaviours and beliefs of ‘dual users’. *Tob Control*. 2011;20(3):239-42.

⁵¹ Popova L, Ling PM. Alternative tobacco product use and smoking cessation: A national study. *American Journal of Public Health*. 2013; 103(5): 923-930.

⁵² Pub.L. 111-31, H.R. 1256 (June 22, 2009)

⁵³ 75 FR 13225 (March 19, 2010)

marketed tobacco products. FDA should use its authority under the FSPTCA to extend these restrictions to e-cigarettes and all newly covered products.⁵⁴ The FDA has the authority under sections 906(d) and 907 of the FSPTCA to issue regulations requiring restrictions on the sale and distribution of tobacco products for the protection of the public health.

The FDA should not allow the presence of a disclaimer on one portion of a manufacturer's website to negate contrasting information posted in other areas of the same website. This duplicity is confusing to consumers.

Claims suggesting that a tobacco product provides “satisfaction,” a “nicotine fix,” or other “pleasures of smoking” are claims about the pharmacological affects of nicotine, and therefore should be regulated under FDA’s drug/device authority.

Although FDA acknowledged in its proposed rule that “claims related to satisfaction, pleasure, enjoyment, and refreshment have been recognized as euphemisms for the delivery of a pharmacologically active dose of nicotine,” and these claims “relate to effects on the structure or function of the body” which would ordinarily trigger regulation under FDA’s drug/device authority, FDA inexplicably stated that it “does not consider these tobacco satisfaction and enjoyment claims to fall within its drug and device regulatory authority.” Further, it stated that it does not consider “claims suggesting that a tobacco product provides an alternative way of obtaining the effects of nicotine, or that a tobacco product will provide the same effects as another tobacco product – such as ‘satisfying smoking alternative,’ ‘provides all the pleasure of smoking,’ ‘get your nicotine fix,’ or ‘provides smokers the same delight, physical and emotional feelings’ – to fall within its drug and device authority.”

FDA specifically invited comment on this part of its proposed rule.

FDA correctly recognized that “satisfaction” is, and has been for decades, a tobacco industry code word for the pharmacological effects of nicotine as an addictive drug (“impact”). ***Therefore, claims about “satisfaction” are claims about the pharmacological impact of nicotine, and are drug claims that should require regulation under FDA’s drug authority, not its tobacco authority.***

In August 2006, Judge Kessler issued her Final Opinion and Findings of Fact in *United States v. Philip Morris*,⁵⁵ the government’s landmark racketeering case against the major cigarette manufacturers, which found the tobacco companies liable for violating civil racketeering laws by lying for decades about the health risks of smoking and the addictive potential of nicotine. In her Opinion and Findings, Judge Kessler laid out 1,700 pages of detailed evidence demonstrating the tobacco industry’s fifty-year conspiracy to

⁵⁴ Master Settlement Agreement, (May 2014). Available at: <http://publichealthlawcenter.org/topics/tobacco-control/tobacco-control-litigation/master-settlement-agreement>

⁵⁵ *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff’d in part & vacated in part*, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam), *cert. denied*, 561 U.S. ___, 130 S. Ct. 3501 (2010).

defraud the public. After Judge Kessler denied tobacco companies' motion to allow them to continue to use deceptive terms such as "light" and "low-tar" in marketing cigarettes overseas, the companies appealed in the U.S. Court of Appeals for the DC Circuit in August 2007. In May 2009, the appellate court upheld Judge Kessler's finding of liability and almost all of Judge Kessler's remedies. In February 2010 the tobacco companies appealed to the U.S. Supreme Court, asking the Court to overturn the finding of liability and the remedies imposed. In June 2010 the U.S. Supreme Court declined to hear appeals in the case, allowing Judge Kessler's judgment, findings of fact, and remedies upheld by the Court of Appeals to stand.

Of particular relevance to FDA's proposed rule, the opinion described the tobacco companies' activities showing how they recognized and controlled nicotine delivery in order to create and sustain smokers' addiction to nicotine to ensure their commercial success. The companies recognized the need to determine the "minimum" and "optimum" nicotine delivery levels necessary to provide sufficient "impact" and "satisfaction" to cigarette smokers. The court found:

Finding 1373, page 517: "Defendants' internal documents demonstrate that, based on their knowledge of nicotine's pharmacological properties and addictive nature, they incorporated physical and chemical design techniques into their commercial products that would assure delivery of the precise levels of nicotine necessary to assure ***taste, impact, and satisfaction***, i.e., to maintain addiction. Henningfield WD, 35:16-36:16, 41:18-42:7, 54:7-15, 66:23-67:12." [emphasis added]

The court specifically rejected any claim that terms like "impact," "satisfaction," or "hit" refer to the taste of the cigarettes. Instead, the court found that these terms concern nicotine's physiological or addictive effects (i.e., how they affect the structure and function of the body, the second prong of the statutory definition of "drugs" or "devices"):

Finding 1379, page 519: "Defendants have claimed that the terms "impact," "satisfaction," "hit," etc., as used in their internal documents, refer only to the taste characteristics of cigarettes. This claim is rejected because the documents themselves prove otherwise. Even though, as noted earlier, the scores of writers of these hundreds of documents do not always use the terms in a consistent manner, ***the numerous internal documents quoted and discussed infra, usually differentiate taste and impact from satisfaction or "hit," and the context makes clear when reference is being made to the taste and sensory attributes of nicotine as opposed to its physiological or addictive effects.***" [emphasis added]

The Findings also showed that the tobacco companies understood the correlation between nicotine delivery and cigarette sales:

Finding 1503, page 565: "On April 7, 1982, BATCo's G.O. Brooks, a research scientist, sent a letter to B&W's William L. Telling regarding a study concluding that when a cigarette's nicotine level "is so low that the nicotine is below the threshold of pharmacological activity then it is possible that the smoking habit

would be rejected by a large number of smokers." 660913609-3633 at 3620 (US 22763). Considering this threshold "satisfaction" level, BATCo senior scientist S.J. Green later warned that "we should be aware of the long-term dangers of following the crowd into ultra-low nicotine deliveries." Green explained, "Nicotine is an important aspect of 'satisfaction,' and if the nicotine delivery is reduced below a threshold 'satisfaction' level, then surely smokers will question more readily why they are indulging in an expensive habit." 110069974-9982 at 9975 (US 20268); see also 400993160-3215 at 3196 (US 75975*); 100051935-1948 (US 34587). Green's warning demonstrates BATCo's understanding that the trend towards ultra-low nicotine deliveries could mean "that the market would extinguish because people would get to the point that smoking really would be a matter of taste and pleasure and not nicotine receptors in the brain; at that point, people would find it easier to quit." Henningfield WD, 97:21-98:3."

The court found that tobacco companies researched, developed, and utilized various designs and methods of nicotine control to ensure that all cigarettes delivered doses of nicotine adequate to create and sustain addiction. In particular, the companies altered the chemical form of nicotine delivered in mainstream cigarette smoke for the purpose of improving nicotine transfer efficiency and increasing the speed with which nicotine is absorbed by smokers. The court found:

Finding 1673, page 625: "The Handbook sets forth the purposes for which Defendants used ammonia technology. For example, "[the ammonia in cigarette smoke] can liberate free nicotine from the blend, which is associated with increases in impact and 'satisfaction' reported by smokers." As the Handbook explained:

'Ammonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine. As a result of such change, the ratio of extractable nicotine to bound nicotine in the smoke may be altered in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster.'

In discussing diammonium phosphate ("DAP") as an additive, the Handbook states that "[s]ince DAP can only provide ammonia, it can act only as an ameliorant, an impact booster, and satisfaction promoter." 621800840-0899 at 0845 (US 86908)."

Further, the court found that the tobacco companies made false and misleading public statement regarding their control of the nicotine content and delivery of their products to ensure that smokers obtained sufficient nicotine to create and sustain addiction:

Finding 1762, page 654: "The words of Defendants themselves establish that the goal of their extensive efforts, through research and experimentation, to control

the levels of nicotine delivery was to ensure that smokers obtained sufficient nicotine to create and sustain addiction:

-- Philip Morris listed as one of the achievements of its Electrophysiological Studies Research Group a discovery “that there are optimal cigarette nicotine deliveries for producing the most favorable physiological and behavioral responses.” ¶947, *supra*.

-- RJR’s “top priority [was] to develop and market low ‘tar’ brands . . . that: [m]aximize the physiological satisfaction per puff -- the single most important need of smokers.” ¶1431, *supra*.

-- BATCo named as a “high priority” development of “alternative designs (that do not invite obvious criticism) which will allow the smoker to obtain significant enhanced deliveries should he so wish.” ¶1460, *supra*.

-- The “major objective” of Lorillard’s study of filter design was to “increase the physiological impact and/or nicotine to tar ratio in ultra low tar cigarettes.” ¶1488, *supra*.”

Considering these and other findings, the court concluded:

Finding 1763, page 654: “Defendants have, over the course of many years, time and again -- and with great self-righteousness -- denied that they manipulated the nicotine in cigarettes so as to increase the addiction and dependence of smokers. Those denials were false.”

In light of the tobacco industry’s documented history of hiding behind terms like “satisfaction” and “pleasure” in their marketing claims while manipulating nicotine to alter the physiological effect of nicotine to increase and maintain smokers’ addiction to their products, there can be no question that any tobacco product claims that use terms like these must be considered claims about the products’ pharmacological effects. Therefore, products that make these kinds of claims must be regulated like other drugs and devices under FDA’s drug/device authority.

Many claims made by manufacturers that non-cigarette tobacco products are less harmful than conventional cigarettes should be regulated as modified risk tobacco claims

Tobacco manufacturers have promoted use of non-cigarette tobacco products as less harmful to health relative to cigarette use. Such modified risk tobacco product (MRTP) claims are likely to influence public perceptions and, in turn, influence product use. The FDA should regulate the products associated with MRTP claims as tobacco products, with penalty enforcement for non-authorized MRTP claims.

We base this recommendation on three lines of evidence:

1. Lower perceived risks are associated with tobacco product initiation and ongoing use.

2. There is wide variation in the public's perceived risk of non-cigarette tobacco products, and MRTP claims could sway these perceptions.
3. Tobacco manufacturers currently make MRTP claims that would qualify those products to fall under FDA regulation as tobacco products.

1. Lower perceived risk or harm is associated with tobacco product use.

Among US high school students, those who have smoked cigarettes estimate lower probabilities of negative health consequences from smoking.⁵⁶ Moreover, among high school never-smokers, lower perceived smoking-related risks are associated with subsequent initiation of cigarette use.⁵⁷

These same relationships hold for non-cigarette tobacco products. In one study of nearly 1500 US adult cigarette smokers and former smokers, for each of e-cigarettes, snus, conventional smokeless, and dissolvable tobacco, those adults who had tried the product were more likely to state that it was less harmful than cigarettes than those who had never tried it.⁵⁸ In a study of high school males, greater perceived risk from using e-cigarettes was inversely associated with having ever-tried e-cigarettes, and the strength of the relationship between perceived risk and behavior was stronger for e-cigarettes than for cigarettes.⁵⁹ In a study of a high school population that included both males and females, for all of e-cigarettes, chewing tobacco, and cigars, individuals who had ever-tried those products perceived lower chances of short-term and long-term negative health outcomes than adolescents who had never tried those products.⁶⁰

2. There is extensive uncertainty among the public regarding the risk of non-cigarette tobacco products relative to cigarettes. Therefore, any MRTP claims from the industry could have meaningful influence in shaping public perceptions.

In a qualitative study of adolescents in Northern California, there was uncertainty and misinformation about the health risks and potential benefits of e-cigarette use.⁶¹ Among high school students, there is much higher variance in their reported perceived

⁵⁶ Halpern-Felsher BL, Biehl M, Kropp RY, Rubinstein ML. Perceived risks and benefits of smoking: Differences among adolescents with different smoking experiences and intentions. *Prev Med.* 2004;39(3):559-567.

⁵⁷ Song AV, Morrell HE, Cornell JL, Ramos ME, Biehl M, Kropp RY, Halpern-Felsher BL. Perceptions of smoking-related risks and benefits as predictors of adolescent smoking initiation. *Am J Public Health.* 2009;99(3):487-492.

⁵⁸ Richardson A, Pearson J, Xiao H, Stalgaitis C, Vallone D. Prevalence, harm perceptions, and reasons for using noncombustible tobacco products among current and former smokers. *Am J Public Health.* 2014 Aug;104(8):1437-1444.

⁵⁹ Chaffee BW, Gansky SA, Halpern-Felsher B, Couch ET, Essex G, Walsh MM. Conditional risk assessment of adolescents' electronic cigarette perceptions. *Am J Health Behav.* 2015 May;39(3):421-432.

⁶⁰ Roditis ML, Delucchi D, Cash D, Halpern-Felsher B. Adolescents' perceptions of health risks, social risks, and benefits differ across tobacco products. [submitted manuscript]

⁶¹ Roditis ML, Halpern-Felsher B. Adolescents' Perceptions of Risks and Benefits of Conventional Cigarettes, E-cigarettes, and Marijuana: A Qualitative Analysis. *J Adolesc Health.* 2015 Aug;57(2):179-185.

probability of specific health risks associated with use of e-cigarettes than with use of cigarettes.⁶²

Uncertainty regarding perceived health risks expands beyond e-cigarettes. In a qualitative study of male adults and adolescents in rural Ohio reported uncertainty and disagreement about the relative health risks of smokeless tobacco compared to cigarettes and other tobacco products.⁶³ While participants near universally agreed that smokeless tobacco was harmful to the health of the user, some participants perceived smokeless tobacco and cigarettes to be equivalently harmful, whereas others believed smokeless tobacco to be a safer alternative to cigarettes.⁶⁴

Likewise, in a survey of young adults age 18-34 that included both tobacco users and non-users, there was a wide range of perceptions regarding the health risks of smokeless tobacco relative to cigarettes.⁶⁵ While most participants responded that conventional smokeless (58%) and snus (59%) were equally “risky” compared to cigarettes, many participants rated the smokeless products as less risky (7%-10%) and many as more risky (22%-32%). The percentage of respondents that selected “don’t know” regarding the risk of snus (9%) was second only the percentage of respondents uncertain about the risk of e-cigarettes (11%).⁶⁶

In a US survey of nearly 1500 adult cigarette smokers and former smokers conducted in 2011, a substantial percentage of participants responded that snus (23%), conventional smokeless (38%), and e-cigarettes (3%) are more harmful than cigarettes, while in the same survey, many adults perceived these products to be less harmful than cigarettes (snus: 18%; ST: 10%; e-cigarettes: 65%).⁶⁷ The percentage reporting “don’t know” was 21% for e-cigarettes, 18% for snus, 4% for conventional ST, and 32% for dissolvable tobacco.

In an ongoing study to assess and compare adolescents’ perceptions of the addictive and pharmacological effects of e-cigarettes, cigars, cigarettes, and smokeless

⁶² Chaffee BW, Gansky SA, Halpern-Felsher B, Couch ET, Essex G, Walsh MM. Conditional risk assessment of adolescents' electronic cigarette perceptions. *Am J Health Behav.* 2015 May;39(3):421-432.

⁶³ Liu ST, Nemeth JM, Klein EG, Ferketich AK, Kwan MP, Wewers ME. Risk perceptions of smokeless tobacco among adolescent and adult users and nonusers. 2015;20(5):599-606.

⁶⁴ Liu ST, Nemeth JM, Klein EG, Ferketich AK, Kwan MP, Wewers ME. Risk perceptions of smokeless tobacco among adolescent and adult users and nonusers. *J Health Commun.* 2015;20(5):599-606.

⁶⁵ Wackowski OA, Delnevo CD. Young Adults' Risk Perceptions of Various Tobacco Products Relative to Cigarettes: Results From the National Young Adult Health Survey. *Health Educ Behav.* 2015 Aug 24. [Epub ahead of print]

⁶⁶ Wackowski OA, Delnevo CD. Young Adults' Risk Perceptions of Various Tobacco Products Relative to Cigarettes: Results From the National Young Adult Health Survey. *Health Educ Behav.* 2015 Aug 24. [Epub ahead of print]

⁶⁷ Richardson A, Pearson J, Xiao H, Stalgaitis C, Vallone D. Prevalence, harm perceptions, and reasons for using noncombustible tobacco products among current and former smokers. *Am J Public Health.* 2014 Aug;104(8):1437-1444.

tobacco, 642 adolescents in California (mean age 16.2 years) provided responses.⁶⁸ Adolescents perceived the risk of addiction as lowest for e-cigarettes, followed by chewing tobacco, cigars and then cigarettes ($p < 0.01$). Adolescents rated e-cigarettes as the least likely to confer pharmacological affects such as feeling high/buzzed or jittery/nervous, and cigarettes were perceived to be most likely to confer these effects ($p < 0.01$ for both). Similarly, adolescents felt it would take on average 17 attempts to quit cigarettes, 12 attempts to quit chewing tobacco, 11 attempts to quit cigars, and 10 attempts to quit e-cigarettes ($p < 0.01$). Adolescents viewed quitting by age 30 as a means to reduce chances of tobacco-related illness for all products. In short, the study found that there are significant differences in adolescents' perceptions related to risks of addiction across tobacco products, with adolescents consistently viewing cigarettes as more addictive than other tobacco products.

The FDA's process for regulating MRTP messages must include any claims related to the addictive potential of all tobacco products, because adolescents, on average, have inaccurate perceptions of the addictive potential of tobacco products, and may be disproportionately influenced by industry statements. Perceived low risk of addiction among adolescents has been linked to tobacco use initiation and continuation.

As discussed earlier, the ability of marketing to shape public perceptions of risk is supported by a 2013 study with 10 focus groups of older smokers (≥ 45 years), the data revealed that older smokers are using e-cigarettes in increasing numbers. Those exposed to e-cigarette advertisements were more likely to perceive e-cigarettes as 1) an effective cessation aid, 2) having less risk than cigarettes, and 3) a way to "deal with no smoking laws." Many believe that e-cigarette advertising promotes dual use of conventional and e-cigarettes.⁶⁹

3. Tobacco manufacturers currently make MRTP claims that would qualify those products to fall under FDA regulation as tobacco products.

The Truth in Advertising.org website⁷⁰ recently conducted an analysis of the marketing and advertising claims made between July-August, 2015 on the websites of e-cigarette companies included in their database.⁷¹ Health claims included messages that e-cigarettes are healthier or safer than (conventional) tobacco, that nicotine is safe, that e-cigarettes produce only water vapor, contain no toxins or carcinogens, produce no second-hand smoke, and have no negative side effects. Claims included messaged contained in blogs, social media, testimonials, and links to studies or media reports displayed on the sites.

⁶⁸ Halpern-Felsher B, Roditis ML. Adolescents' Perceptions of the Addictive and Pharmacological Effects Varies Across Tobacco Products. NIH Tobacco Centers of Regulatory Science 2015 Annual Fall Meeting. Bethesda, MD.

⁶⁹ Cataldo J, Sheon N, Hunter M, et al. E-cigarette marketing and older smokers: road to renormalization. A J Health Behav 2015;39(3):361-371.

⁷⁰ <https://www.truthinadvertising.org/> (Accessed October 31, 2015)

⁷¹ TINA E-Cigarette Database. September 1, 2015. <https://www.truthinadvertising.org/e-cigarette-database/> Accessed October 2015.

Of 159 commercial websites included in the Truth in Advertising.org analysis, 80 (50%) featured a health claim related to reduced or modified risk. For example, the commercial website of the e-cigarette retailer Blaze included the claim, “Electronic cigarettes are infinitely safer than traditional cigarettes.”⁷²

In an analysis of print advertisements for Camel Snus appearing from July 2007 to August 2010,⁷³ a sharp decline in the use of phrases such as “smoke-free” or “pleasure for whenever” (that would refer to both reduced harm of the product relative to cigarettes and the ability to evade smoking restrictions), occurred simultaneously with the 2009 passage of the Family Smoking Prevention and Tobacco Control Act. After 2009, advertising focused on a more ambiguous “break free” campaign. However, in contrast to traditional media campaigns, ***there is evidence suggesting that viral and testimonial-based marketing techniques are being used to make MRTP claims.***

Tobacco manufacturers have historically used viral marketing techniques to promote perceived health benefits of new or alternative tobacco products.⁷⁴ In such an approach, companies rely on existing social networks to propagate messages about their products that can spread quickly and may carry more legitimacy with consumers than more conventional marketing that is perceived to come directly from the manufacturer. Message boards, websites, and social media associated with particular tobacco product brands frequently host apparent consumer testimonials and opinions, which often include MRTP claims. For example, an analysis of the message boards maintained on the brand website for Camel Snus during the period November 2006 to December 2008 report that, among other claims, message board posts indicated that using snus is less harmful to health than smoking cigarettes.⁷⁵

The presence of consumer testimonials on official company websites or marketing material represents an implicit sanctioning of those claims from the tobacco manufacturer. The FDA should consider MRTP claims presented in the form of consumer testimonials on the official websites, online message boards, and other branded marketing modalities of tobacco product manufacturers in the same manner that non-testimonial MTRP claims would be regulated.

FDA’s economic impact analysis does not appropriately analyze the costs and benefits of the proposed rule

Consistent with its regulatory obligations, the FDA has assessed the economic impacts of the proposed rule. The analysis indicates that the proposed rule would result in

⁷² Blaze electronic cigarettes. Are electronic cigarettes safe? October 30, 2012.

<http://www.blazecig.com/blog/are-electronic-cigarettes-safe> Accessed October 2015.

⁷³ Timberlake DS, Pechmann C, Tran SY, Au V.. A content analysis of Camel Snus advertisements in print media..Nicotine Tob Res. 2011 Jun;13(6):431-439.

⁷⁴ Anderson SJ, Ling PM. "And they told two friends...and so on": RJ Reynolds' viral marketing of Eclipse and its potential to mislead the public. Tob Control. 2008 Aug;17(4):222-229.

⁷⁵ Wackowski OA, Lewis MJ, Delnevo CD. Qualitative analysis of Camel Snus' website message board--users' product perceptions, insights and online interactions. Tob Control. 2011 Mar;20(2):e1.

a net benefit to society, arguing that it would reduce ambiguity and uncertainty for investors and traders without imposing any new costs on the industry or others. ***The overall conclusion of a net benefit is valid, although the FDA includes certain considerations in its calculations that are inappropriate and omits another is important.***

Most individuals have an aversion to ambiguity.⁷⁶ In other words, people prefer to make bets with known odds (objective uncertainty) rather than ambiguous odds (subjective uncertainty). The FDA correctly argues that its proposed rule would remove some of the subjective uncertainty that traders and investors face. We agree that this benefit would accrue to individual traders and individual investors, although we question whether the industry itself would benefit from a reduction in rule-making ambiguity.

It is individual “naïve” investors who are the focus of the model of Easley and O’Hara (2009) cited by the FDA that benefit from reductions in ambiguity.⁷⁷ We are not aware of any studies to support the FDA’s assumption, “It is expected that industries are ambiguity averse.” We would expect the opposite. Typically, firms are considered to be risk-neutral, profit-maximizing entities, except in cases where they are focused on short-run profits.⁷⁸ A profit-maximizing firm would also have neutral preferences for ambiguity. The development of new tobacco products under consideration in the proposed rule is by its very nature a long-term investment for the industry, which makes an assumption of risk and ambiguity neutrality most appropriate. This fact implies that in principle the industry should not benefit from the proposed rule.

To the extent that the proposed regulations require review to determine whether they will affect ‘small entities’ as defined, these entities may face liquidity constraints that may benefit on net from ambiguity reduction. However, the issue of social benefits is different from the impact of the regulations on investors, traders, and other small entities. For any cost-benefit and cost-effectiveness analysis using a societal perspective conducted by the FDA for specific regulatory decisions, only the benefits accruing to consumers in consumption of final goods and services are relevant. Any consideration of benefits to investors, traders, firms, and small entities for the purposes of the approval of an FDA regulation per se does not concern the benefits or costs arising from consumption of a final good or service. The two issues – analysis of economic impacts and impacts on small entities – should be kept clearly separated.

The FDA fails to include what is likely the largest benefit of the proposed rule: the welfare gains to consumers of being provided with improved information regarding the safety and effectiveness of tobacco products. The FDA acknowledges that the proposed rule would limit “consumer confusion in the marketplace,” but this benefit is neither described nor quantified in the Benefits section. Manufacturers of tobacco products have a long history of making inaccurate claims about their products’ safety and

⁷⁶ Ellsberg D. Risk, ambiguity, and the Savage axioms. *The Quarterly Journal of Economics*. 1961:643-69.; Camerer C, Weber M. Recent developments in modeling preferences: Uncertainty and ambiguity. *Journal of Risk and Uncertainty*. 1992;5(4):325-70.; Dimmock SG, Kouwenberg R, Wakker PP. Ambiguity attitudes in a large representative sample. *Management Science*. Forthcoming.

⁷⁷ Easley D, O’Hara M. Ambiguity and nonparticipation: The role of regulation. *Review of Financial Studies*. 2009:hnn100.

⁷⁸ Sandmo A. On the theory of the competitive firm under price uncertainty. *The American Economic Review*. 1971:65-73.

effectiveness. (See discussion of Judge Kessler’s ruling above for a description of some of these misleading claims.) This misinformation distorts the beliefs of consumers and can lead them to consume addictive products that have life-long consequences for their health and wellbeing. *Consumers who are confused or misled reap a smaller consumer surplus from their consumption decisions, as in the case of uninformed consumers who pay extra money for brand-name medications that have identical active ingredients and identical physiological effects relative to their cheaper generic counterparts.*⁷⁹

*By limiting the ability of manufacturers to make misleading claims, the proposed rule will increase consumer welfare. A growing body of theoretical and empirical work in the subfield of behavioral industrial organization highlights the ways in which firms take advantage of uninformed or manipulable consumers.*⁸⁰ This economic literature shows that misinformation and obfuscation shifts the surplus away from consumers and toward producers. A related economic literature on persuasion finds that “motivated agents,” such as firms, can manipulate individuals through persuasive communication. When the receivers of information do not form beliefs according to Bayes’ rule of rational updating, persuasion can distort beliefs and change preferences in ways that impose costs on consumers.⁸¹ Given that studies consistently find that consumers violate Bayesian updating,⁸² persuasion by firms is often likely to **reduce** consumer welfare.

The literatures from behavioral industrial organization and persuasion both clearly indicate that any regulations that reduce misleading claims, which will be the practical effect of the proposed rule, will improve the wellbeing of consumers. The FDA needs to incorporate this potentially large benefit into its economic impact analysis.

FDA’s proposed rule should be modified to strengthen FDA’s ability to protect the public health

As a steward of the nation’s public health, FDA is mandated by Congress to ensure that consumers do not unknowingly use potentially harmful or lethal products because of their detrimental reliance on unsubstantiated marketing claims. Products that are made or derived from tobacco that make claims about their ability to treat nicotine addiction and withdrawal, to be used as cessation aids, or to prevent or cure nutritional deficiencies and other health issues, should be regulated under FDA’s drug/device

⁷⁹ Bronnenberg BJ, Dubé J-P, Gentzkow M, Shapiro JM. Do Pharmacists Buy Bayer? Informed Shoppers and the Brand Premium. *The Quarterly Journal of Economics*. 2015;130(4):1669-726.

⁸⁰ Gabaix X, Laibson D. Shrouded Attributes, Consumer Myopia, and Information Suppression in Competitive Markets. *Ibid*. 2006;121(2):505-40.; DellaVigna S, Malmendier U. Contract Design And Self-Control: Theory And Evidence. *Quarterly Journal of Economics*. 2004;119(2):353-402.; Ellison G, Ellison SF. Search, Obfuscation, and Price Elasticities on the Internet. *Econometrica*. 2009;77(2):427-52.; Ellison G, Wolitzky A. A search cost model of obfuscation. *The RAND Journal of Economics*. 2012;43(3):417-41.

⁸¹ DellaVigna S, Gentzkow M. Persuasion: Empirical Evidence. *Annu Rev Econ*. 2010;2:643-69.

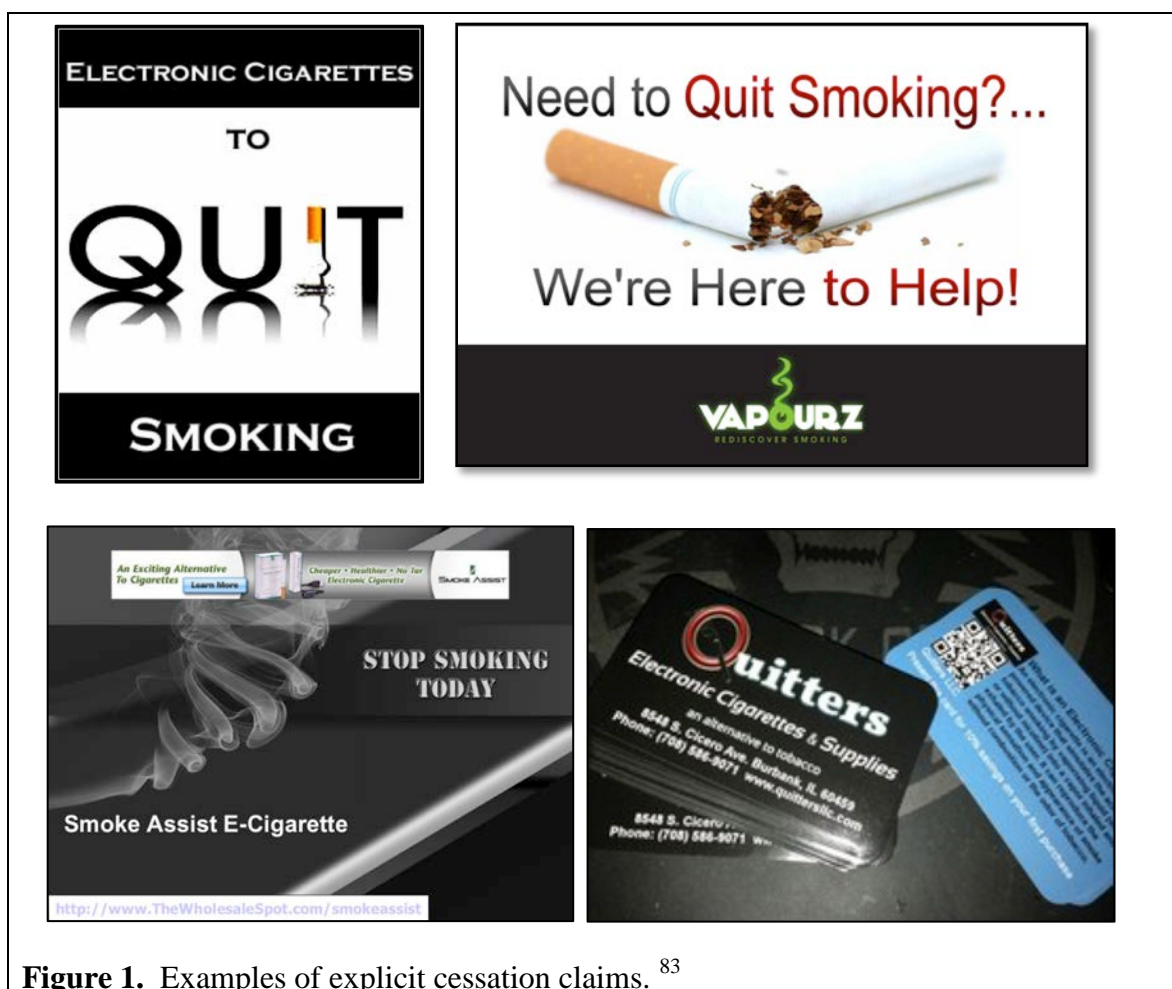
⁸² El-Gamal MA, Grether DM. Are people Bayesian? Uncovering behavioral strategies. *Journal of the American Statistical Association*. 1995;90(432):1137-45.; Tversky A, Kahneman D. Judgment under uncertainty: Heuristics and biases. *Science*. 1974;185(4157):1124-31.; Camerer C. Individual decision making. In: Kagel JH, Roth AE, editors. *The Handbook of Experimental Economics*: Princeton University Press; 1995.; Rabin M. Psychology and Economics. *Journal of Economic Literature*. 1998;36(1):11-46.

authority. FDA's proposed rule is based on a common sense understanding of the "disease prong" of the statutory definition of drugs/devices, and reflects the reality that companies make *implicit* claims about their products' curative benefits in testimonials, blog-posts, and social media, in addition to explicit claims in mainstream media, print, and website ads. Any and all claims about the product's capability to be a cessation or health aid, including testimonials about consumers' successful experiences with a product serving as a cessation aid or energy booster, should trigger regulation under FDA's drug/device authority.

What is less clear is the correctness of FDA's proposal regarding the "structure/function prong" of FDA's drug/device authority. FDA's proposed rule would regulate a product with nicotine, an addictive drug, as a tobacco product rather than a drug product if it is intended to affect the structure or function of the body in any way different from the effects of nicotine that were "customarily" marketed before the March 2000 *Brown & Williamson* case. That case, which ironically concluded that FDA did not have the authority to regulate tobacco products because if it did, every tobacco product would be illegal because no product could be shown to be safe, was ***decided six years before*** the 2006 landmark *United States v. Philip Morris* case (the "RICO case"), which held that the major tobacco companies were racketeers who engaged in a fifty-year history of deceiving the public about the pharmacological and addictive properties of nicotine.

In other words, at the time Brown & Williamson was decided, the way the effects of nicotine were "customarily marketed" (e.g., using euphemistic terms like "satisfaction") was fraudulent and intended to mislead customers about the true effects of nicotine. Surely, FDA should not use fraudulent marketing messages as the standard upon which to determine its regulatory authority.

Rather, any tobacco product that makes claims related to "satisfaction" or "get your nicotine hit" is perpetuating the fraud that the tobacco companies were held liable for in the 2006 RICO case. Any product that makes these or similar claims, in particular claims that refer specifically to nicotine and thus would be likely to make consumers believe the product is a nicotine replacement therapy, should be regulated under FDA's drug/device authorities. Products that are marketed with MRTP claims should be required to get an MRTP order under FDA's tobacco authority, and FDA can and should take immediate enforcement action against those products that are currently being marketed without MRTP authorization.



⁸³ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/j_quit/quit/large/quit_3.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/j_quit/quit/large/quit_52.jpg
http://171.67.24.121/tobacco_web/images/ecig_ads/j_quit/quit/large/quit_25.jpg
http://171.67.24.121/tobacco_web/images/ecig_ads/j_quit/quit/large/quit_8.jpg;
http://tobacco.stanford.edu/tobacco_main/subtheme_ecigs.php?token=fm_ecigs_mt043.php
 (accessed November 9, 2015)

⁸⁴ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/j_quit/quit/large/quit_1.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/j_quit/quit/large/quit_16.jpg;
http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st372.php&token1=fm_ecigs_img16975.php&theme_file=fm_ecigs_mt043.php&theme_name=Helps%20You%20Quit&subtheme_name=Quit (accessed October 29, 2015)



Figure 3. E-cigarette advertisements that claim to boost energy.⁸⁵

⁸⁵ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/energy/large/energy_38.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/energy/large/energy_1.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/energy/large/energy_36.jpg;
http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st542.php&token1=fm_ecigs_img23975.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Energy%20Boost (accessed October 31, 2015)

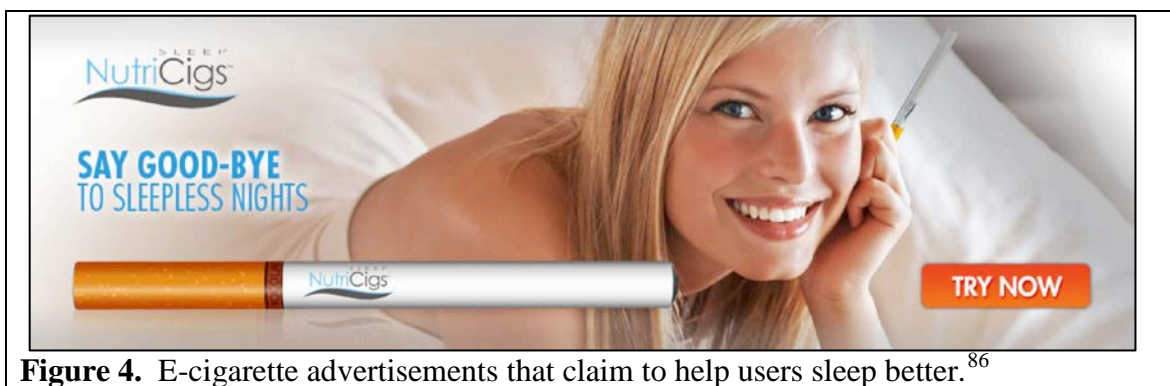


Figure 4. E-cigarette advertisements that claim to help users sleep better.⁸⁶



Figure 5. E-cigarette advertisements using doctors to imply health claims.⁸⁷



Figure 6. Cigarette advertisements using doctors to imply health claims.⁸⁸

⁸⁶ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/calm/large/calm_8.jpg;
http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st508.php&token1=fm_ecigs_img21920.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Calming (accessed October 31, 2015)

⁸⁷ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/doctors/large/doctors_1.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/doctors/large/doctors_2.jpg;
http://171.67.24.121/tobacco_web/images/then_now/ecig_vs_cig/ecigdoc/large/ecigdoc_12.jpg;
http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st384.php&token1=fm_ecigs_img17154.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Doctors%20%20Nurses (accessed October 31, 2015)

⁸⁸ SRITA, http://171.67.24.121/tobacco_web/images/then_now/ecig_vs_cig/ecigdoc/large/ecigdoc_9.jpg;
http://171.67.24.121/tobacco_web/images/then_now/ecig_vs_cig/ecigdoc/large/ecigdoc_1.jpg;
http://171.67.24.121/tobacco_web/images/then_now/ecig_vs_cig/ecigdoc/large/ecigdoc_11.jpg;
http://tobacco.stanford.edu/tobacco_main/subtheme.php?token=fm_mt001.php (accessed October 31, 2015)

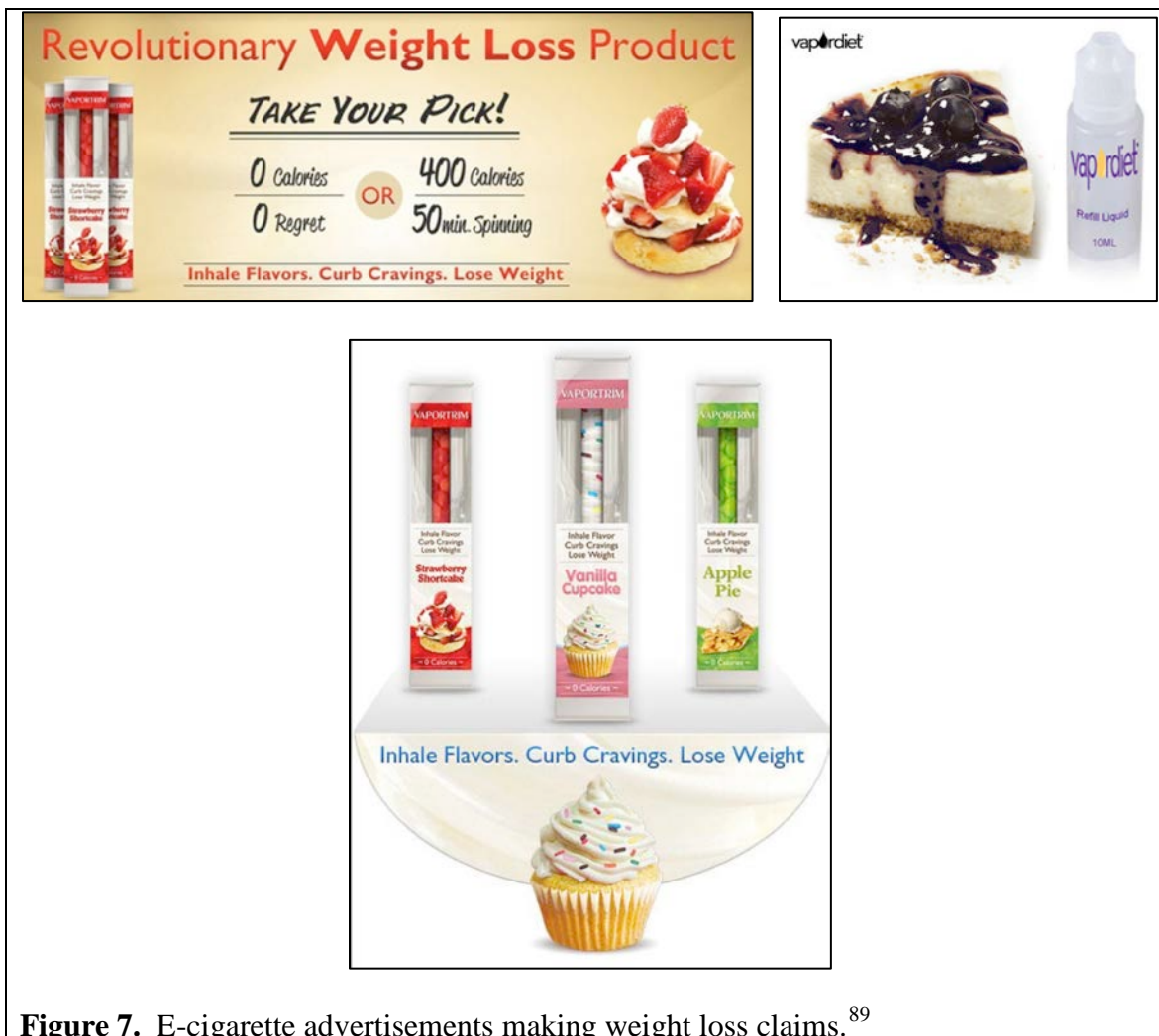
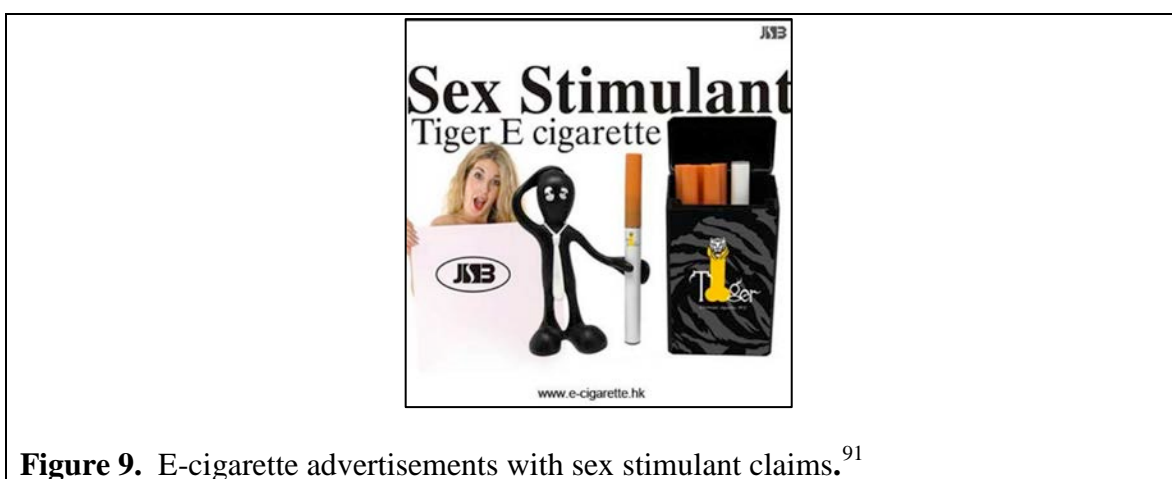
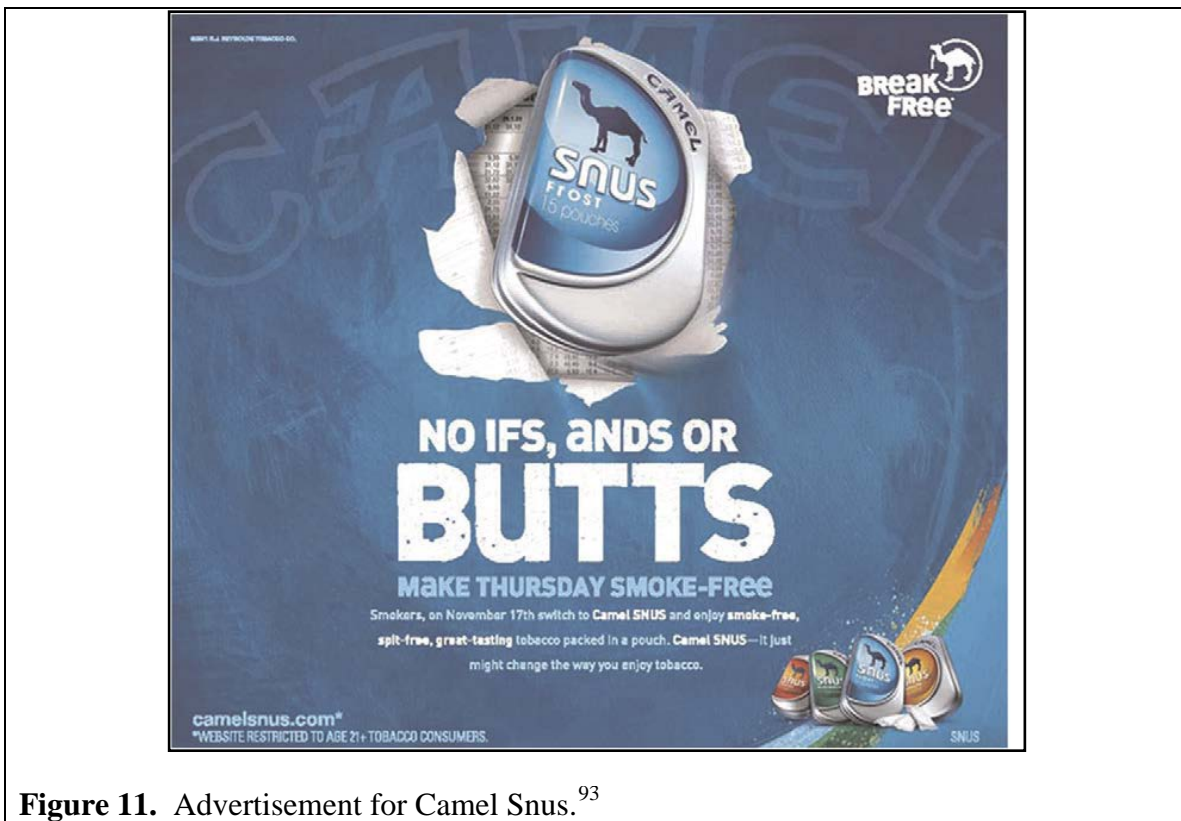


Figure 7. E-cigarette advertisements making weight loss claims.⁸⁹

⁸⁹ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/loseweight/large/lose_18.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/loseweight/large/lose_15.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/loseweight/large/lose_13.jpg;
http://tobacco.stanford.edu/tobacco_main/images/ecigs.php?token2=fm_ecigs_st510.php&token1=fm_ecigs_img21954.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Lose%20Weight (accessed October 31, 2015)

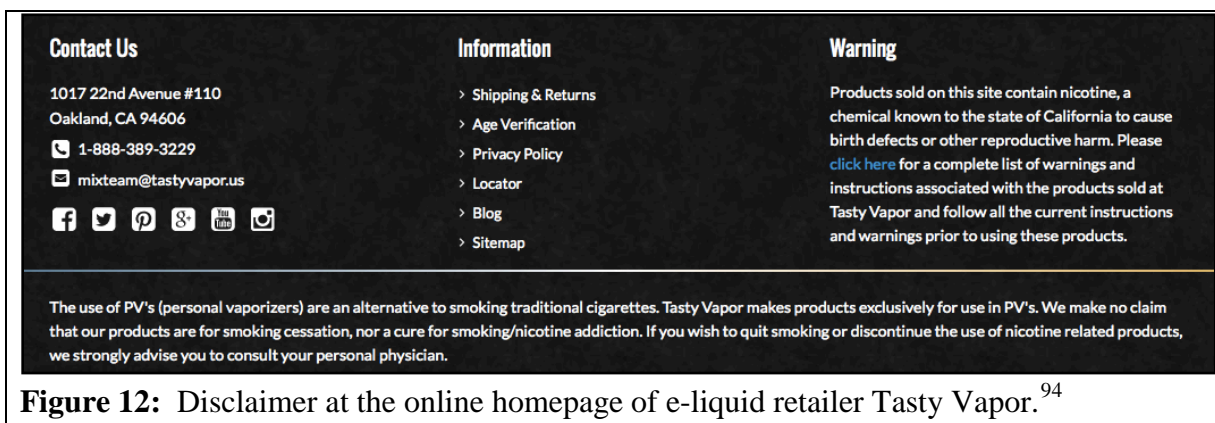


⁹⁰ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/nutritional/large/nutritional_4.jpg;
http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/nutritional/large/nutritional_6.jpg;
http://tobacco.stanford.edu/tobacco_main/images/ecigs.php?token2=fm_ecigs_st509.php&token1=fm_ecigs_img21953.php&theme_file=fm_ecigs_mt036.php&theme_name=Healthier&subtheme_name=Nutritional (accessed October 31, 2015)
⁹¹ SRITA, http://171.67.24.121/tobacco_web/images/ecig_ads/b_health/medicinal/large/med_1.jpg (accessed October 31, 2015)



⁹² <https://www.fasttech.com/products/3009/10004171/1310900-dekang-e-liquid-for-electronic-cigarettes-50ml> (Accessed November 9, 2015)

⁹³ https://trinketsandtrash.org/viewImage.php?file_name=213572.jpg (Accessed November 9, 2015)



⁹⁴ www.tastyvapor.us (Accessed October 31, 2015)

⁹⁵ <http://www.tastyvapor.us/blog/tips-on-how-to-make-the-switch> (Accessed October 31, 2015)



Figure 14. E-cigarettes placed in “smoking cessation” section of Walgreens in Denver, CO.⁹⁶

⁹⁶ Photo by Lucy Popova, Walgreens in Denver, CO, August 2014.