

Juul ads are breaking the law by making unauthorized cessation and therapeutic claims

Lauren Lempert JD MPH

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The *Sottera* case 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.¹ On the other hand, the Court of Appeals in *Sottera Inc. v. Food & Drug Administration*² ruled that the FDA has express authority to regulate e-cigarettes as drug delivery devices when e-cigarette products are “therapeutically marketed” (e.g., as products or treatments for tobacco dependence or to help smokers quit, such as 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)³.

Juul has both explicitly and implicitly made therapeutic claims about their products in their online marketing and other promotional materials. Juul’s mission, boldly proclaimed on its [website](#),⁴ clearly states that Juul’s purpose is to help smokers enjoy healthier lives by quitting smoking: “Improve the lives of the world’s one billion smokers by eliminating cigarettes.”

Juul’s website⁵ features testimonials from customers who are or were smokers about how Juul has helped them curb and eventually quit smoking, and invites other smokers to “join the community” and share their own stories. Following are examples of testimonials from smokers who share their experiences and tips about how they used Juul to help quit smoking:

- Robert: “Every time you want a cigarette just take ten puffs of the JUUL and you will get some satisfaction.” [claim: helps relieve nicotine addiction]
- Sabrina: “Stick with it. At first it was hard to find my happy spot but now that I have my puff down I will never smoke again.” [claim: helps smoker quit]
- Becky: “I appreciate the ease of use and nicotine fix.” [claim: use as nicotine replacement therapy]
- Marcy: “It’s good and it’s satisfying.” [claim: helps relieve nicotine addiction]
- Rabiye: “Try different flavors until you reach one you can enjoy and gives you the same satisfaction as your cigarettes did.” [claim: helps relieve nicotine addiction]
- Angela: “No more smoke breaks. No more chewing endless packs of gum, spraying perfume, sneaking out to smoke, not having to step outside when I am watching tv with my husband.” [claim: helps smoker quit]
- Erika: “Inhale until you feel the same fix as you would get from a cigarette.” [claim: helps relieve nicotine addiction]
- Laura: “Just replace the cigarette with the JUUL! It really helps to keep some physical habits the first week or two. Just focus on using the JUUL instead of a cigarette.” [claim: helps smokers quit]
- Regina: “JUUL means I can still enjoy the pleasure I obtain smoking/vaping, without the stink, mess, judgement and stress.” [claim: helps smokers quit]
- Lindsay: “It actually does feel just like smoking, but now I don’t stink!” [claim: helps smokers switch]

¹ *Smoking Everywhere, Inc. v. U.S. Food and Drug Administration*, 680 F. Supp. 2d 62 (D.D.C. 2010). In *Sottera*, the company that promoted NJOY e-cigarettes sued FDA for an injunction against FDA’s detention of their product in part on the basis that their e-cigarettes were *not* therapeutic drug delivery devices, but rather were intended for and marketed as recreational products. *Sottera, Inc.* prevailed at both the trial court and the Court of Appeals, which rejected FDA’s position that e-cigarettes were unapproved drug devices and agreed with *Sottera, Inc.*

² *Sottera Inc. v. Food and Drug Administration*, 627 F. 3d 891 (U.S. App. DC 2010)

³ 21 U.S.C. section 351 *et seq.*

⁴ <https://www.juul.com/mission-values>

⁵ <https://www.juul.com/community>

- Ricky: I appreciate that it was designed with cigarette smokers in mind. [claim: helps smokers quit]
- Dale: “This is a great alternative to actual tobacco products. Enjoy!” [claim: not a tobacco product]
- Rob: “I appreciate the draw and how it replaces a cigarette.” [claim: helps smokers quit]
- Regina: “JUUL means I can still enjoy the pleasure I obtain smoking/vaping, without the stink, mess, judgement and stress.” [claim: helps smokers quit]

Similar claims and testimonials are made in Juul’s new TV ad campaign that was launched in January 2019.⁶ Moreover, [Juul is pitching](#)⁷ its e-cigarette as an anti-smoking tool to employers and insurers.

These online and TV claims either state outright or suggest that using Juul will help smokers relieve their nicotine addiction without the stress of giving up the behavioral pleasures of smoking.

Publishing these testimonials on Juul’s website represents promotion of its e-cigarette (which is deemed a tobacco product subject to FDA’s tobacco authorities) as therapeutic devices, despite the fact that Juul’s website includes [disclaimers](#)⁸ that its products are not intended for smoking cessation.

Whether a 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. § 201.128.⁹ 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 Juul or other 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 Juul and other e-cigarette companies and their trade associations (e.g., CASAA, SFATA, AVA) have been encouraging their consumers to testify before state and municipal governmental agencies that are seeking to regulate e-cigarettes (e.g., by prohibiting flavors, instituting taxes, or imposing age restrictions) that they use Juul and other e-cigarettes as smoking cessation products also demonstrates that they are promoting their products as having therapeutic benefit.

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.”

Juul and other 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 Act¹⁰, 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.

⁶ <https://www.cnbc.com/2019/01/07/juul-highlights-smokers-switching-to-e-cigarettes-in-ad-campaign.html>

⁷ <https://www.cnbc.com/2019/03/07/juul-e-cigarette-maker-pitches-employers-insurers.html>

⁸ <https://www.juul.com/our-responsibility#regulation>

⁹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=201.128>

¹⁰ 21 USC 387 et seq., Pub. L. 111-31, June 22, 2009

Further, to the extent that Juul's advertising and communications state or imply that Juul is safer or less harmful than conventional cigarettes, these claims are unauthorized modified risk claims under section 911 of the Tobacco Control Act.¹¹

¹¹ 21 USC 387k