

FDA Takes On Electronic Cigarette Companies

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Recently, the Food and Drug Administration (FDA), warned consumers against the use of electronic cigarettes, often referred to as e-cigarettes, concluding they contain traces of toxic substances, including a chemical used in antifreeze, as well as other carcinogens.¹ The agency did not go so far as to ban the products from sale. The analysis comes within months after a Florida company that imports and distributes e-cigarettes filed suit against the federal agency arguing it overstepped its authority by banning shipments of the devices and insisting they go through the drug approval process.² Absent from much of the discussion on websites and blogs is what effect, if any, the recently passed Family Smoking Prevention and Tobacco Control Act (the Act),³ giving the FDA regulatory authority over tobacco, will have on the suit.

Background

Electronic cigarettes are battery-operated devices containing cartridges filled with nicotine, flavoring, and other chemicals.⁴ The device then turns the chemicals into a vapor which is inhaled by the user.⁵ Technically, the devices produce no “smoke,” and thus can be used in places that otherwise ban cigarette and cigar smoking such as bars, restaurants, and airports. They also come in candy and fruit flavors, such as chocolate, bubble gum, and mint, which leads many critics to believe they are being marketed mainly to children and adolescents due to their availability in mall kiosks and online.⁶

Selling from between \$100 to \$200, the e-cigarette looks similar to a normal cigarette or cigar, but longer. They essentially all work the same way:

- a user inhales through a mouthpiece;
- air flow triggers a sensor that switches on a small, battery-powered heater;
- the heater vaporizes liquid nicotine in a small cartridge and activates a light at the “lit” end of the device; (users may opt for a non-nicotine cartridge)
- the heater also vaporizes propylene glycol (PEG) in the cartridge – the same compound used in theatrical smoke;
- the user gets a puff of hot gas that feels a lot like tobacco smoke; and then

¹ Katie Zezima, *Analysis Finds Toxic Substances in Electronic Cigarettes*, N.Y. TIMES, July 23, 2009, <http://www.nytimes.com/2009/07/23/health/policy/23fda.html>.

² The Blog of Legal Times, *FDA Sued Over Electronic Cigarette Embargo*, Apr. 29, 2009, available at <http://legaltimes.typepad.com/blt/2009/04/fda-sued-over-electronic-cigarette-embargo-.html>.

³ Pub. L. No. 111-31, H.R. 1256, 111th Cong. (2009).

⁴ U.S. Food & Drug Admin., News Release, *FDA and Public Health Experts Warn About Electronic Cigarettes*, July 22, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm>.

⁵ *Id.*; Lyndsey Layton, *FDA Cautions Public About Electronic Cigarettes*, WASH. POST, July 22, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/07/22/AR2009072202902.html>.

⁶ *Id.*

- when the user exhales, there is a cloud of PEG vapor that looks like smoke and then dissipates.⁷

The FDA's Division of Pharmaceutical Analysis tested and analyzed 19 varieties of cartridges, which hold the liquid, and two e-cigarettes, one marketed by Florida-based Smoking Everywhere, Inc., and one by NJoy, of Scottsdale, Arizona.⁸ Investigators found the majority of the items tested contained tobacco impurities believed to be harmful.⁹ Additionally, some products tested positive for nicotine even though the product's label touted there was no nicotine present. Several of the cartridges contained detectable levels of nitrosamines, a tobacco-specific compound linked to cancer.¹⁰ One Smoking Everywhere cartridge was found to contain diethylene glycol, a common ingredient found in antifreeze.¹¹

In response to the FDA's findings, the Electronic Cigarette Association (ECA), issued a statement that said:

...the FDA's laboratory analysis of electronic cigarettes released today is too narrow to reach any valid and reliable conclusions and ignores the continued efforts by its member companies to ensure that their products include health warnings and to only market its products as an alternative to long-time, adult smokers.¹²

Former Arizona Congressman and president of the ECA, Matt Salmon, gave the impression in his statement that he believes the FDA is specifically targeting e-cigarettes and not other types of similar products.

"I'm a little shocked that the FDA would release a study that is so narrow in its scope and targets a specific industry when there are a number of nicotine products on the market today not in the FDA's crosshairs. Are they saying that those products and cigarettes themselves are safer to use," said Salmon.¹³

Indeed, the FDA has taken aggressive action against manufacturers and distributors by detaining shipments of e-cigarettes as they enter the United States – mainly from China. Approximately 50 shipments have been seized thus far. The agency is also requiring that the devices be submitted for evaluation and approval. The FDA contends that e-

⁷ Daniel J. DeNoon, *FDA: E-Cigarettes Bad, But Not Banned*, WEBMD HEALTH NEWS, July 22, 2009, <http://www.webmd.com/smoking-cessation/news/20090722/fda-ecigarettes-bad-not-banned>.

⁸ Steven Reinberg, *E-Cigarettes Pose a Health Hazard, FDA Warns*, HEALTHDAY, July 22, 2009, <http://healthday.com/printer.asp?AID=629298>; Shirley S. Wang, *FDA Questions Safety, Quality of Electronic Cigarettes*, WALL ST. J. HEALTH BLOG, July 22, 2009, <http://blogs.wsj.com/health/2009/07/22/fda-questions-safety-quality-of-electronic-cigarettes>.

⁹ *Id.*

¹⁰ Katie Zezima, *supra* note 1.

¹¹ *Id.*

¹² Elec. Cigarette Ass'n, *Response to the FDA*, <http://www.ecassoc.org/response-to-the-fda> (last accessed Aug. 5, 2009).

¹³ *Id.*

cigarettes are both a drug and a device, making them subject to federal regulation. Smoking Everywhere disagreed and filed suit in federal court in April challenging the FDA's jurisdiction over their products. Shortly after filing, NJoy intervened in the matter as well.

Smoking Everywhere and NJoy v. FDA

On April 28, 2009, Smoking Everywhere, Inc., filed suit against the FDA in the U.S. District Court for the District of Columbia, to stop the agency "from improperly exceeding its delegated authority by attempting to regulate electronic cigarettes."¹⁴ Additionally, the companies filed a temporary restraining order and preliminary injunction motion, to prevent the agency from seizing e-cigarette shipments as they enter the United States.¹⁵

In their filings, the companies argue that pursuant to the U.S. Supreme Court case, *FDA v. Brown & Williamson Tobacco Corp.*,¹⁶ the federal agency is precluded from regulating nicotine or its delivery systems because Congress did not specifically delegate that authority to the FDA. The FDA countered by arguing that e-cigarettes are not traditional tobacco products like those addressed in *Brown*.

In 2000, *Brown* held the agency lacked authority to regulate tobacco products because Congress had set forth a specific scheme for regulation of those types of products. Specifically, Justice Sandra Day O'Connor wrote in *Brown*, "Congress [chose] instead to create a distinct regulatory scheme focusing on the labeling and advertising of cigarettes and smokeless tobacco. Its express policy is to protect commerce and the national economy while informing consumers about any adverse health effects. Thus, an FDA ban would plainly contradict congressional intent."¹⁷

In the case of e-cigarettes, however, the agency contends that e-cigarettes are nicotine-delivering devices subject to its regulatory authority. Complicating matters further for the e-cigarette companies in this case is the recent congressional delegation of additional and broad regulatory authority over tobacco products to the FDA.

The Family Smoking Prevention and Tobacco Control Act

In June, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act¹⁸ (the Act), giving the FDA the power to regulate the tobacco industry.¹⁹

¹⁴ William T. Koustas, *et al.*, *FDA Explains the Import Alert Process in Electronic Cigarette Company Suit*, FDA LAW BLOG, May 13, 2009, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2009/05/fda-explains-the-import-alert-process-in-electronic-cigarette-company-suit.html (a copy of the complaint can be obtained at <http://www.fdalawblog.net/files/smoking-everywhere---complaint.pdf>).

¹⁵ The FDA added electronic cigarettes to the import alert system in early 2009. The import alert is a mechanism for FDA headquarters to communicate information and guidance to field personnel regarding products that are not allowed in the county or must be further inspected.

¹⁶ 529 U.S. 120, 120 S.Ct. 1291 (2000).

¹⁷ *Id.* at 121.

¹⁸ Pub. L. No. 111-31, H.R. 1256, 111th Cong. (2009).

Passed by sizable majorities in both the House and the Senate and supported by health conscious organizations such as the American Cancer Society, the Act specifically reverses the Supreme Court's holding in *Brown*. After years of fighting Big Tobacco for control, the federal agency now has the regulatory authority to do the following:

- require disclosure of a tobacco product's contents;
- compel the tobacco industry to research the effect of its products on consumers' health;
- prohibit terms such as "light," "mild," and "low-tar" on tobacco product labels; and
- require warning labels to cover 50 percent of the front and rear of each cigarette pack, with the word, "warning," in capital letters.²⁰

Although nicotine and cigarettes as a whole cannot be banned outright, flavoring such as fruit or mint can. Additionally, new tobacco products seeking to enter the market will be required to meet FDA pre-market standards.²¹

Last month, the FDA filed a brief in the e-cigarette suit explaining the implications of the recently-passed Act on the case. In summary, the agency argued that Congress simply expanded FDA's regulatory authority to include nicotine- and tobacco-containing products that were previously not within its jurisdiction.²² In enacting the law, the agency said, Congress "confirmed its understanding that certain tobacco products are properly regulated as drugs, devices, and combination products" and that the FDA has regulatory authority over them – including e-cigarettes.²³

Conclusion

The determination of whether e-cigarettes are harmful may ultimately cause many communities to revisit and/or amend current no-smoking bans in restaurants, bars, and airports. Until further studies are completed by the FDA and conclusions are widely disseminated to the public, the use of e-cigarettes is a loophole to most smoking bans.

Additionally, a major issue with e-cigarettes is that they are, in fact, attractive to young people. They have been around only for a few years and, thus do not have the same

¹⁹ See Craig A. Conway, *FDA Gains Regulatory Authority Over Tobacco*, HEALTH L. PERSPECTIVES, July 22, 2009, [http://www.law.uh.edu/healthlaw/perspectives/2009/\(CC\)%20Tobacco.pdf](http://www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20Tobacco.pdf).

²⁰ Pub. L. No. 111-31, H.R. 1256, 111th Cong. (2009); see also, e.g. Melissa Healy, *The FDA's Tobacco Road*, L.A. TIMES, June 29, 2009, <http://www.latimes.com/features/health/la-he-tobacco29-2009jun29,0,474954.story>; Gregory D. Curfman, M.D., et al., *Editorial: Tobacco, Public Health, and the FDA*, NEW ENG. J. MED. 10.1056, June 22, 2009, available at <http://content.nejm.org/cgi/reprint/NEJMe0905622v1.pdf>.

²¹ *Id.*

²² *Smoking Everywhere, Inc., and Sottera, Inc., d/b/a NJoy v. U.S. Food & Drug Admin.*, No. 09-cv-0771 (D.C. Dist.) (Defendant's Supplemental Brief in Opposition to Plaintiff's and Intervenor's Motions for a Preliminary Injunction at pg. 2, available at <http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM173193.pdf>).

²³ *Id.*

amount of negative press as do cigarettes. They have flavors like those found in chewing gum and are marketed as a “safe alternative” to smoking cigarettes. Any teenager could believe such advertising, use e-cigarettes, and think no harm is being done to himself or herself. Meanwhile, those teenagers are slowly becoming addicted to the nicotine the e-cigarette label says is not present. Next thing they know, they are purchasing a pack of real cigarettes.

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