How will the Family Smoking Prevention and Tobacco Control Act Impact the Electronic Cigarette Industry?

by Azim Chowdhury

Almost a decade after the Supreme Court determined the U.S. Food and Drug Administration (FDA) did not have jurisdiction over tobacco products in *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (2000), on June 12, 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (FSPTCA). The FSPTCA gives FDA authority to, among other things, control cigarette packaging, regulate the manufacture, distribution, advertising, promotion, sale and use of cigarettes and smokeless tobacco products. The new law will not, however, permit the agency to ban tobacco products or nicotine. President Barack Obama quickly declared the FSPTCA "a long time coming" and signed the bill into law on June 22, 2009. The FSPTCA promises to bring dramatic changes to the tobacco industry; but its effect on the newer smokeless "electronic" or "e-cigarette" industry is less clear.

Battle to Regulate Tobacco

In 1996, FDA attempted to promulgate regulations (Proposed Regulations) governing the promotion, labeling, and accessibility to children and adolescents of tobacco products. After conducting an investigation into the tobacco industry, FDA concluded that cigarettes and smokeless tobacco products were "devices" that were intended to deliver nicotine, a drug, to the body. For cigarettes and smokeless tobacco to be considered a drug or delivery device, FDA had to demonstrate that it was an article "intended" by its manufacturers to prevent or treat disease, or "intended to affect the structure or any function of the body."[1] FDA concluded after its investigation that a cigarette was not simply a repackaged tobacco plant, but a device designed to deliver controlled amounts of nicotine to the body, and that, because of nicotine's forseeable addictive qualities, tobacco companies intended nicotine's addictive effect on consumers.[2] Thus, in FDA's eyes, cigarettes were a drug-device combination subject to their regulatory authority.

But, in 1997 a group of tobacco manufacturers, retailers and advertisers filed suit in federal district court claiming FDA lacked jurisdiction to regulate tobacco products as "customarily marketed"—i.e., without manufacturer claims of any therapeutic benefit. The legal battle led to the Supreme Court's decision in *Brown*. But the *Brown* Court never reached the issue of whether cigarettes were drug-device combinations or if tobacco companies actually intended to deliver addictive nicotine to consumers. The Court instead held that "[r]eading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority to regulate tobacco products as customarily marketed."[3]

After *Brown*, if FDA was to regulate tobacco products, Congress would have to enact legislation giving FDA statutory authority to assert its jurisdiction.

Family Smoking Prevention and Tobacco Control Act

On April 2, 2009, the House of Representatives approved the FSPTCA, giving FDA authority to regulate—but not ban—cigarettes and other tobacco products. Under the FSPTCA, tobacco products would not be regulated under the "safe and effective" standard currently governing drugs and devices under the FDA's purview, but under a new "appropriate for the protection of the public health" standard. On June 11, 2009, the Senate approved its version of the legislation, which the House promptly ratified the next day. President Obama, a long-time smoker still struggling to quit, signed the bipartisan legislation on June 22, 2009.

Pursuant to the final version of the bill,[4] among other things:

- Cigarette packages must have warning labels that cover 50 percent of the front and rear of the package and must bear the word "warning" in capital letters and 17-point font. Additionally, the same warning labels would be required

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in advertising and must comprise at least 20 percent of the advertisement's area;

- Tobacco-related sponsorships of sports and entertainment events will be banned;
- Giveaways of non-tobacco items with the purchase of a tobacco product or in exchange for coupons or proof of purchase will be banned;
- All outdoor tobacco advertising within 1,000 feet of schools and playgrounds will be banned;
- Point-of-sale advertising will be limited to adults-only facilities and advertising in publications with significant teen readership will be limited. The Secretary of Health and Human Services (HHS) will have the authority to develop regulations that impose restrictions on the advertising and promotion of a tobacco product consistent with the First Amendment to the Constitution;
- Cigarette and tobacco vending machines and self-service displays will be restricted to adults-only facilities;
- Retailers will have to verify age for all over-the-counter sales;
- There will be federal enforcement and penalties against retailers who sell to minors;
- Flavored cigarettes (including candy, herb, spices or fruit flavors such as strawberry, grape, orange, clove, cinnamon or vanilla) will be banned;
- Cigarettes advertised as "light," "mild" or "low" giving the impression that they are safer for consumers, will be banned. Furthermore, a manufacturer must first file an application with FDA and receive an order before being permitted to market any tobacco product as presenting a "modified risk;"
- Tobacco companies will be required to provide FDA with information about their products, including the ingredients, additives and constituents;
- FDA will have the authority to require product changes, such as the reduction or elimination of harmful ingredients, additives and constituents, if it determines these changes would protect the public health;
- User fees on tobacco companies will pay for the new regulations; and
- FDA will *not* have authority to ban nicotine or tobacco.

While the impact the FSPTCA will have on the tobacco industry is obvious, the new legislation will also likely dramatically impact the electronic "e-cigarette" or "e-cig" industry.

Electronic Cigarettes

E-cigs have developed over the last few years as an alternative to smoked tobacco products. Typically, an e-cig takes the form of an elongated tube, a mouthpiece, a heating rechargeable battery, and electronic circuits. E-cigs are typically designed to resemble tobacco cigarettes, cigars and pipes. The battery-powered device provides inhaled doses of vaporized nicotine to the user. When a user inhales through the device, air flow is detected by a sensor, which activates a heating element that vaporizes a nicotine solution stored in the mouthpiece (which can be refilled). Although no tobacco, smoke, or combustion is involved, the nicotine vapor still provides a flavor and physical sensation similar to that of inhaled tobacco smoke. Many e-cigs also have a light-emitting diode (LED) which is activated when the user inhales and simulates the glow of an actual, burning cigarette.

Does the FDA have Authority to Regulate E-Cigs?

The strongest case for regulating e-cigs centers around health claims often made by e-cig manufacturers that the product can help smokers break their addictions to tobacco or that the e-cig is a "healthier" or "safer" way to smoke when compared to traditional cigarettes. E-cigs have been touted as containing no tar, hydrogen cyanide or any of the other harmful chemicals and toxins in cigarettes, and for producing no second-hand smoke.[5] The vapor exhaled does not discolor a smoker's teeth or cause bad breath. The eco-friendly e-cigs do not generate cigarette butts and are safer for the environment because they do not burn and are reusable.

Despite these claims, many anti-smoking organizations have come out against the continued sale of e-cigs without FDA-approved clinical trials that demonstrate the safety and effectiveness of the product. To date, no FDA-approved clinical studies have proven e-cigs to be safer than tobacco cigarettes, effective in helping smokers quit, or have considered their long-term health effects.

In September 2008, the World Health Organization (WHO) declared that companies marketing electronic cigarettes should stop claiming the product is a safe and effective anti-smoking therapy. While the WHO "does not discount the possibility that the electronic cigarette could be useful as a smoking cessation aid [,]" the only way to know if this is true is to test.[6] Citing the lack of clinical studies and WHO's statements, on March 23, 2009, Senator Frank R. Lautenberg (D-NJ) sent a letter to then-Acting Commissioner of the FDA, Frank Torti, requesting the agency "take immediate enforcement action against manufacturers or 'electronic cigarettes' and take these products off the market until they are proven safe."

In April 2009, Action on Smoking and Health (ASH), an anti-smoking organization filed a citizen's petition, arguing that FDA must begin regulatory proceedings over e-cigs, as it did with other nicotine products (e.g., gums and patches) as well as cigarette-like devices like "Favor" smokeless cigarettes.[7] The citizen's petition argues that *Brown* would not bar the regulation of e-cigs. In addition, ASH argued that regulation was essential to protect both users (and nonsmokers subject to second-hand vapors) from unnecessary exposure to dangers which may exist from vaporized nicotine.[8]

FDA Action

FDA has made clear that it considers e-cigs a "drug device combination" product pursuant to Section 503(g)(1) of the FDCA and that, in the agency's opinion, the product is not as safe as its proponents claim. In early 2009, FDA began taking steps toward regulation by adding "Electronic Cigarettes and Electronic Cigarette Components" to Import Alert 66-41 and has halted the importation of some e-cig shipments from China.[9] On the Import Alert 66-41, FDA has listed certain e-cigs as "misbranded" and as an "unapproved new drug—product appears to be a combination drug-device product that requires pre-approval, registration and listing with FDA." One of the largest distributors of e-cigs recently filed suit against FDA seeking a restraining order and preliminary injunction to prevent the agency from holding its e-cig product at the border.[10] In its memorandum in response to the action, FDA made clear how it views e-cigs:[11]

> In the proceeding following [the Plaintiff's] attempt to import two shipments of E-Cigarettes, FDA found that [the Plaintiff's] product met the definition of both a drug and device under the Federal Food, Drug, and Cosmetic Act (FDCA). FDA made this determination after examining the product, the claims made in the product labeling, and information [the Plaintiff] submitted to FDA. FDA has similarly determined that other nicotine-containing products, such as gums, transdermal patches, nasal sprays, inhalers, lollipops, lozenges, and hand gels, are within its jurisdiction. Manufacturers and distributors of some of these products have obtained FDA approval to market their products legally in the United States. [The Plaintiff] has chosen not to submit an application for approval of its product, which would require it to submit data showing that the product is safe and effective. As an unapproved drug or device, distribution of E-Cigarettes in commerce in the United States is prohibited. Thus, FDA properly concluded that the shipments of E-Cigarettes at issue here may be refused admission into the United States.

On July 22, 2009, FDA issued a warning against e-cigs.[12] In the News Release, FDA announced that a laboratory analysis of e-cig samples found carcinogens and toxic chemicals. According to the News Release, FDA's Division of Pharmaceutical Analysis analyzed the ingredients in the liquid nicotine from two leading brands of electronic cigarettes. FDA's analyses detected diethylene glycol, a toxic chemical used in antifreeze, in one sample, as well as carcinogens, including nitrosamines, in several other samples. FDA is requesting healthcare professionals and consumers to report serious adverse events or product quality problems related to e-cig use to its MedWatch Adverse Event Reporting program.

Despite FDA's warnings about the hazards of e-cigs, the product's proponents are quick to respond that e-cigs still contain far fewer carcinogens and nitrosamines, including diethylene glycol, than traditional cigarettes. Moreover, e-cigs are highly unlikely to be completely free of carcinogens simply because the liquid nicotine is derived from tobacco—even FDA-approved nicotine replacement products have residual traces of carcinogens.[13] Furthermore, it is the combustion and inhaling of tobacco smoke from conventional cigarettes that is the most responsible for the harmful and deadly consequences of smoking, not nicotine.[14] It is doubtful, however, that any of these claims will have an effect on FDA's position without clinical studies.

Impact of the FSPTCA on E-Cigarette Regulation

Before the FSPTCA passed, one argument for proponents of e-cigs against regulation was that e-cigs were "equivalent" to traditional tobacco cigarettes, and thus, because of *Brown*, outside of the scope of FDA's jurisdiction. Since e-cigs were marketed, sold and used by consumers as the functional equivalent of the tobacco cigarette, and intended only to deliver nicotine for non-therapeutic purposes, e-cigs should not be treated differently than their tobacco counterparts. Opponents argued, on the contrary, FDA had the jurisdiction to regulate e-cigs because *Brown* was expressly limited to "tobacco products," and e-cigs do not contain any tobacco.[15] Additionally, the *Brown* Court determined FDA did not have jurisdiction to regulate (and ban) tobacco products because the "tobacco-specific" legislation passed subsequent to FDA's enabling statute made clear that Congress did not intend such a ban. With the passing of the FSPTCA, however, the proponent's argument that e-cigs should be treated like regular cigarettes is self-defeating. While Congress still does not intend to ban tobacco, it does prefer that it be regulated.

There are several arguments the electronic cigarette industry is poised to argue to avoid being regulated by the FSPTCA. The most obvious argument is that e-cigs are not tobacco products. E-cigs that do not contain nicotine, but compounds similar to nicotine (e.g., lobeline) or synthetic nicotine not derived from tobacco plants, would likely not fall under the definition of a tobacco product. But the FSPTCA also contains language that FDA could use to directly regulate and keep smoking alternatives such as e-cigs off the market. Although the law applies only to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products"[16] deemed by the Secretary, the law also regulates "drug products used to treat tobacco dependence"[17] as well as "modified risk tobacco products,"[18] which sets tough standards for tobacco industry efforts to promote new products as "lower risk." Such a new product—such as e-cigs, perhaps—would have to demonstrate that they not only reduce harm for current smokers, but also "benefit the health of the population as a whole, taking into account the impact on both users and nonusers of tobacco products."[19]

Furthermore, additional overhead and user fees that come with regulation will make it very difficult for small tobacco and e-cig companies to absorb the costs and survive in the market. This likely was a reason the FSPTCA was backed by Phillip Morris USA, the largest tobacco company in the country. Phillip Morris can bear the costs associated with regulation while also solidifying its top position in the market.[20]

Consumer Intent

Although the *Brown* Court did not reach the issue, in attempting to promulgate the 1996 Proposed Regulations, FDA argued that tobacco cigarettes could be regulated as drug delivery devices because nicotine's forseeable addictive qualities and widespread consumer use demonstrated that tobacco companies intended nicotine's addictive effect on consumers. FDA could make a similar argument with e-cigs. Even if FDA cannot point to direct evidence that e-cig companies intend nicotine's addictive effects, the foreseeablility of these effects and widespread consumer use may indicate that these are the forces driving e-cigs purchases, rather than "smoking pleasure."[21] If that is the case, the consumer "intent" could be imputed to e-cig companies and FDA would have a strong case for regulating e-cigs as a combination drug delivery device. This argument is further bolstered by FDA's new authority under the FSPTCA.

E-Cig Manufacturers Could Benefit from Drug Delivery Device Classification

Although nicotine is often portrayed as the sinister addictive component of cigarettes and e-cigs, there is mounting evidence that nicotine has positive effects in diseases such as schizophrenia, ADHD, Alzheimer's disease, Parkinson's disease, ulcerative colitis and Tourette Syndrome.[22] Much of the evidence of nicotine's benefits was derived from epidemiological studies on the effects of smoking. Tobacco smokers, for example, tend to have a lower risk of developing Alzheimer's and Parkinson's disease. There is also evidence indicating that larger numbers of mentally ill (e.g., schizophrenics, bipolar disorder sufferers) smoke tobacco in an attempt to self-medicate their symptoms.[23] But the risks of smoking tobacco have always outweighed the potential health benefits of nicotine. The technology used by e-cigs may provide a way to effectively deliver nicotine into the body without any of the harmful effects of tobacco or smoke. Of course, clinical trials testing the safety and efficacy of e-cig type devices for this use will have to be conducted, but e-cig manufacturers may want to take advantage of their technological know how and begin preparing their FDA submissions.

Conclusion

The FSPTCA is the culmination of a decade's long debate over whether or not tobacco should be regulated by FDA. But just how much the new law will affect the electronic cigarette industry remains to be seen. In all likelihood, FDA will use its authority under both the FDCA and the FSPTCA to rein in e-cigs and regulate the product as a combination drug delivery device. If so, e-cig manufacturers should try to keep the big picture in mind. Regulation may ultimately help prove the e-cig to be a groundbreaking technology that can help tobacco smokers quit, allow adults to enjoy a healthier method of smoking, and help scientists realize the medical benefits of nicotine.

1 FDCA, 21 U.S.C. § 321(g)(1).

2 Gilhooley, Margaret, *Tobacco Unregulated: Why the FDA Failed, and What To Do Now*, 111 Yale L.J. 1179, 1189 (2002).

3 *Id.* at 176. The Brown court determined that because FDA had concluded that tobacco products were unsafe for their intended use (smoking pleasure), the agency would have no choice but to ban tobacco products altogether if given regulatory authority. If given this authority, FDA would have to classify tobacco products as "Class III" devices which cannot be sold unless determined to be "safe" for their intended use. Congress made clear that it did not intend such a ban by enacting tobacco-specific legislation (e.g., Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331–1341), none of which attempted to ban tobacco. Accordingly, the Court held FDA did not have the jurisdictional authority to promulgate the 1996 Proposed Regulations.

4 *See* H.R. 1256.

5 *10 Reasons Electronic Cigarettes Are Better Than Tobacco Cigarettes, by Electronic Cigarette Blog & Store* (June 11, 2009), *available at*, http://www.e-cig.org/2009/06/11/10-reasons-electronic-cigarettes-are-better-than-tobacco-cigarettes/.

6 *Marketers of electronic cigarettes should halt unproved therapy claims*, by the WHO (Sept. 19, 2008), *available at*, http://www.who.int/mediacentre/news/releases/2008/pr34/en/index.html.

7 In a letter dated Feb. 9, 1987, FDA ruled that "Favor" Smokeless or Smoke-Free cigarettes were nothing more than a "nicotine delivery system intended to satisfy a nicotine dependence" and therefore subject to FDA's jurisdiction. The letter is *available at* http//www.health.gov.bc.ca/guildford/pdf/059/00006023.pdf.

8 Banzhaf, John, Esq., *Initial Citizen Petition by Action on Smoking and Health (ASH) Requesting That the FDA Assert Jurisdiction Over This New Nicotine Delivery Device AND Take Whatever Regulatory Action is Appropriate Under its Jurisdiction According to Existing Law*, Action on Smoking and Health, *available at*, http://ash.org/ecigpetition.

9 Import 66-41 operates to bar unapproved or misbranded drugs from being imported into the United States.

10 Smoking Everywhere, Inc. vs. FDA, Memorandum in Support of Plaintiff Smoking Everywhere, Inc.'s Motion For Temporary Restraining Order and Preliminary Injunction, *available at*, http://www.e-cig.org/Smoking-Everywhere-Sues-FDA.pdf.

11 Smoking Everywhere, Inc. v. FDA, Defendant's Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction, *available at*, http://www.fdalawblog.net/files/ecigarettefdamemo.pdf.

12 *FDA and Public Health Experts Warn About Electronic Cigarettes*, FDA News Release, *available at*, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm.

13 Siegel, Michael, *Tobacco-Specific Carcinogens Found in Nicotine Replacement Products; Will Anti-Smoking Groups Call for Removal of these Products from the Market?, available at*, http://tobaccoanalysis.blogspot.com/2009/07/tobacco-specific-carcinogens-found-in.html.

14 Stier, Jeff, *FDA Warning on E-Cigs is Tone Deaf, available at* http://...com/News/FDA-Warning-On-E-Cigs-is-Tone-Deaf-41764.html.

15 If the nicotine contained in the e-cig is derived from tobacco plants, then it could be argued that the e-cig contains tobacco.

16 H.R. 1256 Sec. 901(b).

17 H.R. 1256 Sec. 918 states the Secretary shall:
1) at the request of the applicant, consider designating products for smoking cessation, including nicotine replacement products as fast track research and approval products within the meaning of section 506;
2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and
3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

18 H.R. 1256 Sec. 911.

19 H.R. 1256 Sec. 911(g)(1)(B).

20 Carney, Timothy P., *How Philip Morris Benefits From Tobacco Regulation*, The Wash. Examiner (Apr. 7, 2009), *available at*, http://www.washingtonexaminer.com/politics/How-Philip-Morris-benefits-from-tobacco-regulation-42635857.html.

21 Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d at 161 n. 9.

22 Mandavilli, Apoorva , *Nicotine Fix*, Journal of Nature Medicine, Vol. 10, No. 7, (July 2004), *available at*, http://www.prism.yale.edu/Templates/PRISM%20IN%20THE%20NEWS/Nat%20Medicine%20nicotine%20story%207.04.pdf.

23 *Id*.