The Evolution of the Electronic Cigarette

by Azim Chowdhury

Background

The electronic cigarette or "e-cigarette"—a rechargeable battery-powered device designed to resemble a conventional tobacco cigarette—was originally developed and patented in 2003 by RUYAN Group (Holdings) Ltd. (Ruyan), a company based in Beijing, China. Ruyan first began selling its e-cigarettes in May 2004, and by 2009 saw its annual revenues skyrocket to $54 million USD.[1] By 2007, thanks to the Internet, the novel "tobacco-free" product started getting noticed by consumers in the United States, and its popularity has continued to swell with its growing presence in shopping mall kiosks and convenience stores around the country. The growing popularity and market share of e-cigarettes, which now generate an estimated $100 million annually in sales[2], caused the U.S. Food and Drug Administration (FDA) to take notice and, in September 2008, add "Electronic Cigarettes and Electronic Cigarette Components" to Import Alert 66-41, halting the importation of certain e-cigarette shipments from China. FDA declared e-cigarettes to be unapproved drug-device combination products that could not be sold in the United States without FDA pre-market approval.

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The e-cigarette is designed to resemble and mimic conventional cigarettes by providing inhaled doses of tobacco-derived vaporized nicotine solution. When a user puffs through the mouthpiece, a sensor detects the air flow and activates a heating element (*i.e.*, the atomizer) which vaporizes the solution stored in a removable cartridge in the device. The vapor provides a flavor and physical sensation similar to that of inhaled tobacco smoke, although there is no tobacco, combustion or smoke present.

In response to FDA's import ban, in April 2009, two of the largest U.S. distributors of e-cigarettes, Smoking Everywhere, Inc. (Smoking Everywhere) and Sottera, Inc. d/b/a NJOY (Sottera) filed suit against FDA in the U.S. District Court for

the District of Columbia, seeking to enjoin FDA from denying entry of their products into the country, as well as from regulating their products as drug-delivery devices.[3] The Plaintiffs argued that their products should instead be treated and regulated in the same manner as conventional tobacco cigarettes.

In June 2009, shortly after the law suit was filed, the Family Smoking Prevention Tobacco Control Act (the Tobacco Act) was enacted, giving FDA authority to regulate the manufacture, distribution, advertising, promotion, sale and use of *tobacco products*. A "tobacco product" is defined in the Tobacco Act as "any product made or derived from tobacco that is intended for human consumption."[4] The new tobacco legislation filled the regulatory vacuum with respect to tobacco products created by the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.,* which held that Congress had not yet given FDA authority to regulate "customarily marketed" tobacco products (*i.e.*, tobacco products marketed for recreational use only and without manufacturer claims of therapeutic benefit).[5]

Subsequently, on July 22, 2009, FDA issued a warning against the use of e-cigarettes.[6] The agency announced that its Division of Pharmaceutical Analysis analyzed the liquid nicotine from Smoking Everywhere and Sottera's e-cigarettes and detected diethylene glycol, a toxic chemical used in antifreeze, in one sample, as well as carcinogens, including tobacco specific nitrosamines, in several other samples.[7] Conspicuously missing from FDA's analysis, however, was any mention of what toxins and carcinogens are typically found in traditional tobacco cigarettes. FDA also requested that healthcare professionals and consumers report serious adverse events or product quality problems related to e-cigarette use to its MedWatch Adverse Event Reporting program;[8] to date, FDA has not publicized any adverse events related to e-cigarettes.

The Plaintiffs in *Sottera* argued that because their products contain liquid nicotine that is *derived* from tobacco, their e-cigarettes fall within FDA's tobacco product jurisdiction rather than its drug-device jurisdiction. The Plaintiff's position was initially vindicated when the District Court agreed, and held that because the nicotine was derived from tobacco, the tobacco-free e-cigarettes fell within the meaning of "tobacco product" in the Tobacco Act, and were therefore exempt from FDA regulation as drug-device combination products.[9] More specifically, Judge Richard J. Leon held that because the Plaintiff's e-cigarettes were not marketed to prevent, mitigate or treat the withdrawal symptoms of nicotine addiction, and did not affect the structure and function of the body any more than conventional cigarettes, the product did not fit the definition of a drug in the Food, Drug and Cosmetic Act (FDCA).[10] Accordingly, the District Court granted the Plaintiff's motion to enjoin FDA from continuing to implement the import ban and from treating e-cigarettes as drugs absent claims of therapeutic benefit.[11]

Rather than exercise its authority under the Tobacco Act to establish regulations covering e-cigarettes as tobacco products,[12] FDA continued to advocate that e-cigarettes are drug-delivery devices. It appealed the District Court's decision and filed an emergency motion with the U.S. Court of Appeals for the District of Columbia Circuit to stay the District Court's decision. On appeal, FDA argued that although Sottera did not make express therapeutic claims, its e-cigarettes are nevertheless drug-delivery devices and not tobacco products. FDA maintained that the Supreme Court's decision in *Brown* only applied to "traditional" cigarettes and smokeless tobacco products, not to novel nicotine-delivery systems. Sottera countered, in pertinent part, that if accepted, FDA's position—that any product affecting the structure/function of the body is automatically a drug under the FDCA, even without express therapeutic claims— "would dramatically expand FDA's jurisdiction and produce absurd results that Congress never intended."[13]

On September 9, 2010, just prior to the oral arguments before the Court of Appeals, FDA sent Warning Letters to five e-cigarettes distributors.[14] The letters alleged that each of the companies made unauthorized statements on their websites, labels and advertising materials that demonstrate that their products were intended to affect the structure/function of the body, as well as to mitigate, treat or prevent disease. More specifically, FDA charged that claims suggesting that e-cigarettes could help smokers quit can only be made after approval of a new drug application. Because the five e-cigarette companies were allegedly making such claims without going through FDA's pre-market approval process, their products were unapproved drugs. FDA also sent a letter to the Electronic Cigarettes Association, an organization established to promote industry-wide standards and a code of conduct for e-cigarette technologies, affirming that e-cigarette companies must comply with FDA's pre-market drug approval process before marketing their products.

U.S. Court of Appeals Decision

FDA's continued efforts to characterize e-cigarettes as drug-delivery devices would soon take another blow, however.

On December 7, 2010, the appellate court's three-judge panel in *Sottera* unanimously ruled in favor of Sottera, the remaining plaintiff,[15] and upheld the District Court's decision.[16] The Court held that FDA lacks the authority to regulate e-cigarettes as drugs or devices, because (1) e-cigarettes fall within meaning of "tobacco product," as defined in the Tobacco Act, given that the nicotine used in the Plaintiff's product is derived from tobacco plants and (2) Sottera's e-cigarettes were not marketed with claims of therapeutic benefit, but rather, only for "smoking pleasure."[17] In other words, like traditional cigarettes, Sottera's product did not fall within FDA's drug-device authority because they were not marketed with any drug claims.[18]

The Court's majority (Judges Stephen F. Williams and Brett M. Kavanaugh) made clear that they did not agree with FDA's interpretation of the meaning of the term "tobacco product" in the Supreme Court's decision in *Brown*.[19] FDA argued that in the *Brown* decision, the Supreme Court was only referring to *traditional* cigarettes and smokeless tobacco when it used the phrase "tobacco products," and, therefore, the Supreme Court's ruling that FDA did not have authority to regulate "customarily marketed" tobacco products had no bearing on the present e-cigarette situation.[20] Rather, Judges Williams and Kavanaugh sided with Sottera and held that the *Brown* decision did not just apply to only those tobacco products for which Congress had passed specific regulatory statues (*i.e.*, traditional cigarettes and smokeless tobacco) but to *all* tobacco products as customarily marketed.[21] Accordingly, the Court's majority held that based on *Brown*, as well as Congress' decision to fill the regulatory vacuum by passing the Tobacco Act, it was clear that FDA now has authority to regulate customarily marketed tobacco products under the Tobacco Act, and tobacco products marketed for therapeutic purposes under its drug-device jurisdiction.[22] The majority, however, concluded its opinion with the following caveat: "Of course, in the event that Congress prefers that FDA regulate e-cigarettes under the FDCA's drug-device provisions, it can always so decree."[23]

Concurring Opinion

Judge Merrick B. Garland concurred with the majority, but not entirely for the same reasons. Like the majority, Judge Garland agreed that based on the plain language of the Tobacco Act, Sottera's e-cigarettes fall within meaning of "tobacco product" because the liquid nicotine used in those products is derived from tobacco plants.[24] Therefore, e-cigarettes should be regulated as tobacco products and not drug-delivery devices.[25] However, Judge Garland did not agree that the holding in *Brown* extended to the e-cigarette situation.[26] Rather, he stated that the Supreme Court's decision was only meant to apply to products that actually contain tobacco - which e-cigarettes do not.[27] According to Judge Garland, the reason the Supreme Court in *Brown* held that FDA did not have jurisdiction to regulate customarily marketed tobacco cigarettes as drug-devices was because such products allegedly could not be used safely for any therapeutic purpose, and would thus have to be banned by FDA if the Agency had drug-device authority over them.[28] However, this premise does not hold true for e-cigarettes or other tobacco-free products that deliver pure nicotine; these types of products *could* have therapeutic benefits and would not necessarily have to be banned.[29] Finally, Judge Garland acknowledged FDA's argument that its interpretation of the Tobacco Act, as the Agency charged with interpreting the new law, should be entitled to deference (*i.e.*, Chevron deference).[30] The Judge stated, however, that because there was no final agency action from FDA interpreting the new law, there was no way to award such deference to the Agency's position.[31] He concluded with the following: "What the result would be were the FDA to offer a contrary statutory interpretation in the form of a regulation, I leave for the day the agency decides to take that step."[32]

On December 20, 2010, FDA, refusing to accept what appeared to be inevitable, filed a Petition for a Rehearing and a Rehearing En Banc, as well as a motion to reinstate the stay of the District Court's decision to grant Sottera's preliminary injunction, arguing that the panel's decision was based on a "fundamental misunderstanding" of the *Brown* decision. FDA contended that the panel's ruling would erode incentives for companies to develop nicotine replacement therapies, and would "exacerbate the problem of nicotine addiction and undercut an important tobacco control measure."[33] On January 24, 2011, the Court of Appeals unanimously denied the FDA's en banc rehearing request and left in place the injunction preventing FDA from barring e-cigarette imports and from regulating the products as drug-devices.

The ruling underscored the panel's original decision and forced FDA to consider the extent to which it should regulate e-cigarettes under the Tobacco Act, or appeal to the Supreme Court.

Regulation of E-Cigarettes under the Tobacco Act

Although e-cigarettes meet the tobacco product definition in the Tobacco Act, the new legislation does not automatically include the new products. Section 901 of the Tobacco Act provides

that the law "shall apply to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to *any other tobacco products* that the Secretary [of Health and Human Services] *by regulation* deems to be to be subject" to the law (author's emphasis). On April 5, 2011 – the last day FDA could petition the Supreme Court for a Writ of Certiorari to review the appellate court's decision – FDA published a letter to stakeholders on its website conceding defeat in the e-cigarette litigation and announcing that it planned to regulate e-cigarettes as tobacco products. FDA must now go through a rule-making procedure and promulgate a regulation on e-cigarettes. Specifically, the Tobacco Act requires the Secretary to publish a notice of proposed rulemaking in the Federal Register, provide a comment period of not less than 60 days, and then: (A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or (B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.[34]

Public Perception of E-Cigarettes

FDA's decision to regulate e-cigarettes as tobacco products is in line with the public's desire that these products be regulated. The University of Michigan's C.S. Mott Children's Hospital recently released results of a poll that found that U.S. adults favor restrictions, safety testing and age restrictions for e-cigarettes.[35] Ninety-one percent of adults surveyed thought manufacturers should be required to test e-cigarettes for safety and 85 percent favor prohibiting the sale of e-cigarettes to minors. Strong majorities also prefer that FDA regulate e-cigarettes like other nicotine-containing products and believe there should be marketing restrictions on social networking sites popular among youth.

States Move to Regulate E-Cigarettes

While FDA was pursuing its litigation position, many state legislatures took the initiative with regard to the regulation of e-cigarettes. In January, New York lawmakers advanced a bill that would make the state the first to ban e-cigarettes. In Colorado, Democratic legislators introduced a bill to expand the definition of tobacco products prohibited for sale to minors to include "any device that is designed to deliver inhaled, ingested or physically applied doses of nicotine." The bill further defines a tobacco product as "any cartridge that is designed to deliver inhaled doses of any substance containing any amount of nicotine."[36] In Spokane, Washington the City Council voted unanimously to ban people under the age of 18 from purchasing e-cigarettes.[37] The U.S. Department of Transportation (DOT) has even announced that it intends to impose a ban on e-cigarettes on airplanes.[38]

Although the list of those attempting to ban or impose restrictions on e-cigarettes continues to grow, so does the grass roots movement supporting the product. Supporters of e-cigarettes have claimed victories in Illinois, where advocacy efforts resulted in postponement of voting on a bill to ban sales of e-cigarette,[39] as well as in Virginia, where the Attorney General determined that e-cigarettes were not included in the state smoking ban.[40] Last year, before the DOT recently announced its position, a charter airline even partnered with an e-cigarette company to provide free e-cigarette samples to passengers.[41]

Supporting the pro e-cigarette effort are two studies recently published by researchers from the Boston University School of Public Health and the Johns Hopkins Bloomberg School of Medicine suggesting that the possible banning of e-cigarettes could actually further endanger the public health.[42] The studies—apparently the first unbiased investigations into the use of e-cigarettes—found smokers who used e-cigarettes had a 31 percent quit rate; traditional nicotine replacement therapies such as the nicotine patch and gum have only a 12-18 percent quit rate.[43] The studies did not examine the potential health risks or benefits of the actual e-cigarettes but measured only the quit rates for smokers compared to available smoking cessation products. The studies also claim that the proposed bans could result in former smokers who have switched to using e-cigarettes reverting back to tobacco cigarettes—which, as most would agree, would be far worse for their health.

Conclusion

The evolution of the e-cigarette from a potential drug-delivery device to a FDA-regulated tobacco product is nearly complete. Although e-cigarettes will not require FDA's pre-market approval to be sold, FDA will be able to use its authority under the Tobacco Act to ensure that appropriate age and marketing restrictions are in place, and also require e-cigarette manufacturers and distributors to disclose all ingredients, additives and any potentially harmful constituents used in their products. The e-cigarette industry should also welcome regulation as a way to legitimize their business, and recognize that regulation may ultimately help prove the e-cigarette to be a safer alternative to traditional tobacco products.

1 Jonathan K Noel, Vaughan W Rees and Gregory N Connolly, *Electronic cigarettes: a new 'tobacco' industry?*, Tobacco Control Journal; available at http://media.khi.org/news/documents/2010/10/29/ecigarettes-a_new_tobacco_industry.PDF (last updated Oct. 15, 2010).
2 Alicia Gallegos, *FDA regulation of e-cigarettes rebuffed again*, American Medical News (Feb. 14, 2011); available at http://www.ama-assn.org/amed-news/2011/02/14/gvsb0214.htm.
3 *See Sottera, Inc. v. FDA*, 680 F.Supp.2d 62 (D.C. Cir. Dec. 7, 2010).
4 See the Tobacco Act § 1019(1), 21 U.S.C. § 321(rr)(1).
5 529 U.S. 120 (2000).
6 Transcript for FDA's Media Briefing on Electronic Cigarettes (Jul. 22, 2009, 1:30 PM); available at http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM173405.pdf.
7 Evaluation of e-cigarettes, Final Report on FDA Analyses (May 4, 2009); available at http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf.
8 MedWatch Online Voluntary Reporting Form; available at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm (last updated Jun. 12, 2009).
9 *See Sottera, Inc. v. FDA*, 680 F.Supp.2d at 62.
10 Section 321(g)(1) of the FDCA defines "drug," in pertinent part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." See 21 U.S.C. § 321(g)(1)(B) and (C).
11 *Sottera*, 680 F.Supp.2d at 63.
12 As discussed in the author's November/December 2010 Update Article (Update 2010, Issue 6), Electronic Cigarettes: The Saga Continues.
13 Sottera Appellate Brief at 1 (Statement of the Case); available at http://reason.com/assets/db/12786080313937.pdf.
14 FDA Warning Letters, sent to Gamucci America (Smokey Bayou, Inc.), E-Cig Technology, Inc., E-CigaretteDirect, LLC, Johnson Creek Enterprises, LLC and Ruyan America, Inc.; available at http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm.
15 Plaintiff Smoking Everywhere, Inc. withdrew its initial complaint and was not a party to the appeal.
16 Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).
17 *Id*. at 897.
18 *Id*. at 898-99.
19 *Id*. at 895.
20 *Id*.
21 *Id*.
22 *Id*. at 898.
23 *Id*. at 899.
24 *Id*.
25 *Id*. at 904.
26 *Id*. at 901.
27 *Id*.
28 *Id*. at 900-01.
29 *Id*. at 901.
30 *Id*. at 902-03.
31 *Id*. at 903.
32 *Id*. at 904.
33 Petition for Rehearing and Rehearing En Banc (Dec. 20, 2010); available at http://www.fdalawyersblog.com/FDA%20e-cigarett%20rehearing%20petition.pdf.
34 *See* Tobacco Act, Section 907(d).
35 National Poll on Children's Health (Sep. 13, 2010), available at http://www.med.umich.edu/mott/npch/pdf/091310report.pdf.
36 Ken Green, *Bill seeks to ban sale of e-cigs to minors in Denver, state*, Examiner.com (Feb. 23, 2011, 11:00 AM), http://www.examiner.com/top-news-in-denver/bill-seeks-to-ban-sale-of-e-cigs-to-minors-denver-state#ixzz1FyoQowCf.
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39 Consumer Advocates for Smoke-Free Alternatives Association (CASAA) Newsletter (May 11, 2010), available at http://www.casaa.org/news/article.asp?articleID=98&l=a&;p=.
40 CASAA Newsletter (Jun. 10, 2010); available at http://www.casaa.org/news/article.asp?articleID=99&l=a&;p=.
41 Charisse Jones, *Charter airline gives out free Blu Cigs electronic cigarettes*, USA Today (Nov. 1, 2010); available at http://travel.usatoday.com/flights/2010-11-02-airlinesmoking02_ST_N.htm.
42 Zachary Cahn and Michael Siegel, *Electronic cigarettes as a harm reduction strategy for tobacco control: A step forward or a repeat of past mistakes?*, Journal of Public Health Policy (2010); available at http://www.hsph.harvard.edu/centers-institutes/population-development/files/article.jphp.pdf.
43 Ryan Moore, *New study suggests e-cigarette ban could be bad for public health,* Examiner.com (Feb. 10, 2011, 6:16 PM), http://www.examiner.com/technology-in-cincinnati/new-study-suggests-e-cigarette-ban-could-be-bad-for-public-health.