Electronic Cigarettes: The Saga Continues

by Azim Chowdhury

Although more than a year has passed since Congress passed the Family Smoking Prevention Tobacco Control Act (the Tobacco Act) giving the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, advertising, promotion, sale and use of tobacco products, the jury is still out on whether the new law allows FDA to regulate non-traditional tobacco products, such as electronic cigarettes, that are marketed without claims of therapeutic benefit as drug-device combinations.

Electronic cigarettes or "e-cigarettes," which are designed to resemble traditional cigarettes but are more accurately described as "nicotine atomizers," are battery-powered devices that do not, *per se*, contain any actual tobacco. In lieu of burning tobacco, the nicotine in e-cigarettes comes from removable cartridges of liquid nicotine, which is derived from tobacco plants. When the user puffs on the device, a sensor triggers a heating element which vaporizes the liquid nicotine, which the user inhales. The nicotine vapor provides a flavor and physical sensation similar to that of tobacco smoke, but without the smoke, tar and many carcinogens associated with traditional cigarettes.

FDA has taken the position that e-cigarettes are not tobacco products subject to regulation under the Tobacco Act, but rather, are drug-device combination products requiring pre-market approval under the Federal Food, Drug and Cosmetic Act (FDCA) as new drugs. The e-cigarette industry, on the other hand, considers the product to be an alternative to traditional cigarettes, and generally markets them for customary recreational use, without therapeutic claims. In September 2008, FDA added e-cigarettes and their components to Import Alert 66-41, preventing importation of the products and their components into the United States on the ground that they are unapproved drugs, devices and drug-device combinations. In September 2010, FDA took it one step further and sent Warning Letters to five e-cigarette companies.

In April 2009, in response to FDA's import ban on e-cigarettes, two U.S. e-cigarette distributors, Smoking Everywhere, Inc. and Sottera, Inc. d/b/a NJOY sued FDA in the U.S. District Court for the District of Columbia.[1] The plaintiffs moved for a preliminary injunction barring the Agency from detaining their imported products and from regulating e-cigarettes as drug-devices while the case is litigated.[2]

In January 2010, the District Court granted the plaintiffs' motion for preliminary injunction and held that because the liquid nicotine used in e-cigarettes is distilled from tobacco plants, the product falls within meaning of "tobacco product" in the Tobacco Act. The Tobacco Act defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption."[3] Prior to this legislation, the term was not specifically defined in any case or statute.

The District Court further reasoned that e-cigarettes are not excluded from the definition of tobacco product as drugs or devices because they are not intended to affect the structure of function of the body any more than conventional cigarettes, or to prevent, mitigate or treat the withdrawal symptoms of nicotine addiction.

FDA Appeal of U.S. District Court Decision

FDA immediately filed an emergency motion with the U.S. Court of Appeals for the District of Columbia Circuit to stay the District Court's decision, arguing that the public health would be harmed if these products were allowed to remain on the market. In February 2010, the Court of Appeals granted an administrative stay of the preliminary injunction and, subsequently, a stay pending appeal.

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On appeal, FDA maintained that although NJOY, the remaining plaintiff,[4] did not make any express therapeutic or structure/function claims, its e-cigarettes are nevertheless drugs or devices and not tobacco products. FDA argued that the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) only applied to traditional cigarettes and smokeless tobacco products, despite the Court's use of the broad term "tobacco products" in its decision.

By way of background, in 1996, FDA proposed to regulate "customarily marketed" tobacco products (*i.e.*, tobacco products marketed without manufacturer claims of therapeutic benefit or drug claims) as drugs under the FDCA. A group of tobacco manufacturers, retailers and advertisers brought suit against FDA, arguing that the agency lacked jurisdiction to regulate tobacco products as customarily marketed. The case went to the Supreme Court, where FDA argued that it had jurisdiction over customarily marketed tobacco products because, despite not making any drug claims, tobacco companies necessarily "intended" to affect the structure and function of the body because of nicotine's foreseeable addictive qualities and physiological effects on the body.

The Supreme Court, however, never reached this issue, and held that Congress had not yet given FDA authority to regulate tobacco products as customarily marketed. More specifically, the Supreme Court held that Congress did not intend to ban tobacco products from the market, but that if it gave FDA jurisdiction over tobacco products under the FDCA, that is exactly what would happen because traditional tobacco products are inherently unsafe and dangerous. Thus, after the *Brown* decision, in order for FDA to regulate tobacco products being marketed without drug claims, Congress would have to enact legislation specifically giving FDA authority to do so. Congress filled this regulatory gap in 2009 when it passed the Tobacco Act.

In the *Smoking Everywhere* appeal, FDA argued that the rationale in *Brown* does not extend to nicotine-delivery devices that have never been the subject of any specific federal legislation, such as e-cigarettes. FDA acknowledged that while *Brown* concluded that it would contravene congressional intent for FDA to regulate traditional cigarettes as customarily marketed pursuant to the FDCA because "such regulation would inevitably lead to a ban, a result foreclosed by other legislation," e-cigarettes, on the other hand, are not "carved out from the normal operation of the FDCA."[5] FDA further maintained that the Tobacco Act does not constrict FDA's preexisting authority under the FDCA, and that despite the broad definition of "tobacco product," the new law expressly excludes from that definition any article that is a drug, device or combination product under the FDCA. Specifically, the Tobacco Act excludes from the meaning of tobacco product any "article that is a drug under [21 U.S.C. §321(g)(1)], a device under [21 U.S.C. §321(h)] or a combination product described in [21 U.S.C. § 353(g)]."[6] FDA also reasoned that its determination to regulate e-cigarettes under its drug and device authority, rather than its tobacco authority, is entitled to deference.[7]

Despite FDA's contention that e-cigarettes should be excluded from the meaning of "tobacco product" because they are drugs or devices, a review of the legislative history of the Tobacco Act suggests that by excluding drugs and devices from the definition of tobacco product, Congress may have intended simply to confirm that tobacco-containing products of the type that were *already* subject to FDA's drug/device jurisdiction (such as the nicotine patch, nicotine gum, etc.) would remain subject to that jurisdiction because they are smoking cessation products. The original version of the law (H.R. 1108) stated that (author's emphasis):

> (2) The term "tobacco product" does not mean—
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> (A) a product in the form of conventional food (including water and chewing gum), a product represented for use as or for use in a conventional food, or a product that is intended for ingestion in capsule, tablet, softgel or liquid form; or
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> (B) **an article that is approved or is regulated as a drug by the Food and Drug Administration.**
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> (3) The products described in paragraph (2)(A) shall be subject to chapter IV or chapter V of this Act and the articles described in paragraph (2)(B) shall be subject to chapter V of this Act.
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> (4) A tobacco product may not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetics, medical device, or a dietary supplement).

There is no discussion on the record of whether the more economical language later enacted was intended to alter the scope of the original definition.

NJOY argued that, if accepted, FDA's position in this case that any product that affects the structure/function of the body is a drug under the FDCA, "would dramatically expand FDA's jurisdiction and produce absurd results that Congress never intended."[8] In NJOY's view, this expansive interpretation of the FDCA's drug/device definition "is inconsistent with the overall text of the statute, which makes clear that FDA's drug/device jurisdiction extends only to articles that are intended to offer therapeutic benefits."[9] If therapeutic intent is not viewed as a

limiting principle, NJOY asserted, FDA could enforce its drug/device authority over a universe of articles Congress either chose to regulate under different legislation or never intended to regulate at all. Such articles that would fall under FDA's unrestrained interpretation include fitness equipment, street drugs, weapons or clothing not intended to have a therapeutic effect.

Adding merit to NJOY's argument is the fact FDA has in the past declined to regulate certain products as drugs that have a structure/function affect on the body, but do not make any therapeutic claims. Caffeine, for example, is regulated as a drug when sold in tablets to maintain alertness, but not when added to beverages, even though its presence is known and required to be disclosed on the ingredient label.

As is the case for many regulatory programs, jurisdiction may be dependent upon the intended use. The Environmental Protection Agency (EPA), for instance, regulates pesticides, which are defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."[10] Products such as laundry detergents and cleansers mitigate pests by removing microorganisms are pests that are removed by cleaning. But EPA does not regulate these as pesticides when sold for their cleaning utility. Pesticide status arises if and only if the manufacturer makes a claim regarding control of pests. These examples make it more difficult to follow FDA's logic that e-cigarettes must be drugs or devices simply because they have a structure/function effect. This is especially true now that Congress has given the Agency specific authority to regulate tobacco products while allowing for safer versions of tobacco products to enter the market.

FDA Issues Warning Letters

Although FDA's appeal in *Smoking Everywhere* is still pending, FDA is using the judicial stay to enforce its position that e-cigarettes are drug-device combinations. On September 9, 2010, just prior to the oral argument before the Court of Appeals, FDA sent Warning Letters to five e-cigarette distributors,[11] alleging the companies made statements in their product labeling, advertising and on their websites that demonstrate that their e-cigarettes are unapproved drug-device combinations intended both to affect the structure/function of the body and to mitigate, treat or prevent disease. Specifically, FDA charged that the companies' products are unapproved and/or misbranded drugs because they are making statements that suggest that their products can help smokers quit smoking, and which may only be made after approval of a new drug application. Along with the Warning Letters, FDA also sent a letter to the Electronic Cigarette Association, emphasizing that companies that introduce e-cigarettes to the market will have to comply with the FDCA's pre-market drug approval process.

Regulation of Non-traditional Tobacco Products

Because Congress has now passed a law that specifically gives FDA authority over tobacco products, FDA's position that non-traditional, customarily marketed tobacco products such as e-cigarettes are, by default, drug-device combinations simply because they deliver nicotine seems to defy common sense. One reason why FDA may be pushing to regulate e-cigarettes pursuant to its drug/device authority, rather than its new tobacco authority, is that regulation under the Tobacco Act is not automatic. Section 901(b) of the Tobacco Act provides that it "shall apply to all 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 subject" to the new law (author's emphasis). Thus, because e-cigarettes do not fall within the meaning of "cigarette," "cigarette tobacco," "roll-your-own tobacco" or "smokeless tobacco," the products can only be regulated pursuant to the Tobacco Act if the Secretary undertakes to establish a regulation that specifically covers e-cigarettes.[12] To do this, the Secretary is required to publish a notice of proposed rulemaking in the Federal Register, provide a comment period of not less than 60 days, and then:[13]

> (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
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> (B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

FDA has not yet published a notice of rulemaking that specifically covers e-cigarettes in the Federal Register. Accordingly, although the tobacco-derived products may fall within meaning of "tobacco products," e-cigarettes are not presently an FDA-regulated tobacco product. Furthermore, only after FDA goes through its rulemaking procedures and concludes that e-cigarettes qualify as an "other" tobacco product, could the Tobacco Act's "modified risk" tobacco product provisions come into play.[14]

Pharmaceutical Industry's Role

The role of the pharmaceutical industry is not often discussed in the e-cigarette controversy. In 2009, the global sales

for prescription smoking cessation products surpassed $1.6 billion.[15] Pharmaceutical companies have spent millions of dollars developing smoking cessation and nicotine replacement therapies, and obtaining FDA approval for their drugs and devices.

At the oral arguments before the Court of Appeals in the present litigation, FDA's counsel emphasized that if e-cigarettes were permitted on the market smokers would turn to such products for "nicotine maintenance," using e-cigarettes to continue to get their nicotine fix while not actually quitting. While this would undoubtedly be a "healthier" move for some chronic smokers who are unable or unwilling to quit, FDA emphasized that if enough consumers did this, there would be less incentive for pharmaceutical companies to spend the millions necessary to develop products designed to actually help smokers quit for good. FDA's counsel cited Pfizer's Nicotrol Inhaler as the model example.

Conclusion

FDA's position on e-cigarettes has placed the Agency in a difficult predicament—to argue that e-cigarettes and other non-traditional tobacco products are drugs or devices circumvents Congress' clear intent to regulate non-traditional tobacco products as well as "modified risk" tobacco products pursuant to the Tobacco Act. Prior to the enactment of the Tobacco Act, the only way FDA could regulate non-traditional tobacco products was by treating them as drugs. But the key difference now is that Congress has finally given FDA jurisdiction over tobacco products. Regardless, if FDA succeeds in convincing the Court of Appeals in *Smoking Everywhere* that e-cigarettes should be treated as drugs or devices under the FDCA, the decision will end the availability of e-cigarettes as recreational alternatives to traditional cigarettes. A drug-device combination can only be approved if it is safe and effective. As a practical matter, FDA is not likely to approve an e-cigarette unless it is established by clinical trials as an effective tool for helping users of regular cigarettes quit smoking. There are anecdotal reports that e-cigarettes are a useful transition for smokers trying to quit. If that is true, and FDA prevails in *Smoking Everywhere*, e-cigarettes in the future could likely only be sold by major pharmaceutical companies, if at all.

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1 *Smoking Everywhere, Inc. v. U.S. Food and Drug Admin.*, 680 F.Supp.2d 62 (D.D.C. 2010).

2 As discussed in the author's March/April 2010 *Update* article, *Are Electronic Cigarettes Drug-Device Combination Products, or "Modified Risk" Tobacco Products?*

3 Tobacco Act, Section 101; 21 U.S.C. § 321(rr)(1); available at http://www.govtrack.us/congress/billtext.xpd?bill=h111-1256.

4 Plaintiff Smoking Everywhere, Inc. withdrew its initial complaint and is no longer a party to the appeal.

5 FDA Reply Brief at 18; available at http://www.scribd.com/doc/34740395/FDA-Reply-Brief-Ct-App-July-22-2010.

6 Tobacco Act, Section 101; 21 U.S.C.A. §321(rr)(1) and (2).

7 See *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)).

8 NJOY Appellate Brief at 1 (Statement of the Case); available at http://reason.com/assets/db/12786080313937.pdf

9 NJOY Appellate Brief at 16.

10 See 7 U.S.C. § 136(u).

11 The companies receiving warning letters were: E-CigaretteDirect LLC, Ruyan America Inc., Gamucci America (Smokey Bayou Inc.), E-Cig Technology Inc. and Johnson's Creek Enterprises LLC.

12 Section 900 of the Tobacco Act defines "cigarette" as a tobacco product that meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act (the "FLCAA"), and "includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco." The FLCAA defines cigarette as (a) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and (b) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (a). The term "cigarette tobacco" means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. The term "roll-your-own tobacco" means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes. The term "smokeless tobacco" means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

13 Tobacco Act, Section 907(d).

14 For a detailed discussion on whether e-cigarettes could be considered Modified Risk Tobacco Products, see *Are Electronic Cigarettes Drug-Device Combination Products, or "Modified Risk" Tobacco Products?* March/April 2010 FDLI Update, by Azim Chowdhury.

15 See *World Smoking-Cessation Drug Market 2010-2025*; available at http://www.visiongain.com/Report/439/World-Smoking-Cessation-Drug-Market-2010-2025