SMOKESHOP®

THE INDUSTRY AUTHORITY ON TOBACCO RETAILING

Official Publication of the International Premium Cigar & Pipe Retailers Association (IPCPR) FEBRUARY 2010

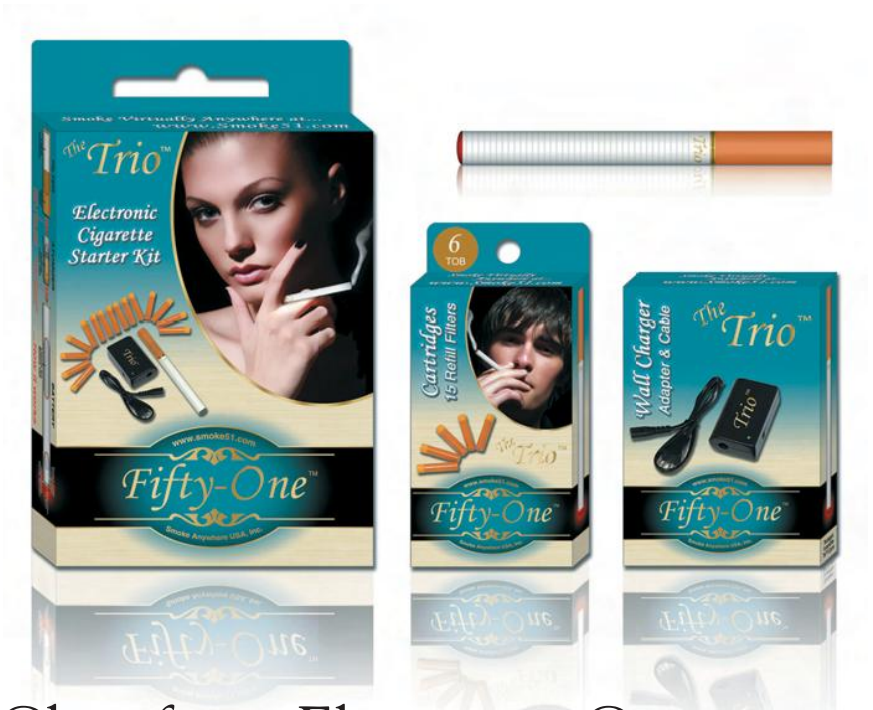
Truly Cigars

Newcomer Tracy Jones Establishes a Winning Business Catering to Customers, Earning Loyalty

PLUS:

- Ernesto-Perez Carrillo's New Start: E.P. Carrillo Cigars
- Electronic Cigarettes: How Will the Feds Classify Them?
- CITMA's Looking Out for the Small Tobacco Companies
- Dr. Smoke: Affordable Promos

www.smokeshopmag.com



> Manufacturers of electronic cigarettes sell starter kits containing all the necessary components, and refill packs and additional accessories, such as these "Fifty-One" brand products from Smoke Anywere USA.

Classifying Electronic Cigarettes

Are they drugs/medical devices, tobacco products, both, or neither? The category's future weighs in the balance as regulators—and courts—decide the answers. **>BY TROUTMAN SANDERS TOBACCO TEAM**

For more than seventy years, the Food and Drug Administration has had the authority to regulate drugs and medical devices. As a general rule, drugs and medical devices may not be sold in the United States unless they have been approved by the FDA. In 2000, the United States Supreme Court ruled that the FDA's authority over drugs and medical devices did not cover cigarettes; however, Congress has recently expanded the FDA's authority to include cigarettes and other tobacco products. The new law gives the FDA broad authority to regulate tobacco products, including their manufacture, marketing and distribution, but the new law does not give the FDA authority to ban tobacco products altogether.

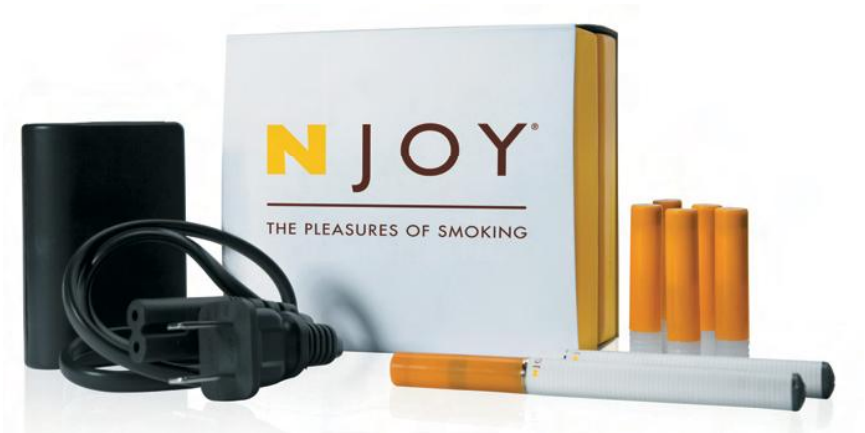
Beginning in 2009, the FDA adopted a new policy classifying electronic cigarettes as drug-medical device combination products. Consistent with that policy, the FDA issued a directive banning the importation of electronic cigarettes into the United States. Because most, if not all, electronic cigarettes are manufactured abroad, the FDA's new policy amounted to a *per se* ban of electronic cigarettes unless they have been approved by the FDA.

Electronic cigarette distributors challenged the FDA's action, arguing that the Supreme Court's decision in *Food & Drug Administration v. Brown & Williamson Tobacco Corp.* forecloses the FDA from regulating electronic cigarettes as drugs, medical devices or drug-device combination products. The electronic cigarette distributors further argued that the Family Smoking Prevention and Tobacco Control Act giving the FDA authority to regulate tobacco products evidenced Congress' intent that electronic cigarettes should not be regulated as drug-device combination products.

On January 14, 2010, the court in *Smoking Everywhere, Inc. v. Food & Drug Administration* granted the distributors' motion for a preliminary injunction, finding that the FDA lacked authority to regulate electronic cigarettes as drugs, medical devices or combination products. The court reasoned that the distributors did not make therapeutic claims regarding their products. However, the court suggested that electronic cigarettes could be regulated as drugs or medical devices if they are explicitly marketed for the therapeutic purpose of treating nicotine withdrawal. The court also noted that electronic cigarettes could be regulated by the FDA as tobacco products under the recently-enacted Family Smoking Prevention and Tobacco Control Act. Most commentators expect that the FDA will ultimately appeal the court's decision, requiring the D.C. Circuit Court of Appeals to address the ultimate question: are electronic cigarettes drug-device combination products that cannot be sold without FDA approval, are they tobacco products subject to regulation under the Family Smoking Prevention and Tobacco Control Act, are they both or are they neither?

WHAT ARE ELECTRONIC CIGARETTES?

In evaluating the FDA's authority to regulate electronic cigarettes, it is important to understand how the products are designed and marketed. An electronic cigarette generally consists of two parts – a heating element and a filter – and is designed to look like a traditional cigarette. The filter acts as the mouthpiece of the cigarette and generally contains nicotine, which is absorbed by the user. The filter attaches to the heating element, which also contains electronics and a battery. The user operates the electronic cigarette by inhaling on the end of the filter, like a traditional cigarette. When a user inhales, the electronics in the heating element detect air flow and signal the battery to heat the nicotine. When the heating element is activated, it evaporates the nicotine mix-



> Njoy's NPRO Starter Kit is offered in a choice of four colors and includes a cigarette-style device, a pack of assorted cartridges, two rechargeable lithium batteries, and a charger.

ture, creating a nicotine vapor that the user inhales. The filter contains flavoring designed to mimic the taste of actual tobacco, but without combustion, flame, tar or other by-products contained in traditional cigarettes. The nicotine contained in an electronic cigarette can be purely synthetic, or it can be derived from a tobacco solution. As discussed below, the derivation of the product's nicotine will likely impact how the product is regulated.

As noted by the court in *Smoking Everywhere*, the marketing of electronic cigarettes will impact how the product is regulated. Some distributors arguably market electronic cigarettes as smoking cessation products, similar to other nicotine replacement products, as a way to wean smokers from traditional cigarettes. Other distributors market electronic cigarettes explicitly *not* as smoking cessation products, but rather as an alternative to traditional cigarettes in situations where traditional cigarettes are either unwelcome or prohibited.

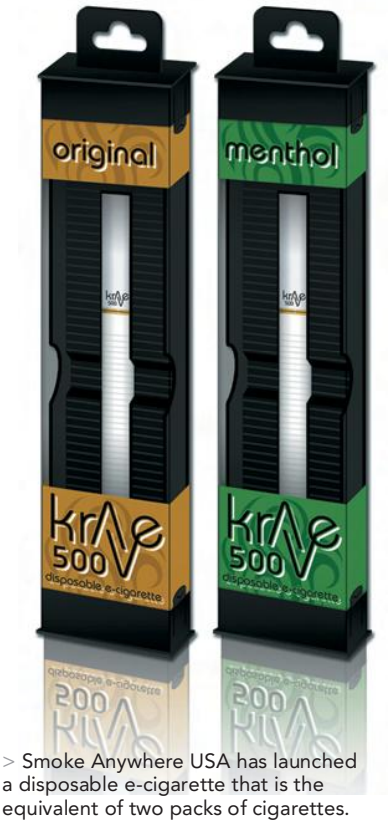
ARE E-CIGARETTES DRUG-DEVICE COMBINATION PRODUCTS?

The FDA's recent attempt to regulate electronic cigarettes is grounded in the FDA's position that electronic cigarettes are drug-device combination products that cannot be sold without FDA preapproval. As noted above, in 2000, the Supreme Court addressed the issue of whether the FDA can regulate traditional cigarettes under the Food Drug and Cosmetic Act ("FDCA"). The Court found that traditional cigarettes were unambiguously excluded from the FDA's jurisdiction. The court reasoned that, because of cigarettes' known health risks and lack of any known health benefits, the FDCA would require the FDA to ban cigarettes. The Court found that such a result would be contrary to Congress' intent, as evidenced by its passage of six different laws regulating tobacco, but not banning tobacco. Accordingly, the Court blocked the implementation of the FDA's proposed tobacco regulations.

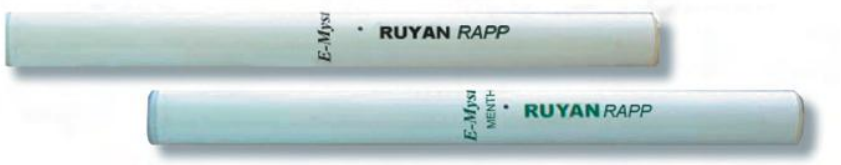
As evidenced by the Supreme Court's decision, Congress intended that cigarettes, as a delivery mechanism for nicotine and intended for use in a non-therapeutic manner, fall outside the scope of the FDCA. The same rationale probably applies to electronic cigarettes, at least to the extent that electronic cigarettes are merely marketed as an alternative to traditional cigarettes, and not for smoking cessation. This position is rooted in the FDCA's definitions, in which a product is generally considered a "drug" or "device" under the FDCA only it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or the product is "intended to affect the structure or any function of the body of man or other animals."

Applying these definitions, electronic cigarette distributors have argued that the products are not intended for use in the diagnosis or cure of a disease, and are not intended to affect the structure or function of the body of man. The phrases "intended use" and "intended to affect" have a settled meaning under the FDCA; the manufacturer's or distributor's intent is gleaned only from objective statements made in the labeling or marketing of a particular product. In other words, the intended use or intended effect of a product is determined only by communications made from the manufacturer or distributor to the consumer. Accordingly, electronic cigarette distributors have argued that electronic cigarettes are not subject to the FDCA if the labeling, promotion or marketing do not claim that the product has therapeutic value or will alter bodily functions. In finding that the FDA did not have authority to regulate electronic cigarettes under the FDCA, the court in *Smoking Everywhere* accepted these arguments.

Many electronic cigarette distributors do not claim, either in their marketing or labeling, that their products can be used for therapeutic purposes or for the purpose of altering a function of the body. Rather, these products are marketed as an alternative to traditional cigarettes, and are intended to replicate the non-therapeutic experience of smoking a traditional cigarette. In such circumstances, the products are not subject to regulation as drug-device combination products. If, on the other



> Smoke Anywhere USA has launched a disposable e-cigarette that is the equivalent of two packs of cigarettes.

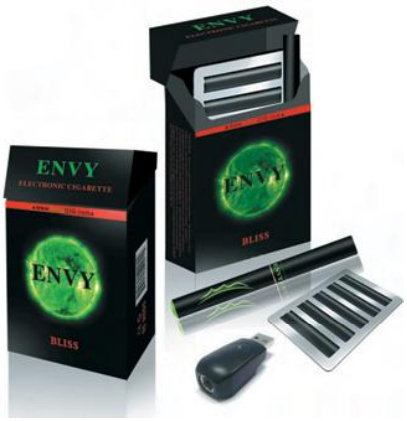


> Citing the ambiguity and confusion surrounding the regulatory and legal status of electronic cigarettes, Ruyan America, Inc. has re-formulated and renamed its product. The company now offers the Ruyan Rapp E-mystic (pronounced "ee mist-stick") a product that contains an established dietary supplement/herbal remedy—lobelia—rather than nicotine. "It tested extremely well in focus groups," says Bill Bartkowski, president of Ruyan America. The product contains neither nicotine nor tobacco and is being marketed under the Dietary Supplement Health and Education Act of 1994, incurring fewer regulatory concerns than nicotine, says Bartkowski.

hand, the distributor markets its product for smoking cessation similar to nicotine gums or patches, the product would probably be deemed as "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and subject to regulation under the FDCA as a drug-device combination product.

ARE ELECTRONIC CIGARETTES TOBACCO PRODUCTS?

Even if electronic cigarettes are not considered drug-device combination products subject to the FDA's authority under the Food Drug and Cosmetic Act, the court in *Smoking Everywhere* noted that they may be considered tobacco products subject to the FDA's authority under the Family Smoking Prevention and Tobacco Control Act ("the Tobacco Act").



> Envy Electronic Cigarettes, Inc.—a Native American-owned manufacturer based in Jupiter, Fla.—produces one of the most established brands in the electronic cigarette category, emphasizing compact size and affordability. Even as the FDA flexes its new control over tobacco products, Envy president Nicholas Van Burren sees tremendous potential and opportunity in the electronic cigarette category.

Whether an electronic cigarettes is considered a "tobacco product" depends on how the product is manufactured. The Tobacco Act defines a tobacco product as "any product *made or derived from tobacco* that is intended for human consumption, including any component, part, or accessory of a tobacco product," except for raw materials other than tobacco used in manufacturing tobacco products (emphasis added). Thus, if a product intended for human consumption is made or derived from tobacco, it is potentially subject to the FDA's authority under the Tobacco Act.

The FDA's initial authority under the Tobacco Act is limited to cigarettes, roll-your-own tobacco and smokeless tobacco, although the FDA has the authority to issue regulations covering any other products deemed to be "tobacco products." Thus, while the FDA presently lacks the authority to regulate electronic cigarettes under the Tobacco Act, the FDA may ultimately regulate electronic cigarettes under the Tobacco Act to the extent that those products are considered "tobacco products."

As discussed above, some electronic cigarettes are manufactured with purely synthetic nicotine. Because such products are not "made or derived from tobacco," these products likely would not be considered "tobacco products" subject to the FDA's authority under the Tobacco Act. On the other hand, other tobacco products contain nicotine derived from a tobacco solution. Such products likely would be considered to be "made or derived from tobacco" and would therefore be subject to the FDA's authority under the Tobacco Act if the FDA issues appropriate regulations.

ARE ELECTRONIC CIGARETTES SUBJECT TO FDA AUTHORITY?

It is clear, based on the FDA's recent activity, that the agency believes it has the right to regulate electronic cigarettes. But from where does that authority stem? The FDA's authority to regulate electronic cigarettes depends on how the products are manufactured and marketed. If the product contains tobacco, it is likely to be regulated under the Tobacco Act. If the product is marketed for smoking cessation, it is probably subject to the FDA's authority under the FDCA. Electronic cigarettes could also be subject to the FDA's authority under both the Tobacco Act and the FDCA. On the other hand, if the product contains synthetic nicotine and is not marketed for smoking cessation, it is probably not subject to the FDA's authority under either statute.

Nevertheless, if an electronic cigarette contains nicotine, the FDA has taken the position that nicotine is a "drug" under the FDCA, and the product should be regulated as a drug-device combination product, irrespective of how the product is marketed. Indeed, the FDA has already required approval for certain over-the-counter products containing varying levels of nicotine that are marketed as smoking cessation products. However, the court's decision in *Smoking Everywhere* prohibits the FDA from regulating electronic cigarettes as combination products if there are no therapeutic claims.

Even if electronic cigarettes are not subject to regulation by the FDA, it is important to note that states are increasingly regulating electronic cigarettes, with efforts by some states to ban the products altogether and efforts by other states to prohibit the use of electronic cigarettes in places where traditional cigarettes are already prohibited.

The ultimate question for the electronic cigarette industry will be how to set the best path for their products' regulation. S

Troutman Sanders LLP, *1001 Haxall Point, Richmond, VA 23219, Tel: (804) 697-1317, Fax: (804) 697-1339; Ashley Taylor, ashley.taylor@troutmansanders.com.*