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Letter

A Deceptive Marketing Strategy: An Early Warning of Industry Behavior After the Premarket Tobacco Application Deadline?

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The U.S. Food and Drug Administration (FDA) has regulated cigarettes, smokeless, and roll-your-own tobacco since the Family Smoking Prevention and Tobacco Control Act (FSPTCA) went into effect in 2009. FDA finalized the "deeming rule" in August 2016, which extended its regulatory authority to all tobacco products in accordance with the FSPTCA.[1] "Tobacco products" are defined as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product,"[2] and intended use may be determined from any relevant source and is not based solely on claims made in a product's labeling or advertising materials.[3]

FDA's regulation of electronic nicotine delivery systems (ENDS) may have a more visible effect after September 2020, when manufacturers must submit premarket tobacco product applications (PMTAs) for any "new" tobacco product, including those deemed "finished tobacco products" that were brought to market on or after August 8, 2016.[4] This PMTA requirement will apply to those mixing ENDS liquids and/or importing, making, or modifying devices, and due to application costs and complexities, the requirement is expected to reduce the number of marketed ENDS liquids and devices.[4] However, a reduction in the number and variety of products on the market may not occur to the degree or as quickly as expected by FDA[5] unless the rule is implemented well. One critical component of these efforts will be adequately monitoring the marketplace for industry practices meant to evade detection and enforcement. Drawing upon examples from the sale of cannabis paraphernalia and hybrid vaporizers designed to vape e-liquids, tetrahydrocannabinol (THC), or cannabidiol (CBD), we highlight deceptive marketing strategies used to indicate a product is for something other than its intended purpose and discuss their potential relevance in the context of implementing the PMTA rule.

For many years, head shops have circumvented prohibitions of the sale of cannabis paraphernalia by claiming bongs and other products are for tobacco use only. The U.S. Department of Justice (DOJ) has acknowledged this strategy, noting, "Recognizing drug paraphernalia often involves considering other factors such as the manner in which items are displayed for sale, descriptive materials or instructions accompanying the items, and the type of business selling the items."[6] With the advent of ENDS-like "personal vaporizers" for the consumption of cannabinoids, such as THC or CBD, a similar tactic has emerged. A manufacturer of vaporizers, KandyPens, includes the following disclaimer on every webpage: "…Our products are NOT for smoking tobacco or to administer illicit drug use of ANY kind. Our products are for aromatherapy purposes ONLY..." (Note: all manufacturer webpages referred to hereafter were archived and are available in Supplementary Material).[7] The phrase "For Aromatherapy Purposes Only" appears in the product description for 15 of 16 devices on the site. Without mentioning THC or CBD explicitly, terms commonly associated with THC and CBD use such as "dab," "wax," "concentrate," and "oil" appear frequently in these product descriptions. Interestingly, when a "verified reviewer" asked about the KandyPens Rubi, "What kind of oils can be used with this vape aside from cbd?", the KandyPens website posted the response: "THC Oil."[8] User reviews on the site commonly use the aforementioned terms and reference THC or CBD, suggesting customers are receiving the message.

Other sites (e.g., Yocanvaporizer.com and Migvapor.com) use similar marketing tactics to sell cannabis paraphernalia and all three, KandyPens included, also sell ENDS devices or hybrid devices. Both KandyPens and Yocanvaporizer.com suggest their hybrid devices, which are referred to as e-liquid vaporizers on Yocanvaporizer.com, are for aromatherapy purposes. KandyPens goes further and also indicates these products should not be used to "smoke tobacco." It is possible they have toxicity or device durability concerns that are associated with the burning of combustible tobacco; however, it is also plausible they are concerned about future FDA tobacco regulations, such as the PMTA requirement, and might hope the language allows them to evade FDA oversight and continue selling their hybrid devices indefinitely or for an extended period of time.

Currently, there is little incentive for most manufacturers of devices marketed for nicotine consumption to include similar language to KandyPens. However, the PMTA requirement may change this calculus, particularly if KandyPens and others are perceived by their competitors to have been allowed to continue selling their products due to this language. Other manufacturers could begin indicating that ENDS devices are for purposes other than delivering nicotine, such as aromatherapy, believing this strategy may also allow them to evade FDA oversight. These examples and scenarios describe one of many potential marketing strategies manufacturers may use to attempt to circumvent rather than comply with the PMTA requirement. Therefore, it will be essential to thoughtfully implement the rule, carefully and comprehensively monitor the marketing strategies that manufacturers use, and quickly enforce the rule when deceptive marketing is identified. To address this particular marketing issue, the FDA may need to learn from the DOJ and consider "the manner in which items are displayed for sale, descriptive materials or instructions accompanying the items, and the type of business selling the items."[6] Existing definitions of "tobacco products" and "intended use" appear to provide the FDA with the regulatory authority to regulate these products; however, should either of these definitions be challenged, the FDA could potentially use its regulatory authority of fragrance products, such as essential oils, to regulate e-liquids and devices as drugs and drug delivery devices when they are marketed for aromatherapy purposes.[9,10]

Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at https://academic.oup.com/ntr.

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Declaration of Interests

Dr. Eissenberg is a paid consultant in litigation against the tobacco industry and also the electronic cigarette industry and is named on a patent for a device that measures the puffing behavior of electronic cigarette users.

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