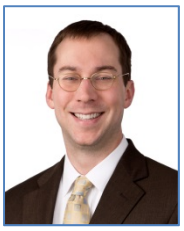
The Minefield Of E-Cigarette Labeling And Promotion



Law360, New York (October 2, 2015, 12:32 PM ET) -- The 2009 Family Smoking Prevention and Tobacco Control Act amended the Food, Drug, and Cosmetic Act and provides the U.S. Food and Drug Administration the authority to regulate the manufacture, distribution and marketing of tobacco products. In April 2014, the FDA issued a proposed rule (the so-called deeming rule) that would deem electronic cigarettes to meet the statutory definition of "tobacco product," thereby extending the FDA's regulatory authority to e-cigarettes.[1]

When the deeming rule is finalized, e-cigarettes may also become subject to many of the marketing restrictions that the FDA has already imposed on traditional tobacco products, such as banning outdoor advertising within 1,000 feet of schools and playgrounds and prohibiting brand sponsorships of sports and entertainment events, among others. Even while the deeming rule has not been made final, however, the legal environment surrounding e-cigarette labeling and advertising continues to evolve at a rapid pace.

While the FDA has been considering the many comments received in response to the proposed deeming rule, the plaintiffs' bar has pressed ahead with a series of threatened actions and lawsuits against e-cigarette manufacturers and distributors based on alleged false advertising and other claims. By way of example, in May 2015, a consumer advocacy group sued various e- cigarette distributors for allegedly failing to include Proposition 65 warnings on their labels advising consumers that use of the products would cause exposure to nicotine, a chemical allegedly known to cause reproductive toxicity.[2]

On Sept. 1, 2015, the makers of Blu e-cigarettes were sued in a proposed class action in federal court in California for alleged violations of California's Unfair Competition Law and Consumers Legal Remedies Act for allegedly failing to disclose that their products expose users to formaldehyde.[3] In May 2015, a federal judge in California also found that portions of a purported class action complaint against NJOY Inc. survived a motion to dismiss because, in allegedly holding out propylene glycol — a common ingredient in e-liquids — as "generally recognized as safe" by the FDA, NJOY had — according to the complaint — failed to disclose that propylene glycol was afforded such status only for use in food, and not when heated and inhaled in e-liquids. As a result, the court held, "a rational juror could conclude that disclosing that propylene glycol and glycerin were 'generally recognized as safe' for use in food when the products as included in NJOY's products were being inhaled was a half truth that could mislead a reasonable consumer."[4]

In establishing marketing claims, industry participants must be aware of the dueling risks of avoiding claims of deceptive advertising or inadequate warnings (which may lead to civil litigation) as well as claims that step over the line separating e-cigarettes from drugs and medical devices. Fortunately, the FDA recently published proposed guidance that, if finalized, should aid industry participants on both counts.

On Sept. 25, 2015, the FDA published a proposed rule that seeks to clarify which regulatory framework (i.e., the drug/device frameworks or the tobacco framework) will apply to particular products based on their intended use.[5] In its proposed rule, the FDA provides examples of claim language that may cause tobacco products to be regulated as drugs or medical devices; this language includes claims such as "treatment of tobacco dependence," "wean yourself off of nicotine," "for people who wish to quit smoking," "prevent relapse," "to reduce withdrawal symptoms" and certain structure/function claims that were not commonly and legally made in the marketing of cigarettes and smokeless tobacco products before March 21, 2000, such as "promotes weight loss."

In its proposed rule, the FDA also clarifies that no smokeless tobacco product will be considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease solely because its labeling or advertising uses the following phrases: "smokeless tobacco," "smokeless tobacco product," "not consumed by smoking," "does not produce smoke," "smokefree," "smoke-free," "without smoke," "no smoke" or "not smoke."

In addition, the FDA states that claims related to satisfaction, pleasure, enjoyment and refreshment "have been recognized as euphemisms for the delivery of a pharmacologically active dose of nicotine," and clarifies that the FDA does not consider these tobacco satisfaction and enjoyment claims to fall within its drug and device regulatory authority. The FDA also states that suggesting a tobacco product provides an alternative way of obtaining the effects of nicotine, or that a tobacco product will provide the same effects as another tobacco product — such as "satisfying smoking alternative," "provides all the pleasure of smoking," "get your nicotine fix" or "provides smokers the same delight, physical and emotional feelings" — will not necessarily cause the tobacco product to be regulated as a drug or device.

The court's ruling in the NJOY case and the FDA's recently proposed rule both suggest that advertising claims that suggest or emphasize *specific* chemical, physical and toxicological effects on the user may be subject to increased scrutiny. Regardless of whether the subject of the claim is the effectiveness of nicotine delivery, a lack of exposure to harmful byproducts or some other characteristic, the more specific, detailed and absolute the comparison between an e-cigarette product and a conventional tobacco product, the higher the risk of both litigation and regulatory concerns. In navigating this evolving minefield, industry participants would be well-advised to avoid specific, unsubstantiated claims

about the effectiveness of their products and focus on the general descriptive and hedonic differences between their products and traditional combustibles.

—By Eric N. Heyer and Neelam Gill, Thompson Hine LLP

Eric Heyer is counsel and Neelam Gill is an associate in Thompson Hine's Washington, D.C., office.

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[1] Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142, *et seq.* (April 25, 2014) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143). The deeming rule would also include tobacco product components or parts that are used in the consumption of a tobacco product, like e-liquid cartridges. It would not include tobacco product accessories, like cigar cases.

[2] *Michael J. Whitney v. ITG Brands LLC, et al.,* Case No. 3:15-cv-04003 (N.D. Cal. filed Sept. 1, 2015).

[3] *Center for Environmental Health v. Space Jam Juice LLC,* Case No. RG 15-770932 (Alameda County, Cal. Super. Ct. (filed May 19, 2015).

[4] *In re NJOY Inc. Consumer Class Action Litigation*, Case No. 2:14-cv-428, at **32-35 (C.D. Cal. May 27, 2015).

[5] Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses," 80 Fed. Reg. 57,756, *et seq.* (Sept. 25, 2015) (to be codified at 21 C.F.R. PTS. 201, 801 and 1100).