

## **COMMITTEE ON BIOETHICAL ISSUES**

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The Food and Drug Administration Office of Regulations Center for Tobacco Products 9200 Corporate Boulevard Rockville, MD 20850

## Subject: Docket No. FDA-2014-N-0189; RIN 0910-AG38

To whom it may concern:

The New York City Bar Association, through its Bioethical Issues Committee and Health Law Committee ("the Committees"), submits this letter of endorsement for the Proposed Rule which would allow The Food and Drug Administration ("FDA") to regulate the sale and distribution of electronic cigarettes and other related products under the Family Smoking Prevention and Tobacco Control Act of 2009.<sup>1</sup> By the terms of the Proposed Rule, the FDA would exercise its authority to "deem" electronic cigarettes as a "tobacco product,"<sup>2</sup> thereby subjecting electronic cigarettes to regulations, such as the imposition of age-related restrictions on access, as well as restrictions on advertising and promotion.

Electronic cigarettes are battery-operated nicotine-delivery systems designed to simulate smoking by vaporizing a liquid solution that typically contains a mixture of elements such as propylene glycol, vegetable glycerin, nicotine and artificial flavoring. The vaporizing process is initiated through the use of a pre-filled disposable cartridge which draws the vapor into the mouth of the consumer, producing an aerosol that resembles tobacco smoke. The product has gained popularity in American and European markets over the past decade, with projected sales of \$1.7 billion dollars in the United States in 2013.<sup>3</sup> Advocates of these devices have emphasized that the product holds promise as a smoking cessation aid and electronic cigarettes have been heavily marketed based on this rationale. As an example, on Super Bowl Sunday 2013, an NJOY e-cigarette commercial was broadcast to 10 million viewers.<sup>4</sup> Critics, however, have argued that the entry of electronic cigarettes into the marketplace threatens to re-normalize

<sup>4</sup> Ibid., 293.

<sup>&</sup>lt;sup>1</sup> Pub.L. 111-31, H.R. 1256.

<sup>&</sup>lt;sup>2</sup> Section 201(rr) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. ch. 9 §321(rr)).

<sup>&</sup>lt;sup>3</sup> The Renormalization of Smoking? E-Cigarettes and the Tobacco Endgame, Fairchild, Bayer & Colgrove, N Engl J Med 2014; 370:293-295.

smoking behavior, gradually eroding the decades-long campaign by US medical experts and public health officials to minimize and ultimately eliminate smoking behavior.<sup>5</sup>

Scientific evidence on the effect of electronic cigarette usage remains inconclusive, although early studies suggest that the devices do not result in increased rates of smoking cessation.<sup>6</sup> Moreover, respected authorities, such as the American Academy of Pediatrics ("AAP"), have voiced strenuous opposition to electronic cigarettes and expressed concern at the proliferation of the product, citing Centers for Disease Control data finding that 6.8% of children in middle and high school have experimented with electronic cigarettes and that one in 50 had used the devices in the past month.<sup>7</sup> Moreover, as the AAP points out, because these products are unregulated, no standards for manufacturing or safety have been applied; accordingly, producers can vary the amount of nicotine in each cartridge which enhances the likelihood of nicotine addiction, particularly in school-age populations.<sup>8</sup>

New York legislators have acted swiftly to impose laws regulating the sale and use of electronic cigarettes. On the statewide level, laws have been enacted which prohibit smoking electronic cigarettes within 100 feet of any public or private school and ban the sale of electronic cigarettes to persons under the age of eighteen.<sup>9</sup> In April 2014, New York City amended the Smoke Free Air Act, making it illegal to use electronic cigarettes at any location in New York City where traditional cigarettes are also banned.<sup>10</sup>

A totality of factors, then, weighs on the side of subjecting electronic cigarettes to regulatory oversight. Among these factors are: (a) inconclusive evidence that the devices aid in the process of tobacco smoking cessation; (b) the variable and non-standardized amounts of nicotine contained in electronic cigarette cartridges; and, (c) the ostensible growing acceptance of the products among school-age children. For these reasons, we support the regulation of electronic cigarettes by the US Food and Drug Administration.

Very truly yours,

Wendy Luft Wendy Luftig, Chair

<sup>&</sup>lt;sup>5</sup> Ibid., 293.

<sup>&</sup>lt;sup>6</sup> A Longitudinal Analysis of Electronic Cigarette Use and Smoking Cessation, Letter, Grana, Popova and Ling, JAMA Internal Medicine, May 2014, Volume 174, No. 5:813.

<sup>&</sup>lt;sup>7</sup> Centers for Disease Control and Prevention. *Notes from the Field: Electronic Cigarette Use Among Middle and* High School Students – United States, 2011-2012. September 6, 2013. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm.

<sup>&</sup>lt;sup>8</sup> American Academy of Pediatrics, Richmond Center of Excellence. Handout on E-Cigarettes. Available at http://www2.aap.org/richmondcenter/pdfs/ECigarette handout.pdf.

<sup>&</sup>lt;sup>9</sup> NY Pub Health Law § 1399 (2013).

<sup>&</sup>lt;sup>10</sup> Local Law 152, N.Y.C. Admin. Code Title 17, Chapter 5 §§ 17-501 to 17-514.