



**REVIEW ARTICLE**

**Overview of Electronic Nicotine Delivery System in US**

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**ABSTRACT**

Electronic Nicotine Delivery Systems (ENDS), also called e-cigarettes, personal vaporizers, vape pens, e-cigars, e-hookah, or vaping devices, are products that produce an aerosolized mixture containing flavoured liquids and nicotine that is inhaled by the user. ENDS can resemble traditional tobacco products like cigarettes, cigars, pipes, or common gadgets like flashlights, flash drives, or pens. Electronic nicotine delivery systems (ENDS) are rapidly growing in popularity among youth. ENDS are hand held devices that produce an aerosolized mixture from a solution typically containing concentrated nicotine, flavouring chemicals, and propylene glycol to be inhaled by the user. Nicotine, the major psychoactive ingredient in ENDS solutions, is both highly addictive and toxic. The concentrated and often flavoured nicotine in ENDS solutions poses a poisoning risk for young children. With flavours, design, and marketing that appeal to youth, ENDS threaten to renormalize and glamorize nicotine and tobacco product use. ENDS are battery-powered; some can be recharged via a USB port, others are disposable. ENDS contain a vaporizer, which is the piece that heats the liquid. Disposable ENDS do not require charging, changing batteries or liquid, last roughly as long as two packs of cigarettes, and are typically around \$10. Rechargeable ENDS 'starter kits' are usually around \$35, typically last as long as a pack and a half of cigarettes before needing to be recharged, and use either a cartridge or tank to store the flavoured liquid.

**KEYWORDS**

Electronic Nicotine Delivery Systems (ENDS), Psychoactive, Ingredient, Disposable, Aerosolized

**INTRODUCTION**

The historic Family Smoking Prevention and Tobacco Control Act, commonly referred to as the Tobacco Control Act, gave FDA sweeping new authority to create a healthier future for America's families by regulating the manufacture, distribution, and marketing of tobacco products. The law, signed on June 22, 2009, ushered in a new era of tobacco control by recognizing that almost all new users of tobacco

products are under age 18—the minimum legal age to purchase. One of the aims of the Tobacco Control Act is to curb the trend of children becoming addicted before they are old enough to understand the risks and prevent these vulnerable new users from dying too young of tobacco-related diseases.

The Tobacco Control Act puts in place specific restrictions on marketing tobacco products to children and gives FDA authority to take further action in the future to protect public health. These provisions ban:

- ✓ Sales to minors.
- ✓ Vending machine sales.

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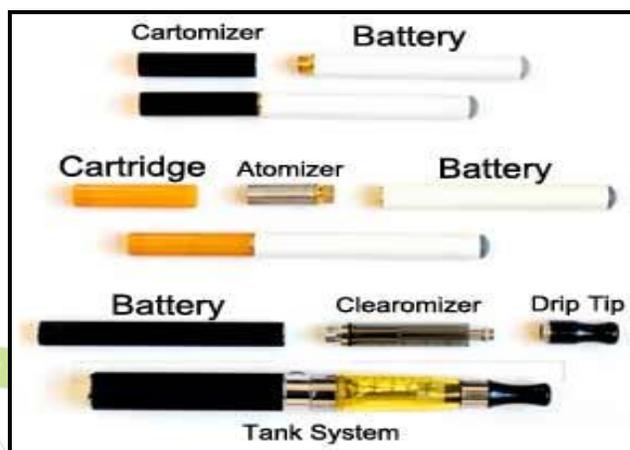
- ✓ The sale of packages of fewer than 20 cigarettes.
- ✓ Tobacco-brand sponsorships of sports and entertainment events or other social or cultural events.
- ✓ Free giveaways of sample cigarettes and brand-name non-tobacco promotional items except in adult-only facilities.

ENDS “Components” or “parts” include, among other things, software or an assembly of materials intended or reasonably expected alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or to be used with or for the human consumption of a tobacco product. For a full definition of ENDS components, parts, and accessories, please read the Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act. Examples of components and parts of ENDS include, but are not limited to:

- E-liquids
- A glass or plastic vial container of e-liquid
- Cartridges
- Atomizers
- Certain batteries
- Cartomizers and clearomizers
- Digital display or lights to adjust settings
- Tank systems
- Drip tips
- Flavourings for ENDS
- Programmable software.

Although commonly referred to as a vapor, the emission from ENDS is most accurately referred to as an aerosol, which is a suspension of fine particles in a gas.<sup>1</sup> Despite variations in terminology, ENDS products generally have several common components that include a flow sensor, aerosol generator, battery, and solution storage area.<sup>2</sup> When a user draws a breath (or “vapes”) from the device, a flow sensor detects the change in pressure and activates the aerosol generator. The generator draws the solution from

the storage area and heats and/or mechanically disperses the solution, creating an aerosol. This aerosol is inhaled by the user, who then exhales it. Nonusers can be exposed to the emissions both from the aerosol that is exhaled as well as from the aerosol that is generated from the device. Some ENDS products have a light-emitting diode that simulates the lit end of a conventional cigarette.



There are more than 460 different brands of ENDS, which vary considerably in price, quality, and design.<sup>3,4</sup> ENDS can be purchased in various retail outlets, including vendors that sell tobacco, “vape” shops, mall kiosks, gas stations, convenience stores, grocery stores, and pharmacies, as well as through Internet vendors. ENDS can be disposable or reusable; the reusable ENDS products have a rechargeable battery.<sup>4</sup> The ENDS solution storage containers also vary widely, ranging from prefilled cartridges to tank-style, large refillable cartridges.<sup>4,5</sup> Although many of the early “first-generation” ENDS were designed to resemble conventional cigarettes, newer ENDS models largely do not and may resemble other common objects such as a pen or flashlight.

## DISCUSSION

### ENDS Solution Components

The solutions used in ENDS products (often referred to as e-liquid or e-juice) can be purchased in pre-packaged cartridges or by volume to fill a refillable cartridge. ENDS solutions are also available through Internet vendors, in stores, and places where ENDS

products are sold. In addition to concentrated nicotine, components of the ENDS solutions generally include flavouring chemicals and carrier solvents, such as propylene glycol and glycerol. Currently, there are no federal quality standards to ensure the accuracy of ENDS solution constituents as advertised or labelled. The refillable cartridges allow the user to deliver other psychoactive substances, including marijuana.

In addition to nicotine, numerous toxicants and carcinogens harmful to human health have been found in ENDS solutions, including aldehydes, tobacco-specific nitrosamines, metals, tobacco alkaloids, and polycyclic aromatic hydrocarbons. These quantitative and qualitative studies illustrate that there are additional components in ENDS solutions that are unknown to users.

Nicotine is the major psychoactive component of an ENDS solution. In a study of ENDS cartridges and refill solutions, there were substantial discrepancies (as much as 89%) between the label and the actual nicotine content. The reported nicotine concentration in ENDS solutions ranges from 0 to 36 mg/mL with cartridges that vary in size. In comparison, a single conventional cigarette contains from 10 to 30 mg of nicotine, although the absorbed nicotine yield for a user is far less, from 0.05 to 3 mg per cigarette. The user's actual nicotine exposure is affected by many factors, including the delivery system, nicotine pharmacokinetics, and individual consumption behaviour.

**Statistics About ENDS Use**

More than 3 million middle and high school students were current users of e-cigarettes in 2015, up from an estimated 2.46 million in 2014.

Sixteen percent of high school and 5.3 percent of middle school students were current users of e-cigarettes in 2015, making e-cigarettes the most commonly used tobacco product among youth for the second consecutive year.

During 2011-2015, e-cigarette use rose from 1.5 percent to 16.0 percent among high school students and from 0.6 percent to 5.3 percent among middle school students.

In 2013-2014, 81% of current youth e-cigarette users cited the availability of appealing flavors as the primary reason for use. In 2014, 12.6% of U.S. adults had ever tried an e-cigarette, and about 3.7% of adults used e-cigarettes daily or some days.

| Years | Youth    |                  | Middle School Students |                  | High School Students |                  |
|-------|----------|------------------|------------------------|------------------|----------------------|------------------|
|       | Ever Use | Past 30 days Use | Ever Use               | Past 30 days Use | Ever Use             | Past 30 days Use |
| 2011  | 3.3%     | 1.1%             | 1.4%                   | 0.6%             | 4.7%                 | 1.5%             |
| 2012  | 6.8%     | 2.1%             | 2.7%                   | 1.1%             | 10.0%                | 2.8%             |
| 2013  | 8.0%     | 3.1%             | 3.0%                   | 1.1%             | 9%                   | 4.5%             |
| 2014  | 19.8%    | 9.3%             | 1.1%                   | 3.9%             | 27.3%                | 13.4%            |

**The Effects of Nicotine on the Developing Brain**

Nicotine is highly addictive and is the primary psychoactive component causing addiction in tobacco products.<sup>25</sup> Nicotine has neurotoxic effects on the developing brain. In early adolescence, development of executive function and neurocognitive processes in the brain has not fully matured. Adolescents are more likely to engage in experimentation with substances such as cigarettes, and they are also physiologically more vulnerable to addiction.<sup>43</sup> Particularly in adolescence, nicotine also has an effect on the brain as a “gateway” drug for cocaine and other illicit drugs.

**Current Scenario in 2015**

- ✓ Sale of ENDS to minors is banned in all but four states – Massachusetts, Michigan, Pennsylvania and Texas – and the District of Columbia. Legislation has been passed in Montana and Oregon to ban sales to minors

in the next year.2013-2015 However, vigorous enforcement of these sales restrictions will be necessary for them to be effective in reducing youth uptake.

- ✓ Three states (New Jersey, North Dakota and Utah) have a ban on ENDS in workplaces, restaurants and bars.
  - Ten states (Arkansas, California, Colorado, Illinois, Minnesota, New Hampshire, Vermont, Virginia, Washington and West Virginia) ban ENDS in schools or on grounds used for instructional purposes.
- ✓ Four states (Hawaii, Delaware, Oregon and North Dakota) prohibit use of ENDS in state workplaces, one state (Maryland) prohibits use on public commuter rail, and five states (Kansas, North Carolina, South Dakota, Oklahoma and Utah) prohibit use in departments of corrections.
- ✓ Ten states (Illinois, Indiana, Minnesota, New Mexico, New York, North Dakota, Tennessee, Vermont, Virginia and Wyoming) require child-resistant packaging. Utah will implement rules for product packaging in 2016.
- ✓ Two states have imposed a tax on ENDS. In Minnesota, one-time use ENDS and cartridges/e-juice containing nicotine are subject to the Tobacco Tax (95% of wholesale), but reusable/refillable devices and components and cartridges/e-juice containing no nicotine are not taxable. North Carolina taxes liquid nicotine at five cents per milliliter.

Form 3741 - Establishment Registration and Product Listing

Form 3741a - Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments

Form 3742 - Listing of Ingredients in Tobacco Products

Form 3743 - Tobacco Health Document Submission

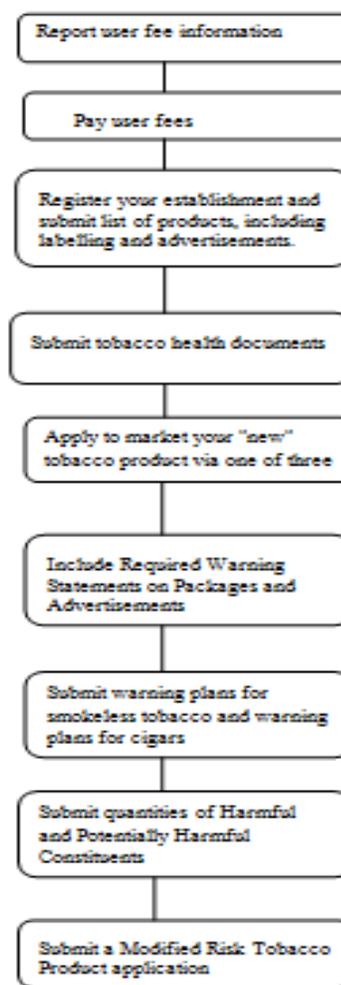
Form 3787a - Cigarette Report: Reporting of Harmful and Potentially Harmful Constituents

Form 3787b - Smokeless Tobacco Product Report: Reporting of Harmful and Potentially Harmful Constituents

Form 3787c - Roll Your Own Tobacco Product Report: Reporting of Harmful and Potentially Harmful Constituents

Form 3852 - User Fees: Report of Tobacco Product Removals Subject to Tax

### Pathway for a Tobacco product to enter the Market



### CONCLUSION

ENDS use is rapidly increasing among youth and, according to the most recent data, ENDS are the most common tobacco product used among youth. ENDS use has the potential to addict youth to nicotine. There are potential health

harms to nonusers of ENDS because of its toxicants, including nicotine, carcinogens, and metal particles found in the second hand and third hand aerosol. There has been an increase in unintentional exposures of children with acute nicotine poisoning from a concentrated nicotine-containing ENDS solution, with at least 1 child death from unintentional ingestion of an ENDS solution.

The increasing use of ENDS among youth threatens 5 decades of public health gains in successfully deglamorizing, restricting, and decreasing the use of tobacco products. Health claims of ENDS as smoking cessation aids are currently unsupported by scientific evidence. There is a crucial need for effective local, state, and federal regulation to protect children and youth from ENDS use and exposure to ENDS second hand and third hand aerosol and concentrated nicotine solution.

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