F I S C A L I M P A C T R E P O R T

SPONSOR Ramos/Candelaria **ORIGINAL DATE** 1/30/2020 **LAST UPDATED** **HB**

SHORT TITLE E-Cigarette and E-Liquid Act **SB** 9

ANALYST Chilton

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Nonrecurring	Fund Affected
FY20	**FY21**		
$1,000.0	$1,000.0	Recurring	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY20	**FY21**	**FY22**		
$0.0	Uncertain	Uncertain	Recurring	E-cigarette and E-liquid administration fund

(Parenthesis ( ) Indicate Revenue Decreases)

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY20	FY21	FY22	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
DPS		$500.0	$500.0	$1,000.0	Recurring	General Fund
RLD	Uncertain	$350.0	$350.0	Estimated $1,000.0 to $2,000.0	Recurring	General Fund
Total	Uncertain	$850.0	$850.0	Estimated $1,850.0 to $2,850.0	Recurring	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

Relates to 2019 HB 256 (passed); HB 552, SB 166, SB 338, SB 450 and 2020 HB 23, HB 195, and SB 9.

SOURCES OF INFORMATION
LFC Files
Responses Received From

Administrative Office of the Courts (AOC)
Administrative Office of the District Attorneys (AODA)
Regulation and Licensing Department (RLD)
Department of Health (DOH)
Department of Public Safety (DPS)

No Response Received
Taxation and Revenue Department (TRD)

SUMMARY

Synopsis of Bill

Senate Bill 9, E-Cigarette and E-Liquid Act, creates an act by the same name, placing the functions of regulating that industry within the Regulation and Licensing Department. It sets criteria for licensure and fees for manufacturers, distributors and retailers of these products. License fees for manufacturers ($1 thousand), distributors ($500) and retailers (first location $150, subsequent locations $10 each) are set; initial licenses are prorated according to the quarter of the fiscal year in which they are first granted. The license must be displayed at each location (manufacturer, distributor, and retailer).

The bill specifies that when a license is not issued, reasons must be given by RLD and the applicant can request a hearing or be allowed to re-apply without additional fees. Licenses which had not been suspended or revoked could be transferred from one location to another, but not from one person to another.

License fees and fees from administrative penalties would be deposited within an "e-cigarette and e-liquid administration fund," created under this act, and augmented by the $1 million appropriation included in this bill.

Flavoring could be added to e-liquids (but see Senate Bill 91, which would prohibit flavorings).

Penalties up to $10 thousand could be assessed for violations of the act, including for selling e-liquids to minors, defined in the bill as being less than 21 years of age. Both in-person and delivery sales would require documentary evidence of age, and pre-payment for delivery orders is required.

Manufacturers are permitted to flavor their nicotine liquids, but cannot "make them attractive to youth," or sell them or give samples to minors, and must sell them in child-resistant containers. Signs must be posted indicating the products cannot be sold to those under 21 years of age, although these prohibitions would not apply to a minor using an FDA-approved tobacco cessation product, specifying the penalties of up to $100 for minors purchasing these products, or $1 thousand for retailers selling them to minors. Unannounced inspections to assure compliance with the act would be conducted.

Tobacco products, including nicotine liquids, could be sold in vending machines only where they were not accessible to minors. Buyers showing false identification would be committing a violation of the act. RLD would be empowered with establishing the regulations for the act, and with enforcing those regulations, including issuing subpoenas for production of records and for licensees to testify in court proceedings with respect to enforcement of the act.

Communities within New Mexico would not be permitted to set policies regarding e-cigarettes and/or liquid nicotine products that would be at variance with the provisions of this act.

Senate Bill 9, E-Cigarette and E-Liquid Act, appropriates $1 million from the general fund to the e-cigarette and e-liquid administration fund for the purpose of regulating and enforcing provisions of the E-cigarette and E-liquid act.

The effective date of this bill is July 1, 2020.

FISCAL IMPLICATIONS

The appropriation of $1 million contained in this bill is a recurring expense to the general fund. Any unexpended or unencumbered balance remaining at the end of each fiscal year shall revert to the general fund.

This bill creates a new fund and provides for continuing appropriations. The LFC has concerns with including continuing appropriation language in the statutory provisions for newly created funds, as earmarking reduces the ability of the legislature to establish spending priorities.

RLD makes note of the $1 million appropriation and that it would require at least $350 thousand for licensure and disciplinary actions, noting further that expenses to set up the program would start immediately, but that license fees and administrative penalty assessments would not begin until the program is fully established.

DPS indicates uncertainty about the cost to that agency of implementing the provisions of SB 9. Their estimate of annual costs of $500 thousand is to cover "three additional commissioned personnel ($250 thousand) and $250 thousand to fund overtime for tobacco enforcement personnel.

AOC indicates that new penalties often increase the workload for the courts, thereby increasing costs.

SIGNIFICANT ISSUES

As the American of Academy notes in their statements about tobacco and nicotine products, these products are notable as having no safe level of use. The Academy's statements also point to the potential for teenagers to become addicted to nicotine through these products, and that 90 percent of adult smokers began their tobacco/nicotine habit prior to the age of 18. Because many teens under 18 prevail upon friends above that age to buy them cigarettes or e-cigarette products, and because their friends are likely to be less than 21 years of age, restricting legal sales to those over 21 years of age is likely to have a large impact upon the availability of these products to those at the highest risk of becoming addicted to nicotine-contained products.

DOH points out the discrepancy this bill would produce between needing to be 18 years of age to purchase all tobacco products except e-cigarettes and e-liquids, and age 21 for e-cigarettes and e-liquids. However, as noted by DOH.

> On December 20, 2019, the President signed legislation to amend the Federal Food, Drug, and Cosmetic Act, and raise the federal minimum age of sale of tobacco products from 18 to

21 years. It is now illegal for a retailer to sell any tobacco product – including cigarettes, cigars and e-cigarettes – to anyone under 21. FDA will provide additional details on this issue as they become available. FDA updates are available at https://www.fda.gov/tobacco-products/compliance-enforcement-training.

The federal law makes this discrepancy in state law moot.

DOH makes many additional comments relating to significant issues raised by this act:

Local tobacco retailer licensing is a regulatory approach that allows government to monitor local businesses that have obtained a special license for selling tobacco products to consumers. The license system can address community concerns about youth access to tobacco products. (https://www.changelabsolutions.org/sites/default/files/TRL_Playbook_FINAL_20150511.pdf).

New Mexico is one of eleven states that does not require a license to sell tobacco products (https://www.publichealthlawcenter.org/sites/default/files/resources/Location-Tobacco-Ecig-Point-Of-Sale-2019.pdf). Implementing comprehensive tobacco retailer licensing could increase compliance with existing tobacco laws and could provide more detailed information about who is selling tobacco products and where they are being sold. This information can support public health efforts to prevent minors from using tobacco products…

Senate Bill 9 proposes a license fee of $150 on a first retail location and $10 for each subsequent retail location. This proposed fee structure could create a financial disparity between smaller, independently owned retailers and larger franchised businesses with many secondary retail locations. Adequate and sustained funding is necessary to fully cover enforcement costs, either through licensing fees or as a provision in a state statute.

Senate Bill 9 proposes penalties for youth who purchase and consume e-cigarettes and liquids. Youth purchase, use, and possession laws pose enforcement challenges by diverting enforcement officials' attention away from preventing retailers from selling tobacco products to minors. Laws that penalize youth tobacco possession, use, and purchase may divert policy attention from effective tobacco control strategies and relieve the tobacco industry of responsibility for its marketing practices (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1766089/pdf/v012p000i6.pdf).

On January 2, 2020, the U.S. Food & Drug Administration (FDA) prioritized enforcement for lack of marketing authorization when the manufacturer has not taken or is not taking adequate measures to prevent minors' access to electronic nicotine delivery systems. These measures shift responsibility from the minor and the retailer employee to the manufacturer and subsequently to the distributor, and retailer (https://www.fda.gov/media/133880/download). The sections of SB9 that seek to enforce regulations pertaining to the manufacture and sale of E-Cigarettes and E-Liquids align with the FDA emphasis on manufacturer and retailer responsibility in preventing the purchase and use of E-Cigarettes and E-Liquids by minors. SB9 also provides penalties which could reduce unlicensed activities.

ADMINISTRATIVE IMPLICATIONS

AOC notes that "There may be an administrative impact on the courts as the result of an increase in caseload and/or in the amount of time necessary to dispose of cases."

RELATIONSHIP with the following bills:

2019 bills:
HB 256 (passed), Add E-cigarettes to clean indoor air act
HB 552, E-cigarette and nicotine liquid act
SB 166, Increase cigarette and e-cigarette tax rates
SB 338, No indoor e-cigarette use
SB 450, E-cigarette and nicotine liquid act
Identical bills HB 260 and SB 343, Flavored E-Cigarette Products Prohibition

2020 Bills
HB 23 and identical SB 9, E-cigarette and e-liquid act
HB 195, Tobacco products act

TECHNICAL ISSUES

RLD makes the following points:

- SB9 allows for the delivery of e-cigarettes and nicotine liquids to the consumer, enforcement of violations at a person's home will be extremely difficult.
- The bill requires that applicants for a distributor and retailer license submit to a background check, but does not indicate what the department can, or should, do with the results of that check. It does not define what, if any, crimes would prohibit an applicant from obtaining a license.
- The bill does not effectively establish separate industry tiers. As with alcohol, establishing the separation of manufacturers, distributors, and retailers ensures economic diversity, provides natural price floors, and avoids monopolization. SB9 does not contain any provision that would prevent persons from holding all three types of licenses.
- The bill does not define a "licensed premises" and is unclear about how many premises may be licensed on one application. The bill seems to indicate that an application can be made for multiple locations.
- While the bill establishes a distance requirement from a "church or other religious building or school" there is no definition for school, church, or other religious building.
- The forms of identification listed do not include IDs issued by tribal entities.
- The bill creates default approval of licensure after 60 days of a complete application being submitted, which may create likelihood of applicants believing they have approval when their application was incomplete or applicants having approval with no record of approval by the department.
- The bill allows for free application process if it occurs within 30 days of being denied. This creates an environment in which applicants may submit "place holder applications" they know will not be approved, purely to save money or to create back log which will be benefited by 60-day time table for default approval.

AODA adds the following three points:

- SB9 imposes both criminal and civil penalties for sales to minors. It sets out cost of fines for each violation. Each sale is considered a separate violation. However, it may be problematic that possible violation of sales to a minor is set per location not holder of license.
  If an owner of a license holds many licenses in differing locations and is negligent about their business practices they may keep their license despite the negligence.
- While SB9 sets out penalties for up to four violations it does not ban submission for a new license of applicants with many violations. Multiple violations at any location should be addressed on the requirements for application or within the penalty section.
- On delivery sales, SB9 does not require the seller to hold the evidence of third party age verification as evidence which may lead to issues when investigating a case, and possibly prosecuting a case if and when the third party is out of the state.

OTHER SUBSTANTIVE ISSUES

Use of e-cigarettes and nicotine-containing liquids have not been proven to be safe or effective in treatment of nicotine addiction in children (see American Academy of Pediatrics statement "Electronic Nicotine Delivery Systems," 2015, attached. Thus the sponsors may consider eliminating the exception (Section 46) for this supposed indication.

LAC/rl/al

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Electronic Nicotine Delivery Systems

SECTION ON TOBACCO CONTROL

abstract

Electronic nicotine delivery systems (ENDS) are rapidly growing in popularity among youth. ENDS are handheld devices that produce an aerosolized mixture from a solution typically containing concentrated nicotine, flavoring chemicals, and propylene glycol to be inhaled by the user. ENDS are marketed under a variety of names, most commonly electronic cigarettes and e-cigarettes. In 2014, more youth reported using ENDS than any other tobacco product. ENDS pose health risks to both users and nonusers. Nicotine, the major psychoactive ingredient in ENDS solutions, is both highly addictive and toxic. In addition to nicotine, other toxicants, carcinogens, and metal particles have been detected in solutions and aerosols of ENDS. Nonusers are involuntarily exposed to the emissions of these devices with secondhand and thirdhand aerosol. The concentrated and often flavored nicotine in ENDS solutions poses a poisoning risk for young children. Reports of acute nicotine toxicity from US poison control centers have been increasing, with at least 1 child death reported from unintentional exposure to a nicotine-containing ENDS solution. With flavors, design, and marketing that appeal to youth, ENDS threaten to renormalize and glamorize nicotine and tobacco product use. There is a critical need for ENDS regulation, legislative action, and counter promotion to protect youth. ENDS have the potential to addict a new generation of youth to nicotine and reverse more than 50 years of progress in tobacco control.

FREE

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

American Academy of Pediatrics Federal advocacy efforts should be coordinated with the AAP Department of Federal Affairs in Washington, DC, and with AAP chapters on state advocacy efforts to protect children from the harmful effects of tobacco use and secondhand smoke exposure.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

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DEFINITIONS

- Secondhand aerosol: emissions from electronic nicotine delivery systems (ENDS) that are discharged into the surrounding environment with ENDS use, both directly from the ENDS and exhaled from the lungs of the user.
- Thirdhand aerosol: ENDS emissions that remain on surfaces and in dust after ENDS use, which can be reemitted into the gas phase or react with oxidants in the environment to yield secondary pollutants.
- ENDS alternate names: electronic cigarettes, e-cigarettes, e-cigs, electronic cigars, e-cigars, electronic hookah, e-hookah, hookah sticks, personal vaporizers, mechanical mods, vape pens, and vaping devices.

BACKGROUND

ENDS, including electronic cigarettes (e-cigarettes), are handheld devices that produce an aerosol from a solution typically containing nicotine,

flavoring chemicals, and carrier solvents such as propylene glycol and vegetable glycerin (glycerol) for inhalation by the user. Wide variability exists in ENDS terminology, product design, and engineering. For the purposes of the current policy statement, the term ENDS encompasses devices that are typically battery operated and produce emissions for inhalation. Alternate names for these products include electronic cigarettes, e-cigarettes, e-cigs, electronic cigars, electronic hookah, e-hookah, hookah sticks, personal vaporizers, mechanical mods, vape pens, and vaping devices.

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.[1] Despite variations in terminology, ENDS products generally have several common components that include a flow sensor, aerosol generator, battery, and solution storage area.[2] 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.[3,4] 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.[4] The ENDS solution storage containers also vary widely, ranging from prefilled cartridges to tank-style, large refillable cartridges.[4,5] 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.

EPIDEMIOLOGY OF YOUTH ENDS USE

ENDS use has increased dramatically among youth. The National Youth Tobacco Survey (NYTS) began surveying ENDS use in 2011, asking questions only about e-cigarettes. Ever use (defined by the NYTS as having ever tried an e-cigarette) among middle school students increased from 1.4% in 2011 to 3% in 2013.[6,7] Current use (defined by the NYTS as use of an e-cigarette at least 1 day in the past 30 days) among middle school students was 0.6% in 2011 and increased to 3.9% in 2014, a 650% increase.[7,8] Among high school students, ever use increased from 4.7% in 2011 to 11.9% in 2013, and current use increased from 1.5% in 2011 to 13.4% in 2014, an 890% increase.[6–9] Other surveys of high school students have found higher current use at 17% to 18%, with ever use as high as 29%.[10,11] The 2014 NYTS and Monitoring the Future survey both documented for the first time that more teenagers used e-cigarettes in the past 30 days than any other tobacco products, including conventional cigarettes.[8,11] ENDS use has been documented as highest among male subjects, non-Hispanic white youth, and Hispanic youth.[8,12]

A 2013 survey of high school students found that e-cigarette-only users had fewer social and behavioral risk factors than conventional cigarette users, raising concern that ENDS are attracting youth who may not otherwise have used tobacco products.[10] In addition, high levels of dual use of ENDS and conventional cigarettes have been noted in both adults[13,14] and youth.[6,9,10,12,15] Among youth, self-reported e-cigarette use was also associated with higher odds of ever or current conventional cigarette smoking.[15] Compared with nonusers, youth who used e-cigarettes perceived them as healthier than cigarettes[10]; however, youth using e-cigarettes were less likely to achieve abstinence from conventional cigarettes.[15]

Youth exposure to ENDS secondhand and thirdhand aerosol has also potentially increased with the increase in adult ENDS use. The percentage of e-cigarette ever use in adults rose from 3.3% in 2010 to 8.5% in 2013, and current use increased from 1% in 2010 to 2.6% in 2013.[13] Adult conventional cigarette smokers exhibited the largest growth in ever use of ENDS, increasing from 9.8% in 2010 to 36.5% in 2013.

ENDS MARKETING AND SALES

The increasing awareness, sales, and use of ENDS is being fueled by the marketing and promotion of ENDS in the media, including television, movies, video games, social media, the Internet, radio and print media, billboards, and point-of-sale advertising, as well as by celebrity role models. Advertisements and promotional efforts in broadcast media have been shown to promote youth initiation and progression of tobacco use.[16] ENDS companies have marketed their products with claims of being "healthier" and "safer" than conventional cigarettes; these claims have not been scientifically validated.[3,17] There are also unsubstantiated claims that ENDS can be used to "smoke anywhere" and both explicit and implicit claims that ENDS are smoking cessation aids (currently unapproved by the US Food and Drug Administration [FDA]).

Among all media outlets, ENDS advertising expenditures increased from $6.4 million in 2011 to $18.3

million in 2012, with the majority spent on magazine and television advertisements.[18] Although tobacco advertisements on television have been legally banned since 1971 because of the Public Health Cigarette Smoking Act, there are no current regulations in place limiting ENDS advertisements.[19] Although the current generation of children and adolescents had not previously been exposed to tobacco advertisements on television, youth exposure to television advertisements for ENDS increased by 256% from 2011 to 2013.[20] In 2013, 80% of US youth aged 12 to 17 years were exposed to an average of 13 ENDS advertisements over the 1-year period. Driven in part by the significant increase in marketing and promotion, ENDS sales represented a billion-dollar industry in 2013, with some forecasters predicting they will eventually surpass sales for conventional cigarettes.[21]

ENDS SOLUTION COMPONENTS

The solutions used in ENDS products (often referred to as e-liquid or e-juice) can be purchased in prepackaged 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 flavoring chemicals and carrier solvents, such as propylene glycol and glycerol.[1] Currently, there are no federal quality standards to ensure the accuracy of ENDS solution constituents as advertised or labeled. The refillable cartridges allow the user to deliver other psychoactive substances, including marijuana.[4]

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.[1,22,23] 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.[1] In a study of 35 ENDS cartridges and refill solutions, there were substantial discrepancies (as much as 89%) between the label and the actual nicotine content.[24] The reported nicotine concentration in ENDS solutions ranges from 0 to 36 mg/mL with cartridges that vary in size.[5,17] 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.[25,26] The user's actual nicotine exposure is affected by many factors, including the delivery system, nicotine pharmacokinetics, and individual consumption behavior.[27,28]

More than 7760 unique flavors of ENDS solutions are advertised, the majority of which are confectionary in nature and appealing to children.[3,29] Popular options include fruit, candy, and dessert flavors such as "Belgian waffle" and chocolate.[3,17] The most commonly offered flavors are tobacco and menthol, which are offered by 93% and 92%, respectively, of ENDS brands.[3] Because cigarettes with candy and fruit flavoring encourage youth experimentation, regular use, and addiction,[30] flavorings (other than menthol) have been banned in conventional cigarettes since the Family Smoking Prevention and Tobacco Control Act of 2009. Although the flavoring chemicals used in ENDS solutions have been cited as "food grade" and "generally recognized as safe," under FDA guidelines, this certification relates only to ingestion, not inhalation.[29] A study of ENDS solutions found that many of the flavoring chemicals contain aldehydes (known respiratory irritants) in sufficient concentrations to be of toxicological concern.[29]

The carrier solvents propylene glycol and vegetable glycerin (glycerol) are used in ENDS solutions to produce an aerosol that, when heated, simulates conventional cigarette smoke.[1] Although these carrier solvents are used in other settings, insufficient data exist on the health effects of repeated long-term inhalation and exposure to these solvents.[31]

ENDS SECONDHAND AND THIRDHAND AEROSOL

The aerosol generated by ENDS is inhaled and then exhaled by the user, and some of the generated aerosol may be directly discharged into the surrounding environment. This aerosol, also referred to as secondhand aerosol or secondhand vapor, can be inhaled by bystanders in a manner similar to secondhand cigarette smoke. Although ENDS advertisers often claim the secondhand aerosol is "harmless water vapor," these claims are false: known harmful toxicants and carcinogens have been found in ENDS emissions.[4] These include polycyclic aromatic hydrocarbons[32] as well as nicotine, volatile organic compounds, ultrafine particles, and particulate matter.[32–34] Metal and silicate particles, some of which occur at higher levels than in conventional cigarettes, have also been detected in ENDS aerosol.[35,36]

Thirdhand aerosol, as with thirdhand smoke, is the residual aerosol that remains on surfaces and in dust after ENDS use; this residual may react with oxidants in the environment to yield secondary pollutants or be reemitted into the gas phase.[37] Because nicotine on surfaces has been shown to be increased after ENDS use,[38] thirdhand aerosol is another potentially harmful unintentional source of nicotine exposure for youth. ENDS use exposes nonusers, including at-risk populations such as children and pregnant women, to nicotine and other harmful toxicants from secondhand and thirdhand aerosol.

In laboratory studies, neonatal mice exposed to the aerosol from a nicotine-containing ENDS solution had detectable levels of plasma cotinine, a metabolite of nicotine.[39] The mice exposed to the ENDS solution containing nicotine had decreased weight gain and impaired postnatal lung growth compared with mice exposed to room air. ENDS solutions have also been shown to be cytotoxic to human embryonic stem cells.[40] These studies raise concern for harm from in utero exposure and neonatal exposure to nicotine-containing ENDS solution.

THE EFFECTS OF NICOTINE ON THE DEVELOPING BRAIN

Nicotine is highly addictive and is the primary psychoactive component causing addiction in tobacco products.[25] Nicotine has neurotoxic effects on the developing brain.[41,42] 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.[43] Particularly in adolescence, nicotine also has an effect on the brain as a "gateway" drug for cocaine and other illicit drugs.[44]

UNINTENTIONAL ENDS EXPOSURE AND TOXICITY

Nicotine is derived from the tobacco plant and, in addition to being highly addictive, is toxic to humans.[25] Nicotine is well absorbed from the respiratory tract, mucosal surfaces, skin, and intestines; thus, nicotine exposure can occur from inhaling, ingesting, or coming in physical contact with a nicotine-containing ENDS solution.[25,45] Although symptoms of acute nicotine toxicity are generally mild and resolve within 12 hours with no treatment, large exposures can be fatal.[46] Symptoms of acute nicotine toxicity are similar to those in a nicotine-naive user and include fine tremor, nausea, tachycardia, and elevated blood pressure.[25] Severe poisonings generally have a biphasic reaction. Early symptoms occur within the first hour of exposure and are characterized by cholinergic excess (increased salivation, vomiting, and diaphoresis); other signs may include cardiac dysrhythmias, seizures, and muscle fasciculations. Late symptoms of severe nicotine poisoning occur between 0.5 and 4 hours and include hypotension, bradycardia, lethargy, and respiratory failure secondary to neuromuscular blockade.

Severe nicotine toxicity in children has been reported with nicotine doses as low as 2 mg.[25] ENDS solutions have been advertised to contain as much as 36 mg/mL of nicotine (3.6%).[17] The oral lethal dose of nicotine by body weight that is estimated to kill 50% of adults is projected at between 0.8 and 13 mg/kg.[25,46] Using the mid-range estimate (6 mg/kg) of a lethal dose of nicotine, an ingestion of the contents of 2 mL (<0.5 teaspoon) of an ENDS concentrated nicotine solution could be fatal to the average 12-kg, 20-month-old child. There is significant risk of pediatric morbidity and mortality with the current unregulated packaging and volume of nicotine concentrations available in ENDS solutions.

There has been an increase in unintentional exposures and poisonings from ENDS in the United States, including inhalations, eye and skin exposures, and ingestions. Calls to poison control centers for ENDS exposures increased from 1 exposure call per month in September 2010 to 215 calls in February 2014.[45] The majority of ENDS exposures were among children 0 to 5 years of age, and 57.8% of ENDS exposures produced adverse health effects, most commonly vomiting, nausea, and eye irritation.[45,47] As of publication date, there has been 1 reported child death in the United States from ingestion of a nicotine-containing ENDS solution.[48] There has also been 1 adult death in the United States from an intentional injection of a nicotine-containing ENDS solution.[47] In addition, the lithium-ion batteries used in ENDS have reportedly caused explosions and fires, most commonly while the battery is charging. The US Fire Administration has cautioned that, because of the shape and construction of ENDS, battery failure may be more likely to result in an explosion that is propelled like a "flaming rocket."[49]

DATA ON USE OF ENDS FOR SMOKING CESSATION

ENDS products have been promoted by some manufacturers, either explicitly or implicitly, as a smoking cessation aid, although they are not approved by the FDA as a smoking cessation product.[3,17] There have been limited studies on its use as a medical device. As of publication date, 1 randomized controlled clinical trial has compared nicotine-containing ENDS, nicotine-replacement therapy (21-mg nicotine patches), and placebo (no nicotine) ENDS.[50] Six-month cessation rates were low overall, and no statistically significant difference was found among the 3 groups. Notable limitations to the study included inadequate behavioral support for all groups and poor participant adherence with study treatments, which was particularly low in the nicotine patch group. Because these results are from a single study, they should be interpreted with caution, considering the low overall tobacco cessation rates in all 3 study groups. An earlier meta-analysis of tobacco dependence treatments (which did not include ENDS) found that the nicotine patch was effective for the treatment of tobacco dependence, with cessation rates of 23% with the nicotine patch alone.[51] Other population-based studies have found no association between ENDS use and successful cessation of conventional cigarette use.[4,52] Overall, there is insufficient evidence to recommend the use of ENDS for smoking cessation.

FEDERAL AND STATE ENDS REGULATION

Although federal regulations ban the sale of conventional cigarettes to youth aged <18 years, there are no current federal age restrictions for purchasing ENDS or ENDS products. The American Academy of Pediatrics (AAP) recommends 21 years as the minimum age of purchase for all tobacco products.[53] In April 2014, the FDA issued a draft regulation that would extend the agency's tobacco authority to cover the sale and distribution of ENDS and other tobacco products similar to conventional cigarettes. Final action on this regulation is pending. Federal regulations on the content, labeling, and packaging of ENDS and ENDS solutions also do not exist as of publication date. Federal legislation is pending that would give the Consumer Product Safety Commission the authority to require child-resistant packaging on liquid nicotine containers sold to consumers. Some states have already enacted legislation mandating child-resistant packaging for ENDS solutions.

The majority of states have enacted laws prohibiting ENDS sales to minors, and a few states have enacted comprehensive laws that prohibit ENDS use in private worksites, restaurants, and bars.[54] Updated information on state ENDS laws is available by contacting the AAP Division of State Government Affairs at stgov@aap.org. There is no current federal regulation of Internet ENDS sales. No federal laws prevent ENDS and ENDS solutions from being purchased by anyone over the Internet, regardless of age.

RECOMMENDED ACTIONS FOR THE PEDIATRICIAN

1. Pediatricians should screen for ENDS use and provide prevention counseling in clinical practice.

a. Screen children and adolescents, parents, and caregivers for ENDS use.

Screening for ENDS use and exposure should be incorporated into the screening for tobacco use. Opportunities to screen include health supervision visits and visits for diseases that may be caused or exacerbated by tobacco smoke exposure, including ENDS secondhand or thirdhand aerosol. Because ENDS products vary widely and are referred to by many names, ask about use of these products by using specific names (eg, electronic cigarettes, e-cigarettes, e-cigs, electronic cigars, electronic hookah, e-hookah, hookah sticks, personal vaporizers, mechanical mods, vape pens, vaping devices). For more information (including an ENDS fact sheet), please refer to the AAP Julius B. Richmond Center of Excellence ENDS Web page (http://www2.aap.org/richmondcenter/ENDS.html).

b. Counsel children and adolescents about the harms of ENDS and the importance of remaining a nonuser of ENDS and all nicotine-containing products.

As part of tobacco use prevention counseling, pediatricians should include prevention counseling about the known hazards of ENDS and the importance of not initiating use of any nicotine-containing product. Personally relevant messages may include the severity and rapid development of nicotine addiction and health effects from ENDS use, lack of regulation of ENDS products and solutions, and the contaminants in the products.

2. ENDS use should not be recommended as a treatment product for tobacco dependence.

No current evidence supports the efficacy or safety of ENDS as a tobacco dependence treatment product. Tobacco-dependent parents, caregivers, and adolescents should be offered behavioral counseling and support and should be educated on, offered, and/or referred to evidence-based, FDA-approved, tobacco dependence treatment medications as appropriate for the individual's severity of tobacco dependence and readiness to quit.[51]

3. Parents, caregivers, and adolescents who use ENDS should be offered or referred for tobacco cessation counseling and FDA-approved tobacco dependence pharmacotherapies appropriate to their level of addiction and readiness to change.

For further information on tobacco cessation counseling and resources for adults and youth, please refer to the following:

- Clinical Practice Policy to Protect Children From Tobacco, Nicotine, and Tobacco Smoke[55]
- Treating Tobacco Use and Dependence (http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/index.html)
- Clinical Effort Against Secondhand Smoke Exposure (http://www2.massgeneral.org/ceasetobacco/)
- American College of Chest Physicians Tobacco Dependence Treatment ToolKit (http://tobaccodependence.chestnet.org/)

4. Pediatricians should recommend to ENDS users that children should avoid contact with ENDS and ENDS solutions as well as secondhand and thirdhand aerosol exposure.

a. Counsel parents and caregivers that ENDS and ENDS solutions should be stored in child-resistant packaging and out of the reach of children.

Although some states have enacted legislation mandating child-resistant packaging, no current federal regulations exist for child-resistant packaging for ENDS and ENDS solutions. Although counseling should be targeted to prevention of ENDS use, if there are household users of ENDS, pediatricians should counsel parents and caregivers about child-resistant packaging, handling, and storage.

b. Counsel parents and caregivers about strategies to reduce exposure to ENDS aerosol, such as instituting bans on ENDS use in the home and car.

The best protection from exposure to ENDS aerosol is for parents and caregivers to not use ENDS. If that is not possible, pediatricians should recommend ENDS-free policies for their home and car.

5. Pediatricians should be familiar with symptoms of acute nicotine poisoning and consider acute nicotine poisoning from ENDS solutions when treating a child with symptoms consistent with acute nicotine poisoning unexplained by other etiologies.

Although most exposures will not require treatment, medical management of severe acute nicotine ingestion is largely symptomatic and supportive. If an exposure occurs or there is concern for exposure, the American Association of Poison Control Centers (1-800-222-1222) should be contacted.

PUBLIC POLICY RECOMMENDATIONS

1. Reduce youth access to ENDS.

a. Ban the sale to and use of ENDS for children and youth younger than 21 years.

Banning the sale of ENDS to youth younger than 21 years will decrease youth access and the potential for nicotine addiction. The AAP recommends 21 years as the minimum legal age of purchase for all tobacco products.

b. Ban Internet sales of ENDS and ENDS solutions.

Prohibition of Internet sales can help regulate the ability to restrict the sale of ENDS to youth. Internet sales of ENDS and ENDS solutions can easily be accessed by minors and used to evade local tobacco control regulations and taxes.

2. Reduce youth demand for ENDS.

a. **Ban all flavors in ENDS.**

Because flavors have been shown to promote tobacco product use among youth,[30] flavoring chemicals, including menthol, should be banned in all ENDS products and solutions. Flavoring chemicals attractive to youth also have the potential to increase risk of ingestion of the ENDS solution by young children.

3. Ban advertising of ENDS in media/Internet/point-of-sale settings that can be viewed by youth.

ENDS advertisements in media, including television, radio and print, billboards, signage, Internet, and point-of-sale (advertisements located where ENDS are sold), promote a positive image of ENDS and encourage youth purchase and use of ENDS. Any promotional activities that can be accessed by children and/or adolescents should be considered advertising to youth.

4. Restrict depictions of ENDS and ENDS use in movies, television shows, and video games. Require any movie, television show, or video game with a depiction of ENDS or ENDS use to have an adult rating.

Tobacco advertisements and promotional efforts in media promote youth tobacco initiation and progression of smoking. Movies, television shows, and video games that depict ENDS or ENDS use should be rated a minimum of R, TV-MA, or Mature, respectively.

5. Protect youth from harms of involuntary ENDS, ENDS solution, and ENDS aerosol exposure.

a. Protect youth and other nonusers from secondhand and thirdhand aerosol exposure.

Because ENDS secondhand and thirdhand aerosol contains nicotine and other harmful toxicants, ENDS use should be prohibited in all public spaces. ENDS use should also be prohibited in all locations where children and youth are cared for, learn, work, and play, including workplaces, restaurants, health care facilities, child care settings, schools, dormitories, entertainment venues, parks, athletic facilities, shopping malls, restaurants, and leisure facilities. School and college campuses should prohibit the sale and use of ENDS. Prohibitions of ENDS should be included as part of tobacco-free and smoke-free laws and policies.

b. Protect children from unintentional nicotine exposure and poisonings.

i. The size of ENDS concentrated nicotine solution prefilled cartridges and containers should be limited to amounts that would not be lethal to a young child if ingested.

ii. ENDS solutions containing nicotine should be dispensed in child-resistant packaging.

iii. Child-resistant caps and other packaging technologies should be used to reduce the risk of exposure to children, including those that restrict the rate and amount of flow of liquid nicotine from a container.[56]

c. Tax ENDS at the same rate as conventional cigarettes.

Smokers, particularly youth, are very price-sensitive[57]; therefore, ENDS and ENDS solutions should be taxed at a rate sufficient to discourage their use among youth and at a level not less than state and federal taxes on conventional cigarettes.

d. Apply funds for public health initiatives to protect youth and to study the health effects of ENDS on users and nonusers.

Research demonstrating the adverse health effects of conventional cigarette use and exposure took decades, while millions of youth and adults died of tobacco-related diseases. It is critical that the funding and development of research on ENDS, ranging from basic science of exposure to effects on public health and youth initiation, progress as

quickly as the increase in youth ENDS use. Research funding should also focus on public health initiatives, including outcomes evaluations.

CONCLUSIONS

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 secondhand and thirdhand 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 secondhand and thirdhand aerosol and concentrated nicotine solution.

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ABBREVIATIONS

AAP: American Academy of Pediatrics
e-cigarettes: electronic cigarettes
ENDS: electronic nicotine delivery systems
FDA: US Food and Drug Administration
NYTS: National Youth Tobacco Survey

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