POLICY RECOMMENDATIONS

to Address the Problem of Electronic Nicotine Delivery Systems (ENDS) in New York State
Electronic Nicotine Delivery Systems or “ENDS” refer inclusively to all forms of electronic cigarettes and similar products whether they contain nicotine or not. These are products that produce an aerosolized mixture containing flavored liquids and usually nicotine that is inhaled by the user. Like conventional cigarettes and other combustible tobacco products, the use of ENDS products pose serious public health risks and concerns that need to be addressed. Presently, there are few regulations applied to ENDS products to protect consumers. In February 2017, the New York State Public Health Association, the American Cancer Society, and the New York State Health Foundation, convened a group of experts to develop recommendations focused on the use and sale of ENDS products in New York State (NYS).

This group of experts and stakeholders gathered to discuss and debate three main areas of inquiry related to ENDS: 1) youth access, 2) tobacco cessation, and 3) health effects. Five priority recommendations for consideration by state and local decision-makers were generated from the proceedings. These recommendations reflect the top five, evidence-based opinions of the individuals attending the ENDS Summit to help reduce the negative consequences of ENDS products:

1. Include all tobacco and ENDS products in the New York Clean Indoor Air Act.
2. Increase the legal age for purchases of all tobacco products, including ENDS, to 21.
3. Increase the tax rate on ENDS and E-liquids and bring ENDS taxes into parity with other tobacco products.
4. Invest in public health education about ENDS products.
5. Maximize education, support, and access for FDA approved cessation strategies for consumers and health care practitioners.
Electronic Nicotine Delivery Systems or “ENDS” refer inclusively to all forms of electronic cigarettes (e-cigarettes) and similar devices whether they contain nicotine or not. These are products that produce an aerosolized mixture containing flavored liquids and usually nicotine that is inhaled by the user. The use of ENDS products raises serious concerns for public health. Perhaps most concerning is the increased use of ENDS products among youth and young adults because of the exposure to harmful chemicals and nicotine on developing brains. In addition, the Surgeon General found that while more research is needed, evidence from several longitudinal studies suggests that e-cigarette use is “strongly associated” with the use of other tobacco products among youth and young adults, including conventional cigarettes. ENDS products are marketed aggressively in ways that have been prohibited for cigarettes since the 1998 Master Settlement Agreement or before. These marketing tactics have included unproven claims of safety and use for smoking cessation.

Efforts to address the increasing use of ENDS products, particularly by youth, are being led nationally by the U.S. Surgeon General, the Department of Health and Human Services and the U.S. Centers for Disease Control and Prevention. For example, the 2016 Surgeon General’s Report entitled E-Cigarette Use Among Youth and Young Adults, chronicles the research to date on ENDS and youth and makes recommendations to reduce ENDS use and prevent the negative impact of ENDS on young people. Also in 2016, the FDA finalized a rule that extends its regulatory authority to all tobacco products, including e-cigarettes, cigars, hookah and pipe tobacco, as part of its goal to improve public health.

5 U.S. Food and Drug Administration. https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm, Page Last Updated: 03/31/2017
The new rules are mostly focused on reducing access to ENDS among those under 18 years of age. In addition, the new rule established an ENDS product review process that will allow the FDA to evaluate factors such as ingredients, product design, health risks, and a product’s appeal to youth and non-users. In May 2017, before the final rules could take full effect, the FDA announced that the agency will be delaying enforcement measures for three months to allow time for additional review.6

New York State Regulatory Environment

In late 2014, New York State enacted a law to protect children from liquid nicotine by requiring child-proof caps on all nicotine-containing e-liquids.7 There is a nation-wide effort to increase the legal age for purchasing tobacco products (including ENDS) and two states have passed the legislation.9 In the past few years, nine counties plus New York City have also enacted local legislation to raise the age of sale to 21 for tobacco and ENDS products, which now covers more than half the state’s population. In addition, eight counties and New York City have enacted laws to close the ENDS loophole in the Clean Indoor Air law.8 Eight states plus the District of Columbia prohibit smoking and the use of ENDS in indoor areas of private worksites, restaurants, and bars.9

8 American Cancer Society Cancer Action Network, May 6, 2017
In January 2017, Governor Cuomo of New York proposed in his FY2018 Executive Budget to establish a tax of 10 cents for every milliliter of fluid used in electronic cigarettes. In addition, the proposal defined electronic cigarette use as smoking, which would automatically require ENDS to be covered by New York’s Clean Indoor Air Act and the Adolescent Tobacco Use Prevention Act that bans smoking on school property. Although both houses supported the ENDS measures in their own budget proposals, in the end, the efforts of the tobacco industry and the vaping retailers led to the ENDS proposals being removed. In May 2017, the debate was revised when the State Assembly passed legislation that would add electronic cigarettes to the state’s Clean Indoor Air Act.

In April, 2017, New York City’s Mayor Bill De Blasio announced his support for a legislative package that would raise the minimum cost of cigarettes to $13 per pack, increase the tax on other tobacco products, cap the number of tobacco and e-cigarette retailers, prohibit pharmacies from selling tobacco products, and require apartment buildings to adopt and disclose smoking policies. All of the tobacco control policies being discussed in the New York City Council have implications for ENDS products if enacted and could help reduce their normalization and uptake, especially among youth.

New York State ENDS Summit

Given the dramatic rise in the use of ENDS products in New York and the lack of product regulation and oversight to date, the New York State Public Health Association and the American Cancer Society, in partnership with the New York State Health Foundation, convened a group of experts (see Appendix A) on February 10, 2017 to identify and prioritize recommendations focused on the use and sale of ENDS products in New York State. The increasing prevalence of ENDS product usage among youth and adults has raised three distinct, yet inter-connected public health questions that were the focus of discussion.

The questions were meant to identify the most important strategies related to:

1. decreasing nicotine exposure and initiation of combustible cigarette smoking among youth;
2. reducing the prevalence of disease associated with long-term tobacco use and determining whether ENDS products have a role; and
3. decreasing the direct and indirect exposure to harmful chemicals in ENDS products.

The Summit agenda included an overview of surveillance data and the scientific literature on ENDS, a summary of interventions that have been implemented in NYS and other regions of the US, breakout sessions dedicated to the three priorities, and final identification of priority recommendations to impact ENDS in New York State.

10 NYS FY 2018 Executive Budget Briefing Book
**Question 1:** What are the most important strategies to reduce access to ENDS, decrease nicotine exposure and delay initiation of cigarette smoking among youth?

**Concerns and Considerations**

Nearly all adult smokers start smoking in their youth. Experts agree that preventing the commencement of smoking is of primary importance in preventing the onset of tobacco dependence, tobacco-related diseases and premature death. Additionally, there are many concerns associated with the impact of nicotine on the developing adolescent brain, including lasting cognitive and behavioral impairments.

Despite having seen a long-term decline in cigarette use among youth in New York, ENDS use among youth is increasing dramatically (see Figure 2). Data suggests that the use of ENDS products that contain nicotine by youth increases the likelihood of their smoking combustible tobacco. For example, one study found that youth who used e-cigarettes were more than six times as likely to start smoking combustible tobacco than those who did not.

ENDS products are marketed using some media channels and approaches that have been banned for cigarettes since the 1998 Master Settlement Agreement or before with tobacco companies, to address marketing targeted specifically to youth. These include TV, radio, print media, billboards, the Internet, and social media ads.

In 2009, because flavoring of combustible cigarettes was attractive to young people, the FDA banned flavored cigarettes, other than menthol, as part of the

» Among NYS high school students, cigarette smoking rates have decreased from 27.1% in 2000 to 4.3% in 2016.

» The use of ENDS among NYS youth nearly doubled between 2014 and 2016, when one in five high school students (20.6%) reported the use of ENDS.

» More than 43.8% of high school students in NYS report having tried ENDS.

» Never smoking U.S. adolescent and young adult e-cigarette users at baseline were 8.3 times more likely to progress to cigarette smoking after 1 year than non-users of e-cigarettes.

14 Primack, Brian, Soneji, Samir, et al, Progression to Traditional Cigarette Smoking After Electronic Cigarette Use Among US Adolescents and Young Adults, JAMA., 2015.

YOUTH ACCESS AND INITIATION

effort to reduce youth smoking.\textsuperscript{18} Today, ENDS products come in more than 7,000 flavors that similarly attract youth, such as, bubble gum, grape, and unicorn flavors. In a 2014 survey, nearly two-thirds of youth e-cigarette users reported using flavored e-cigarettes.\textsuperscript{18}

\textbf{Trends in Any Tobacco Product Use Among High School Students in NYS, 2000—2016}

\begin{figure}
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\includegraphics[width=\textwidth]{figure2.png}
\caption{Trends in Any Tobacco Product Use Among High School Students in NYS, 2000—2016}
\end{figure}

\begin{table}
\centering
\begin{tabular}{|c|c|c|c|c|c|c|c|c|}
\hline
Year & Any Tobacco Products & Cigarettes & ENDS & Other Tobacco Products \\
\hline
2000 & 33.6% & 27.1% & n/a & 18.1% \\
2002 & 26.2% & 20.4% & n/a & 14.6% \\
2004 & 24.3% & 18.5% & n/a & 13.0% \\
2006 & 21.8% & 16.3% & n/a & 11.0% \\
2008 & 22.8% & 14.7% & n/a & 10.0% \\
2010 & 21.2% & 12.6% & n/a & 15.0% \\
2012 & 21.8% & 11.9% & n/a & 14.8% \\
2014 & 19.5% & 7.3% & 10.5% & 16.8% \\
2016 & 25.4% & 4.3% & 20.6% & 12.0% \\
\hline
\end{tabular}
\end{table}


\textsuperscript{18} Corey et al. Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014. MMWR. October 2, 2015 / 64(38);1066-1070.
**ENDS PRODUCTS AND TOBACCO CESSATION**

**Question 2:** What are the most important strategies to reduce the prevalence of disease associated with long-term tobacco use and can ENDS play a role?

**Concerns and Considerations**

Under the right circumstances, e-cigarettes could benefit public health if they help significantly reduce the number of people who use conventional cigarettes and ultimately die of tobacco-related disease. If there is to be a public health benefit from e-cigarettes, it will only come if they are effective at helping smokers end the use of cigarettes and if they are responsibly marketed so they do not re-glamorize tobacco use among young people. However, the evidence to date in the United States is limited and conflicting as to whether they are actually effective at helping smokers quit. In October 2015, the U.S. Preventive Services Task Force comprehensively evaluated the evidence to date and concluded that “the current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation…”. ENDS are not currently approved by the FDA for smoking cessation; yet, ENDS marketing has included unproven claims of safety and use for smoking cessation. The evidence shows that among both youth and adults, concurrent or dual use of combustible tobacco and ENDS is high, which will likely not reduce tobacco-related chronic diseases and death.3, 19

**In 2015, close to 3 out of 4 smokers reported that their health care provider advised them to quit smoking, while only 1 out of 2 smokers reported that their health care provider offered assistance to quit.20**

**More than 27% of smokers used ENDS products the last time they tried to quit.20**

**Nearly 8% of current smokers report that their health care provider advised that they use ENDS products to make a quit attempt.20**

FDA approved cessation medications include a variety of gums, patches, lozenges, sprays, and inhalers that serve as nicotine replacement therapies and two prescription medications that do not contain nicotine. No ENDS producer has ever applied to the Federal Drug Administration to become certified as a cessation product. Many experts and public health professionals report that approved cessation products are not as widely promoted or accessible as they could be and medical professionals need to be better educated in the use and efficacy of tobacco dependence medications. The implementation of proven tobacco cessation treatment has not been maximized by providers assisting patients with quitting.20 Evidence shows that a recommendation and/or prescription for an approved cessation method from a health care provider can double or triple the chance that a smoker will quit.21

Unfortunately providers receive very limited training in tobacco dependence treatment specifically, and addiction in general.22 Time constraints, inadequate health plan reimbursement, and perceived patient resistance have also been reported as reasons for not assisting patients to quit using evidence-based methods.21

Given the mixed results and questions about the quality of existing research, the scientific consensus on using ENDS for cessation is that additional research, including well-designed randomized clinical trials and longitudinal, population studies are necessary before their use should be recommended for smoking cessation. In the meantime, effective treatments do exist and when prescribed properly with more vigilant support, these methods can help patients to quit and reduce the likelihood of long-term dual use of cigarettes and ENDS.

**Taxation Strategies to Increase Smoking Cessation**

New York State’s cigarette excise taxes are the highest in the country ($4.35 per pack), but ENDS products are taxed at significantly lower rates than cigarettes. New York City has local excise tax of $1.50 per package of traditional cigarettes, bringing the combined tax rate to $5.85. NYS currently has no excise tax on ENDS products but state sales taxes do apply. Studies have shown that for every 10 percent increase in the price of cigarettes, there is approximately a 4 percent reduction in overall cigarette consumption and a 6.5 percent reduction in youth consumption. Low-income adults, youth, and pregnant women are especially likely to quit or reduce their smoking when prices increase. Experts agree that tax parity among all tobacco products (including ENDS) is important to discourage youth initiation, discourage dual use of ENDS and combustible tobacco, and to raise revenue to support prevention and cessation programs. The American Cancer Society’s Cancer Action Network recommends that in addition to tax parity for all tobacco products, tax increases should be large enough to produce a meaningful reduction in tobacco consumption.

**SUMMARY OF SELECT TAXES ON ENDS IN THE U.S.**

- **California**: Tax will increase to 65.08% of the wholesale price on July 1, 2017.
- **Kansas**: E-liquid tax of $0.20 per milliliter of consumable material and proportionate tax on all fractional parts otherwise (2016).
- **Minnesota**: E-cigarettes and e-liquid are subject to the tobacco tax, which is currently 95 percent of the wholesale price.
- **North Carolina**: Taxes liquid nicotine at 5 cents per milliliter (2014).
- **Pennsylvania**: Tax rate is 40% of the wholesale price (2016).
- **District of Columbia**: E-cigarettes are exempt from sales tax, however they have an excise tax of 67% of the wholesale price (2015).

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HEALTH EFFECTS AND EXPOSURE ISSUES

Question 3: What are the most important strategies to reduce the direct and indirect exposure to chemicals in ENDS products?

Concerns and Considerations

Studies suggest that ENDS products and ENDS aerosol contain harmful chemicals and the devices, cartridges, and liquid refills are mostly unregulated. Proponents of ENDS often refer to their emissions as vapor, implying water vapor; however, most ENDS do not contain any water. In fact, most ENDS produce aerosols, which contain many different chemicals that can cause eye and respiratory irritation, including short-term peripheral airway constriction.\(^{29,30}\)

Sleiman et al. found the presence of propylene oxide in e-liquid and glycidol in vapors, both compounds considered possible or probable carcinogens. These compounds are produced from heating the solvents propylene glycol and glycerin, two common constituents of e-liquid, and therefore likely to be present in ENDS emissions.\(^{31}\)

ENDS and ENDS-related products pose a major risk of nicotine toxicity through ingestion or skin absorption of liquid nicotine. Less than half a teaspoon of a concentrated nicotine solution can be fatal to the average 26 pound, 20-month-old child.\(^{32}\)

The long-term exposure effects of ENDS products are unclear, and due to their exclusion from the Clean Indoor Air Act they are being used indoors in public spaces such as bars and restaurants. Although studies suggest that nicotine and other toxin levels are lower in ENDS than in traditional cigarettes, research has shown that they can produce toxic aerosols,\(^{33}\) carcinogens,\(^{34}\) and heavy metals to which bystanders may be exposed.\(^{35}\)

30 Callahan-Lyon P. Electronic Cigarettes: Human Health Effects. TOB CONTROL. 2014;23
SUMMARY OF POLICY RECOMMENDATIONS

1. Include all tobacco and ENDS products in the Clean Indoor Air Act.

Current New York State law prohibits the use of combustible tobacco in all indoor worksites and public areas. Several statewide health groups have been advocating to close the ENDS loophole in this law for the past few years. The bill has passed the NYS Assembly twice in the past but was stalled in the Senate. In May 2017, the State Assembly passed A516 that would add electronic cigarettes to the state’s Clean Indoor Air Act. The same bill, S2543, is being considered once again in the State Senate.

2. Limit access by increasing the legal age for purchases of all tobacco products, including ENDS to 21.

At least 95% of smokers initiate cigarette use by the age of 21. Based on a systematic review of the literature, a 2015 Institute of Medicine report concluded that implementing Tobacco 21 is likely to reduce smoking prevalence nationally by 12% and tobacco-related mortality by 10% over the long-term. All of New York City, eight counties and two towns in New York State have raised the age for purchasing cigarettes and ENDS to age 21 meaning that a majority of the state’s population is covered by this law that protects young people. Seven of the counties have passed Tobacco 21 laws in the last year. State Tobacco 21 bills exist in both houses of the New York State legislature (S3978 / A273) where there is growing support for the measure.

SUMMARY OF SELECT ENDS POLICIES BY STATE

» Eleven states plus D.C. have added ENDS to their clean indoor air laws (New Jersey, Oregon, California, Delaware, Vermont, North Dakota, Hawaii, Utah, Oklahoma, Connecticut and Maine).37

» California and Hawaii have increased the age for purchasing tobacco products and ENDS to 21.36

» Eleven states include ENDS in their definition of a tobacco product.37

SUMMARY OF POLICY RECOMMENDATIONS

3. Increase the tax rate on ENDS and ENDS-Related products to achieve parity with other tobacco products.

Youth are at greatest risk from using ENDS but are also most sensitive to price increases. As the State and New York City increased excise taxes on tobacco products over the past decade the youth smoking rate dropped dramatically. Youth are now increasingly using ENDS which have no excise tax in New York at present. The state excise tax rate on cigarettes is currently $4.35 per package. The New York City local excise tax is $1.50 per package, bringing the combined tax rate to $5.85. The statewide tax on cigars and other tobacco products is 75% of the wholesale price. The tax on moist snuff is $2.00 per ounce. Increasing taxes has been shown to decrease smoking especially in low-income communities, pregnant women, and youth.

4. Invest in public health education about ENDS.

The State should provide consistent and evidence-based messages about the health risks of ENDS use and exposure to the chemicals in secondhand aerosol. Targeted messages should be focused on parents, teachers, coaches, and other influencers of youth as well as providers, vulnerable populations and the general public. Youth may require different messages that focus on the influence of the tobacco and vaping industries and how their marketing is designed to manipulate and addict teens to create lifelong customers. Youth empowerment approaches such as the Truth Campaign and “Reality Check” in New York have been used successfully to help reduce youth smoking.

5. Maximize education, support, and access to FDA approved cessation strategies for consumers and health care practitioners.

New York State Medicaid Managed Care plans are now covering all FDA approved cessation medications, but there is a knowledge deficit among providers and consumers about that coverage. More importantly, efforts must be increased to educate providers to help avoid under-treating highly addicted smokers who often relapse and then lose confidence in effective treatment modalities. With only 50.5% of smokers reporting that their providers assisted them with smoking cessation counseling or medications in New York, far more can be done to optimize the use of proven smoking cessation treatments.
NEW YORK STATE ENDS SUMMIT PARTICIPANTS: FEBRUARY 10, 2017

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Likewise, the contents of this document reflect the majority views of the panelists and do not necessarily reflect the official views of the New York State Public Health Association, the American Cancer Society, or the other organizations represented at the February 2017 New York State ENDS Summit.

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