Overview of and Recommendations Regarding Electronic Nicotine Delivery Systems (ENDS)

BACKGROUND AND SCOPE OF THE PROBLEM:

Electronic nicotine delivery systems (ENDS), or e-cigarettes, were introduced in the United States in 2007, and have become a pressing public health concern, especially among youth (Office of the Surgeon General [OSG], 2016, p. 10). Some brands were initially promoted by industry as smoking cessation aids, but e-cigarettes are not currently approved by the U.S. Food and Drug Administration as an aid to quit smoking (U.S. Food and Drug Administration [FDA], 2019a).

E-cigarettes are also known as e-cigs, e-hookahs, mods, vape pens, vapes, and tank systems. Some e-cigarettes look like regular cigarettes and some often resemble everyday items such as USB sticks or highlighters (Centers for Disease Control and Prevention [CDC], n.d.). E-cigarettes are designed to deliver nicotine, flavorings, and other additives via an inhaled aerosol (CDC, 2019c). In addition to being inhaled by the e-cigarette user, this aerosol can also be inhaled secondhand by bystanders (CDC, n.d.). Of all e-cigarettes sold at convenience stores, supermarkets, and other common retailers, 99% contain the drug nicotine (Marynak et al., 2017). The e-cigarette aerosol that users breathe from the device can contain other harmful substances in addition to nicotine, including cancer-causing chemicals and ultrafine particles that reach deep into the lungs (CDC, 2019a).

Nicotine is highly addictive and can affect the developing brain, potentially harming teens and young adults (CDC, 2019b). Nicotine use during adolescence and young adulthood has been associated with impairments in memory, attention, and learning (American Lung Association, 2019). Additionally, the nicotine in e-cigarettes and other tobacco products cause changes in the adolescent brain that make it more vulnerable to addiction to other drugs (U.S. Department of Health and Human Services, n.d.).

Currently, 1 in 5 high school students use e-cigarettes. The rate of use has increased 78% among high school students, from 11.7% in 2017 to 20.8% in 2018 (FDA, 2019e). These youth who use e-cigarettes are more likely to continue on to regular cigarette use (Rand Corporation, 2018). Additionally, youth who use e-cigarettes are 3.5 times more likely to use marijuana (National Institute on Drug Abuse, 2019).

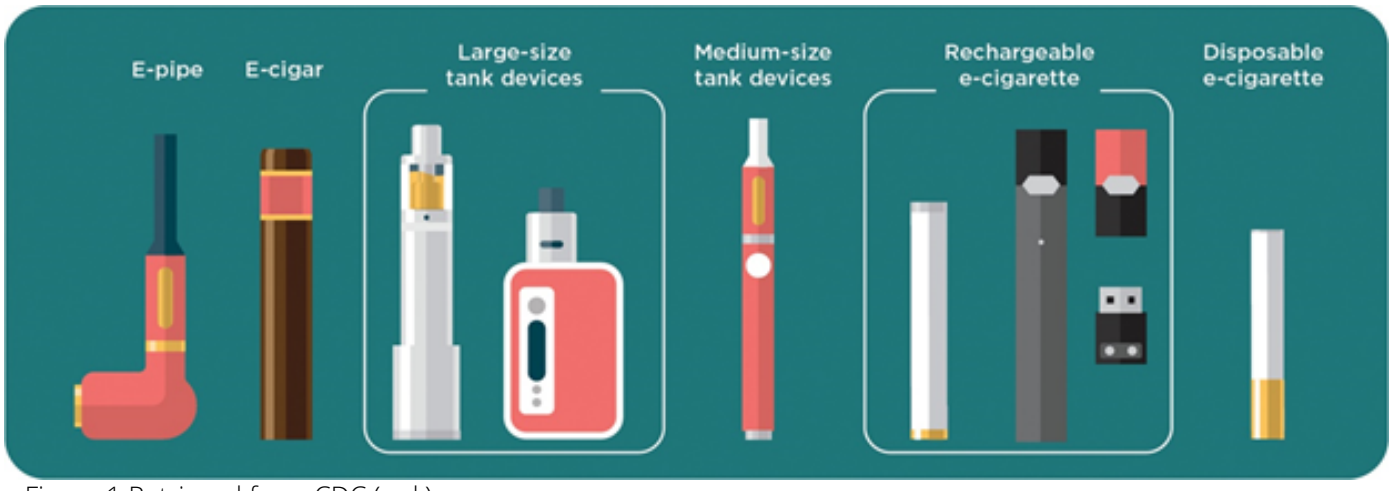

Figure 1 Retrieved from CDC (n.d.)

FEDERAL ACTIONS TO ADDRESS THE PROBLEM:

The Department of Health and Human Services (HHS) and Congress have taken several steps to address e-cigarette use among youth:

- On August 8, 2016, the FDA's foundational "deeming rule" went into effect, giving the FDA's Center for Tobacco Products (CTP) regulatory authority over all ENDS (Sharpless, 2019). This rule required all ENDS to file pre-market tobacco product applications with the FDA within two years. It became immediately illegal to sell ENDS to people younger than 18, and retailers became legally responsible for requiring age verification by photo ID for individuals under 27 to purchase a tobacco product (Sharpless, 2019).

- In 2018, the Surgeon General, Vice Admiral Jerome Adams, released an advisory on E-Cigarette Use Among Youth. The advisory emphasized the importance of protecting youth from nicotine addiction and associated health risks and noted concern about new types of e-cigarettes that have recently entered the market (CDC, 2019c).

- In June 2019, the Senate passed the Lower Health Care Costs Act of 2019 (S.1895), which included provisions to raise the minimum age of legal tobacco product access to 21.

- The FDA issued a warning letter to JUUL Labs in September 2019 for "marketing unauthorized modified risk tobacco products by engaging in labeling, advertising, and/or other activities directed to consumers." According to the letter, JUUL does not have an FDA order in effect that allows the company to advertise its products as modified risk tobacco products (FDA, 2019b).

- On September 11, 2019, HHS announced in a press release that the FDA is in the process of finalizing a compliance policy regarding pre-market authorization requirements for non-tobacco flavored e-cigarette products, including mint and menthol, clearing the market of unauthorized, non-tobacco-flavored e-cigarette products (FDA, 2019d).

- In November 2019, the House Committee on Energy and Commerce passed the Reversing the Youth Tobacco Epidemic Act, which would raise the minimum purchasing age for all tobacco products to 21 years old. It would also ban all flavored tobacco products, including menthol cigarettes, and prohibit all online sales of e-cigarettes.

- In December 2019, as part of a fiscal year 2020 domestic spending bill, Congress passed, and President Trump signed into law Public Law No. 116-94, which raises the legal age of tobacco access to 21 years of age.

- On January 2, 2020, the FDA announced an enforcement policy against certain unauthorized flavored e-cigarette products that appeal to youth, including fruit and mint flavors. Under this policy, companies that do not cease manufacture, distribution, and sale of unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) risk FDA enforcement actions. The flavor restrictions do not extend to tank or mod systems.

FDA'S ROLE:

The U.S. Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) plays an important role in regulating the sale of tobacco products, including ENDS. The FDA does not approve tobacco products since the FDA's traditional "safe and effective" standard for evaluating medical products does not apply to tobacco (FDA, 2019c) Instead, the FDA's Center for Tobacco Products (CTP) authorizes the sale of tobacco products with marketing orders, which are granted based on the product's risks to the population as a whole (FDA, 2019c).

STATE ALCOHOL & DRUG AGENCIES' ROLE IN TOBACCO CONTROL:

The State alcohol and drug agencies oversee the publicly funded substance use prevention, treatment, and recovery service system. The cornerstone of the publicly funded addiction system is the Substance Abuse Prevention and Treatment (SAPT) Block Grant, which is a formula grant for all States and territories that is administered by the Substance Abuse and Mental Health Services Administration (SAMHSA).

In 1992, Congress passed a law with an amendment, referred to as the Synar Amendment, which required States and territories to enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18.

In 1996, SAMHSA issued the Synar regulation, providing further guidance to States related to Synar enforcement (Substance Abuse and Mental Health Services Administration, 2017). The regulation stated that States were to conduct annual, unannounced inspections of tobacco retailers that provide a probability sample of the accessibility of tobacco products to minors under the age of 18. States have since been required to meet at least an 80 percent compliance rate of retailers refusing tobacco sales to minors. A compliance rate below 80 percent could result in penalization of a State's SAPT Block Grant allocation of up to 40 percent. Although State alcohol and drug agencies have to manage implementation of these annual Synar compliance checks, there have not been dedicated federal funds to support implementation.

The tobacco-related provisions included in the final FY 2020 appropriations package raise the age for tobacco access from 18 to 21 and maintain Synar. Additionally, the law lowers the non-compliance penalty on the SAPT Block Grant from 40 percent to 10 percent. The law also affords States with an additional option instead of a penalty to the SAPT Block Grant. This option would be a negotiated corrective action plan. There will be a mandatory 3-year implementation period where no penalties can be levied, and the Secretary of Health and Human Services (HHS) will be able to add an additional 2 years to this transition time. Finally, the law authorizes $18.5 million per year for 5 years (FY 2020-FY 2024) for grants to States to ensure compliance with the new approach to Synar, but does not explicitly clarify which State agency will receive and manage the funds.

NASADAD'S POSITION AND RECOMMENDATIONS:

- NASADAD represents the State alcohol and drug agencies, which have the mission of delivering effective substance use prevention, treatment, and recovery programs. NASADAD is supportive of efforts to regulate e-cigarette products, end tactics that appeal to youth (i.e., flavored e-liquids), and engage retailers in reducing youth access to ENDS.
- NASADAD appreciates HHS's actions to reduce youth use of e-cigarettes, including the Surgeon General's Advisory on E-Cigarette Use Among Youth.
- NASADAD is supportive of recent federal efforts to raise the minimum age of legal tobacco product purchase to 21 across the United States.
- With 20% of youth using e-cigarettes, there should be further efforts to bolster enforcement of age limits. The federal government should provide funds to States to help with these enforcement efforts.
- NASADAD recognizes that while there are many FDA-approved nicotine replacement therapies (NRT) for those 18 and older, none—aside from varenicline (Chantix)—are approved for sale to youth (FDA, 2017). Although NRT products are being used off-label by some clinicians in order to help youth clients with tobacco cessation, more resources must be invested to hasten research on the appropriate treatment protocol for cessation in individuals under the age of 18.
- We recognize that there are counterfeit flavored nicotine products on the market that may have inaccurate label information, new products such as "heat-not-burn" tobacco devices that are popular in other countries, and a variety of devices that are utilized to ingest substances such as marijuana. These and other issues deserve thorough examination as Congress and the Administration consider further action.

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