The Society of Behavioral Medicine supports stronger regulation of electronic nicotine delivery systems (e-cigarettes), incorporation of electronic nicotine delivery systems into clean air policies, and special consideration of product safety standards to protect vulnerable populations.

Background

The use of electronic nicotine delivery systems (ENDS), commonly known as e-cigarettes, is a divisive issue among the tobacco treatment, public health, and medical communities. There are sharp differences of opinion regarding how harmful ENDS use is compared to cigarettes, the potential impact of ENDS use on overall tobacco and nicotine use, and the relationship between ENDS marketing and initiation of use by vulnerable populations (e.g., children).

Researchers are still gathering data in an attempt to answer these questions, and no definitive conclusions can be made at this time. Given these uncertainties, regulatory efforts should be aimed at making ENDS as minimally harmful as possible. The Society of Behavioral Medicine supports stronger regulation of ENDS, incorporation of ENDS into clean air policies, and special consideration of product safety standards to protect vulnerable populations.

Need for Stronger U.S. Federal Regulation of ENDS

ENDS in the U.S. market are almost entirely unregulated on a national level.

ENDS that contain nicotine are considered tobacco products under the U.S. Tobacco Control Act, and are subject to the Food and Drug Administration’s (FDA) tobacco product jurisdiction unless they are marketed for therapeutic purposes (e.g., as cessation aids). FDA regulation would require ingredients and nicotine concentration to be standardized and labeled. However, many ENDS remain unregulated because the FDA’s Center for Tobacco Products has indicated its intention to regulate ENDS as tobacco products, but has not yet finalized this regulation.

In addition to product standards, marketing and advertising of ENDS is under scrutiny, particularly among young consumers. Factors contributing to ENDS popularity among young populations include novelty of the product and youth-oriented flavors (e.g., cotton candy). Currently, ENDS companies are able to market their products without restriction and often direct their mass marketing campaigns toward young populations through marketing on social media. ENDS companies have taken advantage of the online marketplace. A recent evaluation of 57 online ENDS vendors found that many used a variety of sales promotion strategies to market ENDS including use of social network services. Additionally, some of the online ENDS vendors did not have any detectable age verification process for purchase. Thus, children under the age of 18 are exposed to this advertising and may be able to purchase these products without age verification. Federal regulation of ENDS would allow for marketing and advertising restrictions to this vulnerable population.

Although federal regulation is not finalized, some states and localities have passed new laws relating to ENDS. For example, most states have prohibited their sale to youth, and some have subjected ENDS to smoke-free laws or have taxed them.

Importance of Including ENDS in Clean Air Policies

ENDS are marketed as devices that are safe to smoke in public because they do not produce secondhand smoke like traditional cigarettes. Yet, we do not fully understand the safety of inhaled humectants, the main constituent (other than nicotine) in ENDS aerosols. Further, while ENDS do not produce poisonous carbon monoxide, the inhaled vapors from ENDS contain nicotine, exposing nonusers to nicotine in the air. The research on the effects of secondhand exposure to nicotine is limited. Many regulatory
movements have aimed to reduce the prevalence of secondhand smoke, including smoke-free housing laws and smoking bans in public places (e.g., airplanes, restaurants, bars, hospitals). However, many of these regulations do not cover ENDS or secondhand nicotine exposure, and it is up to state-level policymakers, individual establishments, companies, or other agencies to restrict or ban the use of ENDS.

2. Will ENDS Help People Quit Smoking?
Research regarding the benefit of ENDS as cessation devices is still emerging and a recent meta-analysis showed that the data is not conclusive. The authors report that evidence from two trials shows that ENDS may help smokers to stop smoking long-term. For example, a randomized controlled trial has shown that ENDS with nicotine were able to increase smoking abstinence after 6 months, but this was not significantly different compared to using ENDS without nicotine or nicotine patches. In addition, a second study showed that among smokers who had no intention to quit, ENDS use resulted in a 10% reduction in smoking for both nicotine and non-nicotine containing ENDS. However, the effect size is small from these two trials and conclusions about efficacy of ENDS for cessation cannot be made. While ENDS present an opportunity for harm reduction from smoking or as a cessation aid, until ENDS are regulated, these devices should be recommended with caution. FDA-approved medications such as nicotine replacement therapy and other pharmacological agents (e.g., varenicline) coupled with behavioral counseling are still considered to be the most effective strategies for smoking cessation. Further research is necessary to test the efficacy of using ENDS to aid smoking cessation.

3. What are the Public Health Implications of ENDS?
There are many unanswered questions regarding the impact of ENDS on public health. Researchers are still evaluating the potential for abusing ENDS, if/how ENDS affects tobacco use initiation, patterns of use, and progression to potentially more harmful patterns of use. For example, smokers may become dual users of ENDS and traditional cigarettes. Some may view this as harm reduction (i.e., toxic cigarettes are now being replaced by something less toxic, so the harm or risk of health problems is reduced). However, others would not view dual cigarette and ENDS use as harm reduction because it does not reduce the risk of cancer and cardiovascular events. Light smoking carries nearly the same risk for cardiovascular disease as heavy smoking and increases the risk of developing lung cancer. To inform federal regulations, the FDA will need to address these types of public health questions with respect to non-tobacco users (especially youth and pregnant women) as well as current and former smokers.

Summary and Recommendations
Regulation is critical for all future use and possible benefit of ENDS, and there are several important policy implications to consider as we move toward achieving that goal. Other organizations have offered comprehensive outlines of the issues surrounding ENDS and the possible policy implications. Specifically, SBM recommends that policy-
makers consider the policy-related implications related to ENDS regulation in the following areas.

1. ENDS regulation by the FDA
We encourage policymakers to support the regulation of all ENDS by the FDA. All ingredients should be listed, and the nicotine concentration should be standardized and listed on the label.

All marketing of ENDS to youth below age 18 should be banned.

2. Clean Air and Environmental Implications
We encourage policymakers to support a ban on the use of ENDS in places where combustible tobacco product use is prohibited by federal, state, or local law.

3. Child Safety
We encourage policymakers to promote a product standard that requires liquid nicotine refill bottles to be childproof.

We encourage policymakers to take steps to prevent children from confusing ENDS and the liquid refills with products recognized as food or candy (e.g., cotton candy flavored nicotine refill).

4. Future Research
We urge policymakers to support research on ENDS to guide policy decisions.

We encourage investigator-initiated prospective clinical trials to evaluate whether ENDS are in fact less deleterious than traditional cigarettes and whether or not ENDS are effective smoking cessation aids.

References