Position Statement:

Emerging Policy Issues Regarding Electronic Nicotine Delivery Systems: A Need for Regulation

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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[1-2] 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.[3]

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).[4] 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.[5] 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.[6]

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 exhaled vapors from ENDS contain nicotine, exposing nonusers to nicotine in the air.[7] 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).[8] 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.

Special Consideration of Safety Standards to Protect Vulnerable Populations

There are other risks associated with ENDS, including accidental exposures and poisonings associated with liquid nicotine refills.

* The American Association of Poison Control Centers reported 3,067 exposures to liquid nicotine from ENDS in 2015.[9]
* In 2014, more than half of the 3,783 liquid nicotine exposures that year occurred in children under the age of 6.[9]
* Nicotine in the exhaled aerosol of ENDS can persist on indoor surfaces and presents a risk for thirdhand exposure.[10] Thus, anyone touching these indoor surfaces (e.g., non-smokers, pregnant women, children, pets) could transfer nicotine to their skin, eyes, or mouth, further presenting an accidental exposure risk and general health concerns.

Given these considerations, it is important to ensure nicotine refill bottles are childproof to reduce the risk of children's exposure to nicotine.

Important Areas for Future Research

Given that research on the effects of ENDS is limited and emerging, there are three key research questions that have not been addressed completely. Further research is necessary prior to making any specific policy-related recommendations regarding these questions.

1. Are ENDS Safer than Cigarettes?

ENDS are likely less harmful than smoking combustible tobacco. A recent review of available ENDS data concluded that it was reasonable to estimate that ENDS are around 95% less harmful than smoking cigarettes.[11] Although the liquid aerosol from ENDS does not produce carbon monoxide as combusted tobacco does, and the levels of toxicants are lower than those found in cigarette smoke,[12] ENDS do contain an additive that allows for vaporization. The health effects of this additive are not known.[13]

In addition, ENDS typically contain flavoring agents. The FDA Family Smoking Prevention and Tobacco Control Act banned all flavor additives, except menthol, in traditional cigarettes in 2009. Emerging evidence suggests that some flavoring agents found in ENDS liquids (including cinnamon) are toxic to cells.[14] Thus, while ENDS may appear to be a reduced-risk product in comparison to traditional cigarettes, we are only beginning to understand the ways in which these additional additives affect health.

Long-term monitoring of the health effects of ENDS will be required before absolute and relative harm (compared with cigarettes or nicotine replacement therapies) can be established.[15]

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.[16] 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.[17] 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.[18] 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.[13] 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.[19] 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.[13, 20-21] SBM joins these organizations and supports further regulation of ENDS to prevent possible health-related consequences. 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 child-proof.

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

1 Avdalovic, M. V., & Murin, S. (2015). Point: Does the risk of electronic cigarettes exceed potential benefits? yes. *Chest, 148*(3), 580-582. doi:10.1378/chest.15-0538

2 Middlekauff, H. R. (2015). COUNTERPOINT: Does the Risk of Electronic Cigarettes Exceed Potential Benefits? No. *Chest, 148*(3), 582-584. doi:10.1378/chest.15-0540

3 Cobb, N. K., & Abrams, D. B. (2014). The FDA, e-cigarettes, and the demise of combusted tobacco. *N Engl J Med, 371*(16), 1469-1471. doi:10.1056/NEJMp1408448

4 Wasowicz, A., Feleszko, W., & Goniewicz, M. L. (2015). E-Cigarette use among children and young people: the need for regulation. *Expert Rev Respir Med*, 1-3.

5 Mackey, T. K., Miner, A., & Cuomo, R. E. (2015). Exploring the e-cigarette e-commerce marketplace: Identifying internet e-cigarette marketing characteristics and regulatory gaps. *Drug and Alcohol Dependence*. doi:http://dx.doi.org/10.1016/j.drugalcdep.2015.08.032

6 American Nonsmokers' Rights Foundation. (October 2, 2015). U.S. state and local laws regulating use of electronic cigarettes. Retrieved from http://no-smoke.org/pdf/ecigslaws.pdf

7 Czogala, J., Goniewicz, M. L., Fidelus, B., Zielinska-Danch, W., Travers, M. J., & Sobczak, A. (2014). Secondhand exposure to vapors from electronic cigarettes. Nicotine & Tobacco Research, 16(6), 655-662. doi:10.1093/ntr/ntt203

8 U.S. Department of Health and Human Services. (2006). Control of Secondhand Smoke Exposure *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

9 American Association of Poison Control Centers (AAPCC). (December 31, 2015). E-cigarettes and liquid nicotine: Liquid nicotine exposures continue to concern poison control specialists. Retrieved from http://www.aapcc.org/alerts/e-cigarettes

10 Goniewicz, M. L., & Lee, L. (2015). Electronic cigarettes are a source of thirdhand exposure to nicotine. *Nicotine & Tobacco Research, 17*(2), 256-258. doi:10.1093/ntr/ntu152

11 McNeill, A., Brose, L. S., Calder, R., Hitchman, S., Hajek, P., & McRobbie, H. (2015). *E-cigarettes: an evidence update*. London, England: Public Health England.

12 Goniewicz, M. L., Knysak, J., Gawron, M., Kosmider, L., Sobczak, A., Kurek, J., . . . Benowitz, N. (2014). Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tob Control, 23*(2), 133-139. doi:10.1136/tobaccocontrol-2012-050859

13 Brandon, T. H., Goniewicz, M. L., Hanna, N. H., Hatsukami, D. K., Herbst, R. S., Hobin, J. A., . . . Warren, G. W. (2015). Electronic nicotine delivery systems: a policy statement from the American Association for Cancer Research and the American Society of Clinical Oncology. *Clin Cancer Res, 21*(3), 514-525. doi:10.1158/1078-0432.ccr-14-2544

14 Bahl, V., Lin, S., Xu, N., Davis, B., Wang, Y. H., & Talbot, P. (2012). Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. *Reprod Toxicol, 34*(4), 529-537. doi:10.1016/j.reprotox.2012.08.001

15 Initiative, T. T. (December 2015). The truth about: Electronic nicotine delivery systems. Retrieved from http://truthinitiative.org/sites/default/files/ENDS%20Fact%20Sheet%20-%201%204%2016%5B1%5D.pdf

16 McRobbie, H., Bullen, C., Hartmann-Boyce, J., & Hajek, P. (2014). Electronic cigarettes for smoking cessation and reduction. *Cochrane Database Syst Rev, 12*, Cd010216. doi:10.1002/14651858.CD010216.pub2

17 Bullen, C., Williman, J., Howe, C., Laugesen, M., McRobbie, H., Parag, V., & Walker, N. (2013). Study protocol for a randomised controlled trial of electronic cigarettes versus nicotine patch for smoking cessation. BMC Public Health, 13, 210. doi:10.1186/1471-2458-13-210

18 Caponnetto, P., Campagna, D., Cibella, F., Morjaria, J. B., Caruso, M., Russo, C., & Polosa, R. (2013). EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. PLoS One, 8(6), e66317. doi:10.1371/journal.pone.0066317

19 Schane, R. E., Ling, P. M., & Glantz, S. A. (2010). Health effects of light and intermittent smoking: A review. *Circulation, 121*(13), 1518-1522. doi:10.1161/circulationaha.109.904235

20 Bhatnagar, A., Whitsel, L. P., Ribisl, K. M., Bullen, C., Chaloupka, F., Piano, M. R., . . . Benowitz, N. (2014). Electronic cigarettes: A policy statement from the American Heart Association. *Circulation, 130*(16), 1418-1436. doi:10.1161/cir.0000000000000107

21 Crowley, R. A. (2015). Electronic nicotine delivery systems: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med, 162*(8), 583-584. doi:10.7326/m14-2481