Emerging Tobacco Products

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Office on Smoking and Health
Centers for Disease Control and Prevention

Maryland State Council on Cancer Control Cancer Conference
November 18, 2014

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease

Control and Prevention

Centers for Disease Control and Prevention

Office on Smoking and Health

Context: Burned Tobacco is Still a Problem



"The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden."

The health consequences of smoking – 50 years of progress: a report of the Surgeon General. – Atlanta, GA.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

Overview



- Who is using emerging products?
- What are health risks of emerging products?
- Which policy approaches are appropriate for emerging products?

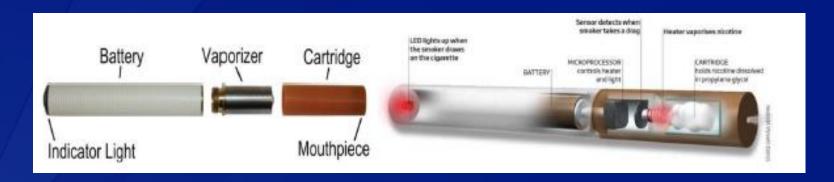
What Are ENDS?

Electronic Cigarettes and Vaping Devices

| Product | Description | Some Brands |
|---|---|----------------|
| Disposable e-cigarette | Cigarette-shaped device consisting of a | NJOY |
| | battery and a cartridge containing an atomizer | OneJoy, Aer |
| 1 | to heat a solution (with or without nicotine). | Disposable, |
| | Not rechargeable or refillable and is intended | Flavorvapes |
| | to be discarded after product stops producing | |
| | aerosol. Sometimes called an e-hookah. | |
| Rechargeable e-cigarette | Cigarette-shaped device consisting of a | Blu, |
| | battery that connects to an atomizer used to | GreenSmoke, |
| | heat a solution typically containing nicotine. | EonSmoke |
| | Often contains an element that regulates puff | |
| | duration and /or how many puffs may be | |
| | taken consecutively. | |
| Pen-style, medium-sized | Larger than a cigarette, often with a higher | Vapor King |
| rechargeable e-cigarette | capacity battery, may contain a prefilled | Storm, |
| | cartridge or a refillable cartridge (often called | Totally |
| and the same of | a clearomizer). These devices often come with | Wicked |
| | a manual switch allowing to regulate length | Tornado |
| | and frequency of puffs. | |
| | | |
| Tank-style, large-sized | Much larger than a cigarette with a higher | Volcano |
| rechargeable e-cigarette | capacity battery and typically contains a large, | Lavatube |
| | refillable cartridge. Often contains manual | |
| switches and a battery casing for customizing | | |
| | battery capacity. Can be easily modified. | |

ENDS

- Delivers nicotine-containing aerosol by heating a solution (typically propylene glycol or glycerol/ glycerin nicotine, and flavoring agents, and other additives)
- Long-term health effects of inhaled propylene glycol and glycerin are unknown



Hutzler, Paschke, Kruschinski, et al. Chemical hazards present in liquids and vapors of electronic cigarettes. Arch Toxicol 2014

ENDS Aerosol is not "Harmless Water Vapor"

- □ Nicotine: 0-36 mg/ml
- Flavorings/additives often not disclosed
- Some analyses show presence of potentially allergenic compounds such as cinnamic aldehyde (highly toxic to human embryonic stem cells)
- Overheating could lead to production of carcinogens, such as formaldehyde, acetaldehyde, acrolein

Bhatnagar et al. Electronic cigarettes: a policy statement from the American Heart Association. Circulation. 2014;130:1418-36.

Behar, Davis, Wang, et al. Identification of toxicants in cinnamon flavored electronic cigarette refill fluids. Toxicology in vitro 2014.

Hutzler, Paschke, Kruschinski, et al. Chemical hazards present in liquids and vapors of electronic cigarettes. Arch Toxicol 2014



ENDS Other Purposes

■ Some ENDS can be used to deliver other substances, like marijuana and caffeine







WARNINGS.

ENDS As Cessation Devices

Not Approved as a Cessation Device Center for Drug Evaluation and Research

In 8 years companies have not approached FDA for approval





Borderud, S. P., Li, Y., Burkhalter, J. E., Sheffer, C. E. and Ostroff, J. S. (2014), Electronic cigarette use among patients with cancer: Characteristics of electronic cigarette users and their smoking cessation outcomes. Cancer. doi: 10.1002/cncr.28811

ENDS and Cessation

Table 2. Population Studies of the Association Between E-Cigarette Use and Cessation of Conventional Cigarette Smoking

| Study | Location and Study Design | Odds of Quitting (95% CI) |
|---------------------------------------|--|------------------------------|
| Longitudinal studies | | |
| Adkison et al4 (2013) | US, UK, Canada, Australia (ITC), surveyed, 1 y apart | 0.81 (0.43-1.53)* |
| Vickerman et al ⁸⁰ (2013) | US quit-line callers from 6 states surveyed at enrollment and 7 mo later | 0.50 (0.40-0.63)† |
| Grana et al ⁷⁹ (2014) | US sample drawn from a nationally representative Internet panel, 1 y apart | 0.76 (0.36-1.60) |
| Choi and Forster ⁸¹ (2014) | Midwestern young adults, 1 y apart | 0.93 (0.19-4.63) |
| Cross-sectional study | | |
| Popova and Ling82 (2013) | US sample drawn from a nationally represented Internet panel | 0.69 (0.52-0.94) * |
| All studies | | |
| Pooled‡ | | 0.61 (0.50-0.75) |

CI indicates confidence interval; E-cigarette, electronic cigarette; and ITC, International Tobacco Control.

Grana, Benowitz, Glantz. E-cigarettes: a scientific review. Circulation 2014;129:1972-86.

^{*}Odds ratios obtained by contacting authors.

[†]Computed by authors of this report on the basis of the numbers reported.

 $[\]pm$ Estimated with a random-effects meta-analysis using Stata 12.1 metan. There was no evidence of heterogeneity (P=0.28) or evidence of publication bias with the use of a funnel plot.

Cessation: Randomized Trials

- 2 trials conducted with control arms
 - Caponnetto et al., 2013 (3 e-cigarette arms)
 - Participants not interested in quitting
 - All arms reduced cigs/day, no difference in quits
 - Bullen et al., 2013
 - Participants wanted to quit
 - Nicotine e-cigarette, zero nicotine e-cigarette, NRT patch
 - 6 month follow-up
 - 50% reduction cigs/day (57%, 45%, 41%, p=0.08)
 - Quitting 7.3%, 4.1%, 5.8% (p=0.5)

Cessation in cancer patients

Borderud et al, 2014

- Patients presenting to Memorial Sloan Kettering Cancer Center 2012-2013 screened for tobacco use, users referred to Tobacco Cessation Program (n=4504)
- Those willing to enroll in treatment program included in study (n=1074)
 - Assessed for e-cigarette use
 - Follow up at 6-12 months for cessation status (n=414)
- Findings:
 - 26% reported past 30 day use of e-cigarettes at baseline;
 92% of e-cigarette users were also smoking.
 - Quarterly prevalence increased from 10.6% to 38.5%

Borderud SP, Li Y, Burkhalter JE, Sheffer CE, Ostroff JS. Electronic cigarette use among patients with cancer: Characteristics of electronic cigarette users and their smoking cessation outcomes. Cancer. 2014 Sep 22.

Cessation in cancer patients

Continued

E-cigarette users :

- Smoked more cigarettes/day
- Reported higher nicotine dependence scores
- Had more frequent and longer duration of prior quit attempts
- No difference in quitting motivation or confidence

At follow up:

- 7-day point prevalence of smoking abstinence was no different in e-cigarette users and non-users (44.4% vs. 43.1%).
- E-cigarette users were less likely to have been abstinent for > 24 hrs
- After adjustment, e-cigarette users as likely to be smoking at follow up as non-users.

Borderud SP, Li Y, Burkhalter JE, Sheffer CE, Ostroff JS. Electronic cigarette use among patients with cancer: Characteristics of electronic cigarette users and their smoking cessation outcomes. Cancer. 2014 Sep 22.

Marketing

ENDS Advertising Expenditures across media markets

□ 2011: \$6.4 million

2012: \$18.3 million

□ 2013: >\$80 million

Celebrity spokespeople





Glamorous women







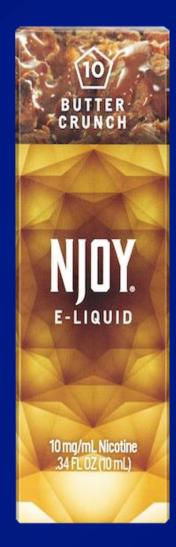
Hundreds of flavors











Sports and music events sponsorship







Use in smoke-free areas



Cheaper price

Smoking Everywhere E-Cigarette is cheaper than smoking real ci



Smoking Everywhere chemicals like tradition like a real cigarette, fe cigarette... It also may



each e-cig is

= ABOUT 3 PACKS
OF CIGARETTES



Slide courtesy Pam Ling, UCSF

Social networking

Blu e-Cigs finally launches new 'Smart Pack' for social smoking, tweakable nicotine intake



THE LATEST SUPERSMOKER

BLUETOOTH

World first! In 2007, we introduced the first electronic cigarette in the world; 7 years later, we are changing the world of electronic smoking for good with the first Supersmoker that can be used to make calls and receive via Bluetooth and play music via the built-in microphone!



Placement Next to Candy

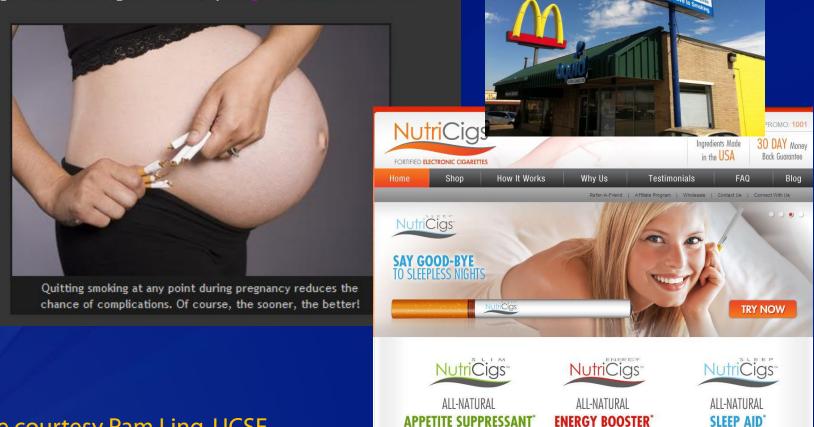


http://www.countertobacco.org/n ews/2014/09/12/njoy-brags-aboute-cigarette-placement-amongcandy



Health Claims

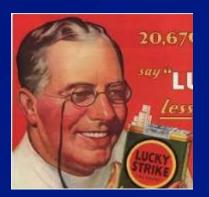
New research on the dangers of smoking to young women and their unborn babies can send chills down any woman's spine. We now have several more compelling reasons to help women realize how important it is to quit smoking or switch to e-cigarettes - ideally e-cigarettes with no micotine.



Slide courtesy Pam Ling, UCSF

Physician Endorsement









What tactics lead to youth smoking?

- Exposure to ads
- Themes in advertising that resonate with youth
- Low prices and price-reducing promotions
- Ease of access to a product
- Candy and fruit-flavored products
- Health claims
- Products that are easier to use

Preventing Tobacco Use Among Youth and Young Adults

A Report of the Surgeon General

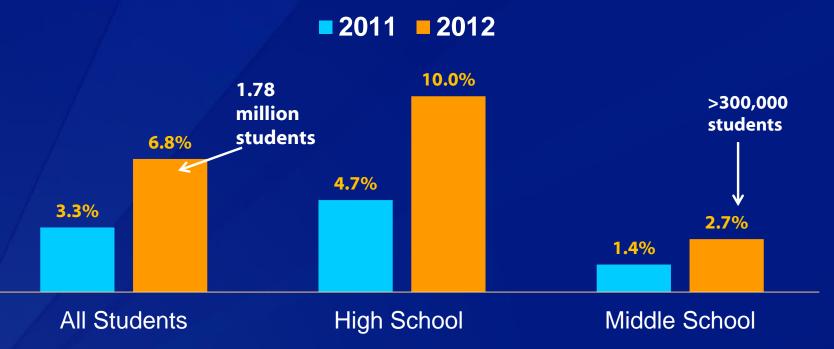


U.S. Department of Health and Human Services

Trends in Use

E-cigarette ever use more than doubled* between 2011 and 2012 among students

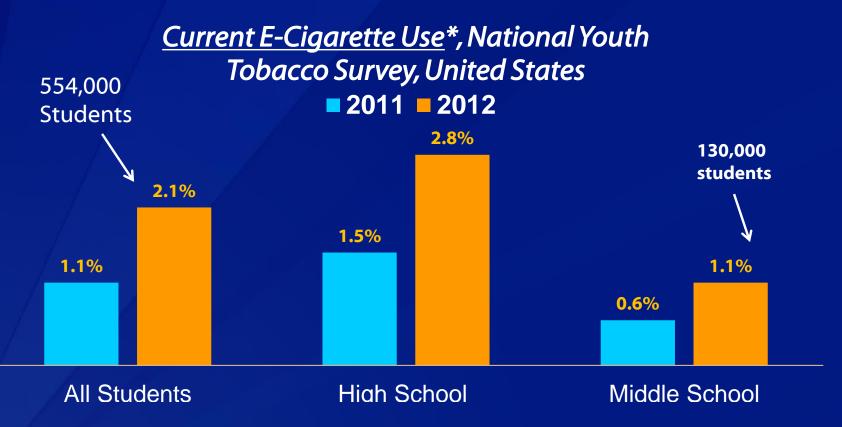
Youth E-cigarette <u>Ever Use</u>, National Youth Tobacco Survey, United States



*Statistically different (p<0.05)

Centers for Disease Control and Prevention (2013). "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012." <u>Morbidity and Mortality Weekly Report</u> **62**(35): 729-730.

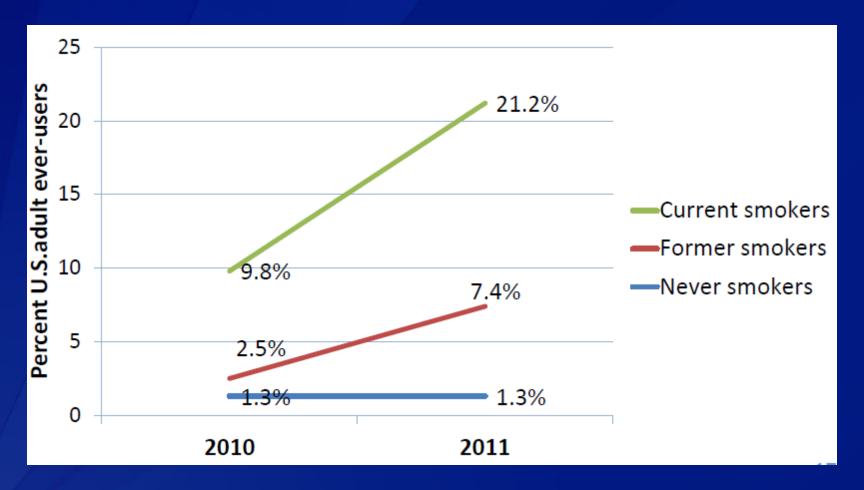
Current e-cigarette use among students more than doubled between 2011 and 2012



* Current use is defined as use on one or more days in the last 30 days

Centers for Disease Control and Prevention (2013). "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012." <u>Morbidity and Mortality Weekly Report</u> **62**(35): 729-730.

E-Cigarette Ever Use 2010-2011

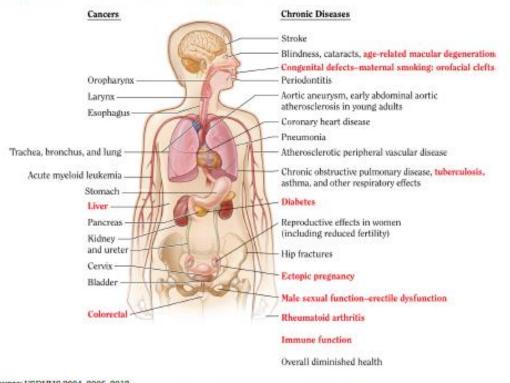


King BA, Patel R, Nguyen KH, Dube SR. Trends in Awareness and Use of Electronic Cigarettes Among U.S. Adults, 2010-2013. Nicotine Tob Res. 2014 Sep 19.

Health Effects

Surgeon General's Report

The health consequences causally linked to smoking Figure 1A



Source: USDHHS 2004, 2006, 2012.

Note: The condition in red is a new disease that has been causally linked to smoking in this report.

ENDS Potential for Harm

- Direct harm
 - Expose children and adolescents, pregnant women, and nonsmokers to 2nd hand aerosol, nicotine
 - Poisonings among users or non-users
 - Uncertain health effects of long term exposure
 - Pulmonary delivery of propylene glycol, glycerin, nicotine
 - Lower toxin burden than cigarettes, but not water vapor









Nicotine 2014 Surgeon General's Report

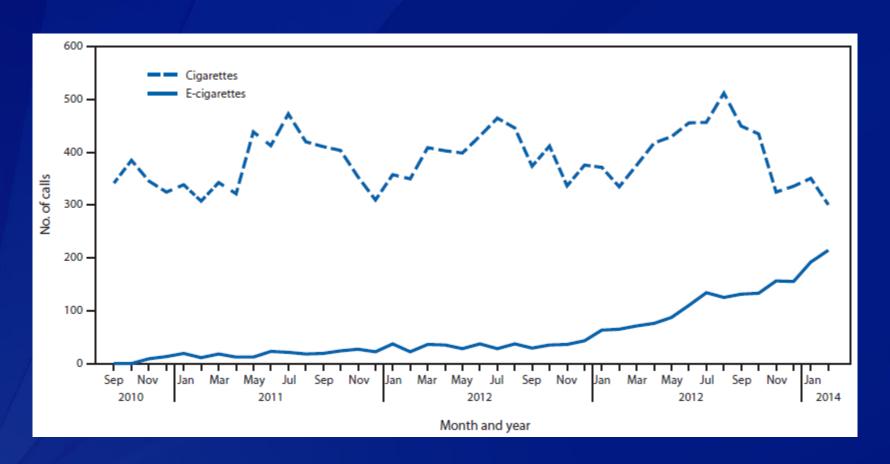
- 1. At high enough doses, nicotine causes acute toxicity
- 2. Nicotine activates multiple biological pathways through which smoking increases risk for disease
- 3. Nicotine exposure during fetal development has lasting adverse consequences for brain development



Nicotine 2014 Surgeon General's Report

- 4. Nicotine adversely affects maternal and fetal health during pregnancy, contributing to multiple adverse outcomes including preterm delivery and stillbirth
- 5. The evidence is suggestive that nicotine exposure during adolescence may have lasting adverse consequences for brain development
- 6. The evidence is inadequate to infer the presence or absence of a causal relationship between exposure to nicotine and risk for cancer.

Number of calls to poison centers for cigarette or e-cigarette exposures, by month — United States, September 2010–February 2014



ENDS Aerosol Second Hand Exposure

- Use of e-cigarettes in the home or car could expose children/nonsmokers to nicotine, as well as to propylene glycol and/or glycerin, and other toxicants, through inhaled aerosolized vapor and surface deposits.
 - Studies of third hand tobacco smoke found that smoke components, including nicotine, are deposited and reemitted from indoor surfaces over time, and can result in substantial nicotine exposure levels.
 - Nicotine from e-cigarettes also deposits on indoor surfaces, creating a reservoir of nicotine that could be ingested, absorbed transdermally, or inhaled by children.

Singer BC, Hodgson AT, Nazaroff WW (2003) Gas-phase organics in environmental tobacco smoke: 2. Exposure-relevant emission factors and indirect exposures from habitual smoking. Atmos Environ 2003:37:5551–5561. Goniewicz ML, Lee L. Electronic cigarettes are a source of thirdhand exposure to nicotine. Nicotine Tob Res e-published August 30, 2014.

ENDS Aerosol Second Hand Exposure

Cigarettes vs. e-cigarettes: Passive exposure at home measured by means of airborne marker and biomarkers *



Montse Ballbè ^{a,b,c,d,e}, Jose M. Martínez-Sánchez ^{a,c,f,*}, Xisca Sureda ^{a,c,e}, Marcela Fu ^{a,c,e}, Raúl Pérez-Ortuño ^g, José A. Pascual ^{g,h}, Esteve Saltó ^{i,j}, Esteve Fernández ^{a,b,c,e}

ARTICLE INFO

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ABSTRACT

Background: There is scarce evidence about passive exposure to the vapour released or exhaled from electronic cigarettes (e-cigarettes) under real conditions. The aim of this study is to characterise passive exposure to nicotine from e-cigarettes' vapour and conventional cigarettes' smoke at home among non-smokers under real-use conditions.

Methods: We conducted an observational study with 54 non-smoker volunteers from different homes:

Montse Ballbè, Jose M. Martínez-Sánchez, Xisca Sureda, Marcela Fu, Raúl Pérez-Ortuño, José A. Pascual, Esteve Saltó, Esteve Fernández, Cigarettes vs. e-cigarettes: Passive exposure at home measured by means of airborne marker and biomarkers, Environmental Research, Volume 135, November 2014, Pages 76-80.

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Potential Harmful Interaction with Cigarettes

- Glamorize and renormalize tobacco use
- Lead to regular use of nicotine and/or use of cigarettes in youth or adult non-smokers
- Delay quitting and/or diminish the chances a smoker will quit by leading to long-term dual use
- Discourage smokers from using proven quit methods
- Increase former smoker relapse

ENDS Potential for Benefit

Only under two circumstances:

- Are completely substituted for all combusted tobacco products in established adult smokers who would otherwise continue smoking
- Assist in rapid transition to a society with little or no use of burned products

Dual Use

- Most e-cigarette users are current or former smokers
- Smokers often begin using e-cigarettes to cut back or quit smoking and become dual users
- Cutting back on traditional cigarettes does not reduce risk of all-cause mortality
- Cutting back on traditional cigarettes does not reduce risk of CVD in a linear fashion

U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, Georgia. . U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office on Smoking and Health 2014.

U.S. Department of Health and Human Services. How Tobacco Smoke Causes Disease: The Biology and behavioral Basis for Smoking Attributable Disease. A Report of the Surgeon General. Atlanta Georgia. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office on Smoking and Health 2010.

Bjartveit and Tverday. Health Consequences of smoking 1-4 cigarettes per day. Tobacco Control 2005.

Reducing smoking without quitting

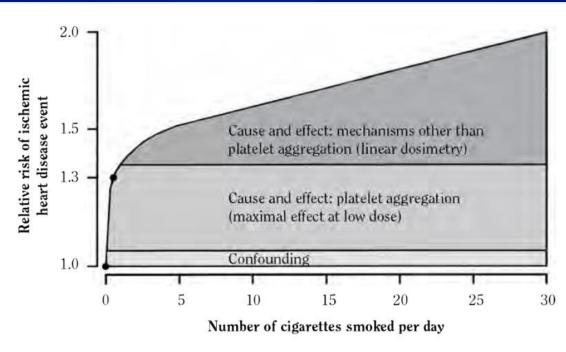


Figure 6.3 Dose-response relationship between number of cigarettes smoked per day and relative risk of ischemic heart disease

Source: Law and Wald 2003. Reprinted with permission from Elsevier, © 2003.

Note: The dose-response relationship between exposure to tobacco smoke and ischemic heart disease events is compartmentalized into separate associations attributable to confounding (difference between smokers and nonsmokers in blood pressure, body weight, blood lipids, and diet), cause and effect maximal at low dose, and cause and effect with linear dosimetry.

U.S. Department of Health and Human Services. How Tobacco Smoke Causes Disease: The Biology and behavioral Basis for Smoking Attributable Disease. A Report of the Surgeon General. Atlanta Georgia. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office on Smoking and Health 2010.

Provider knowledge and beliefs

- Statewide sample of physicians and NPs providing care to children 11-17 years of age in MN, 2013
 - Self-reported knowledge about e-cigarettes
 - 18% "nothing at all"
 - 65%"a little"
 - Very or somewhat uncomfortable talking to patients: 53%
- National survey of obstetricians/gynecologists 2012
 - 14% e- cigarettes have no adverse effects during pregnancy
 - 2/3 wanted to know more about the potential health effects of noncombustible tobacco products;
 - Only 5% believed themselves to be fully informed

Pepper, McRee, and Gilkey. Health providers' beliefs and attitudes about electronic cigarettes and preventive counseling for adolescent patients. Journal of Adolescent Health 2014.

England LJ, Anderson BL, Tong VT, et al. Screening practices and attitudes of obstetricians-gynecologists toward new and emerging tobacco products. Am J Obstet Gynecol. 2014 May 29

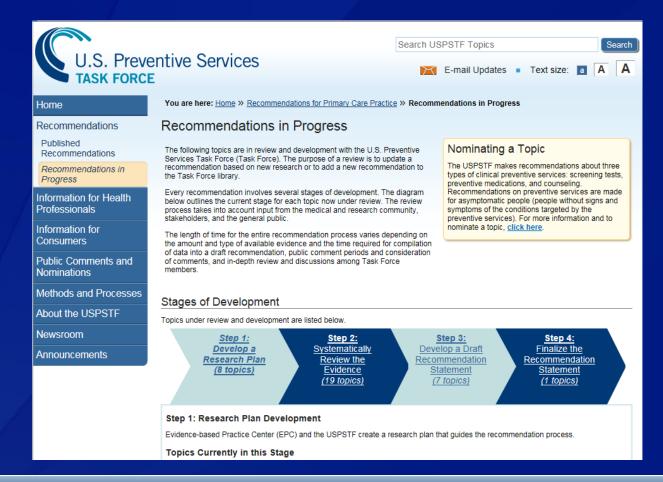
Provider knowledge and beliefs

- Random sample of NC physicians surveyed in 2013
 - 48% reported that patients sometimes or frequently ask about e-cigarettes
 - 67% indicated that e-cigarettes are a helpful smoking cessation aid
 - 35% recommend e-cigarettes to their patients
 - 13% believed that e-cigarettes are approved by the FDA for smoking cessation

Pepper, McRee, and Gilkey. Health providers' beliefs and attitudes about electronic cigarettes and preventive counseling for adolescent patients. Journal of Adolescent Health 2014.

What do existing recommendations say?

US Preventive Services Task Force



III. Contextual Questions

Contextual questions will not be systematically reviewed and are not shown in the Analytic Framework.

1. What is the efficacy and safety of electronic cigarettes as an aid for smoking cessation in current adult smokers?

North American Quitline Consortium

NAQC Issue Paper

NAQC's Issue Papers aim to provide critical knowledge on important quitline topics and guidance for decision making.

Integration of Tobacco Cessation Medications in State and Provincial Quitlines:

A Review of the Evidence and the Practice with Recommendations (2014 Update)

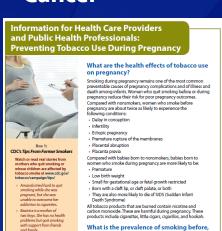
Tobacco dependence treatment professionals, including quitlines, are struggling with how to address e-cigarette use in the context of cessation. In the absence of established best practices, quitlines are creating treatment protocols for counseling and medications delivery. In the fall 2014, NAQC will publish an evidence synthesis on the topic to address these important questions.

http://c.ymcdn.com/sites/www.naquitline.org/resource/resmgr/lssue_Papers/MedicationsUpdateIssuePaperr.pdf

Other Recommendations

- **American Heart Association**
- **Forum of International Respiratory Societies** (FIRS)
- **American Lung Association**
- **CDC (Division of Reproductive Health)**
- **International Association for the Study of Lung** Cancer

OPEN



during, and after pregnancy?

Before preanancy

before pregnancy.

CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) monitors the prevalence of smoking before, during, and after

pregnancy based on a mother's self-report. In 2011, data from 24 states (representing about 40% of US live births) showed:

About 23% of women smoked during the 3 months

COMMENTARY

E-Cigarettes and Cancer Patients

K. Michael Cummings, PhD, MPH, Carolyn M. Dresler, MD, MPA, John K. Field, PhD, FRCPath, Jesme Fox, MB ChB, MBA, Ellen R, Gritz, PhD, Nasser H, Hanna, MD, Norihiko Ikeda, MD, PhD, Jacek Jassem, MD, PhD, James L. Mulshine, MD, Matthew J. Peters, MD, FRACP, Nise H. Yamaguchi, MD, PhD, Graham Warren, MD, PhD, and Caicun Zhou, MD, PhD

The increasing popularity and availability of electronic cigarettes (i.e., e-cigarettes) in many countries have promoted debate among health professionals as to what to recommend to their patients who might be struggling to stop smoking or asking about e-cigarettes. In the absence of evidence-based guidelines for using e-cigarettes for smoking cessation, some health professionals have urged caution about recommending them due to the limited evidence of their safety and efficacy, while others have argued that e-cigarettes are obviously a better alternative to continued clearette smoking and should be encouraged. The leadership of the International Association for the Study of Lung Cancer asked the Tobacco Control and Smoking Cessation Committee to formulate a statement on the use of e-cigarettes by cancer patients to help guide clinical practice. Below is this statement, which we will update periodically as new evidence

Key Words: Electronic cigarette, Smoking cessation, Lung cancer. (JThorac Oncol. 2014:9: 438-441)

into the lungs.4 As a result, most people develop a strong long-lasting addiction to cigarettes, which makes it hard to avoid the repeated exposures to harmful smoke toxins.5

The adverse effects of smoking continue after a cancer diagnosis. Continued smoking increases the risk for treatment-related complications, recurrence, the development of a second primary cancer, and mortality from both cancer-related and non-cancer-related causes. 4,6-11 The adverse effects of smoking are noted across cancer disease sites and affect treatment outcomes for surgery, chemotherapy, radiotherapy, and targeted therapy such as biological therapies. Several studies have demonstrated that smoking cessation at or following a cancer diagnosis can reverse the adverse effects of tobacco on cancer treatment outcomes. 12-15

Obviously, the best preventative measure to curb the adverse health effects associated with smoking is abstaining from smoking or tobacco cessation. Treatment-related guide lines are available to provide a foundation upon which to base

Circulation



Electronic Cigarette: A. Policy Statement From the American Heart Association Arous Blantages, Laune P. Winter, Krut M. Robal, Chris Ballen, Frank Chalougha, Mantam R. Arus Blantages, Laune P. Winter, Krut M. Robal, Chris Ballen, Frank Chalougha, Mantam R. on behalf of the American Heart Association Advocacy Coordinating Committee. Council on Cardiovascular and Stroke Nursing. Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research

Circulation. 2014;130:1418-1436, originally published online August 24, 2014; doi: 10.1161/CIR.000000000000107

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The online version of this article, along with updated information and services, is located on the World Wide Web at:

PULMONARY PERSPECTIV



Electronic Cigarettes

Position Statement of the Forum of International Respiratory Societies

ean E. Schraufnagel¹, Francesco Blasi², M. Bradley Drummond⁹, David C. L. Lam⁴, Ehsan Latif⁴, Mark J. Rosen⁶, laul Sansores⁷, and Richard Van Zyl-Smit⁸; on behalf of the Forum of International Respiratory Societies*

Amoruny, Crisci Clee, Seep, and Alloyy, Department of Modoire, University of Illinois of Chicago, Chicago, Brios: "Department incorporation yand Transporation, University of Miller, RCDS Fordacovor Cui Genral, Miller, Bully, "Funiorized Chicago, Brios: Organized Chicago, "Amoruno Chicago, "Experiment for Tockoco, Corred International Home, Apart Endorsolated and Lung Disease-See," Editorized projects SRP, Diver, Department for Tockoco, Corred International Home, Aparts Endorsolated and Lung Disease-See, Editorized, Fordament Chicago, "Amoruno Chicago, of Chicago, "Editorized Chicago, "Amoruno de Insegnizacion en Editorizacion," Editorizacional Chicago, "Amoruno de Insegnizacion en Editorizacion," Editorizacion, "Amoruno Chicago, "Amoruno de Insegnizacion en Editorizacion," Editorizacion, "Amoruno Chicago, "Amoruno de Insegnizacion en Editorizacion," Editorizacion, "Amoruno de Insegnizacion, "Editorizacion," Editorizacion, "Amoruno de Insegnizacion, "Amoruno de Insegnizacion, "Amoruno de Insegnizacion," Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion," Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion," Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion," "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion," "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion," "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion, "Amoruno del Insegnizacion," "Amoruno del Insegnizacion, "Amoruno del Inse



American Lung Association Statement on E-Cigarettes

Your Lungs Lung Disease Finding Cures Healthy Air Stop Smoking

Home > Stop Smoking > Tobacco Control Advocacy > Federal

» About Smoking » How To Quit » Tobacco Contro

Advocacy

» States & Communitie » Reports & Resources » Lung Action Network » Workplace Wellness » Tobacco-Free Colleges and Universities

The American Lung Association is very concerned about the potential health consequences of electronic cigarettes, as well as the unproven claims that they can be used to help smokers quit. There is presently no government oversight of these products and absent Food and Drug Administration (FDA) regulation, there is no way for the public health, medical community or consumers to know what chemicals are contained in e-cloarettes or what the short and long term health implications might be. In <u>extensive comments filed</u> with the FDA in <u>early August</u>, the American Lung Association called on the Obama Administration to finalize its regulation to regulate e-cigarettes by the end of 2014.

The FDA has not approved any e-cigarette as a safe or effective method to help smokers guit. When smokers are ready to guit, they should call 1-800-OUIT NOW or talk with their doctors about using one of the seven FDA-approved medications proven to be safe and effective in helping smokers quit.

Regulation

State action on ENDS

- No sales to minors (34 states)
- No use where smoking is not allowed (3 states)
- Additional promising strategies may include retailer licensing, marketing restrictions, taxation
- CDC will soon track ENDS legislation on http://www.cdc.gov/tobacco/state_system/

States and Communities Rationale for prohibiting ENDS use in all places where smoking is not allowed

- Compare to clean air, not cigarette smoke
- There are no manufacturing standards
- Potential to expose youth, pregnant women, and nonsmokers to aerosolized nicotine and other toxins
- No evidence public use is necessary for smokers to "switch" – could enable dual use

Smokeless Tobacco

Smokeless Tobacco

Types of smokeless tobacco:

- Chewing tobacco (loose leaf, plug, or twist and may come in flavors)
- Snuff (moist, dry, or in packets [U.S. snus])
- Dissolvables (lozenges, sticks, strips, orbs)











Snus

- A type of moist snuff
- Packaged in ready-to-use pouches that resemble small tea bags
- Pouch is placed between cheek or teeth and gums, does not require spitting
- Market share data unavailable











Dissolvables



| Form | Description | Market Share (in 2011) | | | | |
|----------|--|------------------------|--|--|--|--|
| Lozenges | Resemble pellets or tablets | Data unavailable | | | | |
| Orbs | Resemble small mints | Data unavailable | | | | |
| Sticks | Toothpick-like appearance | Data unavailable | | | | |
| Strips | Thin sheets like breath or medication strips | Data unavailable | | | | |

Health Effects (Smokeless)

- Nicotine addiction
- Cancer of the mouth, esophagus and pancreas
- Leukoplakia, gum disease
- Increased risk for preterm birth and stillbirth when used during pregnancy (Swedish snus)
- Nicotine poisoning in children
- May increase the risk of death from heart disease and stroke

U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, Georgia. . U.S. Department of Health and Human Services , Centers for Disease Control and Prevention. Office on Smoking and Health 2014.

Piano MR, Benowitz NL, FitzGerald GA, et al. Impact of smokeless tobacco products on cardiovascular disease: Implications for Policy, Prevention, and Treatement. A policy statement from the American Heart Association. Circulation 2010;122:1520-44.

Table 3
Mean values of total moisture, total nicotine, and pH and unprotonated nicotine using either 10 mL or 20 mL of water for each domestic oral tobacco product type.

| Tobacco type | Number of brands | Total moisture (%) Mean | (mg/g, wet) | | | | rotonated nicotine g,wet) n | |
|-------------------|------------------|-------------------------------|-------------|-------|-------|-------|-----------------------------------|--|
| | | | | 10 mL | 20 mL | 10 mL | 20 mL | |
| Dry snuff | 5 | 6.52 | 17.6 | 5.86 | 5.99 | 0.13 | 0.18 | |
| Loose leaf | 3 | 21.9 | 6.29 | 5.74 | 5.82 | 0.04 | 0.04 | |
| Twist | 3 | 15.0 | 30.6 | 5.34 | 5.39 | 0.10 | 0.11 | |
| Plug | 4 | 18.3 | 8.68 | 5.48 | 5.55 | 0.03 | 0.03 | |
| Dry snuff (pouch) | 4 | 6.18 | 11.7 | 6.94 | 6.98 | 1.00 | 1.14 | |
| Snus | 3 | 25.9 | 10.1 | 7.64 | 7.64 | 2.97 | 3.01 | |

Lawler, Stanfill, Zhang, Ashley, Watson. Chemical characterization of domestic oral products: Total nicotine, pH, unprotonated nicotine, and tobacco-specific N-nitrosamines. Food and Chemical Toxicity 2013 57:380-6.

 Table 5

 Levels of five tobacco-specific N-nitrosamines found in 29 brands representative of seven types of oral tobacco marketed in the United States.

| Tobacco product type | Brand | NAB a (ng/g, w | | | NNK (ng/g, wet) | | NNN (ng/g, wet) | | NNAL (ng/g, wet) | | Total TSNAs (ng/g, wet) | |
|----------------------|--|------------------------------------|---|---|--|--|---|--|---|---|---|--|
| | | Mean ^b | (SD) ^c | Mean | (SD) | Mean | (SD) | Mean | (SD) | Mean | (SD) | Sum |
| Plug | Days o Work | 30 | (10) | 762 | (79) | 340 | (28) | 2920 | (900) | 41 | (1.1) | 4090 |
| | Conwood Sun Cured | 69 | (10) | 1520 | (260) | 844 | (226) | 3130 | (260) | 11 | (11) | 5580 |
| | Levi Garrett | 199 | (29) | 1330 | (100) | 941 | (78) | 5140 | (90) | 140 | (49) | 7750 |
| | Taylor's Pride Plug Chew | 183 | (6.1) | 1400 | (100) | 803 | (83) | 4640 | (350) | 188 | (44) | 7210 |
| Loose Leaf | Beech-Nut Chew | 23 | (2.3) | 563 | (28) | 300 | (32) | 1640 | (60) | 21 | (0.9) | 2550 |
| | Taylor's Pride Chew | 76 | (17) | 796 | (72) | 306 | (22) | 2830 | (240) | 90 | (80) | 4100 |
| | Red Man Chew | 16 | (2.5) | 351 | (27) | 238 | (23) | 942 | (22) | 20 ^d | (23) | 1550 |
| Snus | Camel Snus Frost | 28 | (1.3) | 265 | (37) | 146 | (13) | 425 | (53) | 20 | (3.0) | 884 |
| | Camel Snus Spice | 28 | (8.5) | 259 | (35) | 84 | (22) | 369 | (59) | 21 | (12) | 761 |
| | Camel Snus Original | 26 | (10) | 251 | (32) | 140 | (58) | 389 | (111) | 20 | (14) | 826 |
| Dissolvable | Stonewall Wintergreen Stonewall Java Stonewall Natural Ariva Java Ariva Wintergreen Camel Orbs Mellow Camel Orbs Fresh | 10 11 11 7.0 8.0 15 | (0.2) (1.3) (1.5) (1.4) (0.8) (0.4) (0.4) | 218 251 247 178 176 176 194 | (9.3) (8.0) (4.0) (11) (3.8) (15) (26) | 49 63 73 54 52 147 202 | (5.4) (3.5) (6.4) (5.2) (1.4) (7.1) (4.4) | 94 103 117 74 77 189 193 | (5.8) (17) (8.5) (6.8) (14) (3.7) (8.7) | n.d. n.d. n.d. n.d. n.d. 5.6 | (-) (-) (-) (-) (-) (1.4) (1.8) | 428 448 313 313 533 612 |

Lawler, Stanfill, Zhang, Ashley, Watson. Chemical characterization of domestic oral products: Total nicotine, pH, unprotonated nicotine, and tobacco-specific N-nitrosamines. Food and Chemical Toxicity 2013 57:380-6.

- Camel and Marlboro Snus are top-selling brands
- **2006-2010, 147 samples**
- Compared with 2006
 - Pouch size increased in both brands
 - Camel snus pouches were higher in total, unprotonated nicotine and NNN /NNK by 1.9, 2.4, 3.3- fold respectively.
 - Marlboro snus pouches were higher in total, unprotonated nicotine by 2.1, 1.9, fold, respectively but 1.5-fold lower in NNN /NNK.

Stepanov I, Jensen J, Biener L, Bliss RL, Hecht SS, Hatsukami DK. Increased pouch sizes and resulting changes in the amounts of nicotine and tobacco-specific N-nitrosamines in single pouches of Camel Snus and Marlboro Snus. Nicotine Tob Res. 2012 Oct;14(10):1241-5.

- 2011, 216 samples gathered from 6 US regions, compared with samples collected in 2010
 - TSNA levels increased in Marlboro and Camel snus, and in some Camel dissolvables
 - Unprotonated nicotine levels did not change compared with 2010, but varied by region, as much as 3.2-fold

Stepanov I, Biener L, Yershova K, Nyman AL, Bliss R, Parascandola M, Hatsukami DK. Monitoring tobacco-specific N-nitrosamines and nicotine in novel smokeless tobacco products: findings from round II of the new product watch. Nicotine Tob Res. 2014 Aug;16(8):1070-8.

TobaccoToday

home archives about

← The C-Store Pipe-Tobacco Opportunity

It's Official: Big Pharma is Lobbying Against Electronic Cigarettes- Dr.

Michael Siegel →

Swedish Match submits 100,000+ page Modified Risk Tobacco Product (MRTP) application to FDA to truthfully market General Snus to smokers as less hazardous alternative to cigarettes

June 14th, 2014 | Current Issues, Regulations: FDA etc., Snus, Snuff & Alternative Products in US Markets, tobacco, Tobacco Harm Reduction | ECigInsider

RICHMOND, Va. — **Copyright 2014 The Associated Press**- Smokeless tobacco maker Swedish Match is asking the Food and Drug Administration to certify its General-branded pouches of tobacco as less harmful than cigarettes.

The company with its North American headquarters in Richmond, Virginia, is filing an application with the FDA to approve the snus (pronounced "snoose") products as "modified risk."

http://www.tobaccotoday.info/2014/06/14/swedish-match-submits-100000-page-modified-risk-tobacco-product-mrtp-application-to-fda-to-truthfully-market-general-snus-to-smokers-as-less-hazardous-alternative-to-cigarettes/

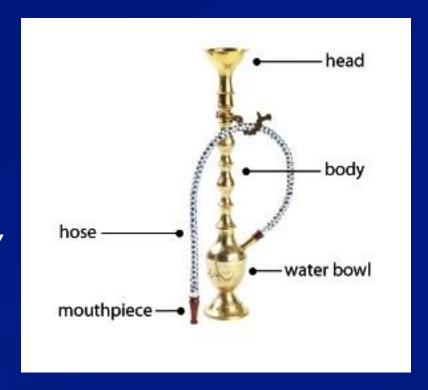
Dissolvables



http://www.journalnow.com/business/business_news/local/article_9d001b58-f9f2-11e2-8fad-0019bb30f31a.html

Hookah

- Water pipes that are used to smoke specially made tobacco that comes in different flavors, such as apple, mint, cherry, chocolate, coconut, licorice, cappuccino
- Also called narghile, argileh, shisha, hubble-bubble, and goza
- Often smoked in groups, mouth piece shared.



Hookah

- Many users think it is less harmful, hookah smoking has many of the same health risks as cigarette smoking (cancer, cardiovascular disease)
- Hookahs produce high levels of carcinogens and carbon monoxide
- An hour-long hookah session can involve
 200 puffs, and 90,000 ml of smoke inhaled,
 compared with 20 puffs from smoking a single

compared with 20 puffs from smoking a single cigarette, or 500 ml smoke



Hookah

High school seniors

1 of 5 boys, 1 of 6 girls used hookah in the last year

College students

22-40% used in last year

Adults

 18.2% of 18-24 year olds use everyday, some days, or rarely



1. Prevalence and Correlates of Smoking and Cessation-Related Behavior among Survivors of Ten Cancers: Findings from a Nation-Wide Survey Nine Years after Diagnosis, Cancer Epidemiol Biomarkers Prev, Published online Aug 6, 2014 doi: 10.1158/1055-9965.EPI-14-0046

College Students

- Study of 2 universities in the Southeast, 2000 students
- Marijuana (19.2%) and hookah (16.4%) were the most commonly used products in the last month
- **□** E-cigarettes were lower (4.5%)
- There were high rates of concurrent use, esp. in ecigarette users
- Marijuana was the most positively perceived product followed by hookah and e-cigarettes

Berg, Stratton, Schauer et al. Perceived Harm, Addictiveness, and Social Acceptability of Tobacco Products and Marijuana Among Young Adults: Marijuana, Hookah, and Electronic Cigarettes Win. Substance use and misuse 2014

PERCEPTIONS OF TOBACCO PRODUCTS AND MARIJUANA

TABLE 2. Concurrent use of tobacco products and marijuana

| Product | Cigarettes $n = 315 16.0\%$ | Cigar products $n = 293 14.9\%$ | Smokeless tobacco $n = 51 \ 2.6\%$ | Hookah $n = 322 \ 16.4\%$ | Electronic cigarettes $n = 884.5\%$ | Marijuana n = 377 19.2% |
|-----------------------|-----------------------------|---------------------------------|------------------------------------|---------------------------|-------------------------------------|----------------------------|
| Cigarettes | _ | 43.3% | 56.9% | 41.0% | 71.6% | 38.7% |
| Cigar products | 40.3% | _ | 54.9% | 39.8% | 46.6% | 47.5% |
| Smokeless tobacco | 9.2% | 9.6% | _ | 7.1% | 17.0% | 5.0% |
| Hookah | 41.9% | 43.7% | 45.1% | _ | 54.5% | 41.1% |
| Electronic cigarettes | 20.0% | 14.0% | 29.4% | 14.9% | _ | 12.5% |
| Marijuana | 46.3% | 61.1% | 37.3% | 48.1% | 53.4% | _ |

Note: All chi-squared p-values < 0.001. To interpret, among users of column heading, % also using row heading in the past 30 days. Example: Of the 315 cigarette smokers, 40.3% also smoked cigar products in the past 30 days.

5

FDA Center for Tobacco Products

Proposed newly "deemed" products would include electronic cigarettes, cigars, pipe tobacco, certain dissolvables that are not "smokeless tobacco," gels, and waterpipe tobacco. Once the proposed rule becomes final, FDA can use regulatory tools, such as age restrictions and requiring scientific review of new tobacco products and claims to reduce tobaccorelated disease and death

FDA Regulation of e-Cigarettes

Only e-cigarettes that are marketed for therapeutic purposes are currently regulated by the FDA Center for Drug Evaluation and Research (CDER). Currently, the FDA Center for Tobacco Products (CTP) regulates

- · cigarettes,
- · cigarette tobacco,
- · roll-your-own tobacco, and
- smokeless tobacco.

FDA has issued a proposed rule that would extend the agency's tobacco authority to cover additional products that meet the legal definition of a tobacco product, such as e-cigarettes. FDA's Extending Authorities to Additional Tobacco Products webpage offers more information on the proposed rule.

For more information on current regulation:

- Tobacco Product Regulation
- · Nicotine-Containing Products

Key Take Away Points



Summary

- ✓ ENDS are not "safe"
- Unregulated sale and distribution driving demand
- Cessation claims are unproven
- Potential for harm and benefit depends on the context of combusted tobacco products
- Dual use/delayed quitting is a major concern

Key Take Away Points



- Emerging smokeless products are not without risk and their use can result in exposure to high levels of nicotine and carcinogens
- Hookah is used less frequently than cigarettes, but a single hookah session can result in high levels of exposure to carcinogens and carbon monoxide
- Many young adults who use hookah use other tobacco products concurrently

Contact

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CDC Office on Smoking and Health



www.cdc.gov/tobacco









Resources

USPHSTF

- http://www.uspreventiveservicestaskforce.org/
- U.S. Preventive Services
 TASK FORCE

Smoking Cessation For

Pregnancy And Beyond: A Virtual Clinic

come to Smoking Cessation for Pregnancy and ond. Now freely available thanks to a generous rd from the CDC.

- http://www.fda.gov/TobaccoProducts/default.htm
- http://www.tobaccofreekids.org/tobacco_unfiltered/tag/e-

<u>cigarettes</u>

CDC

- http://www.cdc.gov/tobacco/campaign/tips/
- http://www.cdc.gov/reproductivehealth/TobaccoUsePregnancy/Providers.html

Online training

- http://iml.dartmouth.edu/education/dsr/
- https://www.smokingcessationandpregnancy.org/



Resources

Electronic cigarettes

- http://www.fda.gov/TobaccoProducts/default.htm
- http://www.tobaccofreekids.org/tobacco_unfiltered/tag/ecigarettes
- http://www.cdc.gov/reproductivehealth/TobaccoUsePregnancy/Providers.html
- http://publichealthlawcenter.org/programs/tobacco-control-legalconsortium







