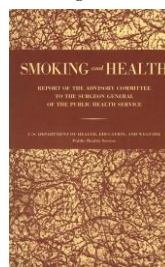


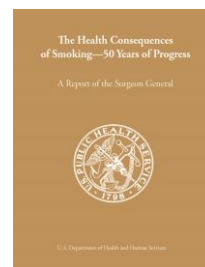
*The New Landscape of Tobacco Products: E-cigarettes and Other Emerging Nicotine Delivery Devices*

Jim D. Martin, MS  
 Director of Policy and Programs  
 Tobacco Prevention and Control Branch  
 Chronic Disease and Injury Section  
 Division of Public Health  
 NC Department of Health and Human Services  
 5-24-2017

**The Health Consequences of Smoking:  
 50 Years of Progress**  
 A Report of the Surgeon General



1964



2014

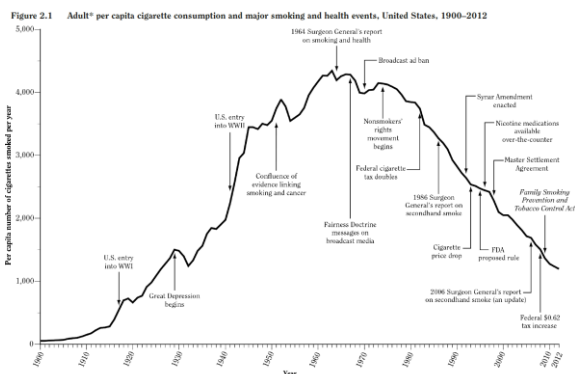


Figure 2.1 Adult\* per capita cigarette consumption and major smoking and health events, United States, 1900-2012  
 Sources: Adapted from Warner 1985 with permission from Massachusetts Medical Society, ©1985; U.S. Department of Health and Human Services 1989; Creek et al. 1994; U.S. Department of Agriculture 2000; U.S. Census Bureau 2013; U.S. Department of the Treasury 2013.  
 Adults ≥18 years of age as reported annually by the Census Bureau.

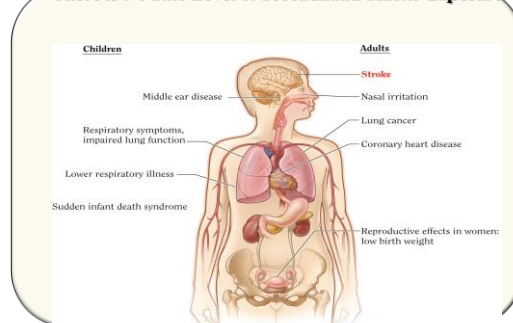
*Key Findings from the 2014 Surgeon General's Report*

- Tobacco use is the number one preventable cause of premature death and disability.
- Smoking causes heart disease, stroke, cancer and lung diseases (including **asthma**, emphysema, bronchitis, and chronic airway obstruction) and diabetes.
- For every person who dies from a smoking-related disease, 30 more people suffer with at least one serious illness from smoking.

*Key Findings from the 2014 Surgeon General's Report*

- ▶ Secondhand smoke (SHS) causes premature death and disease in non-smokers.
- ▶ Secondhand smoke contains more than 7,000 chemicals.
- ▶ Children exposed to SHS are at an increased risk for acute respiratory infection, ear problems and **asthma**.

**There is No Safe Level of Secondhand Smoke Exposure**



Source: 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...

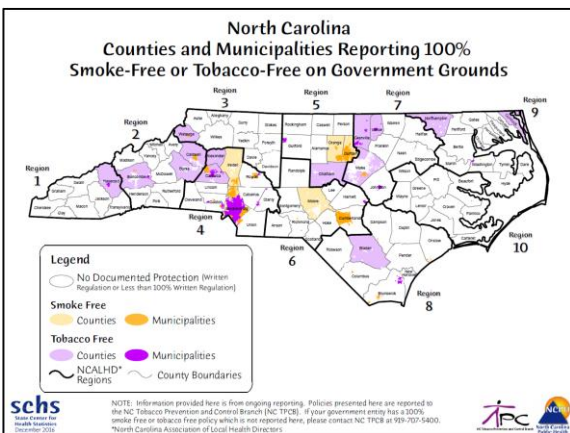
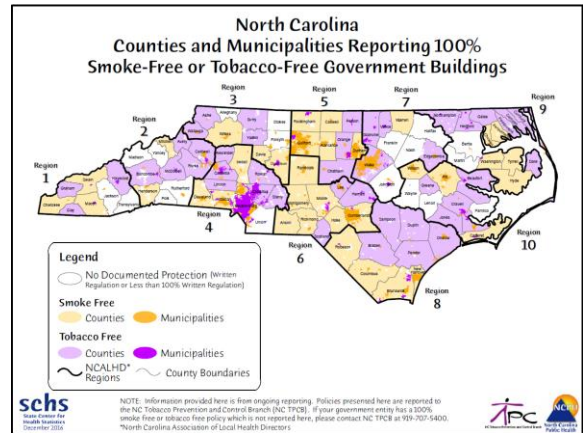
## Secondhand Smoke and Asthma

- Secondhand smoke exposure causes children who already have asthma to experience more frequent and severe attacks.
- The EPA estimates that 200,000 to 1,000,000 asthmatic children have their condition worsened by exposure to secondhand smoke.
- Secondhand smoke exposure is associated with increased respiratory-related school absenteeism among children, especially those with asthma.

Source: Americans for Nonsmokers' Rights, 2015

## Preventing Asthma Attacks

- Eliminate Exposure to Secondhand Smoke
  - Public Areas (such as restaurants and other public places)
  - Schools and Daycare Centers
  - Colleges
  - Multi-unit housing



## Progress in Tobacco-free Environments in North Carolina

- Hospitals**  
All 127 acute care hospitals in North Carolina have a 100% tobacco-free campus wide policy.  
- Community hospital behavioral health units means more consumers treated in tobacco-free environments
- State Operated Healthcare Facilities**  
All 14 State Operated Mental Health, Developmental, Alcohol and Drug Abuse Treatment Centers have a 100% tobacco-free campus wide policy.
- Public Schools K-12**  
State law requires local boards of education to prohibit the use of tobacco at all times.
- Community Colleges and Private/Independent Colleges**  
Community colleges and private/independent colleges and universities may prohibit smoking and all tobacco product use in their buildings and on their grounds.
- UNC University System**  
State law authorizes the sixteen campuses of the UNC system to prohibit smoking on their grounds- within 100 linear feet of a building; UNC and ECU Medical Care Facilities authorized to prohibit smoking on all grounds.
- Prisons**  
State law prohibits any person from using tobacco products inside or on the grounds of a state correctional facility.



## Tips from Former Smokers: Real People, Real Stories

### Terrie's Story

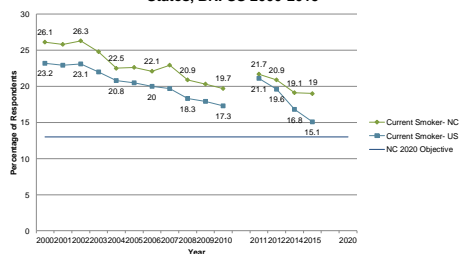


### Amanda's Story



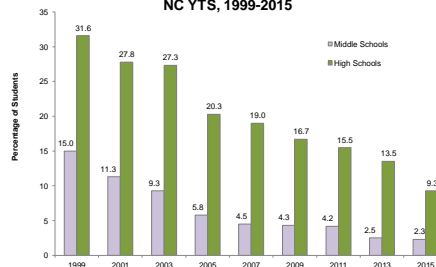
- ◆ An evidence-based telephone tobacco treatment service
- ◆ Consists of four treatment sessions
  - Special 10 treatment sessions and protocol for pregnant women
- ◆ Highly trained, professional Quit Coaches
- ◆ Available free to all North Carolina residents
- ◆ Accessible 24 hours a day, 7 days a week
- ◆ English, Spanish and interpretation service
- ◆ Integrated with an interactive web based tobacco treatment program

Percentage of Smokers in North Carolina and United States, BRFSS 2000-2015



Note: The BRFSS methodology changed in 2011 so we can not compare data from 2000-2010 to 2011-2015. We have showed this change by including a break in the trend line.  
Source: North Carolina Department of Health and Human Services, Division of Public Health, State Center for Health Statistics, North Carolina Behavioral Risk Factor Surveillance System (NC BRFSS), 2000-2015. <http://www.ahrq.state.nc.us/ncbrfss/>

NC Middle & High School Current\* Smoking Prevalence: NC YTS, 1999-2015



\*Current use is defined as using 1+ days of past 30 days.

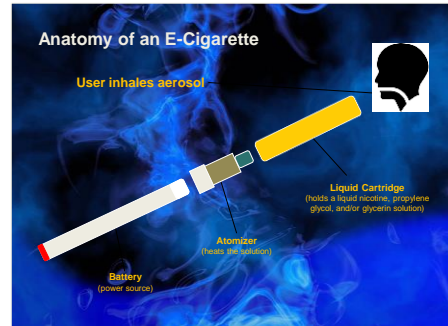
## Changing Landscape of Tobacco Products

## Electronic Cigarettes (Also Known as Electronic Nicotine Delivery Systems (ENDS) or E-cigarettes)

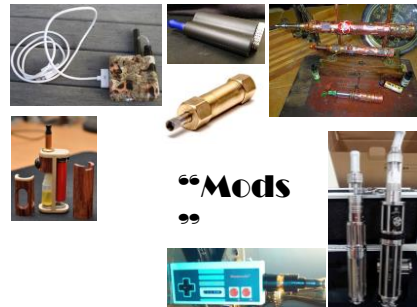
Image Source: Wake Forest Baptist Medical Center

### Terms for Various Electronic Cigarettes

- Cigalikes
- E-cigars
- E-pipes
- E-Hookah
- Vape Pens
- Hookah Pens
- Personal Vaporizers
- Mods



### Types of E-Cigarettes



### Hookah Pens “Cooler and Better”



### E-liquid

- Nicotine derived from tobacco; amounts vary by product (0-36 mg/ml)
- Solvent propylene glycol, vegetable glycerin
- Flavorings
- Other additives
  - Sweeteners

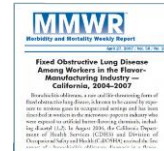
## Flavors and Brands

- Over 460 brands (Zhu et al., 2014)
- 7,764 unique flavors



Image Sources:  
www.ecigaretterevue.com

**Flavors**  
Flavors, including many with diacetyl, are associated with respiratory irritation and disease.



Employee wearing protective gear



MMWR, 2007. Apr 27:56(16);  
Farsalinos, K.E., et al (2015). Nicotine & Tobacco Research;  
Tierney, P. A., et al (2015). Tobacco Control

## Nicotine Delivery

- Potential to deliver nicotine directly to pulmonary system for rapid absorption
- Newer products can deliver as much, or more nicotine than conventional cigarettes (Talih et al., 2014)
- Nicotine delivery varies by
  - Product design (voltage, heating element, nicotine solution)
  - Puffing behavior (volume, velocity, intervals)

## It's an Aerosol, Not a Vapor

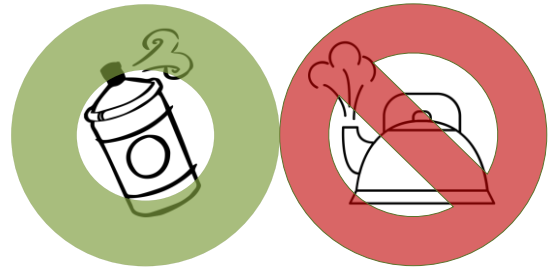


Image Credit: via theounproject.com

## What's in the Aerosol?

- Perception of harmlessness "water vapor"
- Nicotine
- Several harmful toxins have been found, but at levels lower than conventional cigarettes; depends largely on the device voltage
- Fine and ultrafine particles delivered are *similar* to conventional cigarettes— some tobacco specific carcinogens have been documented
- Propylene glycol--can cause respiratory illness (Grana et al., 2014)
- Heavy Metals have been documented: tin, silver, iron, nickel aluminum, sodium, chromium, copper, magnesium, manganese, lead, potassium and silicate nanoparticles

## Emissions from E-cigarettes

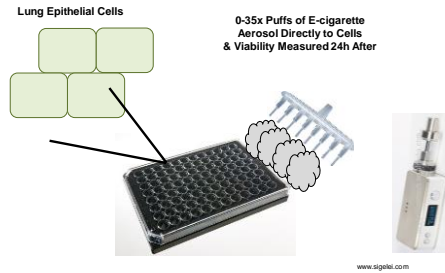


Research at UNC-CH School of Medicine (TCORS)

Methods: E-cigarette Aerosol Exposures

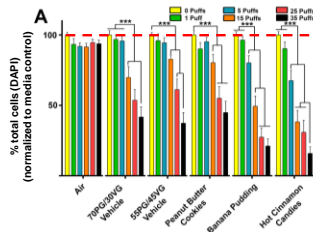
Secondhand Aerosol

- Exhaled air contains (Schripp et al., 2012 and RTI 2015)
  - Nicotine
  - Ultrafine particles—inhaled deep in the lungs, and may cause cancer
  - Propylene glycol-- can cause respiratory illness (Grana et al., 2014)
  - Artificial flavorings
  - Heavy metals



32

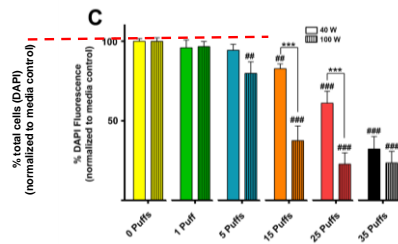
Cell screening data after flavored e-liquid aerosol exposures show similar flavor-dependent dose-dependent decreases in cell viability ≥ 5 puffs



33

Roswell, TR, et al. (2017).Am J Physiol Lung/ Accepted

Increasing e-cigarette device power (W) increases amount of aerosol produced in each puff, which speeds up negative effects of PG/VG aerosol



34

Roswell, TR, et al. (2017).Am J Physiol Lung/ Accepted

2016 Report of the Surgeon General  
KEY FINDINGS  
7 Major Conclusions

**Major Conclusions**

1. E-cigarettes are a rapidly emerging and diversified product class. These devices typically deliver nicotine, flavonoids, and other additives to users in an artificial aerosol. These additives are related to a variety of names, including “cigs,” “tobacco,” “fruit,” “mint,” “tiramisu,” “candy,” and “fresh e-cigarettes.”
2. E-cigarette use among youth and young adults has become a public health concern. In 2014, current use of e-cigarettes by young adults 18–29 years of age surpassed that of adults 25 years of age and older.
3. E-cigarettes are now the most commonly used tobacco product among youth, increasing conventional cigarette use in 2014. E-cigarettes use is strongly associated with the use of other tobacco products among youth and young adults, including tobacco.
4. The use of products containing nicotine poses dangers to youth, pregnant women, and babies. The use of products containing nicotine to other forms among youth, including in e-cigarettes, is unsafe.
5. E-cigarettes are not harmless. They can contain harmful and potentially harmful constituents, including nicotine. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain.
6. E-cigarettes are marketed by promoting flavor and using a wide variety of media delivery and approaches that have been used in the past for non-tobacco conventional tobacco products for youth and young adults.
7. Action can be taken at the national, state, local, and territorial levels to address e-cigarette use among youth and young adults. Action could include increasing e-cigarette use surveillance activities, providing access to e-cigarettes for youth, and for policies, retail licenses, regulation of e-cigarette marketing directed at youth, and education on factors targeting youth and young adults.

E-Cigarette Use Among Youth and Young Adults  
A Report of the Surgeon General

**Major Conclusion #1**

E-cigarettes are a rapidly emerging and diversified product class



Major Conclusion #2

E-cigarette use among youth and young adults has become a public health concern.

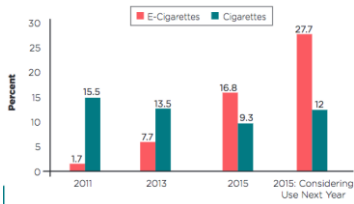


Major Conclusion #3

"E-cigarettes are now the **most commonly used tobacco product among youth**, surpassing conventional cigarettes in 2014.

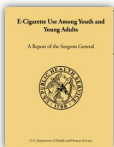
E-cigarette use is **strongly associated with the use of other tobacco products** among youth and young adults, including combustible tobacco products."

Current E-Cigarette Use - NC High School Students: NC YTS, 2011-2015



*Among Youth, E-cigarette Use May Lead to Conventional Cigarette Use*

U.S. adolescents and young adults who had never smoked, but used e-cigarettes at baseline were 8.3 times more likely to progress to cigarette smoking after 1 year than nonusers of e-cigarettes



Major Conclusion #4

The use of products containing **nicotine poses dangers to youth, pregnant women, and fetuses**. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.



Major Conclusion #5



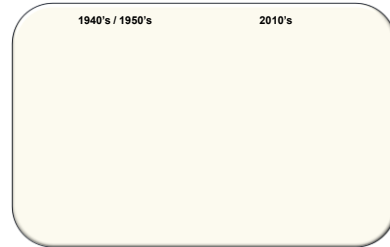
"E-cigarette aerosol is **not harmless**. It can contain harmful and potentially harmful constituents, including **nicotine, ultrafine particles, heavy metals and volatile organic compounds**. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain."



## Major Conclusion #6

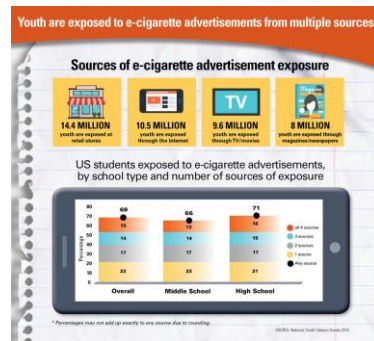
“E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults.”

## E-cigarette Marketing Uses Traditional Tactics



Source: Centers for Disease Control and Prevention, 2016

## A Majority of Current Youth E-cigarette Users Report Using Flavored E-cigarettes



## E-Cigarettes Potential for Harm if:



## Dual Users



• A majority of adult e-cigarette users also smoke conventional cigarettes.



<http://dx.doi.org/10.15585/mmwr.mm65.42.a7>



## E-cigarettes - Poisoning



## Explosions and Fires



### Major Conclusion #1

"Action can be taken at the national, state, local, tribal, and territorial levels to address e-cigarette use among youth and young adults.

- Actions could include:
- incorporating e-cigarettes into smoke-free policies,
  - preventing access to e-cigarettes by youth,
  - price and tax policies,
  - retail licensure,
  - regulation of e-cigarette marketing likely to attract youth, and
  - educational initiatives targeting youth and young adults."

### Family Smoking Prevention and Tobacco Control Act of 2009

Provides FDA authority to regulate:

- cigarettes,
- cigarette tobacco,
- roll-your-own tobacco,
- smokeless tobacco, and
- any other tobacco products that the Agency by regulation deems to be subject to the law.



### 2015 FDA Deeming of Tobacco Products Became Effective August 2016

The new rule includes currently marketed products:








### FDA Final Rule

The rule includes the following provisions:

- Prohibits sales to children under 18 (retail and online), requires age verification for all sales and provides for federal enforcement and penalties against retailers and online vendors who sell to minors
- Restricts vending machines to adult-only facilities
- Prohibits free samples

**FDA Final Rule New Manufacturer Requirements:**

	Registering manufacturing establishments and providing product listings to the FDA		Reporting ingredients, and harmful and potentially harmful constituents
	Requiring premarket review and authorization of new tobacco products by the FDA		Placing health warnings on product packages and advertisements
			
Not marketing newly deemed tobacco products (including e-cigarettes) with modified risk claims unless authorized by the FDA.			

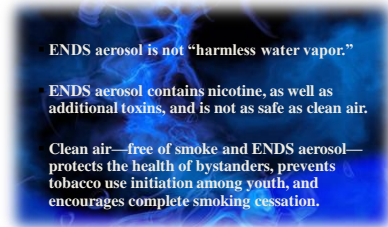
**The FDA Final does not include:**

- Banning flavorings in e-cigarettes that may appeal to youth
- Restricting marketing that appeals to kids

**Current Federal, State and Local Government Regulations on E-Cigarettes**

- Implications for Community/Clinical Connections

**Evidence-Based Interventions are Key: Protect Clean Indoor Air Standards**



ENDS aerosol is not “harmless water vapor.”

ENDS aerosol contains nicotine, as well as additional toxins, and is not as safe as clean air.

Clean air—free of smoke and ENDS aerosol—protects the health of bystanders, prevents tobacco use initiation among youth, and encourages complete smoking cessation.

**New Signage**



**NC Counties and Municipalities that Specifically Prohibit Use of E-Cigarettes**

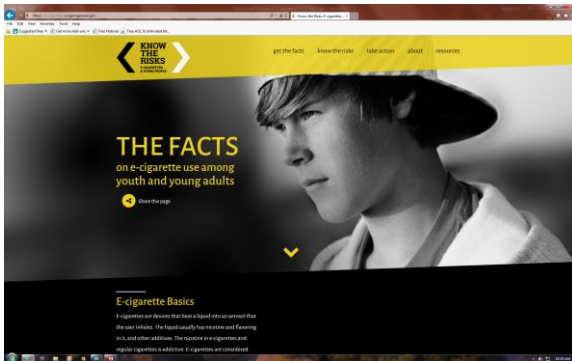
**Counties (32)**

- Catawba
- Beaufort
- New Hanover
- Transylvania
- Hyde
- Pender
- Rutherford
- Pitt
- Mecklenburg
- Haywood
- Granville
- Vance
- Clay
- Henderson
- Chatham
- Person
- Bladen
- Durham
- Surry
- Dare
- Alamance
- Orange
- Iredell
- Lee
- Wake
- Yadkin
- Cabarrus
- Brunswick
- Tyrell
- Wilson
- Wilkes
- Bertie

**Municipalities (35)**

- Brookford
- Chapel Hill
- Catawba
- Saluda
- Wilmington
- Waynesville
- Henderson
- Butler
- Canton
- Creedmoor
- Kittrell
- Lewis
- Middleburg
- Oxford
- Stem
- Stall
- Rowboro
- Duck
- Kill Devil Hills
- Kitty Hawk
- Manteo
- Nags Head
- Southern Shores
- Asheville
- Elon
- Durham
- Granite Falls
- Rolesville
- Kannapolis
- Hayesville
- Durn
- Bessemer City
- North Wilkesboro
- Ronda
- Wilkesboro

Source: Information compiled from ongoing reporting and documentation collected by the NC Tobacco Prevention and Control Branch. Updated May 2017.



## Cessation

- There are 7 products approved by the FDA for cessation...these products have gone through clinical trials and have shown that when used in combination with cessation counseling double the chances for cessation
- E-cigarettes are not approved as a cessation device
  - FDA has sent warning letters to e-cigarette manufacturers regarding false cessation claims
- E-cigarettes are commonly used along with cigarettes - Dual users (undermining true cessation attempts)



[www.quitlineinc.com](http://www.quitlineinc.com)



## 2017 Legislative Update

- HB 276 Strengthen Youth Tobacco Prevention/Funds
- QuitlineNC Funds
- Budget Picture

## Rationale to Regulate E-cigarettes

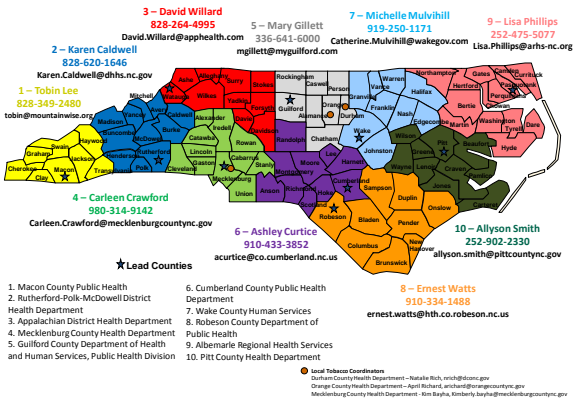
- If treated differently, implies acceptance of addiction to nicotine delivery products, complicating the health message
- Permitting e-cigarettes encourages dual usage (cigarettes and e-cigarettes) in lieu of cessation in some individuals who might otherwise quit
- Exposes children, adolescents and pregnant women to nicotine and other toxins in e-cigarette aerosol
- Creates potential confusion regarding rules and mixed health message

## Summary



- ✓ E-cigarettes are now the most commonly used tobacco product among U.S. youth.
- ✓ Youth use of tobacco products in any form, including e-cigarettes, is **unsafe**.
- ✓ Based on current findings, researchers believe that e-cigarettes could increase users' risk for oral cancer.
- ✓ E-cigarettes are not currently an FDA-approved quit aid.
- ✓ The tobacco product landscape continues to diversify, and it's critical to modernize tobacco control strategies to adapt to these changes.
- ✓ Multiple different stakeholders can take action to implement policies and strategies that can clearly reduce the public health threat posed by tobacco use, including e-cigarettes.

**Tobacco Prevention and Control Branch (TPCB) Funds Regions 2015-2020**



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