

Business & Professions Subcommittee

Wednesday, October 23, 2019
12:30 PM – 2:30 PM
Webster Hall (212 Knott)

Meeting Packet

Jose Oliva
Speaker

Heather Fitzenhagen
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Business & Professions Subcommittee

Start Date and Time:	Wednesday, October 23, 2019 12:30 pm
End Date and Time:	Wednesday, October 23, 2019 02:30 pm
Location:	Webster Hall (212 Knott)
Duration:	2.00 hrs

Discussion of Vaping, Nicotine Dispensing Devises and Florida's Regulation of Tobacco Products

NOTICE FINALIZED on 10/16/2019 4:03PM by Rigas.Amanda

The Florida House of Representatives

Commerce Committee

Business & Professions Subcommittee

Jose Oliva
Speaker

Heather Fitzenhagen
Chair

AGENDA

Wednesday, October 23, 2019
Webster Hall (212 Knott)
12:30 PM – 2:30 PM

I. Call to Order & Roll Call

II. Welcoming Remarks

III. Discussion of Vaping, Nicotine Dispensing Devises and Florida's Regulation of Tobacco Products

IV. Adjournment

303 House Office Building, 402 South Monroe Street, Tallahassee, Florida 32399-1300
(850) 717-4873 Fax: (850) 413-0419

Public Health Impact of
E-Cigarette/Vaping Use

Department of Health

Public Health Impact of E-Cigarette/Vaping Use



Department of Health

Scott A. Rivkees, MD
State Surgeon General
Florida Department of Health

Florida Department of Health

The role of the Department of Health is to:

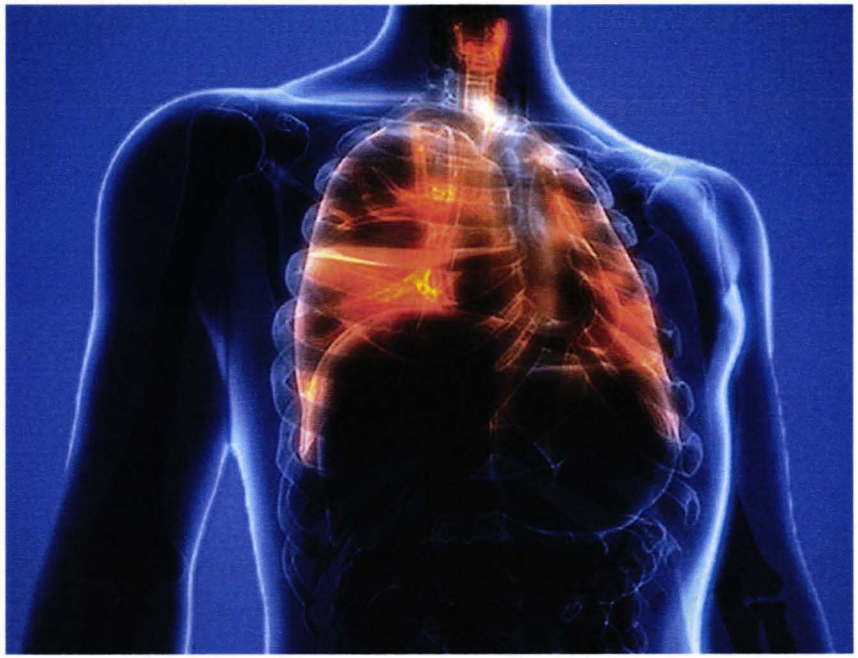
- Identify, diagnose, and conduct surveillance of diseases and health conditions in the state and accumulate the health statistics necessary to establish trends
- Implement interventions that prevent or limit the impact or spread of diseases and health conditions
- Collect, manage, and analyze vital statistics and other health data to inform the public and formulate public health policy and planning

Department of Health

Vaping is the act of inhaling and exhaling an aerosol, often referred to as vapor, which is produced by an e-cigarette or similar device.

The term is used because e-cigarettes do not produce tobacco smoke, but rather an aerosol, often mistaken for water vapor, that actually consists of fine particles.

Many of these particles contain varying amounts of toxic chemicals, which have been linked to cancer, as well as respiratory and heart disease.



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

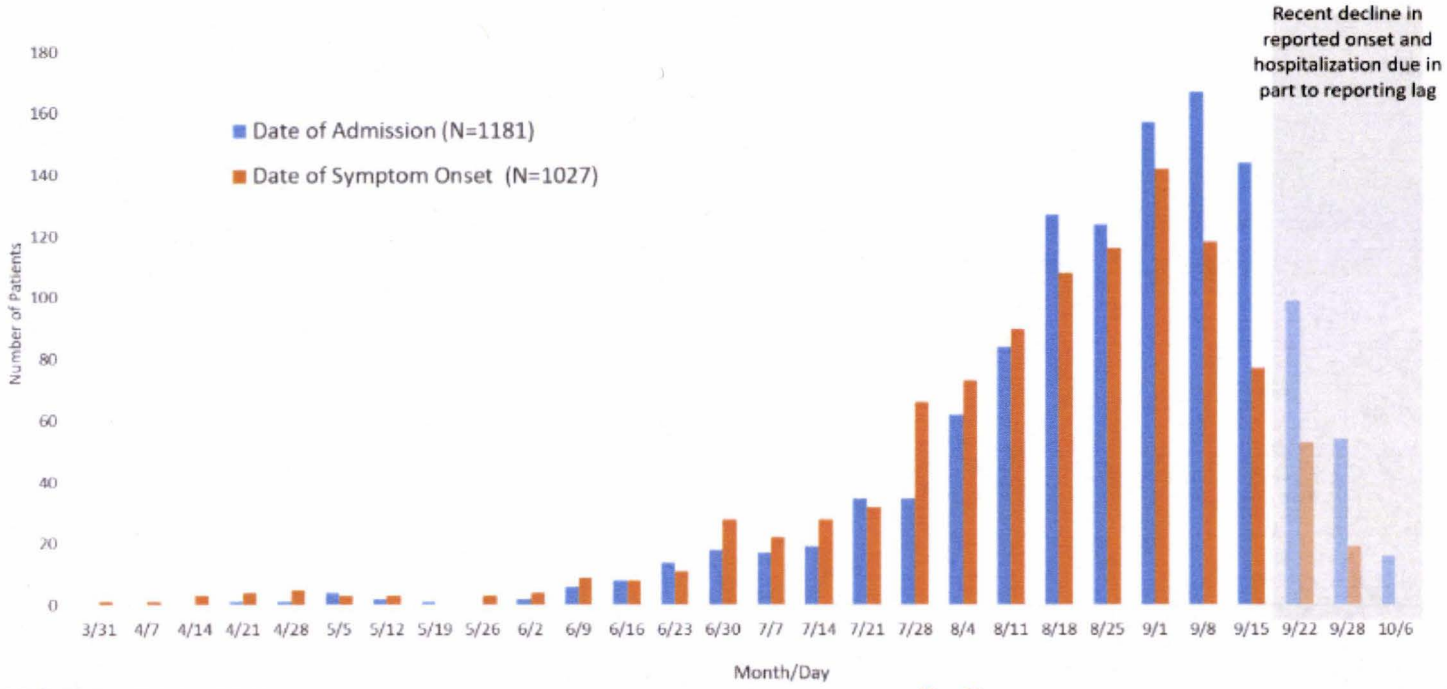
Department of Health

- Most e-cigarette devices have a battery, a heating element, and a receptacle to hold a liquid.
- The devices heat a liquid – typically containing nicotine, flavorings, and other chemicals – and produce an aerosol.
- E-cigarettes are known by many different names. They are sometimes called "e-cigs," "mods," "vape pens," "vapes," and "tank systems."
- They are also called by their brand names, such as JUUL.



Department of Health

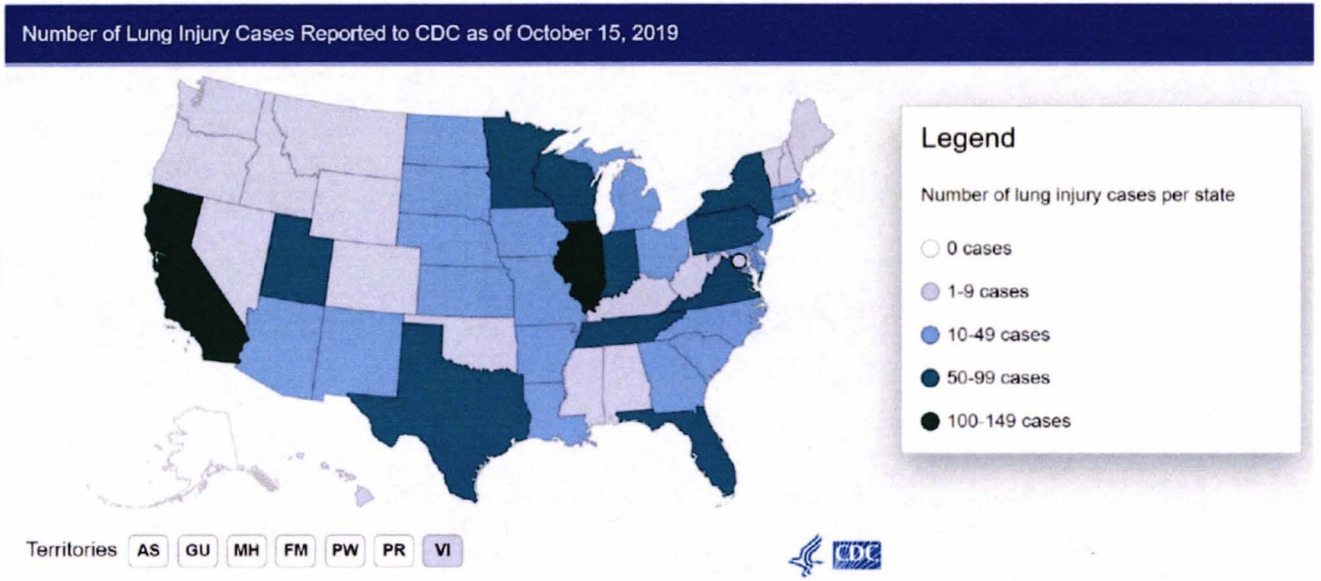
Dates of symptom onset and hospital admission for patients with lung injury associated with e-cigarette use, or vaping - United States



CDC Data. Oct. 11, 2019.

The current outbreak of vaping-related lung disease and deaths is new.

Department of Health



The current outbreak of vaping-related lung disease and deaths is a national problem.

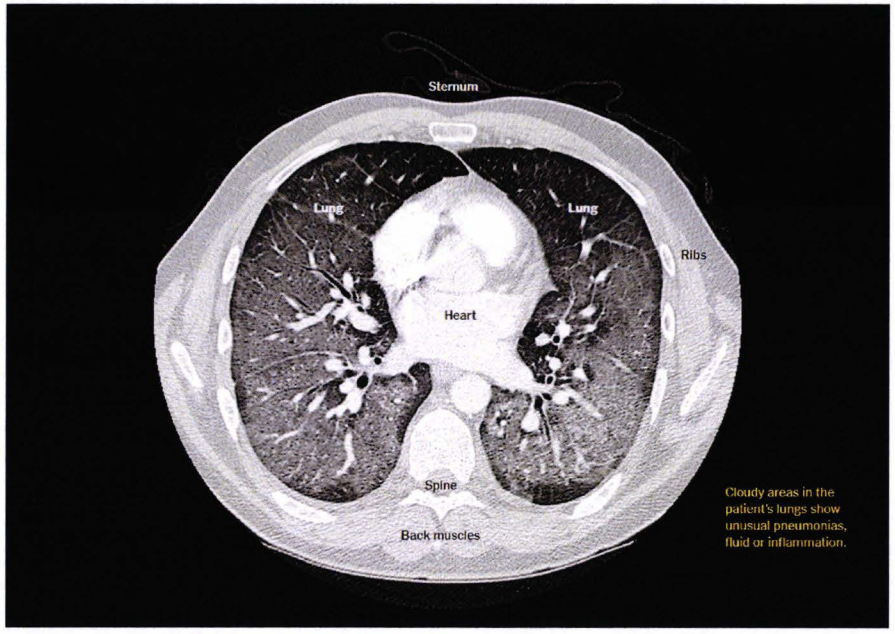
US: 1,479 cases, 33 Deaths

FL: 68 cases, 1 Death

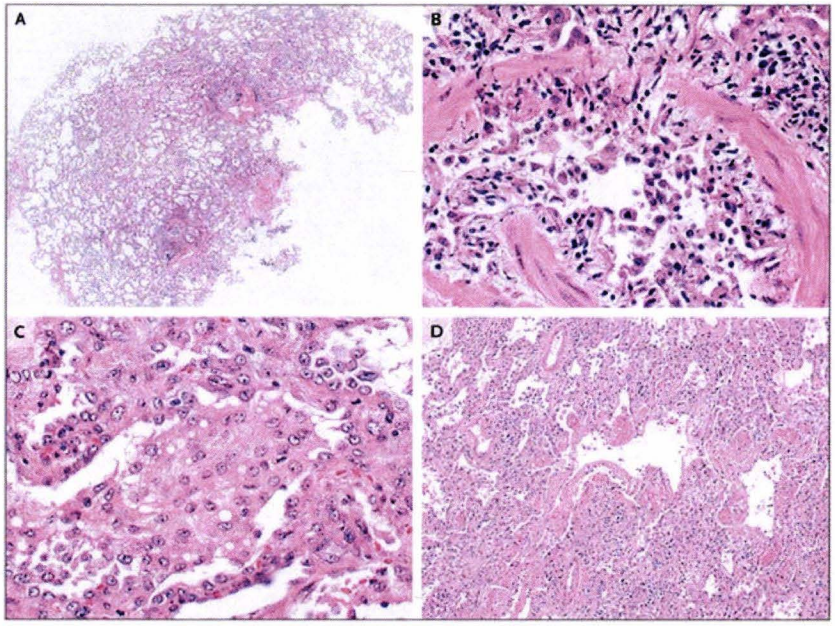
CDC Data. Oct. 15, 2019.

Department of Health

Vaping-related lung disease resembles a chemical burn



By The New York Times | Source: Intermountain Healthcare



October 2, 2019, NEJM

Department of Health

Lung Injury Associated with Vaping

- No specific cause has been identified
- CDC and FDA are investigating

- Most patients have been young and otherwise healthy
  - Report gradual onset of various symptoms over days to weeks
  - Respiratory (cough, chest pain, shortness of breath)
  - Gastrointestinal (GI) (abdominal pain, nausea, vomiting, diarrhea)
  - Systemic symptoms (fatigue, fever, weight loss)

Department of Health

Lung Injury Associated with Vaping

Florida	National
68 cases	1,479 cases
21 counties	49 states and 1 U.S. territory
1 confirmed death	33 deaths in 24 states
69% of cases are male	70% of cases are male
8% of cases are under 18 years old	16% of cases are under 18 years old
Age range of 15–72 years old	Age range of 13–75 years old
Median age of 24.5 years old	Median age of 23 years old

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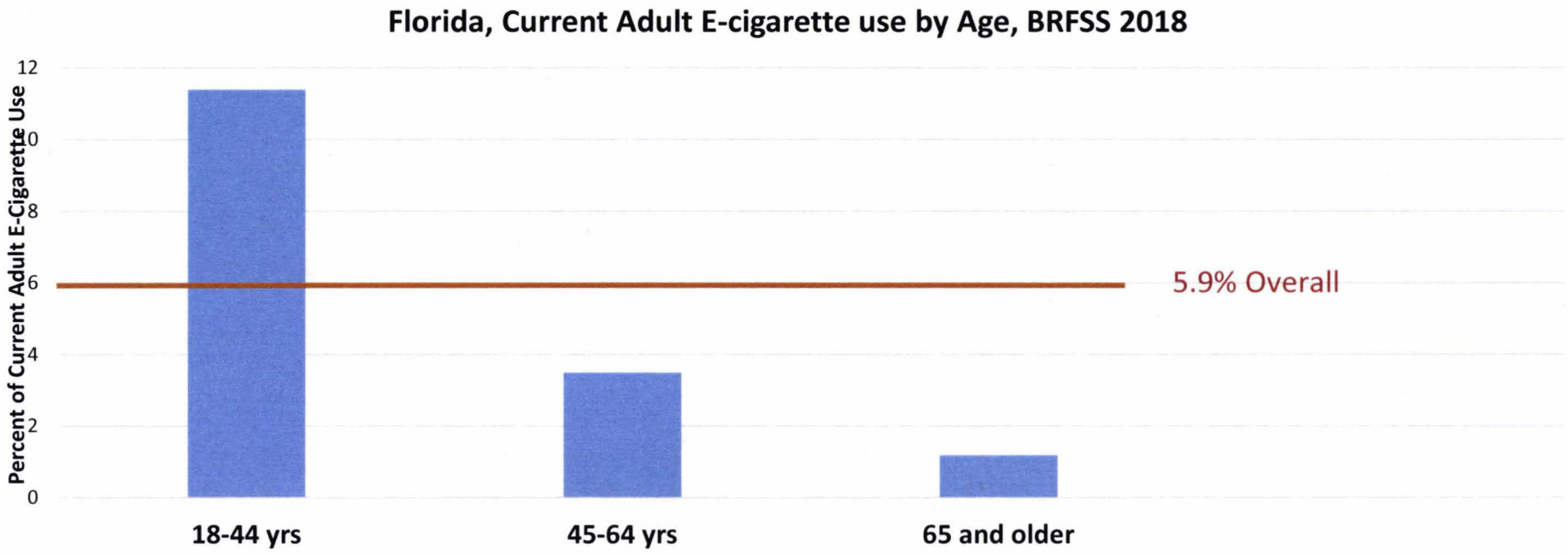
Product components associated with lung injury

Among 849 patients with information on substances used in e-cigarette, or vaping, products in the 3 months prior to symptom onset:

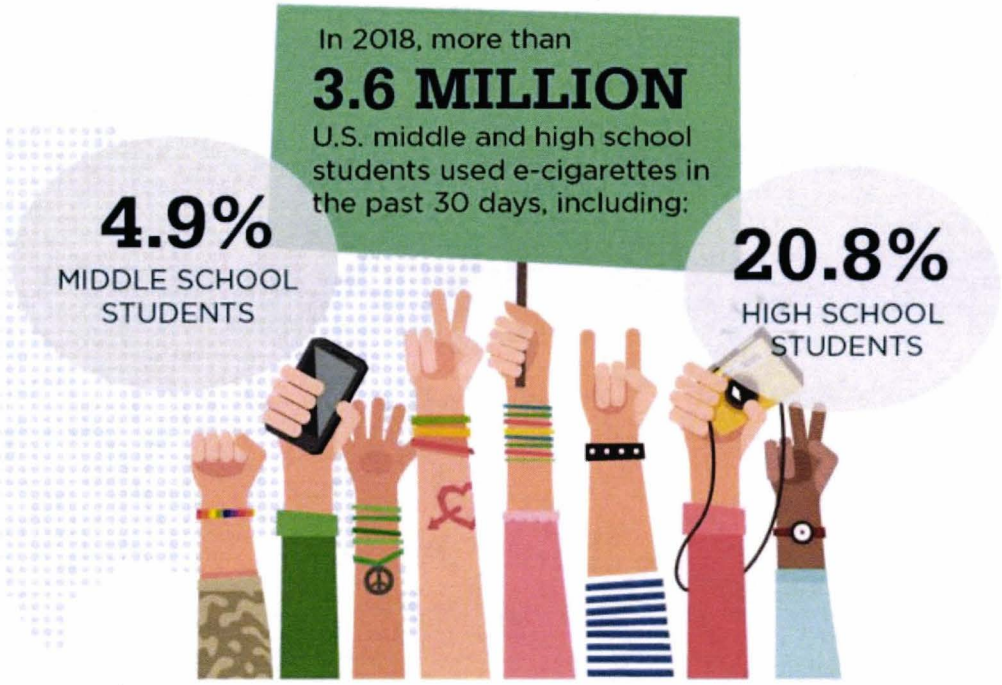
- 78% reported using THC-containing products; 31% reported exclusive use of THC-containing products
- 58% reported using nicotine-containing products; 10% reported exclusive use of nicotine-containing products

CDC 10/15/19

Department of Health



Department of Health

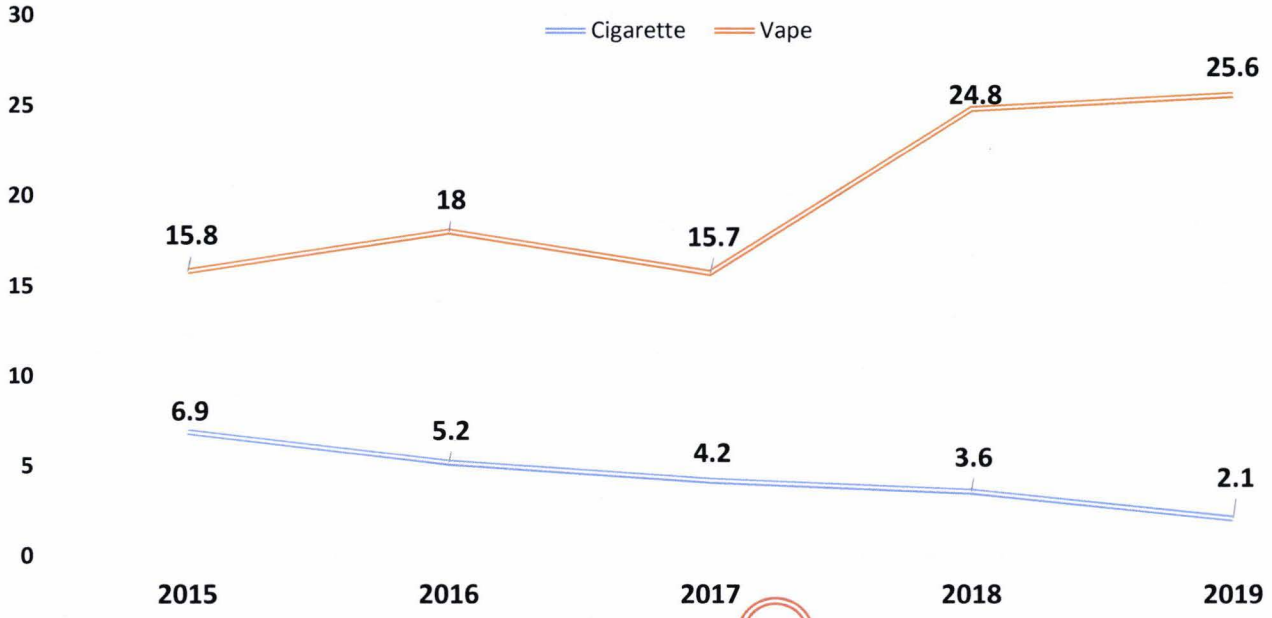


Outbreak follows a large rise in e-cigarette/vaping use in youth.

CDC Oct. 16, 2019

Department of Health

PERCENT OF FLORIDA HIGH SCHOOL USE CURRENT E-CIGARETTE USE VS CIGARETTE SMOKING 2015-2019



Florida Youth Tobacco Survey
2015-2019

Factors Contributing to Youth Vaping

- Flavored products
- Product innovation
- Marketing
- Access
- Nicotine is an addictive drug

Department of Health

Flavored Products













Department of Health

Product Innovation



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Marketing





Department of Health

Easy Access

- Convenience stores
- Vape shops
- Internet sales



Nicotine

- Nicotine is addictive
- Nicotine is not the primary cause of most smoking-related disease, but it is the reason people continue to smoke
- The large majority of e-cigarettes contain nicotine
- JUUL 5% nicotine vs. 1-2% for many others

Department of Health

Responding to the Vaping Lung Disease Outbreak

- Working closely with CDC and FDA
- Reporting cases
- Issued alert to medical providers 8/30/2019
- Media marketing

Responding to the Youth e-Epidemic

- Tobacco Free Florida is developing new youth vaping content
  - TV spots, radio spots, digital display ads, social media posts, long-format social media video
- Currently in formative testing
- Student-based activities



Department of Health

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

CDC Recommendations (10/15/19)

- People should not use e-cigarette, or vaping, products that contain THC.
- People should not buy any type of e-cigarette, or vaping products, particularly those containing THC, off the street.
- People should not modify or add any substances to e-cigarette.
- E-cigarette, or vaping, products should never be used by youths, young adults, or women who are pregnant.
- Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products.
- People should refrain from using e-cigarette, or vaping, products that contain nicotine.

Department of Health

FDA Recommendations 10/4/2019

- Do not use vaping products that contain THC.
- Do not use vaping products—particularly those containing THC—obtained off the street or from other illicit or social sources.
- Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments.
- No youth or pregnant women should be using any vaping product, regardless of the substance.
- Adults who do not currently use tobacco products should not start using these products. If you are an adult who uses e-cigarettes instead of cigarette smoking, do not return to smoking cigarettes.
- The FDA recommends contacting your health care provider for more information about the use of THC to treat medical conditions.

No vaping product has been approved by the FDA for therapeutic use or is authorized for marketing by the FDA.

Thank you!

Questions

Cigarette & Tobacco Regulation
In Florida

Cigarette and Tobacco Regulation in Florida

Division of Alcoholic Beverages and Tobacco

House Business and Professions Subcommittee
October 23, 2019

Introduction

- Division Overview
- Cigarette and Tobacco Regulation in Florida
- Licensing Population
- Excise Tax and Surcharge Collection
- Compliance Activities
- Revenue Distribution

Division Overview

The Division of Alcoholic Beverages and Tobacco licenses the manufacture, distribution, sale and service of alcoholic beverage and tobacco products in Florida.

Licensing

- Processing license applications and renewals.
- Verifying an applicant's qualifications for licensure under the Beverage Law and chapters 210 and 569, Florida Statutes.

49 FTE Positions

Auditing

- Collecting and auditing of the excise tax due to the state.
- Conducting compliance audits to ensure compliance with special licensing requirements.

84 FTE Positions

Enforcement

- Conducting routine compliance inspections.
- Conducting minimum age of purchase surveys.
- Conducting criminal and administrative investigations.

188 FTE Positions

Cigarette and Tobacco Regulation in Florida

Florida Licenses and Regulates Cigarettes and Other Tobacco Products

- Cigarettes, defined in s. 210.01(1), F.S.
  - Any roll for smoking, except one of which the tobacco is fully naturally fermented, without regard to the kind of tobacco or other substances used in the inner roll or the nature or composition of the material in which the roll is wrapped, which is made wholly or in part of tobacco irrespective of size or shape and whether such tobacco is flavored, adulterated or mixed with any other ingredient.
  - Florida's cigarette distribution system includes three levels: the manufacturer (supplier), the distributor (wholesaler), and the vendor (retailer).

Cigarette and Tobacco Regulation in Florida

Florida Licenses and Regulates Cigarettes and Other Tobacco Products

- Cigarettes, continued:
  - All cigarette packages intended for sale or distribution to consumers subject to taxation under s. 210.02, must have a stamp furnished by the Division affixed to the package, unless otherwise provided by law.
  - Section 210.185, F.S., prohibits selling, distributing, acquiring, holding, owning, possessing, transporting, or importing cigarettes in this state under certain circumstances, including when cigarettes are marked for export only, when the packages fail to comply with federal law (including the Federal Cigarette Labeling and Advertising Act), when the ingredients have not been properly submitted to HHS, or when the package has been altered to remove or obscure any required label or warning, or to make the package non-compliant with federal law.
  - All cigarettes sold or offered for sale in this state, or sold or offered for sale to persons in this state, must be tested, marked, and have a written certification filed by the manufacturer with the Division, in accordance with the "Reduced Cigarette Ignition Propensity Standard and Firefighter Protection Act" (s. 633.142, F.S.).

Cigarette and Tobacco Regulation in Florida

Florida Licenses and Regulates Cigarettes and Other Tobacco Products

- Tobacco Products, defined in s. 210.25(12), F.S.
  - Loose tobacco suitable for smoking; snuff; snuff flour; cavendish; plug and twist tobacco; fine cuts and other chewing tobaccos; shorts; refuse scraps; clippings, cuttings, and sweepings of tobacco, and other kinds and forms of tobacco prepared in such manner as to be suitable for chewing; but "tobacco products" does not include cigarettes, as defined by s. 210.01(1), or cigars.
- Florida's other tobacco products distribution system includes the distributor (wholesaler) and vendor (retailer).
  - Distributor, defined in s. 210.25(5), F.S.

    (a) Any person engaged in the business of selling tobacco products in this state who brings, or causes to be brought, into this state from outside the state any tobacco products for sale;
    (b) Any person who makes, manufactures, or fabricates tobacco products in this state for sale in this state; or
    (c) Any person engaged in the business of selling tobacco outside this state who ships or transports tobacco products to retailers in this state to be sold by those retailers.

Cigarette and Tobacco Regulation in Florida

Florida Licenses and Regulates Cigarettes and Other Tobacco Products

- Tobacco Products, as defined in s. 569.002, F.S.
    - "Tobacco products" includes loose tobacco leaves, and products made from tobacco leaves, in whole or in part, and cigarette wrappers, which can be used for smoking, sniffing, or chewing.
- The Division does not regulate "nicotine products". "Nicotine products" are defined in s. 877.112, F.S. as "...any product that contains nicotine, including liquid nicotine, that is intended for human consumption, whether inhaled, chewed, absorbed, dissolved, or ingested by any means, but does not include a...[t]obacco product, as defined in s. 569.002."

Cigarette and Tobacco Regulation in Florida

Florida Licenses and Regulates Cigarettes and Other Tobacco Products

- Retail Tobacco Product Dealer Permit (RTPD)-
  - Each person, firm, association, or corporation that seeks to deal, at retail, in tobacco products within this state, or to allow a tobacco products vending machine to be located on its premises in this state, must obtain a retail tobacco products dealer permit for each place of business or the premises where tobacco products are sold…
  - Permits may be issued only to persons who are 18 years of age or older or to corporations the officers of which are 18 years of age or older.

Cigarette and Tobacco Regulation in Florida

Florida Licenses and Regulates Cigarettes and Other Tobacco Products

- A dealer that sells tobacco products shall post a clear and conspicuous sign in each place of business where such products are sold which substantially states the following:

  THE SALE OF TOBACCO PRODUCTS TO PERSONS UNDER THE AGE OF 18 IS AGAINST FLORIDA LAW. PROOF OF AGE IS REQUIRED FOR PURCHASE.

- A dealer that sells tobacco products and nicotine products or nicotine dispensing devices, as defined in s. 877.112, may use a sign that substantially states the following:

  THE SALE OF TOBACCO PRODUCTS, NICOTINE PRODUCTS, OR NICOTINE DISPENSING DEVICES TO PERSONS UNDER THE AGE OF 18 IS AGAINST FLORIDA LAW. PROOF OF AGE IS REQUIRED FOR PURCHASE.

- Any dealer that sells tobacco products shall provide at the checkout counter in a location clearly visible to the dealer or the dealer's agent or employee instructional material in a calendar format or similar format to assist in determining whether a person is of legal age to purchase tobacco products. This point of sale material must contain substantially the following language:

  IF YOU WERE NOT BORN BEFORE THIS DATE

  (insert date and applicable year)

  YOU CANNOT BUY TOBACCO PRODUCTS.

Florida Licenses and Regulates Cigarettes and Other Tobacco Products

Responsible Retail Tobacco Products Dealer:

To qualify as a responsible retail tobacco products dealer, the dealer must establish and implement procedures designed to ensure that the dealer's employees comply with the provisions of this chapter. The dealer must provide a training program for the dealer's employees which addresses the use and sale of tobacco products and which includes at least the following topics:

- (a) Laws covering the sale of tobacco products.
- (b) Methods of recognizing and handling customers under 18 years of age.
- (c) Procedures for proper examination of identification cards in order to verify that customers are not under 18 years of age.
- (d) The use of the age audit identification function on electronic point-of-sale equipment, where available.

License Population Statewide

Manufacturers		Fee	2018/2019 Licensees
CMFG	Cigarette Manufacturer	$100	31
Distributors			
CDA	Cigarette Distributor Agent	$100	5
CWD	Cigarette Wholesale Dealer	$100	241
CIMP	Cigarette Importer	$100	12
EXP	Cigarette Exporter	$100	20
CGR	Cigar Wholesale Dealer	No Fee	615
TWD	Tobacco Wholesale Dealer for Other Tobacco	$25	319
			Total 1,212
Vendors			
RTPD	Retail Tobacco Product Dealer With Alcohol License	$50	23,705
RTPD	Retail Tobacco Product Dealer Without Alcohol License	$50	3,884
			Total 27,589

Excise Tax and Surcharge Collection

Tax and surcharge payments are collected at intervals of one month, on or before the 10th of each month, and the payment is accompanied by statutorily required reports.

Tax and surcharge rates are dependent on the type of product being sold.

The 2009 Florida Legislature passed the Protecting Florida's Health Act, which levies a surcharge on cigarettes, wraps, and tobacco products other than cigars. Cigars are excluded from surcharge and excise taxation per s. 210.25(12), F.S.

During FY 2018-19, the Division collected over $254,000,000 in cigarette excise tax, over $758,000,000 in cigarette surcharge, over $38,000,000 in other tobacco products excise tax, and over $91,000,000 in other tobacco products surcharge.



The Division maintains an Electronic Data Submission (EDS) system.

- Approximately 90% of tax remitting licensees are currently reporting electronically

Florida dbpr Department of Business & Professional Regulation

Compliance Activities

In FY 18-19, the Division performed over 52,000 alcoholic beverage and tobacco inspections, with a staff of 188 dedicated Bureau of Enforcement employees across 12 district offices.

- Routine compliance inspections resulted in an approximately 64% compliance rate at the time of inspection.

- The most common violations cited during inspections are related to a failure to post all necessary signage and licenses, and failure to maintain records as required by law.

In FY 17-18 and FY18-19, the Division performed over 5,500 total tobacco compliance surveys to determine whether licensees were complying with minimum age of purchase restrictions in Florida law.

Nearly 91% of the aforementioned tobacco-related compliance surveys resulted in vendor compliance.

Revenue Distribution

Retail Tobacco Permit Fees:

10% of each retail tobacco dealer permits transferred Department of Education to provide for teacher training and for research and evaluation to reduce and prevent the use of tobacco products by children.

Cigarette Excise Taxes:

8% to Service Charge to General Revenue Fund, and .9% to the Alcoholic Beverage and Tobacco Trust Fund to provide for operational costs.

Cigarette Excise Taxes Net (after the above reductions):

4.04% of Cigarette Excise Tax or $5,560,553 (whichever is greater) is transferred to the H. Lee Moffitt Cancer Center and Research Institute;

29.3% of Cigarette Excise Tax collections is transferred to the Public Medical Assistance Trust Fund in the Department of Health for indigent health care;

2.9% of Cigarette Excise Taxes transferred to Department of Revenue for the Revenue Sharing Trust Fund for counties;

1% (not to exceed $3M) is transferred to the Biomedical Research Trust Fund in the Department of Health for the advancement of cures for cancer afflicting pediatric populations, and the balance of the cigarette tax revenue collections after payment of all of the above is transferred to the General Revenue Fund.

Other Tobacco Products (OTP) Excises Taxes – 100% of collections are deposited directly into the General Revenue Fund.

Cigarette and OTP Surcharge Revenues – are transferred into the Health Care Trust Fund within the Agency for Health Care Administration.

Florida dbpr Department of Business & Professional Regulation

Contact Information

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Legislative Affairs Director
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850-487-4827

2019 Florida Youth Substance Abuse Survey Overview



2019 Florida Youth Substance Abuse Survey Overview

Ute Gazioch, Director of Substance Abuse and Mental Health

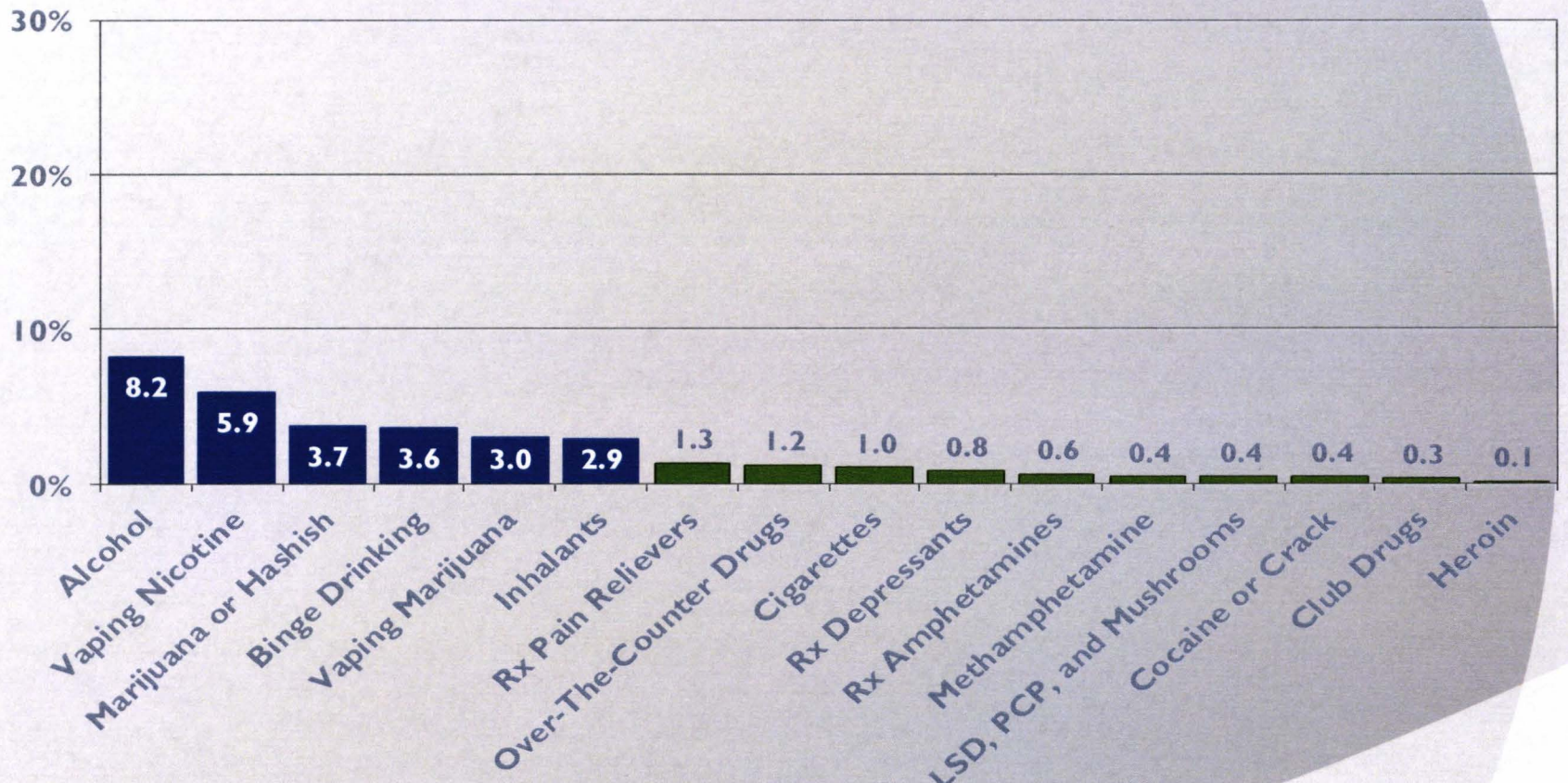
House Business & Professions Subcommittee
October 23, 2019

Background and Methods

- Since 2002, the Florida Youth Substance Abuse Survey is administered each spring to public middle and high school students across Florida.
- In even numbered years, sample size is larger to produce county-level estimates.
- In odd numbered years, sample size is only large enough to produce state-level estimates.
- In 2019, students were surveyed in 40 out of the 67 counties.
- Final sample size was 9,819 across grades 6 through 12.
- The margin of error is less than 2.0 percentage points for middle school and high school prevalence rates.

Past-30-Day Prevalence

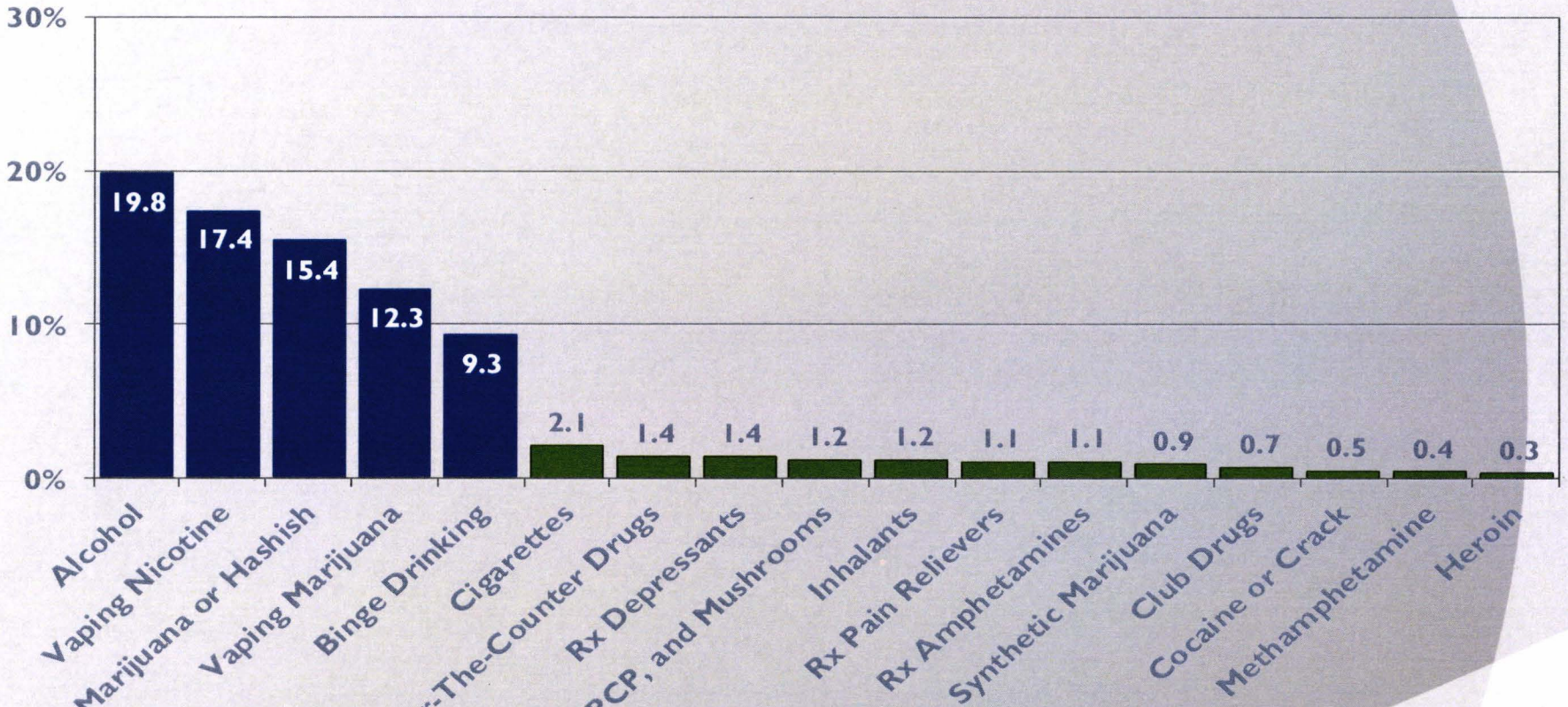
Middle School



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Past-30-Day Prevalence

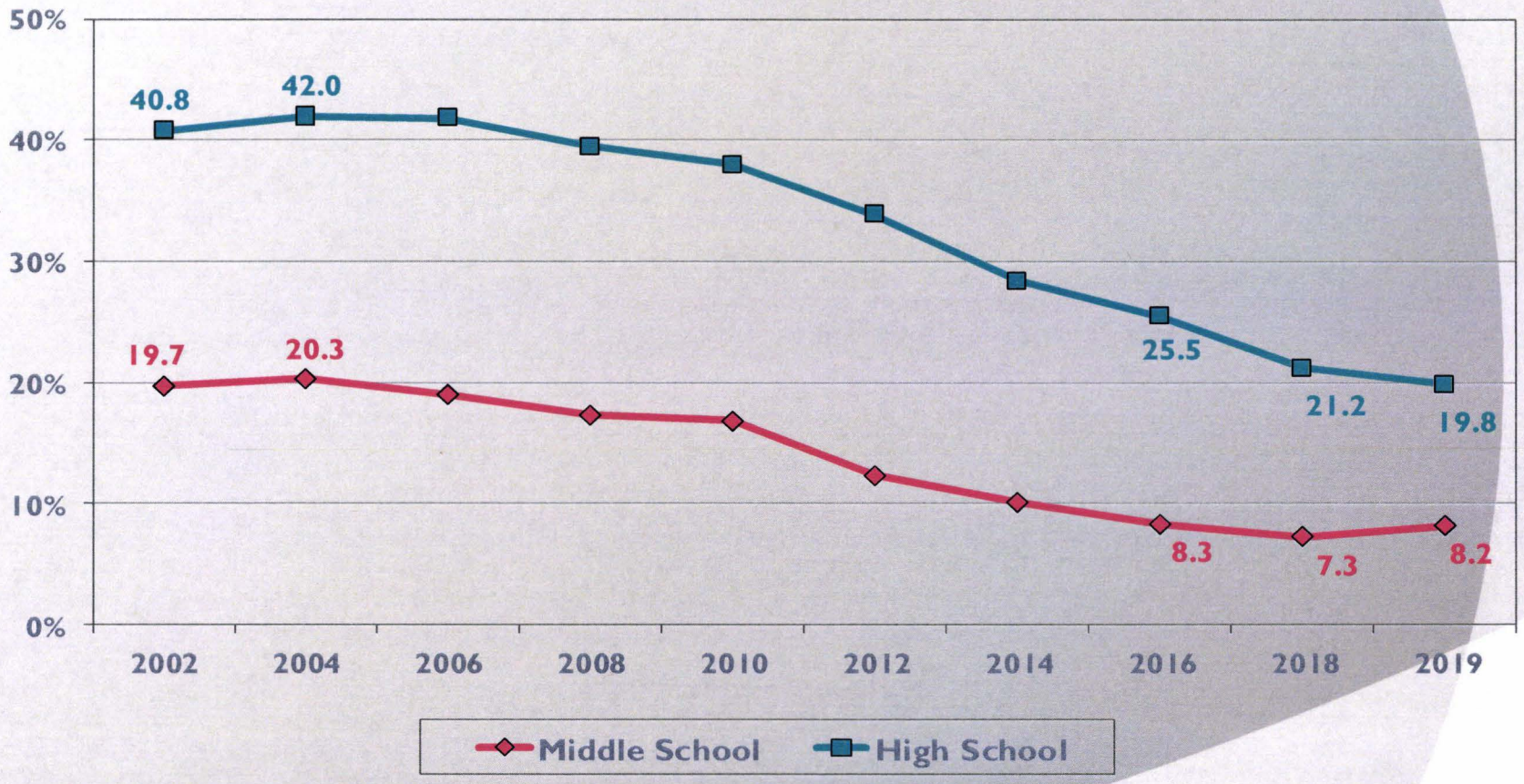
High School



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Alcohol

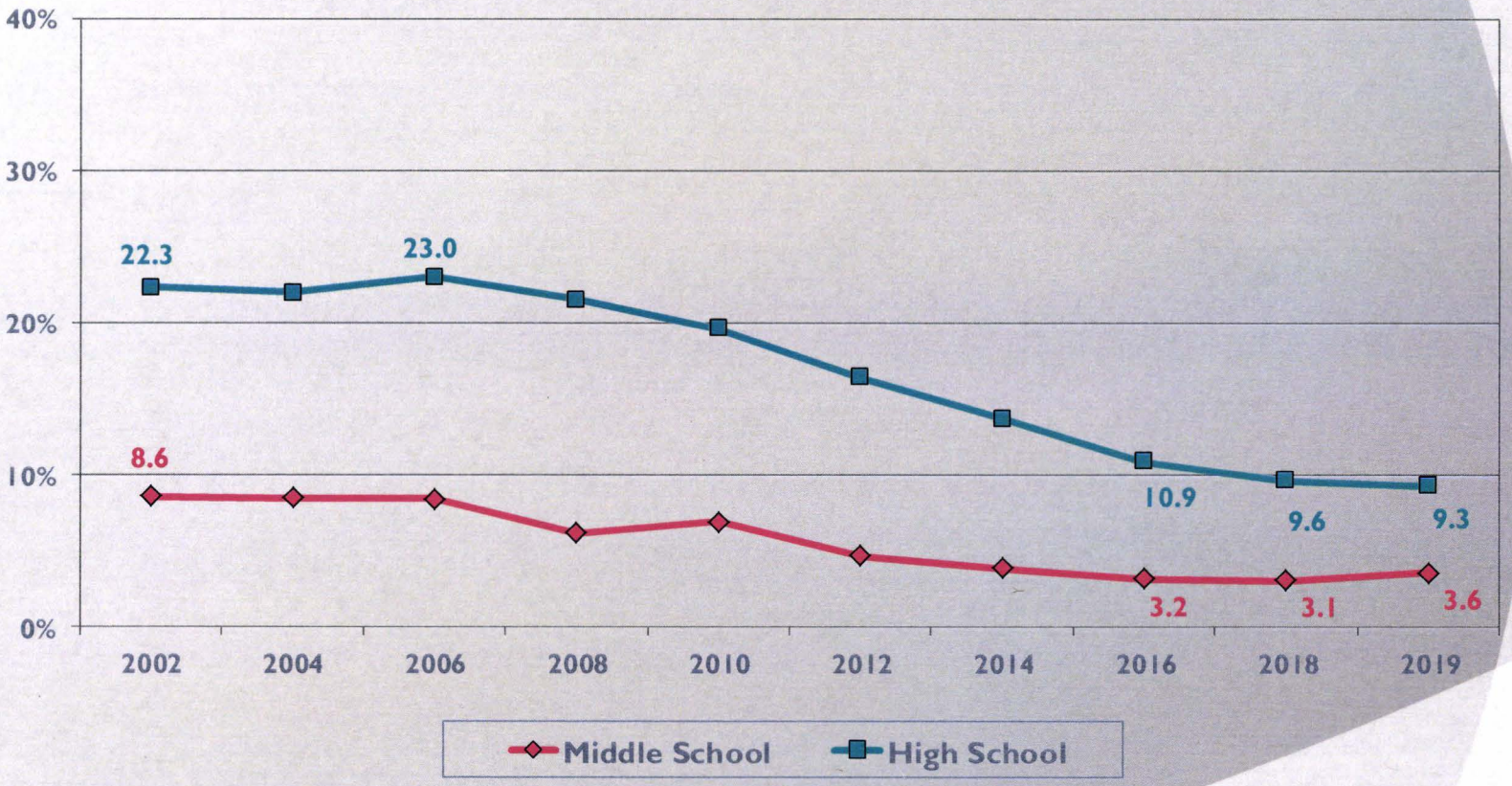
Past-30-Day Prevalence by Grade Cohort



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Binge Drinking

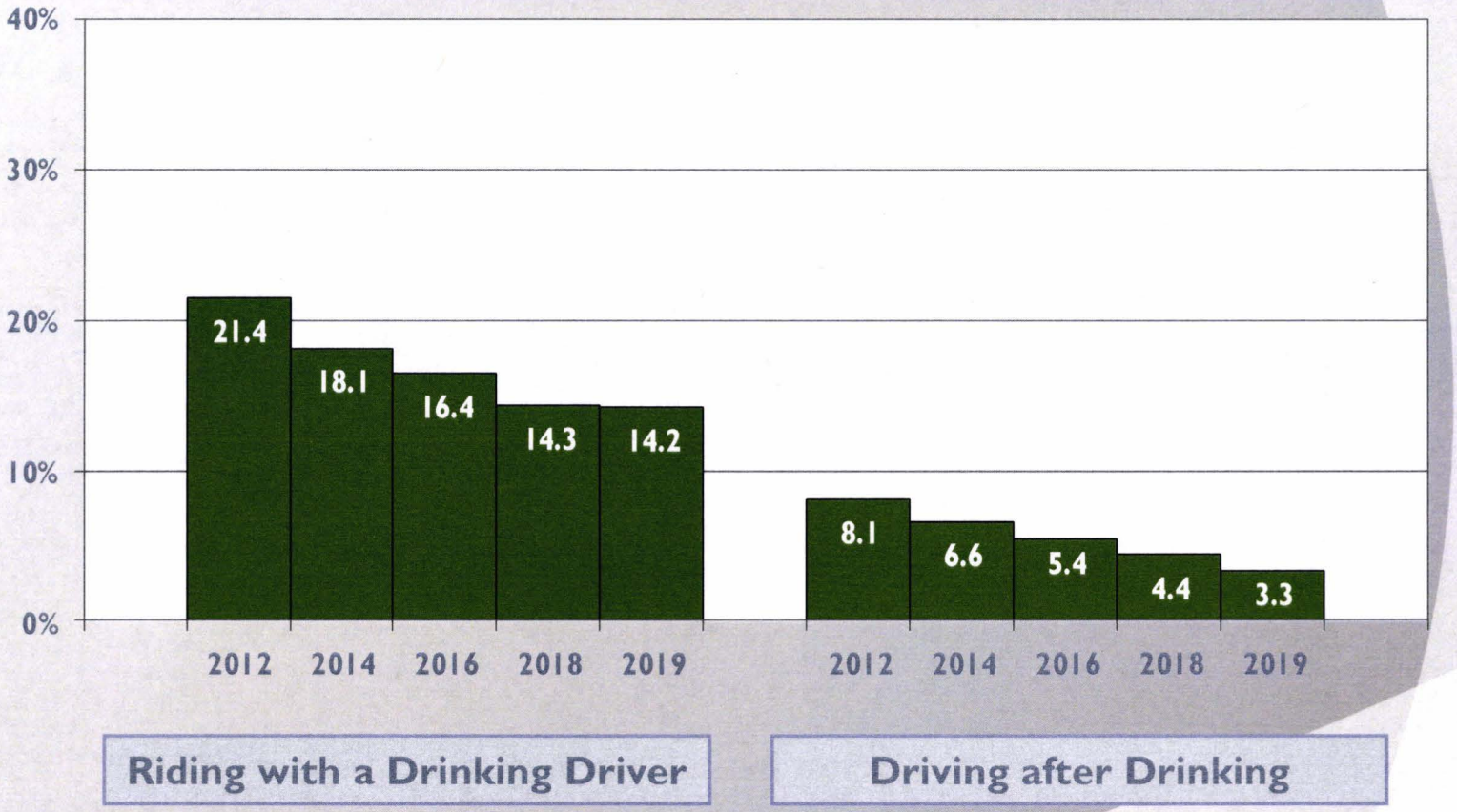
Prevalence by Grade Cohort



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Alcohol and Driving Trends

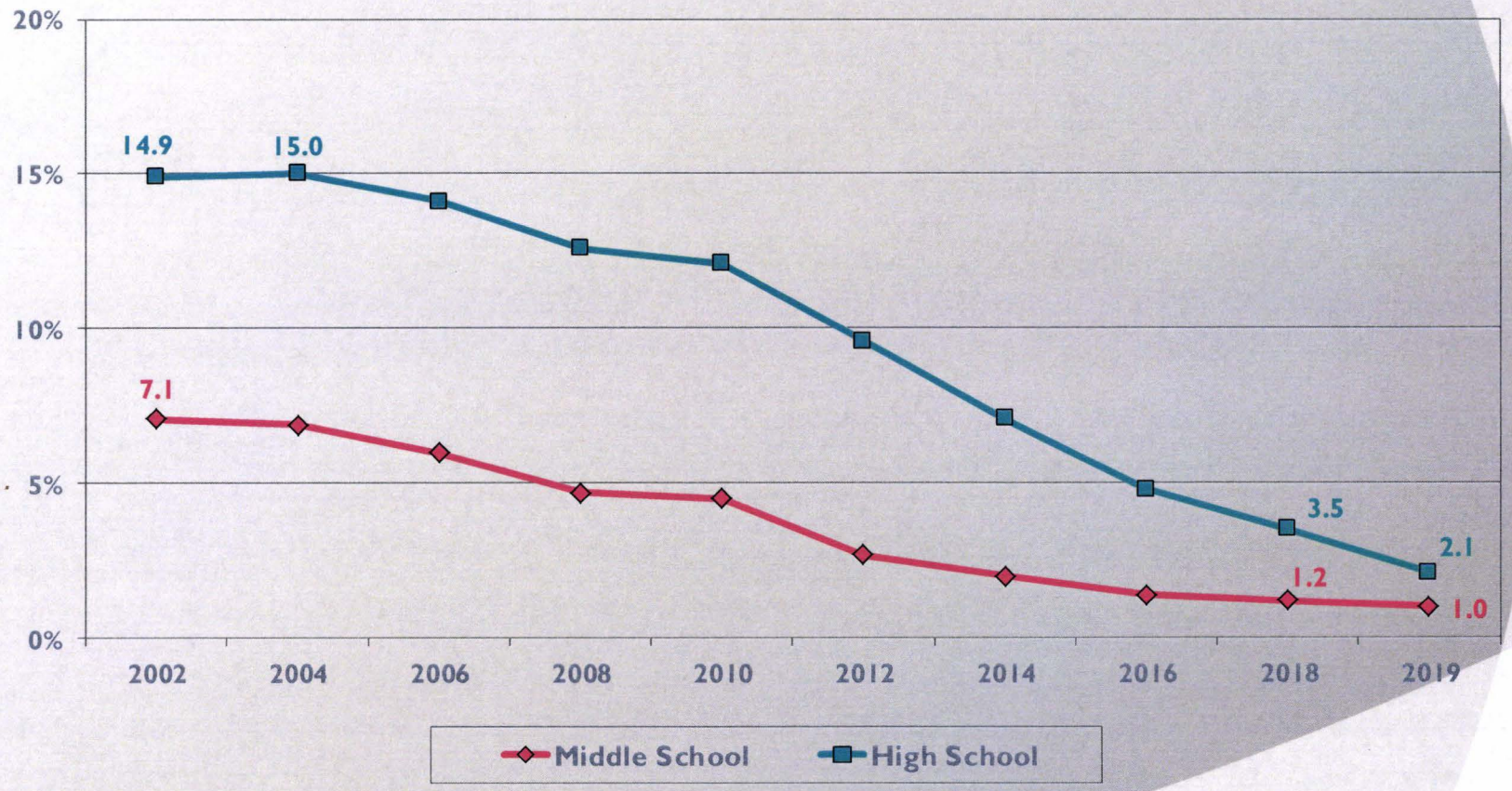
Past-30-Day Prevalence Among High School Students



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Cigarettes

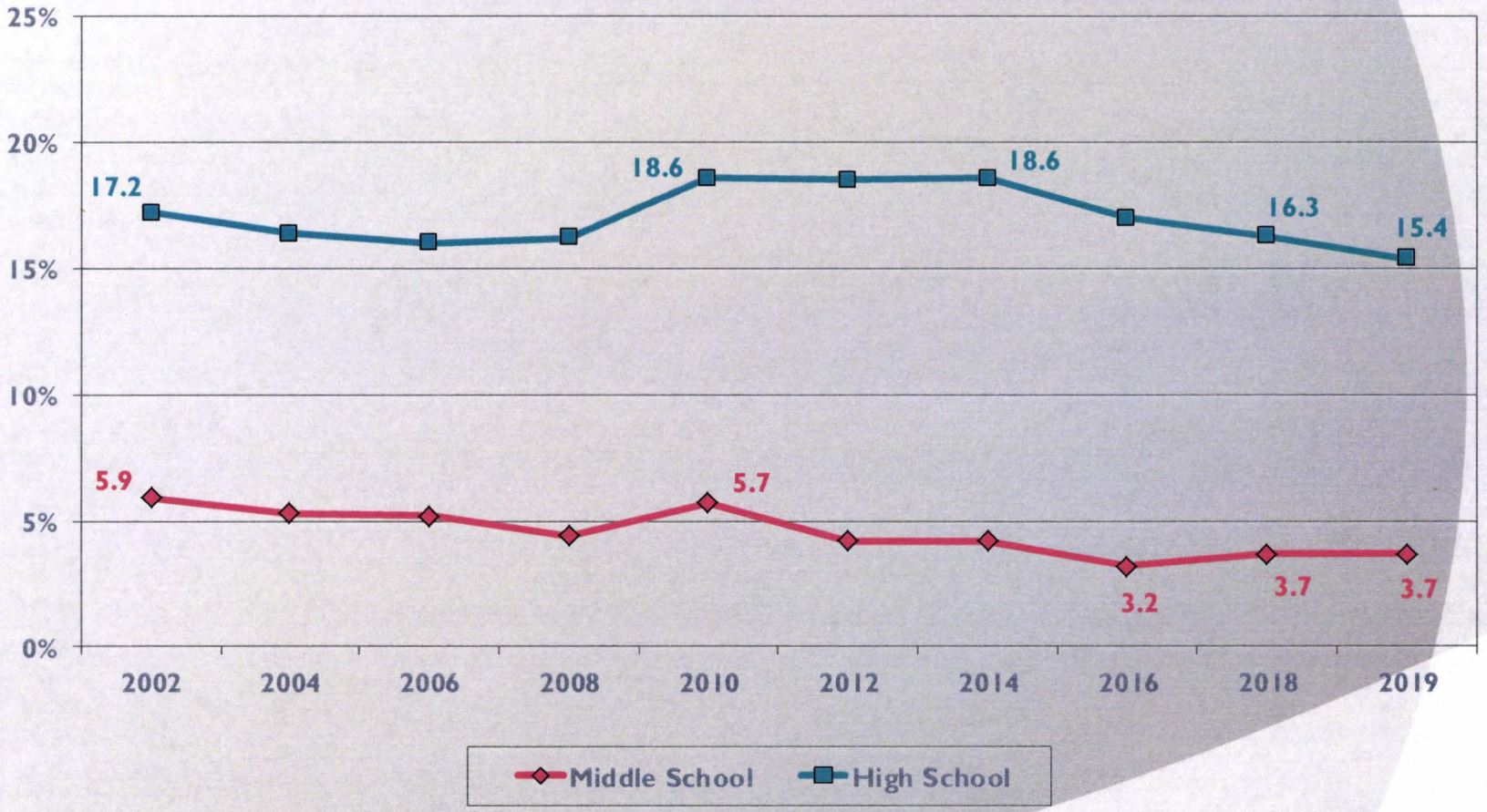
Past-30-Day Prevalence by Grade Cohort



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Marijuana

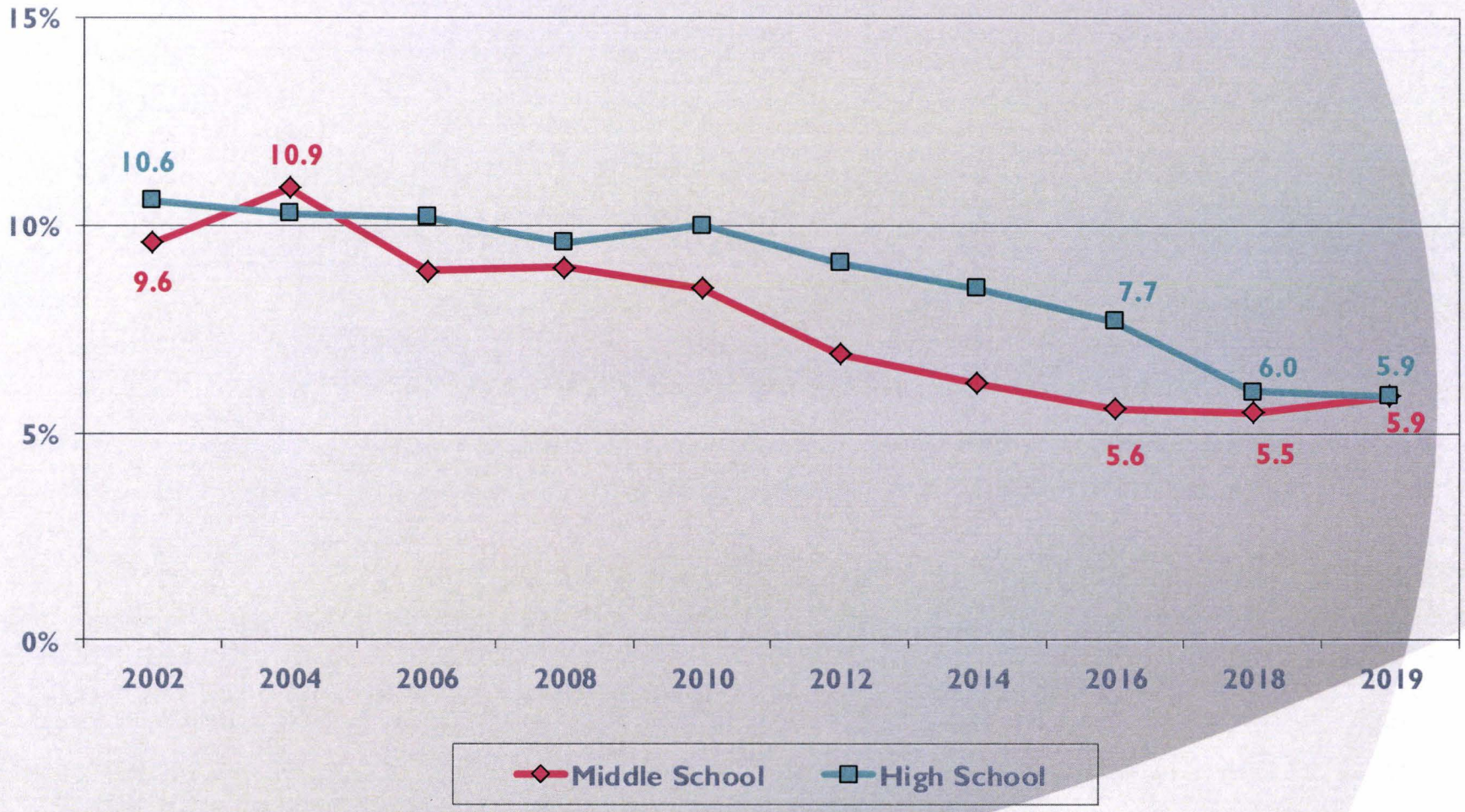
Past-30-Day Prevalence by Grade Cohort



FLORIDA DEPARTMENT OF CHILDREN AND FAMILIES
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Use of Any Illicit Drug (Other than Marijuana)

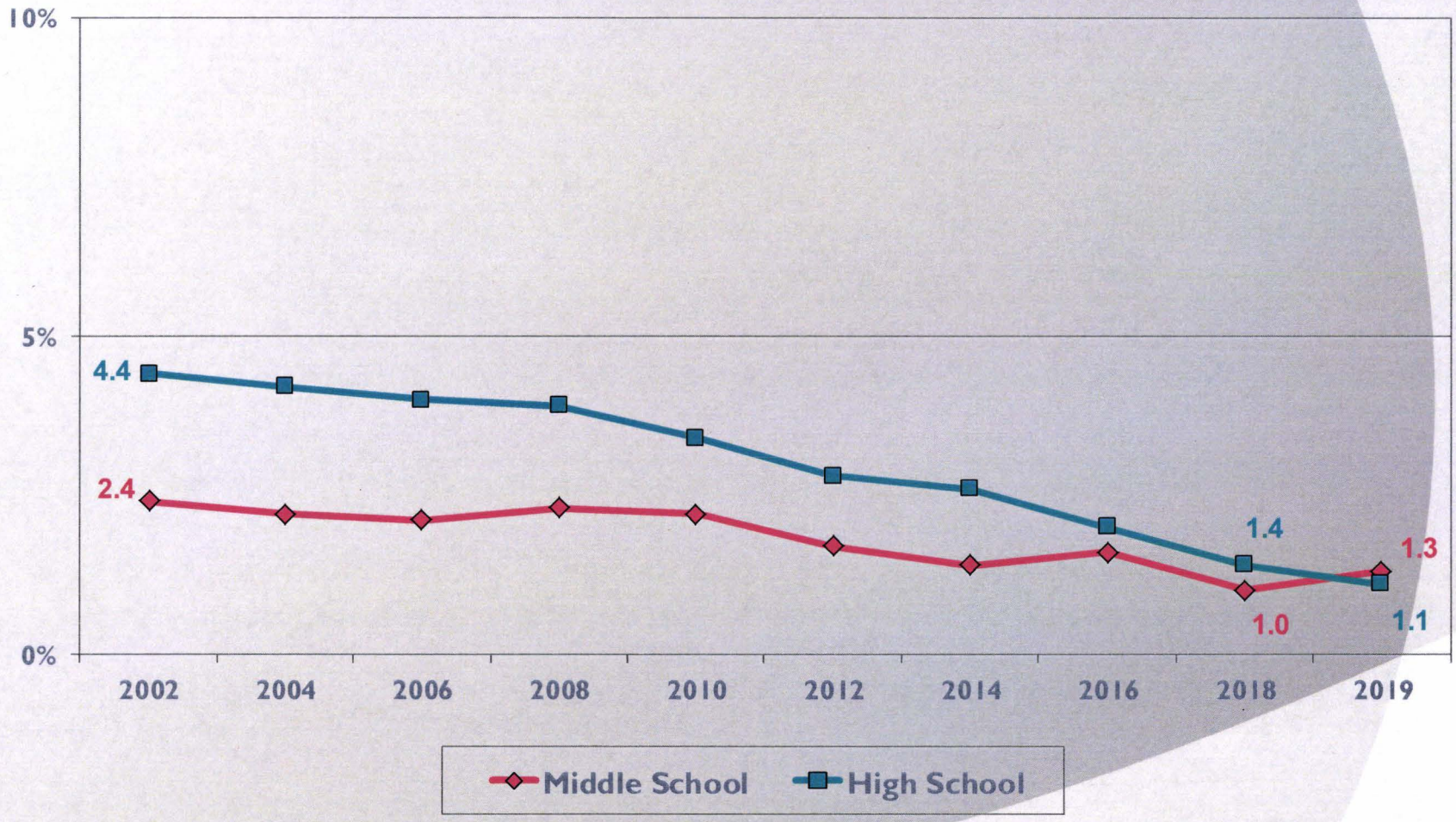
Past-30-Day Prevalence by Grade Cohort



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Prescription Pain Relievers

Past-30-Day Prevalence by Grade Cohort

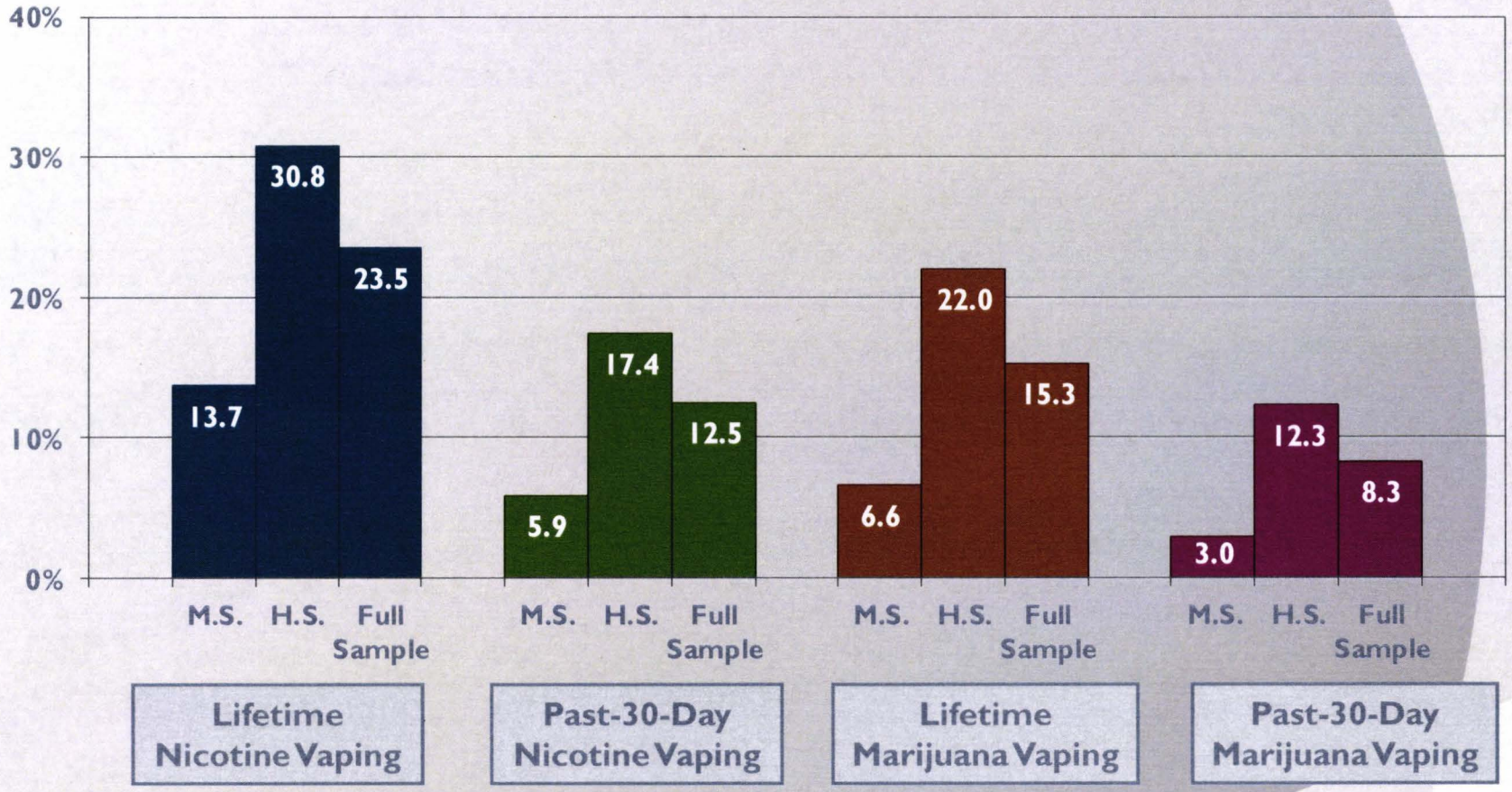


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11

Vaping Nicotine and Vaping Marijuana

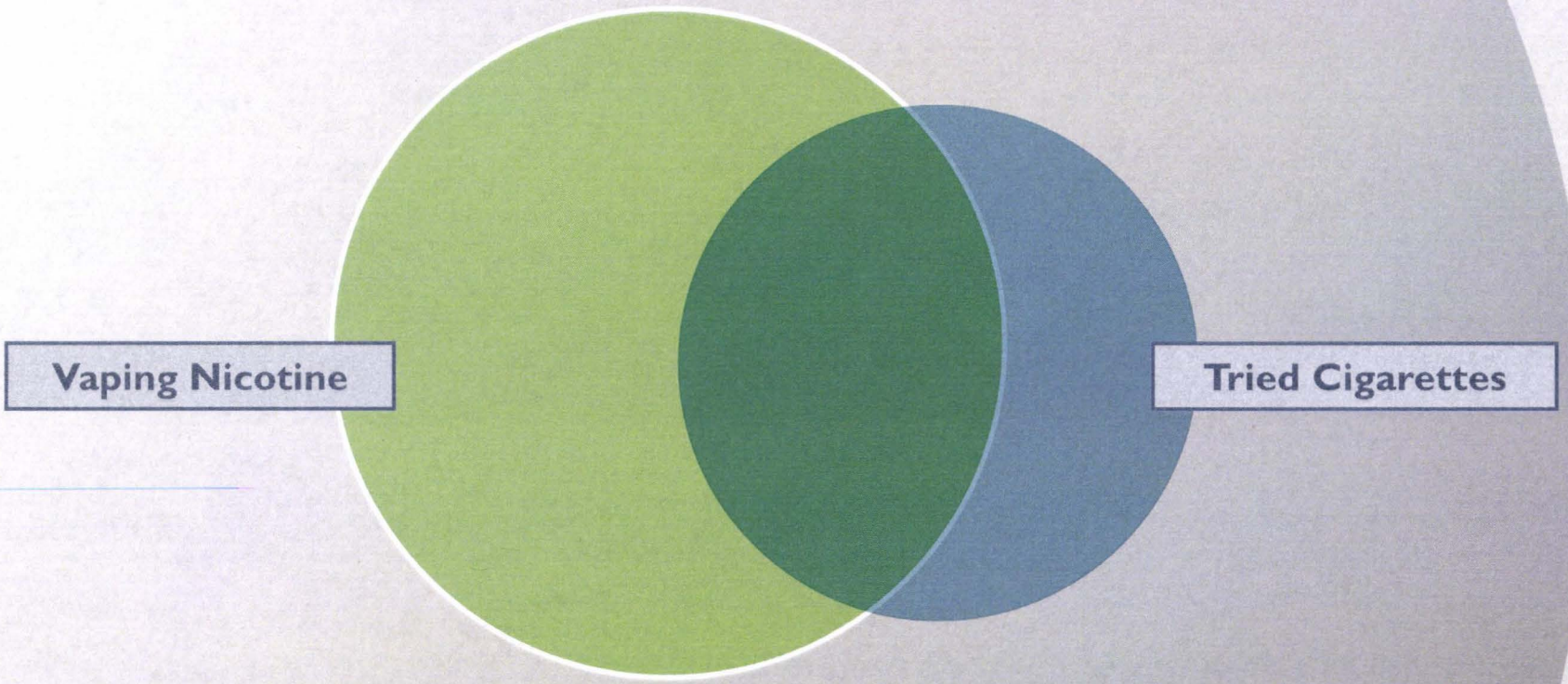
Lifetime and Past-30-Day Prevalence



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Vaping Nicotine and Smoking Cigarettes

Past-30-Day and Lifetime Prevalence



71.9% of current vapers have never tried cigarettes.

FLORIDA DEPARTMENT OF CHILDREN AND FAMILIES
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Trend Summary

- Among high school students, alcohol, cigarette, marijuana, and Rx pain reliever use continue their long-term decline.
- Among middle school students, the substance use decline has stalled.
- The majority of students who vape nicotine did not transition from smoking cigarettes. Their vaping is independent of cigarette use.

Questions?

15

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OF CHILDREN AND FAMILIES
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Pathology of Vaping-Associated Lung Injury

MAYO CLINIC

Pathology of Vaping-Associated Lung Injury

Andras Khoor, MD, PhD
Mayo Clinic Florida

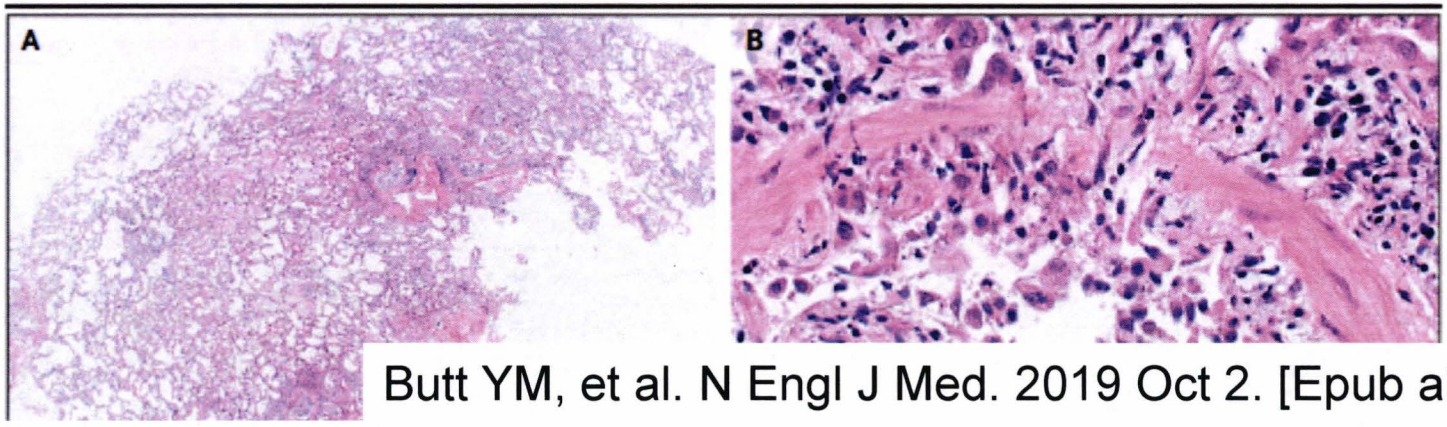
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The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Pathology of Vaping-Associated Lung Injury

TO THE EDITOR: Despite the accumulating data on the clinical and imaging features of vaping-associated lung injury,[1,2] its pathology is poorly understood. We reviewed lung biopsies from 17 patients (13 men; median age, 35 years [range, 19–67]), all of whom had a history of vaping (71% with marijuana or cannabis oils) and were clinically suspected to have vaping-associated lung injury. Presentation was acute or subacute in all cases, with bilateral pulmonary opacities; all but two patients presented in 2019. Eleven met the criteria for a "confirmed" diagnosis of vaping-related lung injury; the remaining six met the criteria for a "probable" designation. In all cases, histopathological findings showed patterns of acute lung injury, including acute fibrinous pneumonitis, diffuse alveolar damage, or organizing pneumonia, usually bronchiolocentric and accompanied by bronchiolitis (Fig. 1; also see the Supplementary Appendix, available with the full text of this letter at NEJM.org). No histologic findings were specific, but foamy macrophages and pneu-



Butt YM, et al. N Engl J Med. 2019 Oct 2. [Epub ahead of print]

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Introduction

- Use of electronic cigarette ("e-cigarette") devices has exploded in popularity in recent years
- These battery-operated devices
  - heat liquids, oils, or waxes containing nicotine, cannabinoids, synthetic cannabinoids, illicit drugs, and other chemical compounds,
  - producing an aerosolized vapor
  - that can be inhaled, or vaped, by the user

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Aim

- To characterize the pathologic changes that occur in the lung:
  - Exogenous lipoid pneumonia?
    - Much recent attention has been given to the possibility that vaping-associated lung injury may represent exogenous lipoid pneumonia
  - Acute lung injury pattern?
    - Acute lung injury patterns include:
      - acute fibrinous pneumonitis,
      - diffuse alveolar damage, and
      - organizing pneumonia

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Methods

- The study was approved by the Institutional Review Board at Mayo Clinic (IRB# 19-008434)
- In all cases,
  - a diagnosis of vaping-associated lung injury was favored clinically, and
  - biopsies were performed to confirm this clinical impression and rule out other causes

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Methods (continued)

- Cases were classified using criteria for vaping-related lung injury recently proposed by the CDC
  - "Confirmed"
    - 1) use of an e-cigarette or vaping device within 90 days of symptom onset
    - 2) presence of pulmonary infiltrates
    - 3) absence of clinical and laboratory evidence of infection
    - 4) absence of evidence for alternative diagnoses
  - "Probable"
    - Identical criteria with the exception of #3

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Results: Patient Demographics

- A total of 17 patients met the inclusion criteria
- Most patients were
  - young adults (median age 35 years, range 19-67) and
  - most were men (76%)

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Results: Clinical Findings

- Eleven patients met CDC criteria for a "confirmed" diagnosis, with the remaining six patients meeting CDC criteria for a "probable" designation
- All patients had a history of vaping in the weeks and days prior to presentation

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Results: Clinical Findings (continued)

- Two patients were vaping in an attempt to quit smoking tobacco
- Twelve patients (71%) reported vaping
  - tetrahydrocannabinol (THC),
  - cannabis oils,
  - cannabidiol (CBD), or
  - other non-nicotine products
- Both manufactured prepackaged vape pods and open access tank style vaporizers were used

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Results: Pathologic Findings

- In all cases, pathologic findings showed patterns of acute lung injury, including
  - acute fibrinous pneumonitis
  - diffuse alveolar damage, or
  - organizing pneumonia
- None of our cases showed histologic evidence of exogenous lipoid pneumonia

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Supplementary Table S3. Frequency of Histopathologic Features in Vaping-Associated Acute Lung Injury

Histologic Feature	Number of cases with feature / Number of cases with relevant structures present for evaluation (%)
Foamy / Vacuolated Macrophages	17 / 17 (100)
Foamy / Vacuolated Pneumocytes	17 / 17 (100)
Intraalveolar Fibrin	16 / 17 (94)
Organizing Pneumonia	14 / 17 (82)
Bronchiolitis	7 / 9 (78)
Bronchiolar Mucosal Ulceration	6 / 9 (67)
Interstitial Edema	11 / 17 (65)
Neutrophils	9 / 17 (53)
Chronic Interstitial Inflammation	9 / 17 (53)
Pigmented Macrophages	7 / 17 (41)
Eosinophils	5 / 17 (29)
Hyaline Membranes	4 / 17 (24)
Peribronchiolar Metaplasia	2 / 9 (22)
Organizing Fibrinous Pleuritis	1* / 7 (14)
Interstitial Fibrosis	1 / 17 (6)
Pleural Fibrosis	0 / 7 (0)
Granulomas	0 / 17 (0)
Exogenous Lipoid Pneumonia	0 / 17 (0)

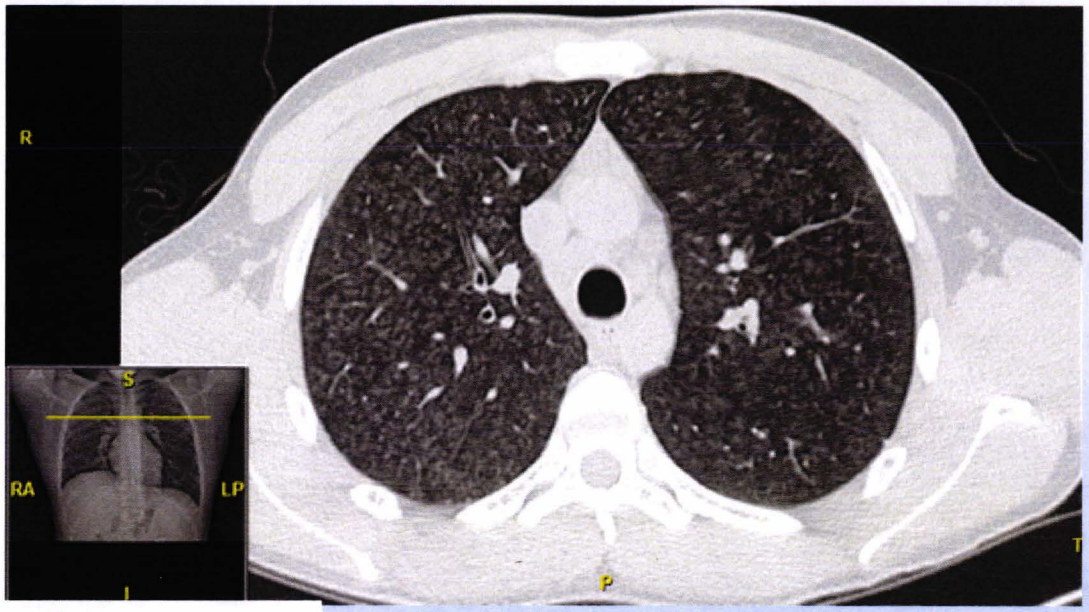
Case #17

- 19-year-old man presented with
  - cough,
  - pain when swallowing,
  - nausea, and
  - vomiting

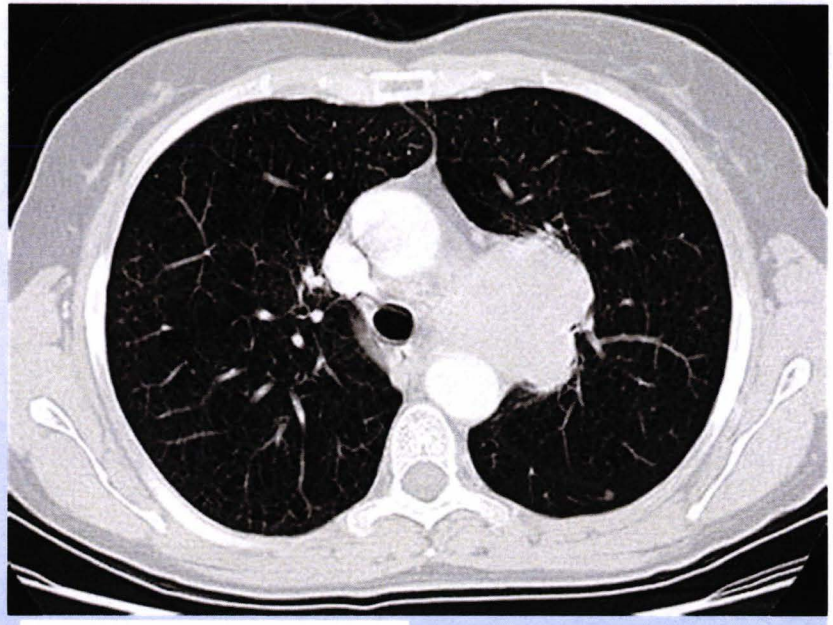
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Chest CT



Case #17

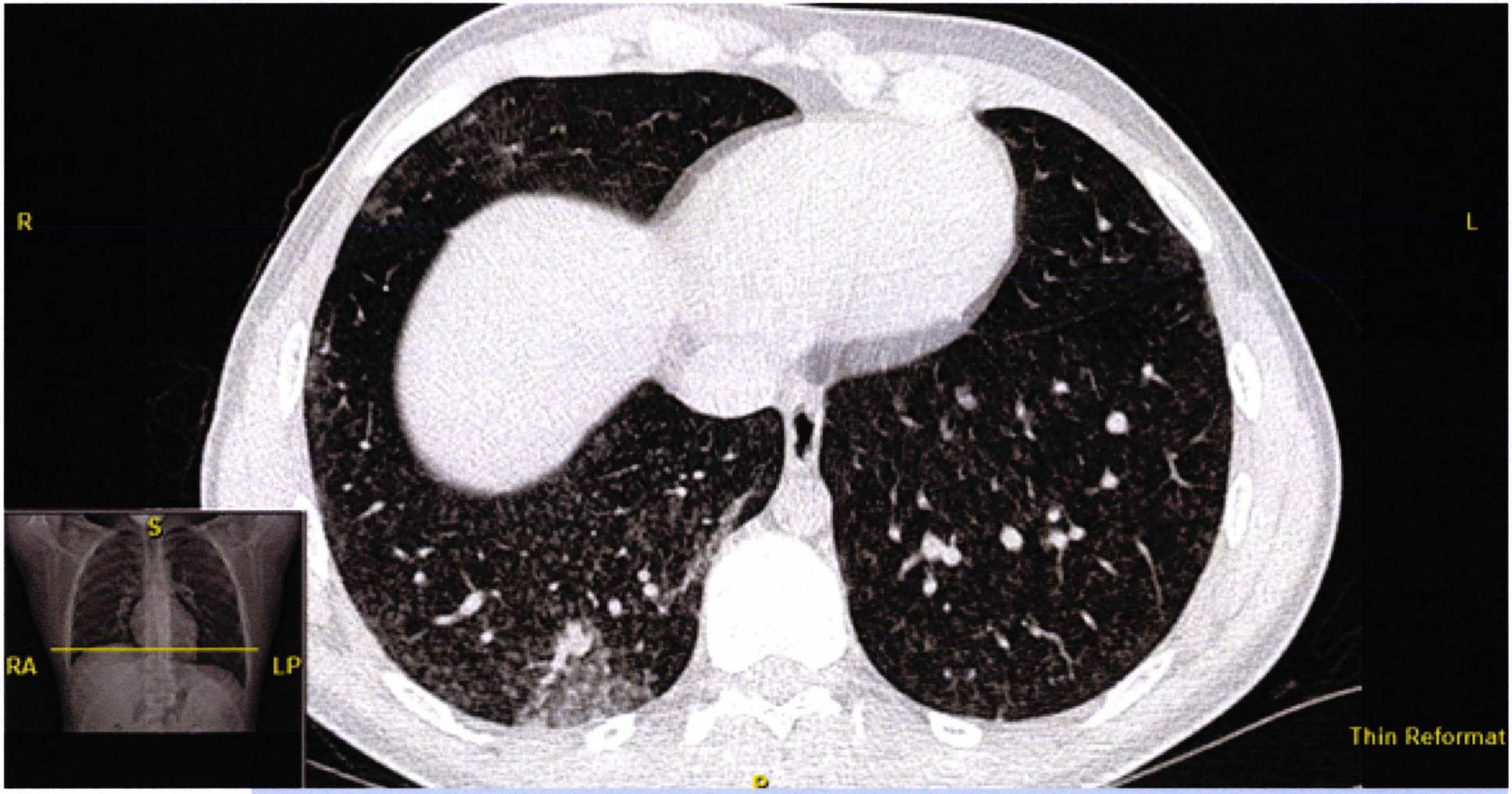


Normal lung

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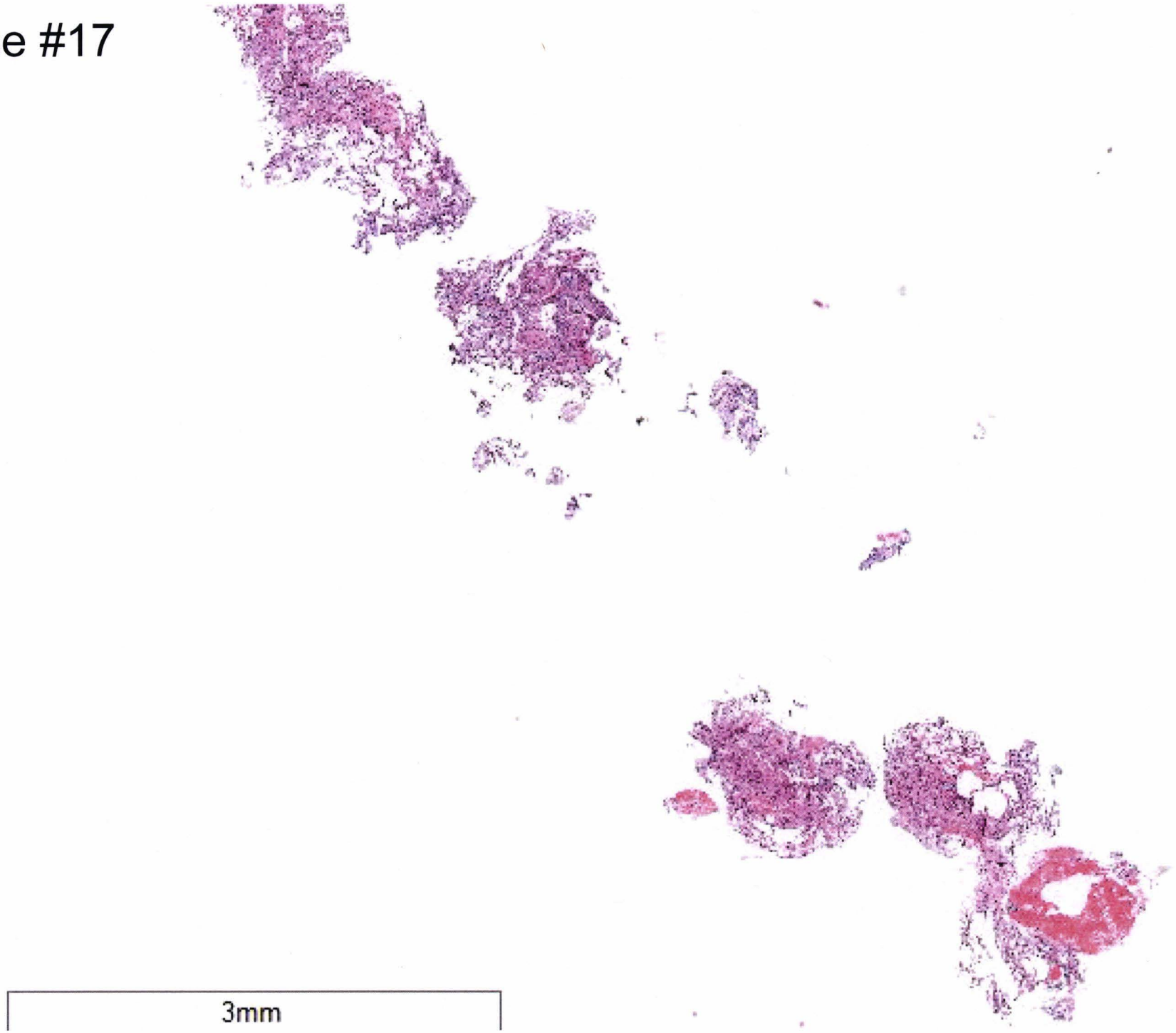
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Chest CT

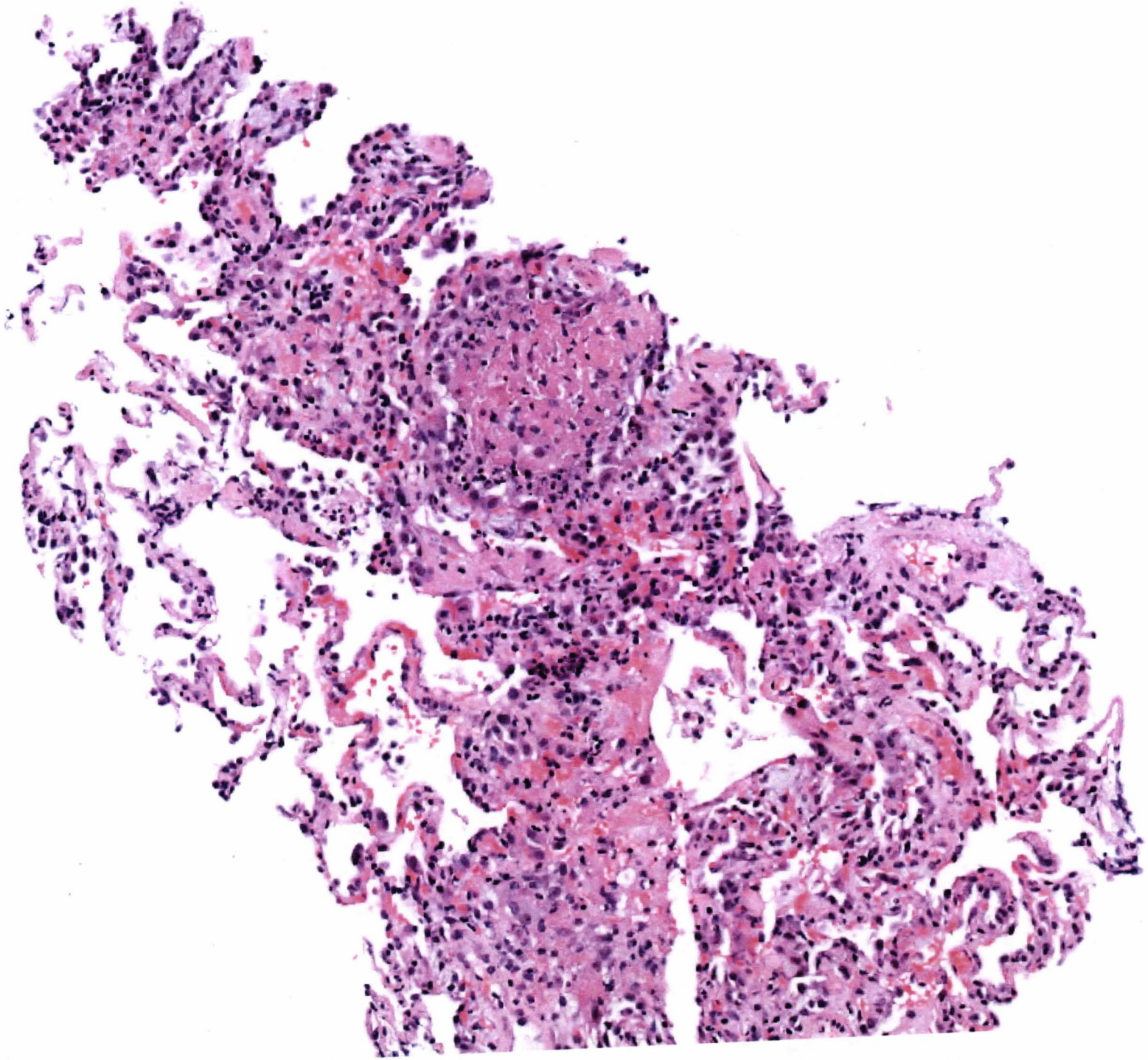


Case #17

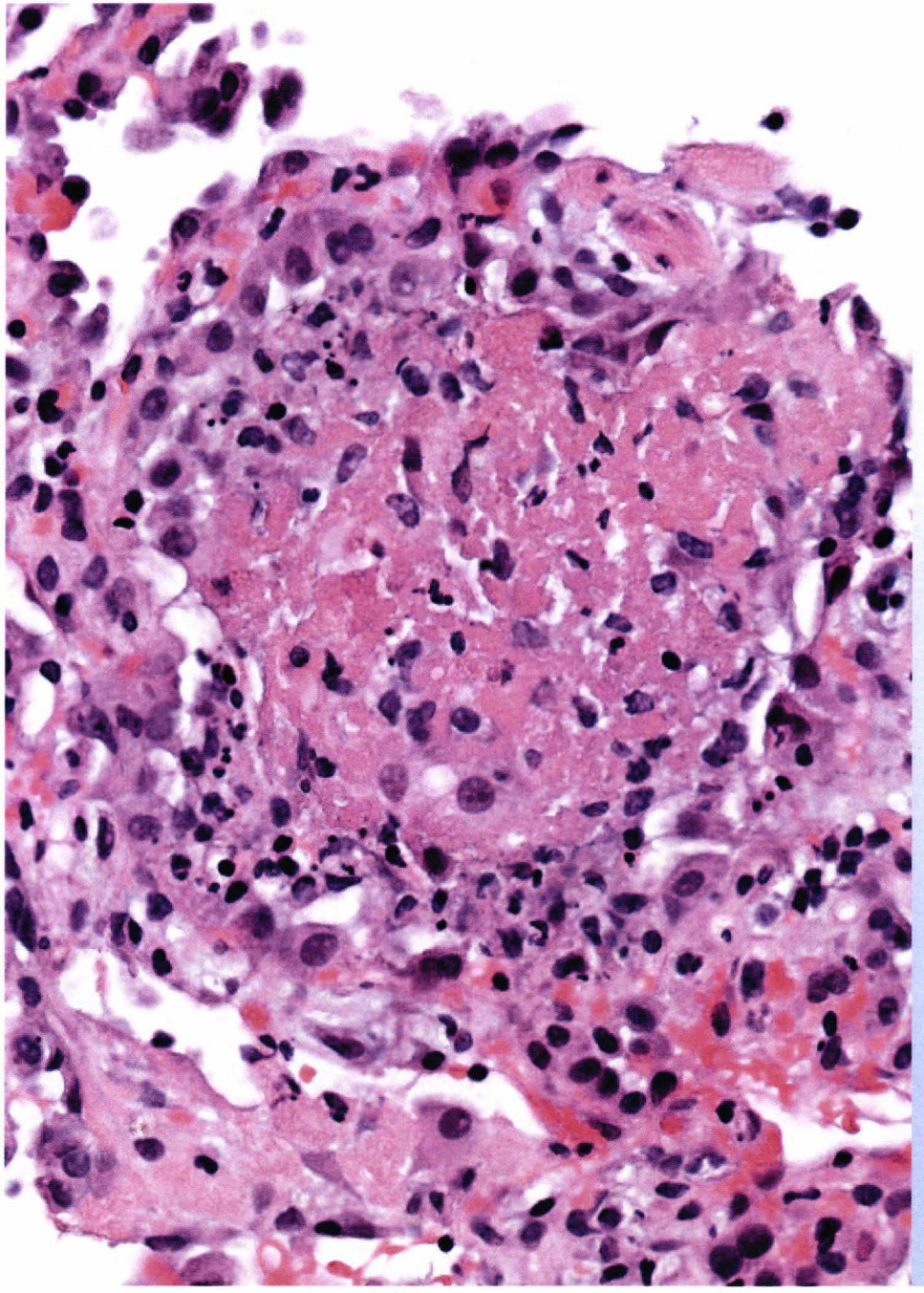
Case #17



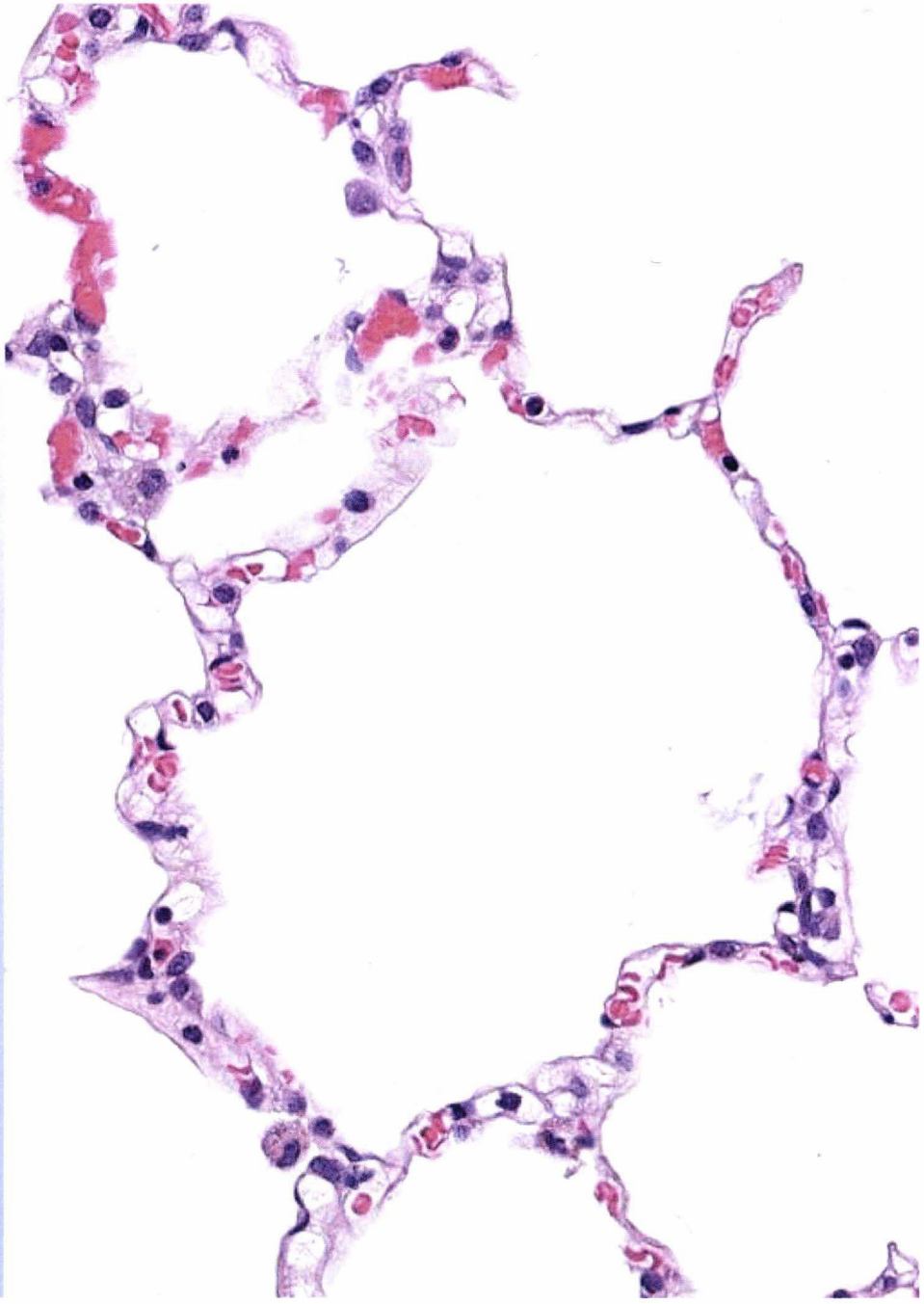
Case #17



Case #17



Normal lung



Results: Outcomes

- Information was available in seven patients:
  - two patients (both with diffuse alveolar damage) died of their illness
  - the other five were improving or improved at the time of last follow-up

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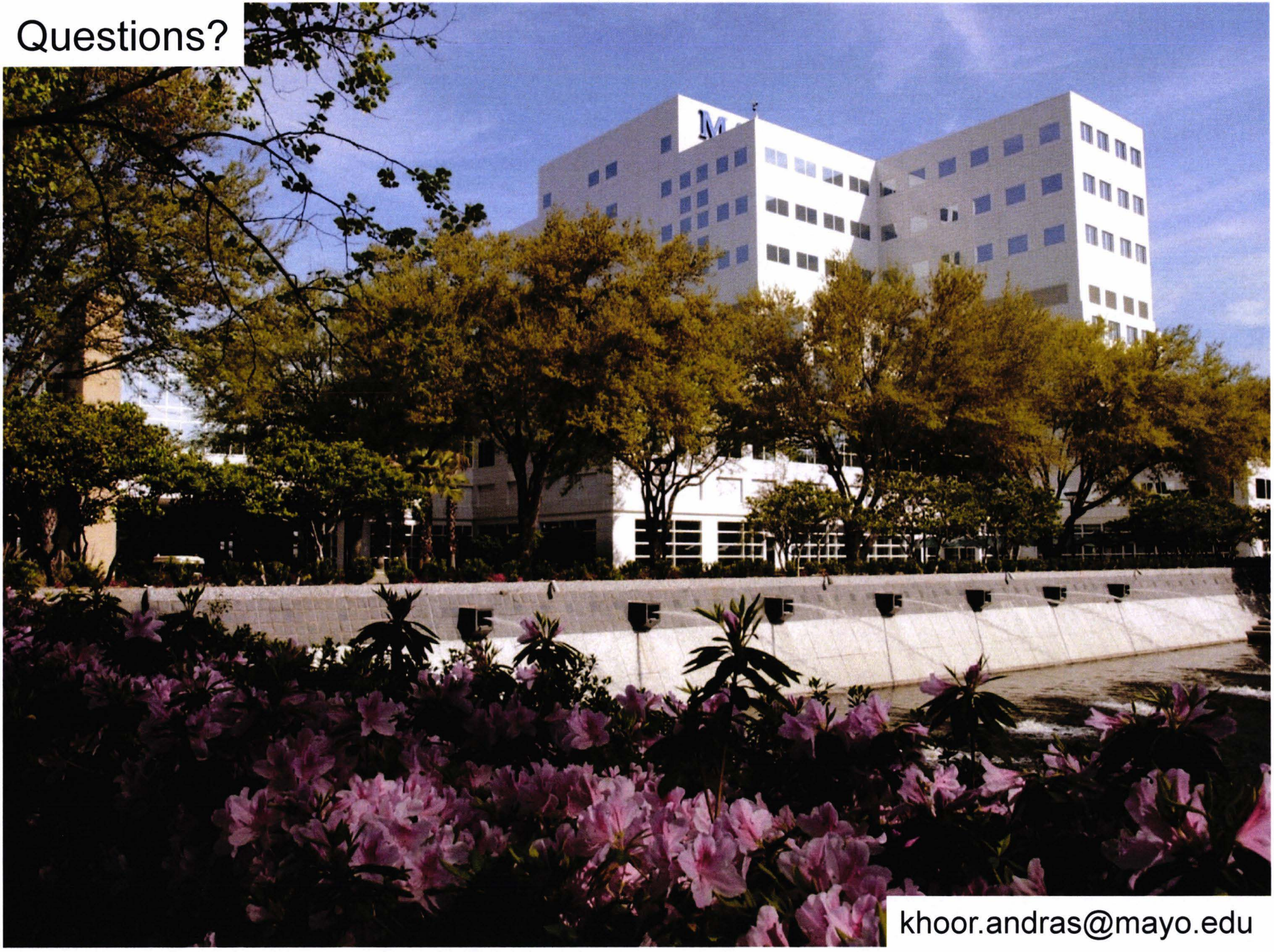
Conclusions

- We believe that the histologic changes suggest that vaping-associated lung injury represents
  - a form of airway-centered chemical pneumonitis from one or more inhaled toxic substances
  - not exogenous lipoid pneumonia
- The agents responsible remain unknown

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Questions?



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E-cigarette Liquid Composition

- Propylene glycol
- Glycerin
- Contaminants, including
  - polycyclic aromatic hydrocarbons,
  - nitrosamines,
  - endotoxins,
  - diacetyl, and
  - a wide variety of other organic and inorganic chemicals and flavoring compounds

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Regulating Tobacco Products

Florida House of Representatives

Business & Professions Subcommittee

Wednesday, October 23, 2019

Heather Youmans

Senior Director, Florida Government Relations

Evidence-Based Policies



- Regular and significant increases in taxes on all tobacco products, including e-cigarettes
- Comprehensive smoke-free laws that include e-cigarettes
- Fully funding and implementing tobacco control programs in accordance with US Center for Disease Control's (CDC's) Best Practices
- Comprehensive coverage of US Food and Drug Administration (FDA) approved cessation treatments and individual, group and phone counseling

Evidence-Based Policies

Cancer Action Network℠
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- Raising the age of sale to 21 for all tobacco products (Tobacco 21) with strong retailer compliance and active enforcement
- Restricting the sale of ALL flavored tobacco products, including menthol cigarettes
- Protecting authority to pass local laws, stronger than the minimum standard set by state laws

Policy Background – Electronic Cigarettes

- ***Sottera, Inc.* v. *Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010)**
  - In 2008, the FDA stopped shipments of e-cigarettes into the United States
  - The FDA claimed the products were unapproved drug-device combination products under the Federal Food, Drug, and Cosmetic Act that were intended to help treat the withdrawal symptoms of nicotine addiction
  - Two e-cigarette distributors sued the FDA requesting a preliminary injunction. They claimed the products were tobacco products for "smoking pleasure," not drug-device combination products

Policy Background – Electronic Cigarettes

Between the filing of the lawsuit and a decision for a preliminary injunction, Congress passed the **Family Smoking Prevention and Tobacco Control Act** (Tobacco Control Act) and it was signed into law.

Ultimately, The D.C. Circuit found that under the Tobacco Control Act, all products made or derived from tobacco and intended for human consumption that are "marketed for therapeutic purposes" are subject to FDA's drug and/or device provisions, whereas "customarily marketed tobacco products" are subject to regulation as "tobacco products".

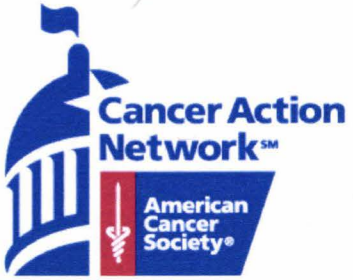
The FDA decided not to appeal the decision to the Supreme Court and instead issued a statement of its intent to regulate e-cigarettes as a tobacco product.

What is considered a "Tobacco Product"?

FDA finalized a rule, effective August 8, 2016

- Cigarettes
- Smokeless tobacco
- E-cigarettes and other Electronic Nicotine Delivery Systems (ENDS)
- Hookah (waterpipe) tobacco
- Pipe tobacco
- Cigars
- Nicotine gels
- Dissolvables

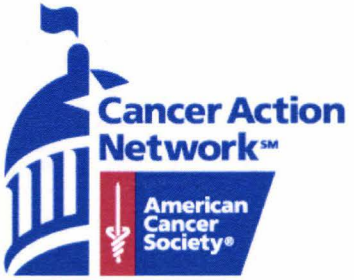
FDA Inaction on E-cigarettes



- FDA has yet to require e-cigarettes to go through premarket review and receive a marketing order from the FDA

- FDA has not removed flavored e-cigarettes including, mint and menthol, from the market

Current State Regulations of E-cigarettes



- Only 4 states fund tobacco control programs at more than 50% of CDC's recommended funding level
- Only 18 states and DC have excise taxes on e-cigarettes
  - Only 7 of these states come close to taxing them at a rate parallel to the state tax on cigarettes
- Only 18 states and DC prohibit the use of e-cigarettes in 100% smoke-free venues

State of Play in Florida

- E-cigarettes are not defined as tobacco products
  - E-cigarette retailers are not required to obtain a tobacco license
- No excise tax on e-cigarettes
- E-cigarettes were just added to the Florida Clean Indoor Air Act (Amendment 9), but all smoking is still allowed in stand-alone bars
- E-cigarettes were added to the program of work for Tobacco Free Florida, but the program is only funded at 36.3% of CDC's recommendation and additional spending authority provided for education exclusively focused on youth

State of Play in Florida

- No type of counseling (individual, group, or telephone) and no FDA approved tobacco cessation medication coverage for Medicaid enrollees
- 2 local jurisdictions have Tobacco 21 laws

Tobacco 21 – Evidence-Based Policy

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What Does a Comprehensive Tobacco 21 Law Include?

- Covers all tobacco products, including electronic cigarettes
- Provides public education and training and technical assistance to retailers
- Implements measures for active enforcement, such as retailer licensing and penalties, including license suspension and revocation
- Does not create new categories of products, which would exempt them from other tobacco control laws
- Does not penalize youth
- Does not preempt other jurisdictions from passing strong tobacco control laws

Tobacco 21

- State & Local State-of-Play
  - 18 states, DC and at least 500 localities now have T21 laws
    - Strength of the laws vary widely

State Tobacco Retailer Licensing Laws



- 37 states and DC require retailers that sell cigarettes to obtain a license or permit
- 36 states require a retailer license to sell other tobacco products
- 20 states require a retailer license to sell e-cigarette

In Conclusion

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- Florida needs to take a comprehensive approach to combating the tobacco and e-cigarette epidemic
  - Update the definition of "tobacco products" to include all products that are available on the market
  - Require tobacco retail licensing for all retailers, including e-cigarette retailers
  - Legislation increasing the age of sale for tobacco products should include all products, all people and preserve local control
  - Impose a State Tax: 85% of wholesale price would put e-cigarettes inline with the tax on other non-cigarette tobacco products

Thank You

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www.FightCancer.org