



Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies Part 15 Public Hearing

January 18, 2019

FDA White Oak Campus
10903 New Hampshire Ave, Building 31, Room 1503, Section A
Silver Spring, Maryland 20993

FDA's Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies

Part 15 Public Hearing

January 18, 2019

FDA White Oak Campus

10903 New Hampshire Ave, Building 31, Room 1503, Section A
Silver Spring, Maryland 20993

AGENDA (revised 1/15/2019)

Each presentation is allotted ten minutes. Five minutes [noted in brackets] are allotted following each presentation to offer an opportunity for the panel to ask clarifying questions.

9:00 – 9:15 am Opening Remarks

Dr. Scott Gottlieb
Commissioner

Food and Drug Administration

Dr. Jennifer Rodriguez Pippins
Presiding Officer
Office of the Commissioner

Food and Drug Administration

9:15 - 9:25 am [9:25 - 9:30 am]

Dr. Bonnie Halpern-Felsher
“What FDA should do to reduce youth addiction to e-cigarettes”

Stanford University

9:30 – 9:40 am [9:40-9:45 am]

Ms. Spike Babaian

New York State Vapor Association

“Youth Vaping Epidemic? What is best for public health?”

9:45 – 9:55 am [9:55 – 10:00 am]

Ms. Ronnie Newman and
Ms. Anjali Talcherkar

International Association for Human Values

“The SKY Bio-Psycho-Social Program for Youth Empowerment: Applications for Youth Nicotine Addiction Treatment and Prevention”

10:00 – 10:10 am [10:10 – 10:15 am]

Mr. Bill Godshall

Smokefree Pennsylvania

“Still No Evidence of a Youth Nicotine Vaping Epidemic”

10:15 – 10:25 am [10:25 – 10:30 am]

Dr. Susanne Tanski

American Academy of Pediatrics

“Tobacco Cessation for Adolescents”

10:30 – 10:40 BREAK

10:40 – 10:50 am [10:50-10:55 am]

Mrs. Ruthanne McCormack

Rockville Centre Coalition for Youth

“Rockville Centre Coalition for Youth”

10:55 – 11:05 am [11:05 am – 11:10 am]

Dr. Daniel Hussar

Philadelphia College of Pharmacy at the University of the Sciences

“Reducing Addiction to Nicotine: Strategies Hidden in Plain Sight”

11:10 – 11:20 am [11:20 - 11:25 am]

Mr. Don Seibert

Smokenders Online, LLC

“The Need for Non-Drug Therapies In Reducing Teen Vaping”

11:25 -11:35 am [11:35 – 11:40 am]

Ms. Lauren Lempert

University of California, San Fransisco, Center for Tobacco
Control Research and Education

“FDA is asking the wrong questions to help eliminate youth e-cigarette use”

11:40 – 11:50 am [11:50 – 11:55 pm]

Mr. Mark Anton

Smoke-Free Alternatives Trade Association

“Reducing Youth Access to Vapor Products”

11:55 am– 12:55 pm LUNCH

12:55 – 1:05 pm [1:05-1:10 pm]

Mr. Jack O’Toole

FreshAir Sensor

“Effective Detection of Vaping as a Method of Reducing Youth Use”

1:10 – 1:20 pm [1:20 - 1:25 pm]

Mrs. Jennifer Folkenroth

American Lung Association

“Steps FDA Can Take to Eliminate Youth E-Cigarette Use”

1:25 – 1:35 pm [1:35 – 1:40 pm]

Mr. Larry Flick

The American E-Liquid Manufacturing Association

“Youth Vaping: ENDS Regulation Should Not Differentiate Based on Flavors”

1:40 – 1:50 pm [1:50 – 1:55 pm]

Mr. Michael Diaz

Michelo Spa

TBD

1:55 – 2:05 pm [2:05 – 2:10 pm]

Dr. Amanda Graham

Truth Initiative

“Comment on Eliminating Youth Electronic Cigarette Use: The Role For Drug Therapies”

2:05 – 3:05 pm Open Public Hearing

3:05 – 3:15 pm Concluding remarks

Dr. Jennifer Rodriguez Pippins

Food and Drug Administration

Presiding Officer

Office of the Commissioner

must be tested (Aviation flight crew members and air traffic controllers);

(c) An occupation identified in 49 CFR 382.103 by the Federal Motor Carrier Safety Administration, in which the employee must be tested (Commercial drivers);

(d) An occupation identified in 49 CFR 219.3 by the Federal Railroad Administration, in which the employee must be tested (Railroad operating crew members);

(e) An occupation identified in 49 CFR 655.3 by the Federal Transit Administration, in which the employee must be tested (Public transportation operators);

(f) An occupation identified in 49 CFR 199.2 by the Pipeline and Hazardous Materials Safety Administration, in which the employee must be tested (Pipeline operation and maintenance crew members);

(g) An occupation identified in 46 CFR 16.201 by the United States Coast Guard, in which the employee must be tested (Crewmembers and maritime credential holders on a commercial vessel);

(h) An occupation specifically identified in Federal law as requiring an employee to be tested for controlled substances;

(i) An occupation specifically identified in the State law of that State as requiring an employee to be tested for controlled substances; and

(j) An occupation where the State has a factual basis for finding that employers hiring employees in that occupation conduct pre- or post-hire drug testing as a standard eligibility requirement for obtaining or maintaining employment in the occupation.

§ 620.4 Testing of unemployment compensation applicants for the unlawful use of a controlled substance.

(a) States may require drug testing for unemployment compensation applicants, as defined in § 620.2, for the unlawful use of one or more controlled substances, as defined in § 620.2, as a condition of eligibility for unemployment compensation, if the individual is one for whom suitable work, as defined in State law, as defined in § 620.2 of, is only available in an occupation that regularly conducts drug testing as identified under § 620.3.

(b) A State conducting drug testing as a condition of unemployment compensation eligibility, as provided in paragraph (a) of this section, may only elect to require drug testing of applicants for whom the only suitable work is available in one or more of the occupations listed under § 620.3. States

are not required to apply drug testing to any applicants for whom the only suitable work is available in one or all of the occupations listed.

(c) No State is required to drug test UC applicants under this part 620.

§ 620.5 Conformity and substantial compliance.

(a) *In general.* A State law implementing the drug testing of applicants for unemployment compensation must conform with—and the law's administration must substantially comply with—the requirements of this part 620 for purposes of certification under 42 U.S.C. 502(a), governing State eligibility to receive Federal grants for the administration of its UC program.

(b) *Resolving Issues of Conformity and Substantial Compliance.* For the purposes of resolving issues of conformity and substantial compliance with the requirements of this part 620, the provisions of 20 CFR 601.5 apply.

Molly E. Conway,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2018–23952 Filed 11–2–18; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2018–N–3952]

Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing to discuss its efforts to eliminate youth electronic cigarette (e-cigarette) use as well as other tobacco product use, with a focus on the potential role of drug therapies to support youth e-cigarette cessation and the issues impacting the development of such therapies.

DATES: The public hearing will be held on December 5, 2018, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to present at the public hearing must register by Friday,

November 23, 2018. Persons seeking to attend, but not present at, the public hearing must register by Monday, December 3, 2018. Section II provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until Wednesday, January 2, 2019.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room A, Silver Spring, MD 20993–0002. Entrance for public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before Wednesday, January 2, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of Wednesday, January 2, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-N-3952 for “Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies; Public Hearing; Request for Comments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the received electronic and written/paper comments, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Theresa Wells, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1202, Silver Spring, MD 20993, 703-380-3900, Theresa.wells@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Nearly all tobacco product use begins during youth and young adulthood (Ref. 1). While the current use of any tobacco product among U.S. middle and high school students has decreased from 2011–2017, there has been an alarming increase in e-cigarette use over this time. In fact, since 2014, e-cigarettes¹ have been the most commonly used tobacco products among youth, used by 1.73 million (11.7 percent) high school students and 390,000 (3.3 percent) middle school students in 2017 (Ref. 2). Youth e-cigarette use raises a number of health concerns including risk of addiction to nicotine early on in life, potential harm to the developing adolescent brain, and exposure to chemicals including carbonyl compounds and volatile organic compounds known to have adverse health effects; the full range of possible health effects is not yet completely understood (Ref. 3).

On April 24, 2018, FDA announced its Youth Tobacco Prevention Plan. This plan focuses on three key strategies: Prevention of youth access to tobacco products, curbing the marketing of tobacco products aimed at youth, and educating teens about the dangers of using any tobacco products.² FDA recently launched an expansion of its “The Real Cost” campaign to educate youth on the dangers of e-cigarette use³ and increased enforcement actions to

address this critically important public health concern.⁴

In addition to the prevention of initiation, which will be the cornerstone of any successful effort to curb youth e-cigarette use, FDA is also exploring additional approaches to address youth e-cigarette use. One such approach may be the development of drug therapies, as part of multimodal treatment strategies, including behavioral interventions, to support tobacco product cessation. To date, research on youth tobacco product cessation has been limited and focused on smoking (*i.e.*, combustible products) cessation. One recent review found a paucity of data on either behavioral or drug therapies for smoking cessation in young people (age less than 20 years) and concluded that “there continues to be a need for well-designed, adequately powered, randomized controlled trials of interventions for this population of smokers” (Ref. 4). FDA is not aware of any research examining either drug or behavioral interventions for the cessation of youth or adult e-cigarette use. In contrast, there is a large body of research on adult smoking cessation, and multiple drugs for smoking cessation are approved for the adult population, including a variety of prescription and over-the-counter nicotine replacement therapy (NRT) products, as well as the prescription drugs varenicline and bupropion hydrochloride sustained release (see Appendix A).

II. Purpose and Scope of the Public Hearing

FDA is holding a public hearing to obtain the public’s perspectives on the potential role drug therapies may play in the broader effort to eliminate youth e-cigarette and other tobacco product use, as well as the appropriate methods and study designs for evaluating youth e-cigarette cessation therapies and the safety and efficacy of such therapies. The Agency has determined that a public hearing is the most appropriate way to ensure public engagement on this issue, which is of great importance to the public health. FDA believes it is critical to obtain input across the medical and research fields, the pharmaceutical and tobacco industries, and among public health stakeholders (including adolescents) regarding approaches to eliminate youth e-cigarette and other tobacco product use, including exploring whether there is a need for drug therapies to support youth e-cigarette cessation, and if so, how FDA

¹ An e-cigarette is one type of electronic nicotine delivery system, which also includes e-cigs, e-hookah, vape pens, personal vaporizers, and electronic pipes. See <https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm> and Ref. 2.

² <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm>.

³ <https://www.fda.gov/tobaccoproducts/publichealtheducation/publiceducationcampaigns/therealcostcampaign/default.htm>.

⁴ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm>.

can support the development of such therapies.

Questions for Commenters To Address

Considering the broad range of activities focused on this public health issue, FDA is interested in the public's view on approaches to eliminating e-cigarette and other tobacco product use among youth. Although FDA welcomes all feedback on any public health, scientific, regulatory or legal considerations relating to this topic, we particularly encourage commenters to consider the following questions as they prepare their comments or statements. Responses to questions should include supporting scientific justification.

1. FDA notes that the factors driving e-cigarette use among youth likely differ from those in the adult population. How might such differences impact the need for, or use of, drug therapies for e-cigarette cessation among youth?

2. FDA is interested in whether there is a population of youth e-cigarette users who would be likely to benefit from the use of drug therapies for e-cigarette cessation. What age groups (older adolescent vs. younger adolescent), patterns in tobacco use (duration and frequency of use), and clinical features (level of addiction, presence/absence of comorbidities including psychiatric disease) might characterize this population? What types of products (NRT vs. non-NRT; prescription vs. over-the-counter) might be useful?

3. Describe the scientific, clinical, and societal factors that could either encourage or impede the conduct of clinical trials designed to evaluate drugs intended for youth e-cigarette cessation. What approaches could be used to encourage research and overcome barriers to research?

4. What methods and study designs are appropriate for assessing drug therapies for youth e-cigarette cessation? What are the appropriate control groups? What are the most informative endpoints and the best assessment tools to evaluate these endpoints?

5. Acknowledging that to date research has been limited, are there data available from the adult experience with smoking cessation that could potentially be leveraged in the effort to develop drug therapies for youth e-cigarette cessation? Have any drug therapies demonstrated potential to help adults discontinue e-cigarette use? Are there differences between adolescents and adults that impact the ability to extrapolate efficacy findings from the adult population to the adolescent population? Could existing NRT products be useful for youth e-cigarette cessation?

6. While this hearing is focused on the topic of e-cigarette use among youth, as e-cigarettes are currently the most commonly used form of tobacco in this population, FDA also welcomes comments regarding the potential need for drug therapies to support cessation of other tobacco products, including combustible products (*i.e.*, cigarettes or cigars) and smokeless tobacco products, among youth and the issues impacting the development of such therapies.

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. For those interested in presenting at the meeting, either with a formal oral presentation or as a speaker in the open public hearing session, please register by Friday, November 23, 2018, at <https://www.eventbrite.com/e/fda-pediatric-tobacco-cessation-part-15-public-hearing-tickets-50167147288>. If you wish to attend either in person or by Webcast (see *Streaming Webcast of the Public Hearing*), please register for the hearing by Monday December 3, 2018, at <https://www.eventbrite.com/e/fda-pediatric-tobacco-cessation-part-15-public-hearing-tickets-50167147288>. Those without internet or email access can register and/or request to participate as an open public hearing speaker or a formal presenter by contacting Theresa Wells by the above dates (see **FOR FURTHER INFORMATION CONTACT**).

FDA will try to accommodate all persons who wish to make a presentation. Formal oral presenters may use an accompanying slide deck, while those participating in the Open Public Hearing will have less allotted time than formal oral presenters and will deliver oral testimony only (no accompanying slide deck). Individuals wishing to present should identify the number of the specific question, or questions, they wish to address. This will help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. Individual organizations are limited to a single presentation slot. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Registered presenters making a formal oral presentation are encouraged to submit an electronic copy of their presentation (PowerPoint or PDF) to OMPTFeedback@fda.hhs.gov with the subject line "Eliminating Youth

Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies" on or before Wednesday, November 28, 2018. Persons registered to present are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. Actual presentation times, however, may vary based on how the meeting progresses in real-time. An agenda for the hearing and any other background materials will be made available 5 days before the hearing at <https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm620744.htm>.

If you need special accommodations because of a disability, please contact Theresa Wells (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live Webcast of the hearing. To join the hearing via the Webcast, please go to <https://collaboration.fda.gov/ptc120518>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see *Comments*). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's website at <https://www.fda.gov>.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, and the Center for Tobacco Products. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members can pose questions; they can question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public

administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction.

Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

- 1.* U.S. Department of Health and Human Services (2014). "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 available at: <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>.
- 2.* Wang T.W., A. Gentzke, S. Sharapova, et al. (2018). "Tobacco Product Use Among Middle and High School Students—United States, 2011–2017." *Morbidity and Mortality Weekly Report (MMWR)*

67:629–633, available at <https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm>).

- 3.* U.S. Department of Health and Human Services (2016). "E-Cigarette Use Among Youth and Young Adults: 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 available at: https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.
4. Fanshawe T.R., W. Halliwell, N. Lindson, et al. (2017). "Tobacco Cessation Interventions for Young People." Cochrane Database of Systematic Reviews, Rev.11:CD003289, available at <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003289.pub6/epdf/full>.

BILLING CODE 4164–01–P

Appendix A: Summary of FDA-Approved Active NDAs of NRTs and non-NRTs Indicated for Smoking Cessation (October 5, 2018)

Product Name (NDA #, holder)	OTC or Rx (Date approved, Date Rx→OTC)	Route (Doses)	Indication	Adult Treatment Duration and Schedule	Pediatric Labeling
NRT Therapies					
Nicorette gum (nicotine polacrilex) (NDA 018612 for 2 mg, NDA 020066 for 4 mg, GSK)	Approved as prescription on 1/13/84 for 2 mg; 6/8/92 for 4 mg; Rx→OTC for both on 2/9/96.	Oral (2, 4 mg gum)	Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.	12 weeks (for longer use, talk to health care provider): <ul style="list-style-type: none">• Wk 1-6: 1 per 1-2 hr• Wk 7-9: 1 per 2-4 hr• Wk 10-12: 1 per 4-8 hr If smoke 1* cigarette within 30 min of waking up, use 4 mg; if more than 30 min, use 2 mg.	If you are under 18 years of age ask a doctor before use.
NicoDerm CQ (nicotine) (NDA 020165; Sanofi Aventis)	Approved as prescription on 11/7/91; Rx→OTC on 8/2/96.	Patch (7, 14, 21 mg)	Same as above	10 weeks and 8 weeks (for longer use, talk to health care provider): If > 10 cigarettes/day: <ul style="list-style-type: none">• Wk 1-6: one 21 mg/day• Wk 7-8: one 14 mg/day• Wk 9-10: one 7 mg/day If ≤ 10 cigarettes/day: <ul style="list-style-type: none">• Wk 1-6: one 14 mg/day• Wk 7-8: one 7 mg/day	Same as above
Habitrol (nicotine) (NDA 020076; Dr. Reddy's)	Approved as prescription on 11/27/91; Rx→OTC on 11/12/99.	Patch (7, 14, 21 mg)	Same as above	8 weeks (for longer use, talk to health care provider): If > 10 cigarettes/day: <ul style="list-style-type: none">• Wk 1-4: one 21 mg/day• Wk 5-6: one 14 mg/day• Wk 7-8: one 7 mg/day If ≤ 10 cigarettes/day: <ul style="list-style-type: none">• Wk 1-6: one 14 mg/day• Wk 7-8: one 7 mg/day	Same as above

Product Name (NDA #, holder)	OTC or Rx (Date approved, Date Rx→OTC)	Route (Doses)	Indication	Adult Treatment Duration and Schedule	Pediatric Labeling
Nicotrol NS (nicotine) (NDA 020385; Pfizer)	Prescription (3/22/96; N/A)	Nasal spray (50 microliter spray delivering 0.5 mg)	<ul style="list-style-type: none"> Indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms Should be used as a part of a comprehensive behavioral smoking cessation program 	2 sprays (one per nostril) = 1 dose <ul style="list-style-type: none"> Starting dose: 1-2 doses/hour Maximum doses/hour: 5 Maximum doses/day: 40 Maximum recommended duration of treatment: 3 months The safety and efficacy of the continued use of Nicotrol NS for periods longer than 6 months have not been adequately studied and such use is not recommended.	Under Pediatric Use: Not recommended for use in the pediatric population because its safety and effectiveness in children and adolescents who smoke have not been evaluated.
Nicotrol Inhaler (nicotine) (NDA 020714; Pharmacia and Upjohn)	Prescription (5/2/97; N/A)	Inhalant (10 mg cartridge; 4 mg delivered)	<ul style="list-style-type: none"> Indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms Recommended for use as part of a comprehensive behavioral smoking cessation program. 	The recommended duration of treatment is 3 months, after which patients may be weaned from the inhaler by gradual reduction of the daily dose over the following 6 to 12 weeks. The safety and efficacy of the continued use of Nicotrol Inhaler for periods longer than 6 months have not been studied and such use is not recommended.	Safety and effectiveness in pediatric and adolescent patients below the age of 18 years have not been established for any nicotine replacement product. However, no specific medical risk is known or expected in nicotine dependent adolescents. NICOTROL Inhaler should be used for the treatment of tobacco dependence in the older adolescent only if the potential benefit justifies the potential risk.

Product Name (NDA #, holder)	OTC or Rx (Date approved; Date Rx→OTC)	Route (Doses)	Indication	Adult Treatment Duration and Schedule	Pediatric Labeling
Nicorette lozenge (nicotine polacrilex) (NDA 021330; GSK)	OTC (10/31/02; N/A)	Oral (2, 4 mg)	Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking	12 weeks (for longer use, talk to health care provider): <ul style="list-style-type: none"> Wk 1-6: 1 per 1-2 hr Wk 7-9: 1 per 2-4 hr Wk 10-12: 1 per 4-8 hr If smoke 1 st cigarette within 30 min of waking up, use 4 mg; if more than 30 min, use 2 mg.	If you are under 18 years of age ask a doctor before use. No studies have been done to show if this product will work for you.
Nicorette mini lozenge (nicotine polacrilex) (NDA 022360; GSK)	OTC (5/18/09; N/A)	Oral (2, 4 mg)	Same as above	Same as above	Same as above
Non-NRT Therapies					
Zyban (bupropion hydrochloride sustained release) (NDA 020711; GSK)	Prescription (5/14/97; N/A)	Oral (150 mg)	<ul style="list-style-type: none"> Indicated as an aid to smoking cessation treatment 	7-12 weeks: <ul style="list-style-type: none"> Start at one 150-mg tablet per day for 3 days Can increase to 300 mg per day given as one 150-mg tablet twice each day, with 8 hours between Patient may benefit from ongoing treatment.	Safety and effectiveness in the pediatric population have not been established. Boxed Warning for suicidality in children, adolescents, and young adults in setting of bupropion use as an antidepressant.

Dated: October 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24126 Filed 11–2–18; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2018–D–1459]

Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics.” The draft guidance, when finalized, will provide questions and answers on topics related primarily to implementing two final rules, one entitled “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments,” and the other entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels.” This draft guidance also discusses formatting issues for dual-column labeling, products that have limited space for nutrition labeling, and additional issues dealing with compliance.

DATES: Submit either electronic or written comments on the draft guidance by January 4, 2019 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–D–1459 for “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential

with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-



Stanford
M E D I C I N E

What FDA should do to reduce youth addiction to e-cigarettes

Bonnie Halpern-Felsher, PhD
Professor of Pediatrics
Project Lead, UCSF TCORS



Stanford
Children's Health

Lucile Packard
Children's Hospital
Stanford

No Evidence for Pharmacological Approaches for Youth Cessation

- No FDA-approved NRTs for youth
- No evidence of effectiveness when used off label
- Need more research using RCTs, with those under age 18

Youth Plan to Quit “Later”

- Evidence that the tobacco industry cannot be trusted and is manipulating them to use their products motivates quit attempts among youth
- Messaging that e-cigarettes are “harm reduction” presents industry as trustworthy
- Social factors more important than health effects



FDA Lets E-cigarettes Make Cessation Claims

FDA Saying E-cigs Help Adults Quit Smoking Aggravates Problem

- For most adults, e-cigarettes thwart quit attempts
 - and ultimately increase nicotine use
- Youth recognize cessation claims and believe OK to use
 - Supports “I’ll quit later”

95% OF VAPERS
 PLAN TO NEVER GO BACK TO ANALOGS AGAIN

Explicit claim

NEVER GOING BACK

PROVAPOR
 Like Comment

#VAPEPROVARI

Implicit claim

Paper or plastic?

NJOY
 KING

Implicit claim

blu PLUS+ #PlusWorks
works for you

Explicit claim

Fake plastic!
 The babies have kept me smoke free for months now. **19**

- Richard G.

Veppo
www.VeppoCig.com

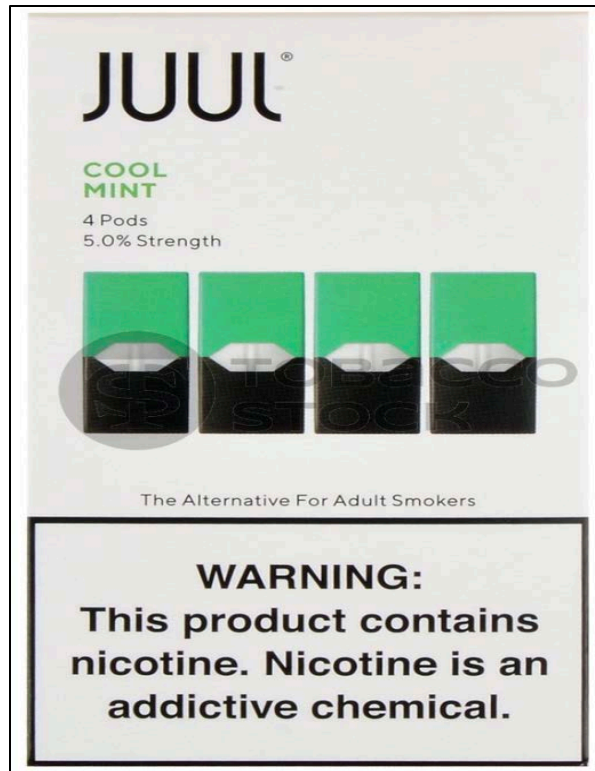
Youth Don't Understand Addiction

- Don't recognize that addiction means that they will
 - find it difficult to stop smoking
 - continue smoking longer than they want
- Perceive Juuls as less harmful and less addictive
 - but more nicotine dependence is being reported

Roditis, Lee, & Halpern-Felsher, 2015

McKelvey, Baiocchi, & Halpern-Felsher, 2018

Youth Don't Understand Addiction



Youth Don't Understand Addiction



Warning that simply says a product is addictive or contains an addictive chemical not understood by youth

How Much is That?



5% strength
of what?



59 mg/mL !

How much is
5%?

What FDA Should Do for Youth

Eliminate ALL Flavors

- Youth use flavors
- Youth unlikely to use e-cigarettes without flavors
- Must prohibit ALL flavors, including mint and menthol



Eliminate ALL Flavors

- Youth use flavors
- Youth unlikely to use e-cigarettes without flavors
- Must prohibit ALL flavors, including mint and menthol
- **Little evidence adults need flavors to quit smoking**



First Flavors Used by Participants Reporting Juul & Other E-cigarette Use

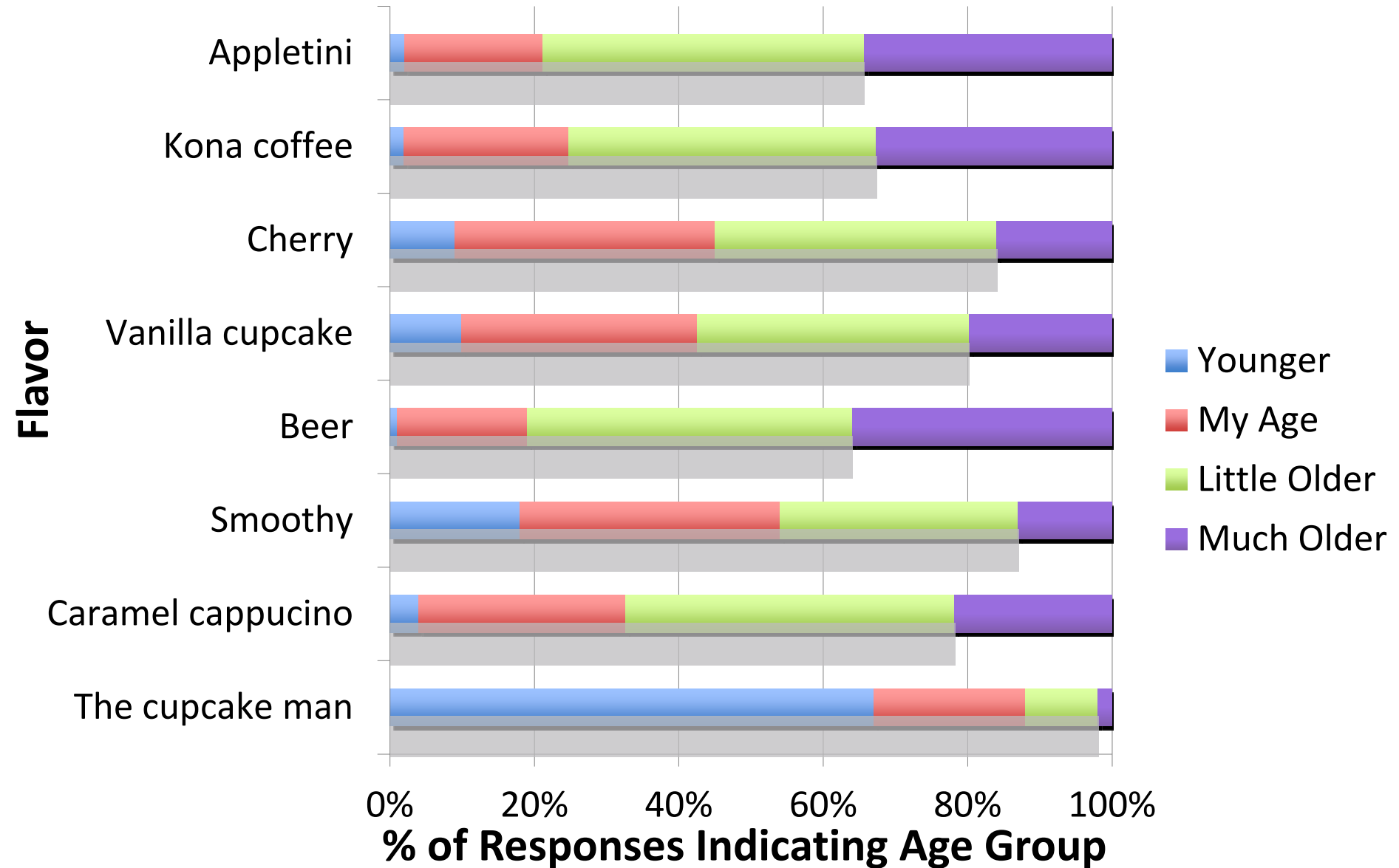
	Juuls (N, %)	Other e-cigarettes (N, %)
First product flavored (yes)	73.8%	84.4%
First flavor used		
	Juuls	Other e-cigarettes
Tobacco	1.5%	0.9%
Menthol/mint	26.9%	12.0%
Fruit	28.4%	46.3%
Dessert/sweets	4.5%	17.6%
Coffee/tea	0	0.9%
Don't know/other	32.9%	21.3%

Eliminate ALL Ads for Flavors

- Youth report ads for flavored e-cigarettes target them



Target Age Group Attributed to Ads by Flavor



In Sum, FDA Should

- Eliminate all flavors and ads for flavors
- Stop saying e-cigs are safe(r)
 - Prohibit e-cig companies from making unauthorized reduced risk claims
- Stop saying e-cigs help quit smoking
 - Prohibit e-cig companies from making unauthorized therapeutic claims
- Stop reinforcing youth thinking they can quit “later”
 - Youth don’t understand addiction or believe they are addicted



Youth Vaping Epidemic?

What is best for public health?

Spike Babaian
Technical Analysis Director
New York State Vapor Association
spike@nysva.org

Epidemic?




Dictionary

Search for a word



ep·i·dem·ic

/,epə'demik/ 

noun

1. a widespread occurrence of an infectious disease in a community at a particular time.

"a flu epidemic"

synonyms: [outbreak](#), [plague](#), [pandemic](#), [epizootic](#)

"an epidemic of typhoid"

adjective

1. relating to or of the nature of an epidemic.

"shoplifting has reached epidemic proportions"

synonyms: [rife](#), [rampant](#), [widespread](#), [wide-ranging](#), [extensive](#), [pervasive](#); [More](#)



Translations, word origin, and more definitions

Experimentation or Epidemic?



Past 30 day use of vapor products does not qualify as addiction or dependence. Without knowing whether the user is dependent on nicotine, it is unrealistic to consider it an epidemic.

CDC might consider some qualifying questions on dependence for NYTS in 2019.

Diagnosing Dependence



ICD-10 Diagnostic guidelines

A definite diagnosis of dependence should usually be made **only if three or more of the following have been present together** at some time during the previous year:

- A strong desire or sense of compulsion to take the substance;
- Difficulties in controlling substance-taking behaviour in terms of its onset, termination, or levels of use;
- A physiological withdrawal state when substance use has ceased or have been reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- Evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses (clear examples of this are found in alcohol- and opiate-dependent individuals who may take daily doses sufficient to incapacitate or kill nontolerant users);
- Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects;
- Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.

Youth smoking at an all time low!



According to CDC Data from NYTS from 2011 to 2017 the past 30 day smoking rate of high school students dropped by more than half to the lowest rate in history.

Youth vaping at an all time high?



NYTS (National Youth Tobacco Survey) data from the CDC asks about past 30 day e-cigarette use. This is the number they use to determine that e-cigarette use is at an all time high according to Dr. Gottlieb. Except that each year since 2015 they add a new vapor product to the list.

NYTS 2015 Questions



"The next 12 questions are about electronic cigarettes or e-cigarettes. E-cigarettes are electronic devices that usually contain a nicotine-based liquid that is vaporized and inhaled. You may also know them as **vape-pens, hookah-pens, electronic hookahs (e-hookahs), electronic cigars (e-cigars), electronic pipes (e-pipes), or evaporizers.**"

NYTS 2016 Questions



"The next 13 questions are about electronic cigarettes or e-cigarettes. E-cigarettes are battery powered devices that usually contain a nicotine-based liquid that is vaporized and inhaled. You may know them as **vape-pens, hookah-pens, e-hookahs, e-cigars, e-pipes, personal vaporizers or mods**. Some brand examples include NJOY, Blu, Vuse, MarkTen, Logic, Vapin Plus, eGo, Halo. "

NYTS 2017 Questions



"The next 11 questions are about electronic cigarettes or e-cigarettes. E-cigarettes are battery powered devices that usually contain a nicotine-based liquid that is vaporized and inhaled. You may also know them as **e-cigs, vape-pens, hookah-pens, e-hookahs, e-cigars, e-pipes, personal vaporizers, or mods**. Some brand examples include NJOY, Blu, Vuse, MarkTen, Logic, Vapin Plus, eGo, and Halo. "

Marijuana Legalization



In the past 2 years a number of additional states have legalized and decriminalized marijuana use. In the NYTS questions above, each year since 2015 the item “vape-pens” was included. This term refers to electronic devices used to vaporize marijuana. So does “personal vaporizer”.

“Hookah pen” and “e-hookahs” are not typically used with nicotine and are often used with flavor only.

If you do an internet search for vape pen and see what comes up you can clearly see it is not intended for nicotine use.

Youtube search results for some of the terms used in NYTS...

Personal Vaporizer



← → ↻ 🔒 https://www.youtube.com/results?search_query=personal+vaporizer ☆ 🗨️ 📧


☰ YouTube personal vaporizer 🔍


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👤 My channel
🔥 Trending
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 **Apex Dry Herb Vaporizer Review** 6:47
Marijuana Product Review: Apex Portable Personal Dry Herb Vaporizer Pen
RuffHouse Studios 📺
4 years ago • 104,286 views
Bogart reviews the excellent Apex Dry Herb Vaporizer pen for use with marijuana. Check out more about the Apex Vape pen here: ...

 **Haus Personal Vaporizer Starter Kit** 5:55
BluDog35
3 years ago • 3,207 views
Unboxing.

 **Personal Vaporizer** 8:28
Kang Vaping
4 years ago • 48,325 views
PLEASE SUBSCRIBE US:) video ini di buat agar kalian tau apa itu PV atau vaping, kritik, saran, apapun langsung saja comment ...

 **10 DRY HERB VAPES IN 5 MINUTES** 5:57
10 Dry Herb Vaporizers In 5 Minutes | How To Choose A Vaporizer | Sneaky Pete's Vaporizer...
Sneaky Pete Vaporizers
5 months ago • 280,280 views
http://www.vapenorth.ca - http://www.sneakypetevaporizers.com Fury 2 - http://bit.ly/2rqJYpR ...

Vape Pens



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How To Use a Pre-Filled CBD Cartridge Vape Pen
LaynieGanja • 148K views • 1 year ago
This is the CBD Vape Pen I use on the go for fast relief of aches and stress. People are using CBD products for a wide variety of ...

How to Fill Your CCell Cartridge with Distillate Concentrates | tips & tricks | TheDabSpot
The Dab Spot • 361K views • 1 year ago
ccell website: <http://bit.ly/ccelldotcom> Checking out more of the CCELL Disposable Concentrate cartridges today! Learn tips on ...

Brass Knuckle VS Bloom Vape Pen
THE GRASS SKIRT LOUNGE • 8.5K views • 10 months ago
Hey everyone, this is K.D. from the Grass Skirt Lounge. What we are trying to do is educate people, especially those who are new ...

How to use an Oil Cartridge Vape Pen | Euphoria Wellness | Medical Marijuana Las Vegas
Euphoria Marijuana • 548K views • 2 years ago
<http://www.EuphoriaWellnessNV.com/> 702-960-7200 7780 South Jones Blvd Las Vegas, NV 89139
Today we will be teaching ...

Vaped Keenod Keuchain-Flis Battery Vape Pen for Pre-Filled

Hookah Pen



← → ↺ 🔒 https://www.youtube.com/results?search_query=hookah+pens ☆ 5x 37 V


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E shisha pen (E hookah pen) unboxind and taste
Anhar Tech
2 years ago • 297,148 views
don't forget to like and subscribe thanks :)

 10:05
Grape Flavoured "electronic Hookah" e-Cigarette vape pen! WTF even?
Blunty
5 years ago • 754,584 views
Discovered a "nicotine free" e-cigarette today, called the "electronic Hookah", it's Grape flavoured (actually available in a variety of ...

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My First eHookah Review! | Hookah Pen Central | TiaVapes
TiaVapes
4 years ago • 450,773 views
Join my Patreon for awesome rewards: https://www.patreon.com/TiaVapes
⇒ Help our unborn son: ...

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Imperial Hookah Pen Review
ekate12adonis
5 years ago • 584,309 views
Just reviewing the imperial hookah pen. If y'all want another review just let me know. Also check out and follow my Instagram for ...

e-Hookah



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Lucid LivingTV	2
Brave Wilderness	4
MahafsounLair	1
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VAPING ON AN E HOOKAH! | Aspire Proteus eHookah Review | IndoorSmokers

IndoorSmokers
2 years ago • 1,784,544 views
Today I Review the Aspire Proteus ehookah. Get It Here: <http://bit.ly/aspireProteus> LIKE ME ON FACEBOOK: ...

Kangerm M2 200w E-Hookah! | IndoorSmokers

IndoorSmokers
6 months ago • 25,119 views
Today Mike & I Review the Kangerm M2 200w E-Hookah! Get it Here: <http://bit.ly/Kangerm> Get the Ejuice Here: ...

Aspire Glass Hookah & Proteus E Hookah for VAPING!!! - Review

Zophie Vapes
2 years ago • 118,176 views
My first eHookah! Come visit me on Facebook: <https://www.facebook.com/zophievapes/>

ASPIRE E-HOOKAH

The Aspire E Hookah: Hookah Review (2017)

DMZ tv
1 year ago • 7,217 views
What is an E hookah??? Why is DMZ Covering it??? These are questions that we will be talking on today's show. But to keep it ...

Nicotine?



The question NYTS asks does not differentiate between e-cigarettes with nicotine, without nicotine or those which are used for marijuana concentrates.

According to MTF data, the number of youth using vapor products without nicotine or with marijuana concentrates is likely to be a high proportion of the youth using e-cigarettes.

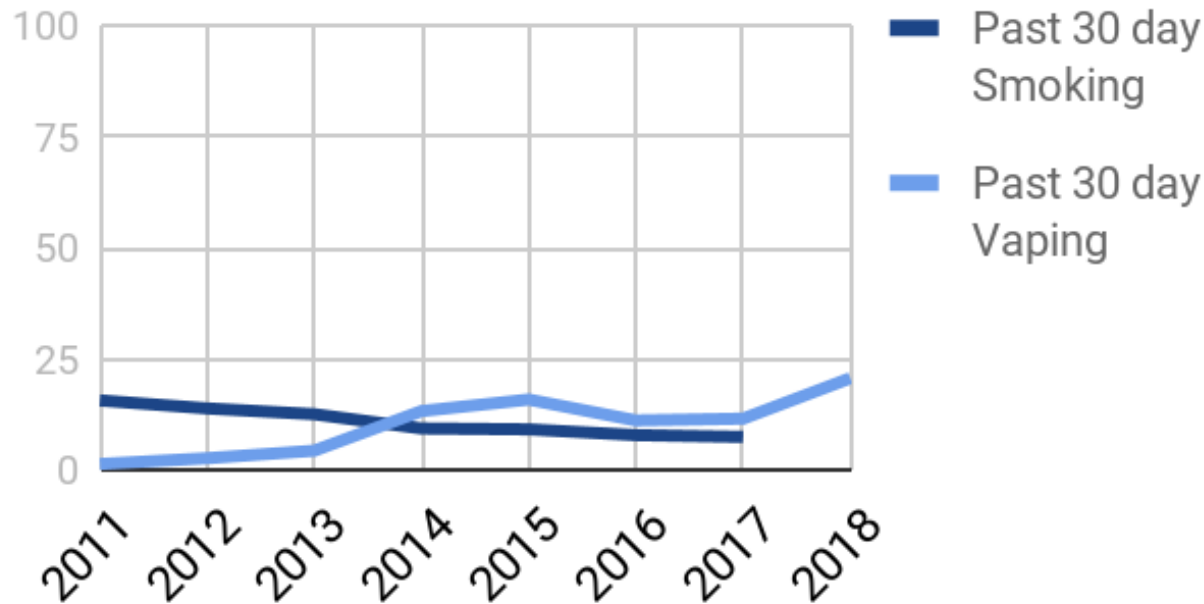
Stating that youth are getting addicted to nicotine without actually knowing whether they are using nicotine in the first place is misleading and not based in science.

<https://www.drugabuse.gov/related-topics/trends-statistics/monitoring-future/monitoring-future-survey-overview-findings-2015>

Youth Smoking vs. Vaping



High School Smoking vs Vaping



Correlation?



Clarifying NYTS Data



Reasons for youth use...

Adding clarifying questions to 2019 NYTS would help determine reasons for use among youth.

- Nicotine (for pleasure? Self-medicating mental illness?)
- Marijuana? (for pleasure? Self-medicating mental illness?)
- Non Nicotine liquid? (Social status? Peer approval? Parental imitation)

To reduce/prevent youth use, it is important to qualify what substance is being used in vapor products and for what reasons.

Risk vs Benefit



Part of our task today is to weigh the potential risks and benefits of the options to help youth cease use of e-cigarettes.

Options:

- Pharmaceutical Methods
- OTC NRTs
- Therapy/Counseling

Chantix side effects



<ul style="list-style-type: none">~flatulence~nausea (may persist for several months)~stomach pain~indigestion~constipation~gas~Vomiting~irritability	<ul style="list-style-type: none">~headaches~weakness~tiredness~unusual and violent dreams~sleep problems (insomnia)~dry mouth~unpleasant taste in mouth~sleep disturbance	<ul style="list-style-type: none">~aggressive behavior~agitation~depressed mood~suicidal behavior/ideation~homicidal behavior/ideation~burning feeling in feet/toes~unusual pain in the legs when walking
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Bupropion side effects



Increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults

<ul style="list-style-type: none">~nausea~stomach pain~indigestion~constipation~Vomiting~irritability~seizures~rashes~tremors	<ul style="list-style-type: none">~headaches~sleep problems (insomnia)~dry mouth~sleep disturbance~dizziness~excessive sweating~confusion~impotence~menstrual problems	<ul style="list-style-type: none">~agitation~hostility~blurred vision~tachycardia~auditory disturbance~cardiac arrhythmia
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<https://www.rxlist.com/wellbutrin-drug.htm#description>

NRT side effects



- ~chest pains
- ~heart palpitations
- ~nausea
- ~vomiting
- ~stomach pain
- ~indigestion

- ~headaches
- ~dizziness
- ~rapid heartbeat
- ~skin irritation
- ~rashes
- ~sleep problems (insomnia)

- ~mouth sore
- ~throat sore
- ~mouth ulcers
- ~hiccups
- ~coughing

E-cigarette side effects



~mouth or throat irritation ~cough ~anxiety/nervousness	~depressed mood ~nausea ~eye irritation	~insomnia ~headache
---	---	------------------------

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5959444/>

<https://www.fda.gov/downloads/TobaccoProducts/AboutCTP/UCM393323.pdf>

Risks?



If FDA approved cessation products have a longer list of more extreme side effects than the products they are are being used to treat, then does it provide a health benefit to youth to treat use/dependence of that product?

Therapy and Addiction Counseling



Therapy and addiction counseling combined with truthful education may provide a better way with lower risk.

Benefits of reducing youth vaping?



Remove the possibility that nicotine might harm the adolescent brain if it is found to increase the potential for addiction in youth and adolescents.

Remove risk of addiction to nicotine which could potentially lead to smoking combustible tobacco if it is found to be a gateway.

Both of which are potential issues. Neither of which is supported by evidence.

Summary



- ~Does an epidemic of nicotine addiction among youth exist?
- ~Youth smoking at an all time low.
- ~Youth vaping has been rising as youth smoking has decreased.
- ~Is there correlation between these?
- ~Importance of asking the right questions.
- ~Determining nicotine dependence.
- ~Adjust NYTS questions to determine type of vapor products used by youth.
- ~Adjust NYTS questions to determine reasons for youth use.
- ~Best options for youth cessation. (Smoking Cessation or Nicotine Cessation?)
- ~Known side effects of approved cessation methods show substantially more risk than known side effects of vapor products.
- ~Potential benefits of reducing youth vaping?
- ~Potential risks of reducing youth vaping?



Limiting Access



Limiting youth access has the unintended effect of limiting adult access to a product that keeps them off of combustible tobacco.

Parents who smoke, leave access to cigarettes for their children who live in the household.

“Twelve-year-olds whose parents smoked were more than two times as likely to begin smoking cigarettes on a daily basis between the ages of 13 and 21 than were children whose parents didn’t use tobacco.”

“Even in an era of declining rates of teenage cigarette use in the United States, children of current and former smokers face an elevated risk of smoking.”

[https://www.jahonline.org/article/S1054-139X\(05\)00086-8/abstract](https://www.jahonline.org/article/S1054-139X(05)00086-8/abstract)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3876755/>

ADDCHART! Showing #1 access from friend/family

Easier to steal one of these from a parent...



Than one of these...



The SKY Bio-Psycho-Social Program for Youth Empowerment: Applications for Youth Nicotine Addiction Treatment and Prevention

Ronnie Newman, Ed.M., C.A.S.

Director of Research & Health Promotion

Anjali Talcherkar, M.A

International Association for Human Values

www.skyschools.org

ronnie.newman@iahv.org

anjalit@iahv.org



International Association
for Human Values

Risk Factors for sustaining nicotine use in Youth

Biological:

- Withdrawal symptoms
- Craving



Risk Factors for initiation and maintenance of nicotine use in Youth

Psychological:

- Anxiety
- Depression
- Low self esteem
- Stress (e.g., academic and peer stress)



Risk Factors for initiation and maintenance of nicotine use in Youth

Social:

- Peer influence
- Social status
- Fear of rejection & isolation



The need for bio-psycho-social programs for augmenting medication therapies

- **Social and psychological factors are difficult to address with medications alone**
- **Augmenting with bio-psycho-social programs can fill in therapeutic gaps**



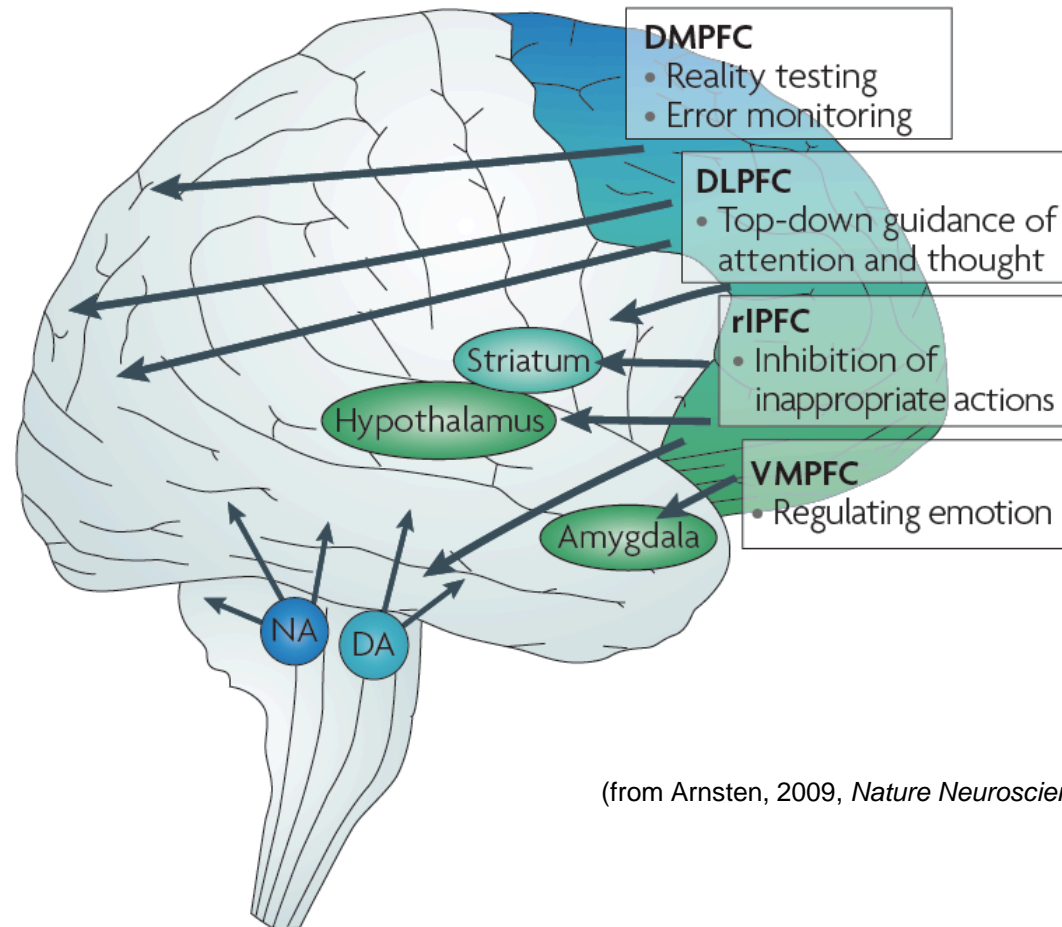
Withdrawal Syndrome driven by Stress Response



Factors can Over-ride Drug Therapy

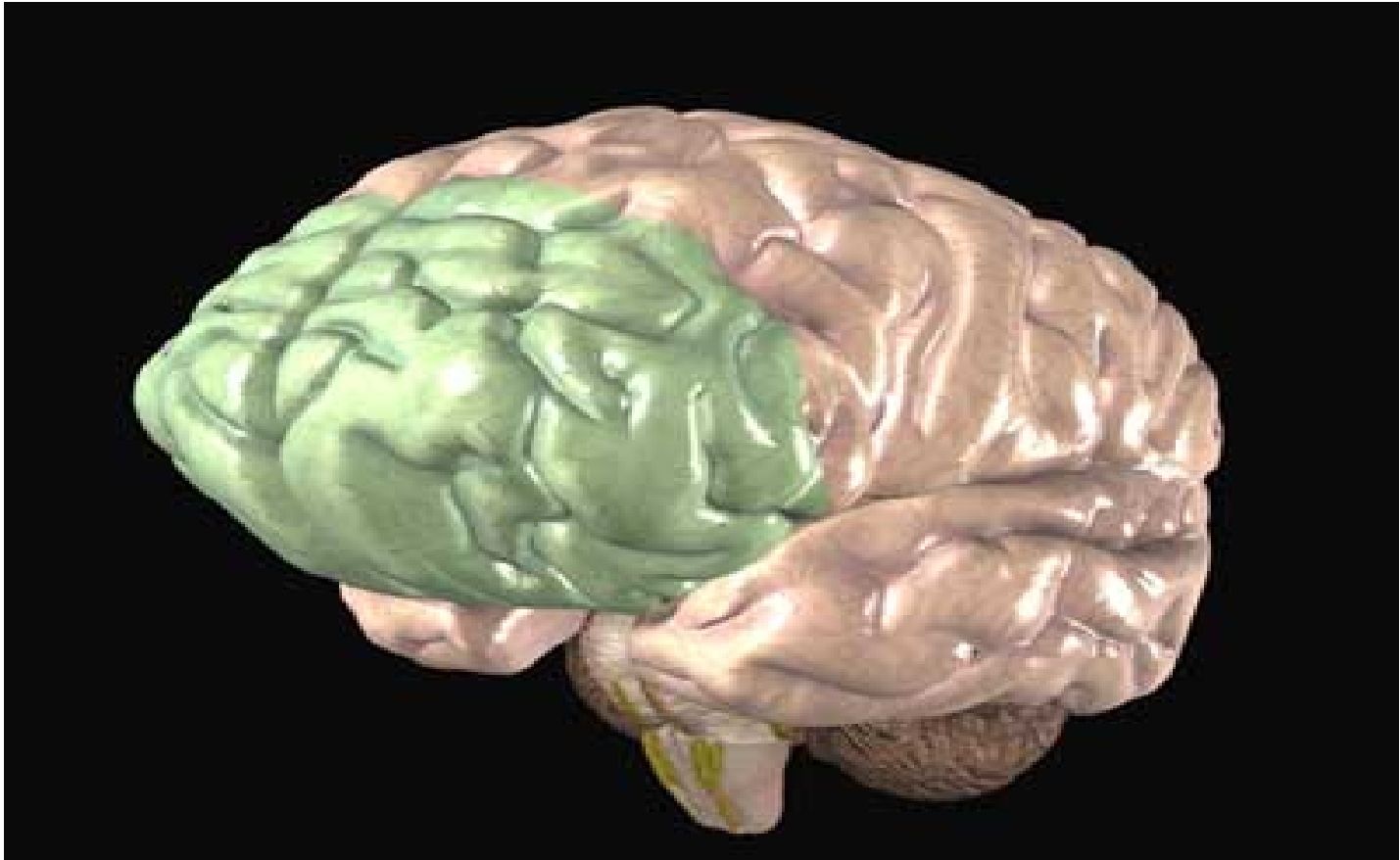


Prefrontal Cortex regulates BEHAVIOR and EMOTIONS during non-stress conditions

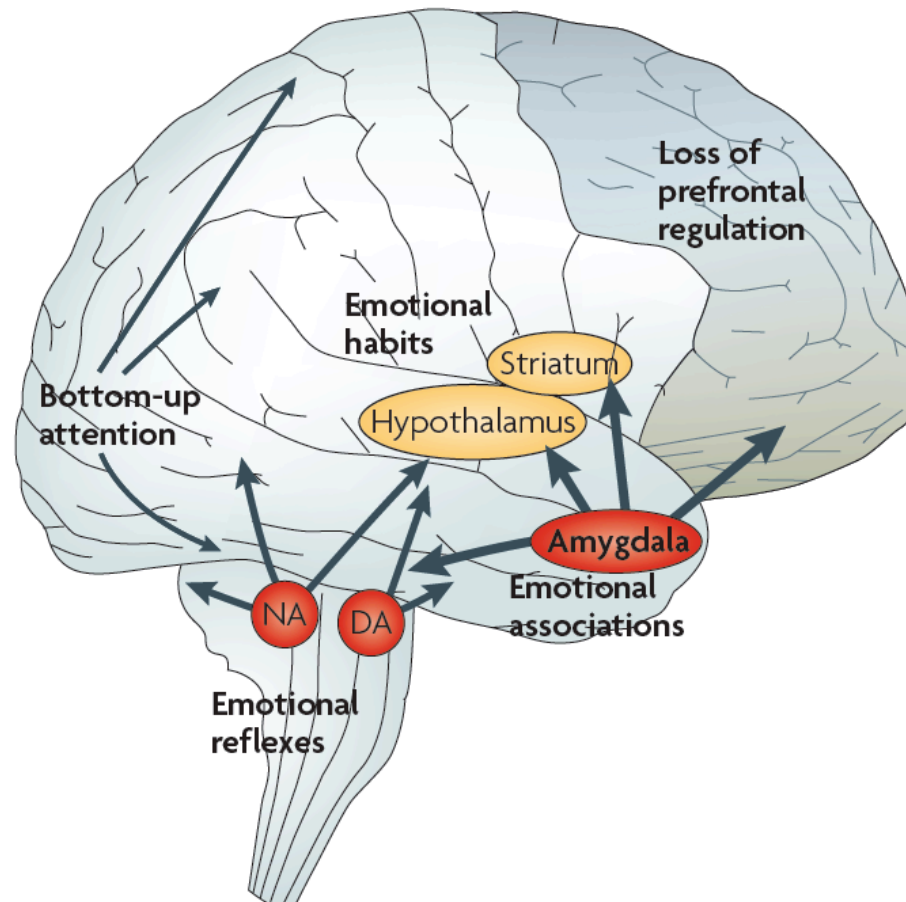


(from Arnsten, 2009, *Nature Neuroscience Reviews*)

The *Wizard* Brian



Prefrontal dysregulation (LOSS of CONTROL) during stress/depressed conditions



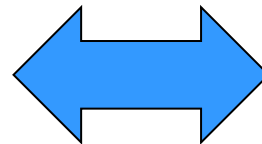
(from Arnsten, 2009, *Nature Neuroscience Reviews*)

The *Lizard* Brain

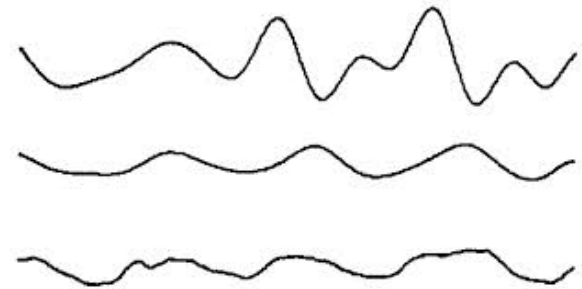


Emotions & Breath

A “two-way street” between emotions & breath



BREATH



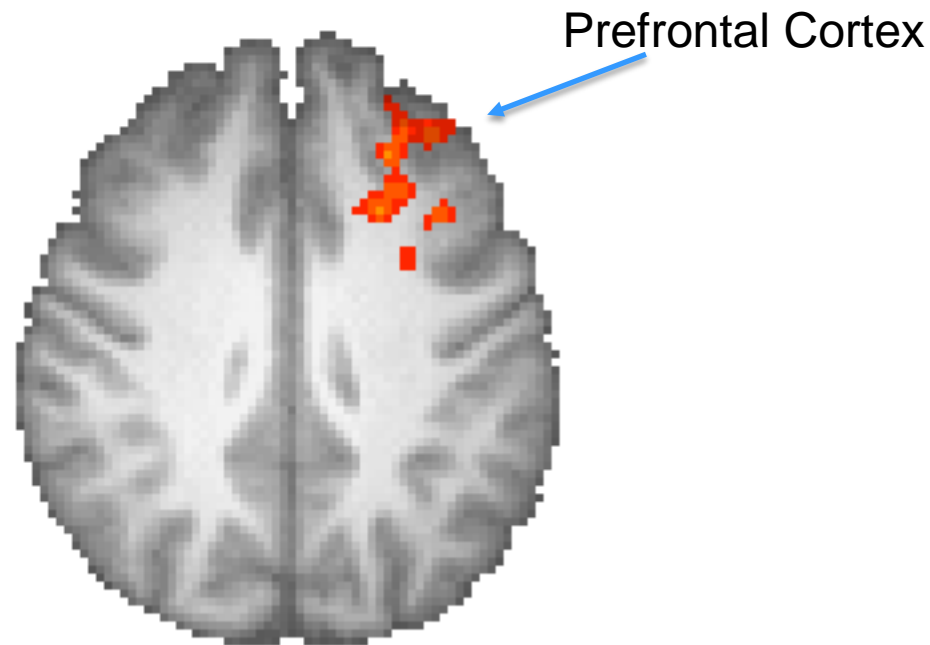
Phillippot, Chappelle, Blairy, 2002;

SKY Youth Program & Addiction: Protects against risks of initiation, sustained use, and relapse

- **Prevention** - healthy coping strategies and positive social support to reduce risk of tobacco initiation
- **Acute cessation** – powerful stress relief to reduce risk of relapse during withdrawal symptoms/stress
- **Prolonged abstinence** – protection against relapse during episodes of stress

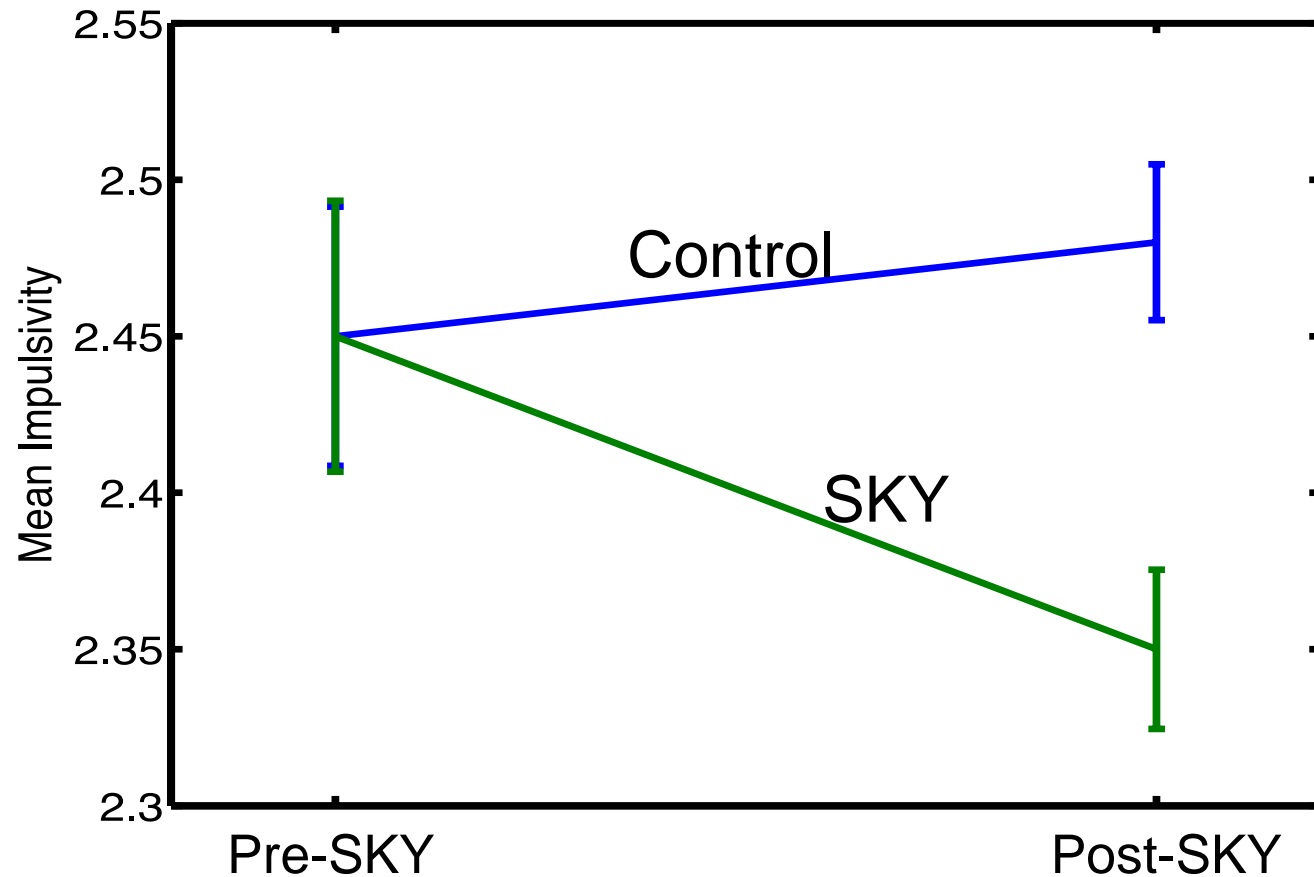


SKY breathing techniques increase prefrontal cortex function during emotion regulation in adolescents



Comparison of fMRI brain activation during emotion regulation after SKY breathing vs. after simple relaxation

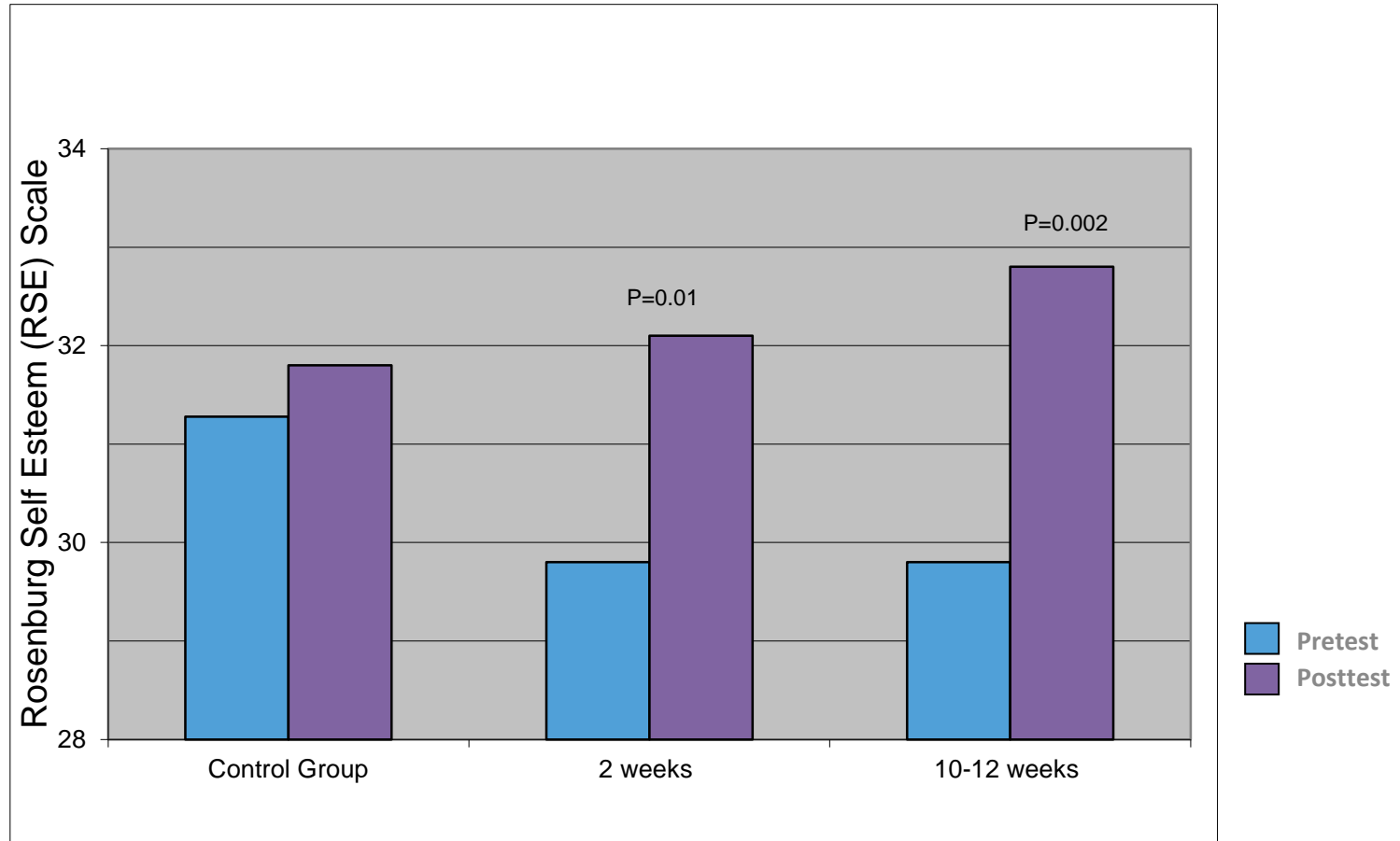
SKY Youth Program Reduces Impulsivity



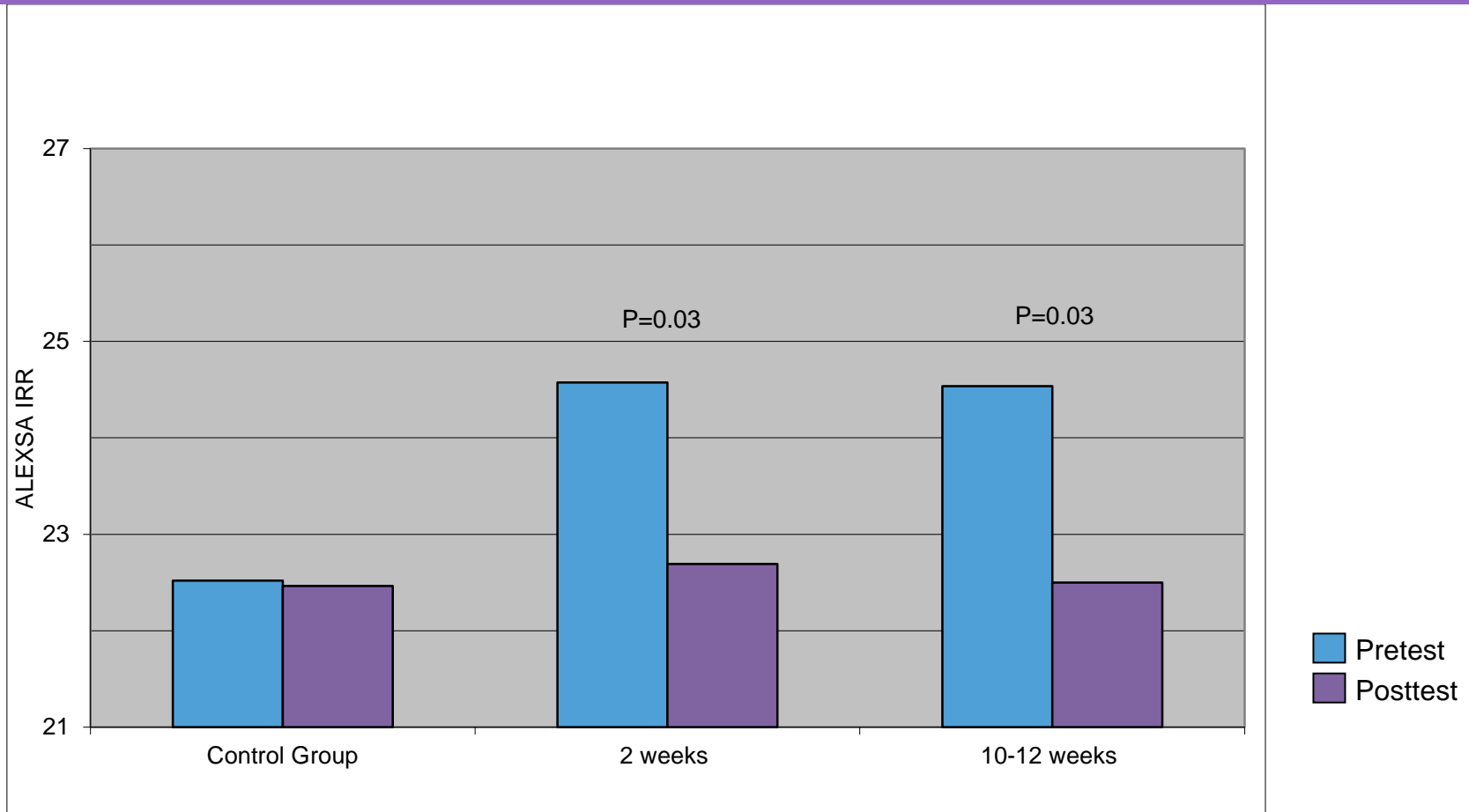
Group x Time, $p < 0.0005$

Ghahremani, et al. *Journal of Adolescent Health* (2013)

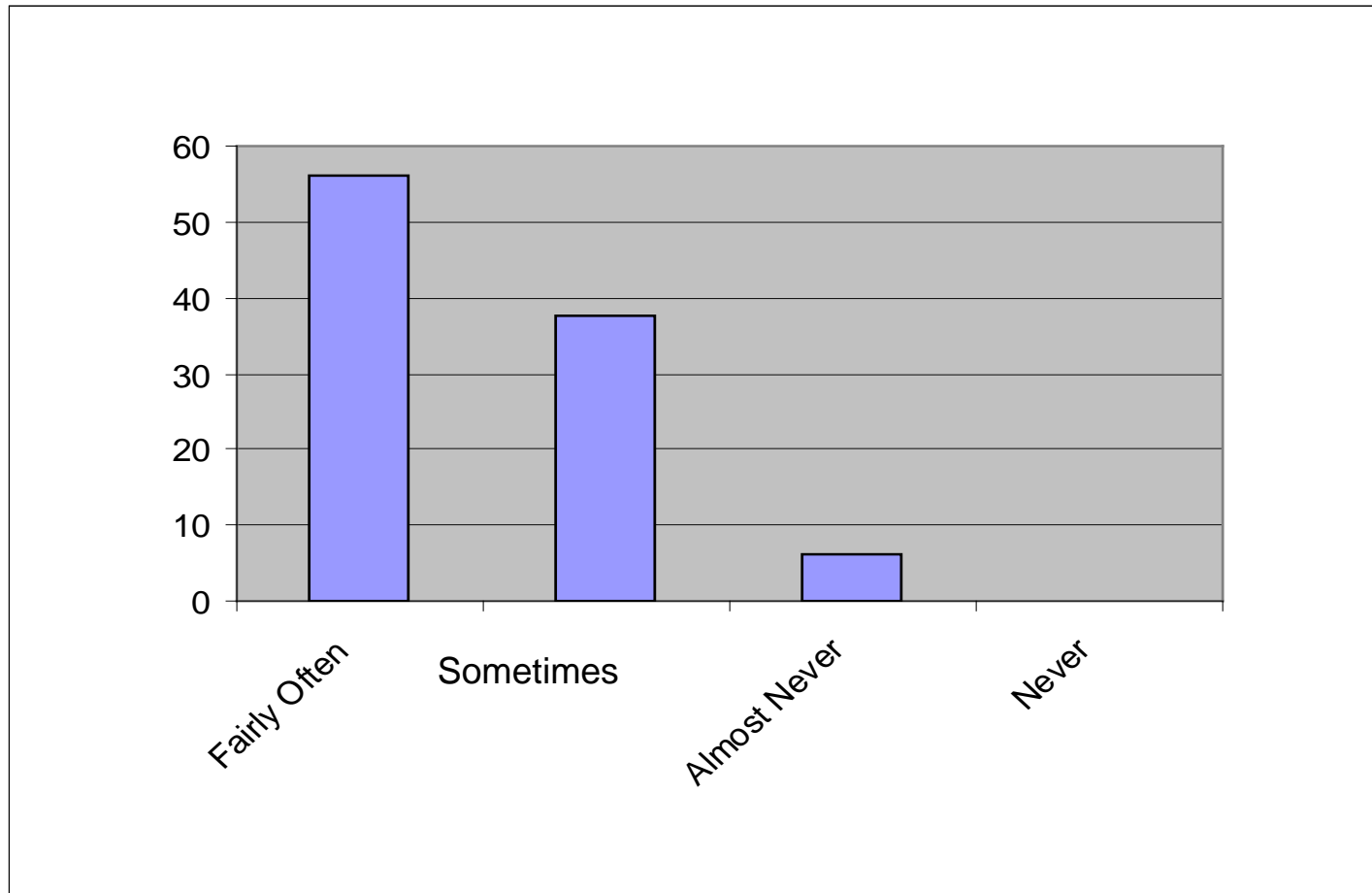
SKY Increases Adolescent Self Esteem



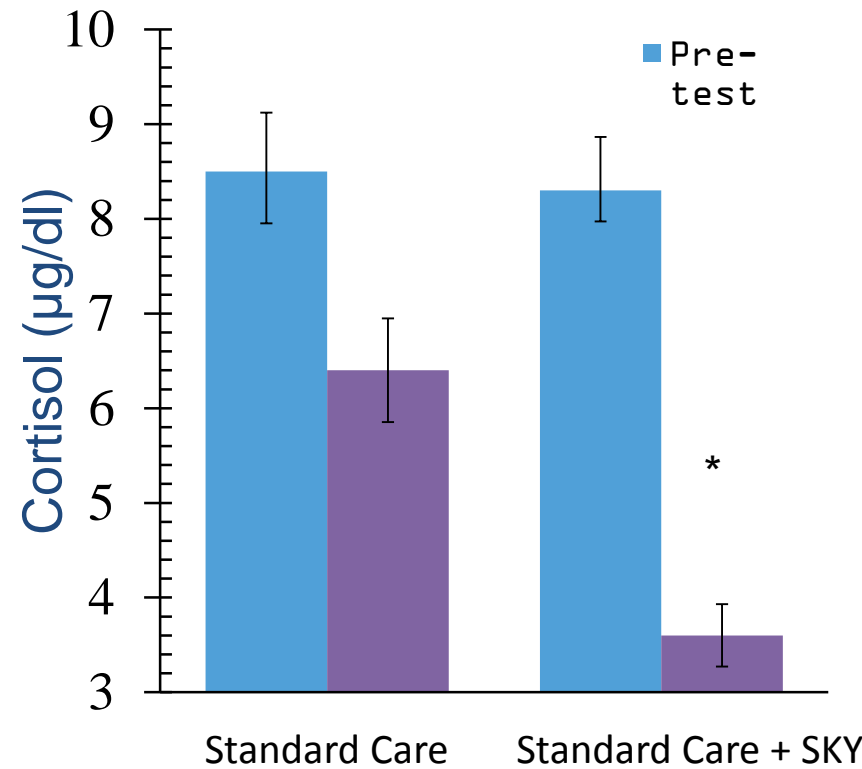
SKY Reduces Emotional Reactivity in Youth: Improved Emotion Regulation



Evidence for SKY in adolescents:
90% of students reported using *SKY breathing techniques*
when feeling stressed or upset



SKY Reduces Cortisol Levels during Recovery (Major Stress Hormone)

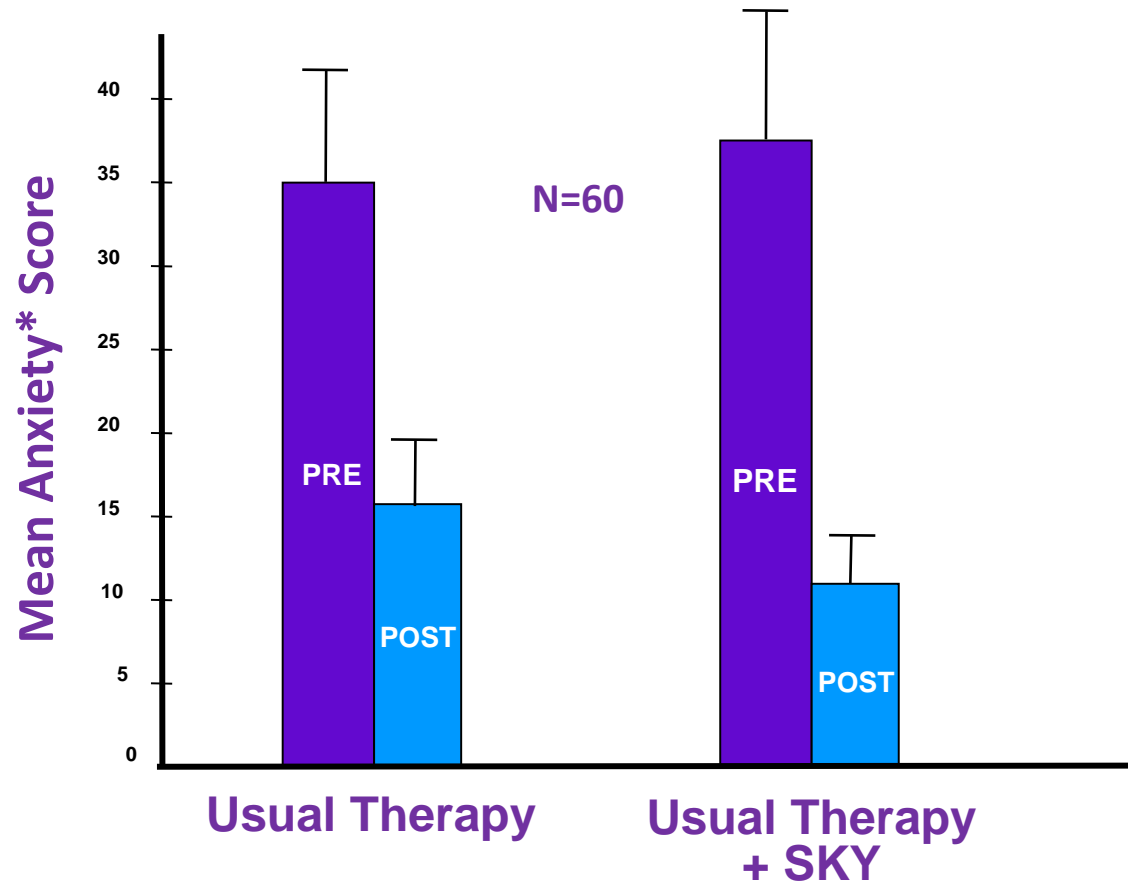


* - p value <0.05

Adding SKY to conventional treatment for individuals in addiction recovery was twice as effective in reducing cortisol levels as conventional treatment alone.

Vedamurthachar et al., 2006

SKY Reduces Anxiety in Alcohol Dependent Patients



What School Administrators Say

“In the last two weeks we have had more problems with violent episodes and substance use than during the rest of the year combined, probably due to FCAT (state testing) pressure. There were a lot of problem students in the SKY Youth Program, but not one of them has gotten involved with this. **That says a lot!** ”

~ Melissa Wolin, Principal, Palm Springs Middle School, Hialeah, FL

Take Home Points

- To successfully address youth nicotine addiction, **a multi-pronged approach is required.**
- Medication-based therapies alone are **insufficient.**
- **Bio-psycho-social programs, like the SKY Youth Program, can fill this therapeutic** gap by addressing the biological, psychological, and social risk factors associated with addiction.
- The SKY Youth Program is **evidence-based, cost-effective, and sustainable.**

Cost Effective Partnerships?

Joint funding for programs:

- *Department Health & Human Services
- *Department of Education
- *Department of Criminal Justice

THANK YOU!



www.skyschools.org



International Association
for Human Values

Still No Evidence of a Youth Nicotine Vaping Epidemic

January 18, 2019

Presentation to FDA

William T. Godshall, MPH

Smokefree Pennsylvania

1926 Monongahela Avenue

Pittsburgh, PA 15217

412-351-5880

billgodshall@Verizon.net

According to DHHS data and scientific evidence

- Many/most youth who vape are NOT vaping nicotine.
- Many high school students who vape are 18 year old adults.
- Very few never smoking youth vape daily or frequently.
- Youth smoking has sharply declined as youth vaping increased.
- Vaping is far less harmful than cigarette smoking.
- No evidence daily nicotine use increases human disease risk.
- Nicotine is very similar to caffeine.
- Chantix and Zyban pose more risks than nicotine.
- Youth engage in many far more harmful behaviors than nicotine use.

Teen marijuana vaping has sharply increased

The 2017 NYTS found 49.8% of 6th-12th graders who ever used an e-cigarette used an e-cigarette containing THC, marijuana, wax or hash oil, up from 38% in 2016.

Teens also vape caffeine, vitamins and melatonin.

The 2016 NYTS found 46.5% of 6th-12th graders who ever used an e-cigarette reported using “any substance other than nicotine”, up from 35.7% in 2015.

The 2017 NYTS didn't ask this question.

https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html

NIDA's MTF found more 8th-12th graders (%)
vape just flavoring or marijuana than nicotine

<http://monitoringthefuture.org/data/18data/18drtbl7.pdf>

	2017	2018
Any Vaping	12.0	19.2
Nicotine	7.5	14.2
Marijuana	3.6	5.7
Just Flavoring	8.0	11.5

The 2017 YRBS found past 30 day electronic vapor product use by 9th-12th graders highest in 9 of 10 states that legalized marijuana (all >20%).

Note that 11 States didn't ask this question (AL, GA, IN, MN, MS, NJ, OH, OR, SD, WA, WY)

** Legalized Marijuana; *Legalized RX Marijuana

https://www.cdc.gov/healthyyouth/data/yrbs/2017_tables/tobacco_use.htm#t66_down

Highest States	Lowest States
26.2% - Colorado**	7.6% - Utah
25.5% - Hawaii*	9.0% - Iowa
24.7% - New Mexico*	9.4% - Nebraska
23.8% - New Hampshire*	10.3% - Texas
22.5% - Montana*	10.6% - Kansas
22.2% - Louisiana*	10.9% - Missouri
22.1% - North Carolina	11.3% - Pennsylvania*
20.6% - North Dakota*	11.5% - Tennessee
20.1% - Massachusetts**	11.6% - Wisconsin
20.1% - Rhode Island*	11.8% - Virginia

Analysis of 2016 MTF found 12th grade smokers were far more likely to vape nicotine (61.3%) than nonsmokers (18.1%) and never smokers (14.3%).

The 2016 MTF also found 12th grade never smokers (76%) and nonsmokers (69.6%) were far more likely than smokers (31%) to vape 'just flavors'.

<https://www.ncbi.nlm.nih.gov/pubmed/30033026>

Many 9th-12th graders who vape are 18+ adults (not youth), and the 2009 TCA prohibits FDA from banning the sale of any tobacco product to anyone 18 or older.

The 2017 YRBS found 34% of 9th-12th graders who used a vapor product in the past 30 days were 18+ adults.

Note that CDC buried this key finding in a footnote in Table 72 at

<https://www.cdc.gov/mmwr/volumes/67/ss/ss6708a1.htm>

Analysis of 2017 NYTS found 18.5% of e-cigarette users in grades 9-12 were 18+ (including 16% of exclusive e-cig users, and 23% of dual users).

<https://rodutobaccotruth.blogspot.com/2018/10/not-all-teen-smokers-vapers-are.html>

Daily (1.1%) and frequent (1.6%) e-cigarette use by 6th-12th graders was very similar from 2014 to 2017, experimental use declined from 2015 to 2017, and CDC has released very little 2018 data (NYTS)

https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html

Days	2014	2015	2016	2017	2018
0	89.3	87.4	90.0	90.6	?
1+	8.8	11.2	8.4	8.2	13.8
3+	4.5	6.2	4.9	4.8	?
6+	3.0	4.2	3.1	3.2	?
10+	2.3	2.8	2.2	2.5	?
20+	1.4	1.7	1.4	1.6	3.4
All 30	0.9	1.1	1.1	1.1	?

Daily (5.2%) and frequent (7.6%) e-cigarette use by 6th-12th graders who ever used an e-cigarette changed little from 2014 to 2017, while experimental use declined (NYTS).

https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html

Days	2014	2015	2016	2017	2018
1+	45.4	42.1	37.2	38.9	?
3+	23.2	23.3	21.7	22.7	?
6+	15.5	15.8	13.7	15.2	?
10+	11.9	10.5	9.7	11.8	?
20+	7.2	6.4	6.2	7.6	?
All 30	4.6	4.1	4.9	5.2	?

In 2017, 12th graders comprised 45% of 9th-12th graders who frequently used e-cigarettes (20+ of past 30 days), and most 12th graders were 18+. NYTS data provided by Christine Delnevo

Grade	1+ of Past 30 Days	20+ of Past 30 Days
9	8.8	1.0
10	11.4	2.0
11	11.8	2.2
12	15.2	4.4
9-12	11.7	2.3

The YRBS found **past 30 day use (%) of electronic vapor products by 9th-12th graders declined by 45% from 2015 to 2017** (from 24.1% to 13.2%).

<https://www.cdc.gov/mmwr/volumes/65/ss/pdfs/ss6506.pdf> (Table 41)

https://www.cdc.gov/healthyyouth/data/yrbs/2017_tables/tobacco_use.htm#t66_down (Table 66)

Grade	2015	2017
9	19.7	9.5
10	23.2	11.4
11	25.9	14.1
12	28.2	18.3
9-12	24.1	13.2

The 2017 YRBS found 2.4% of 9th-12th graders vaped daily, and 3.3% vaped frequently, and 12th graders were far more likely to use vapor products daily, frequently and in the past 30 days than 9th-11th graders .

https://www.cdc.gov/healthyyouth/data/yrbs/2017_tables/tobacco_use.htm#t66_down (Tables 66, 68 & 70)

Grade	1+ Days	20+ Days	All 30 Days
9	9.5	1.8	1.2
10	11.4	2.7	1.7
11	14.1	3.7	2.7
12	18.3	5.0	4.0
9-12	13.2	3.3	2.4

The 2015 NYTS found cigarette smokers in grades 6-12 were exponentially more likely to use e-cigarettes than never smokers.
(‘frequent’ use = 20+ of past 30 days; ‘infrequent’ use = <20 of past 30 days)

Just 0.3% of never smokers were frequent e-cigarette users.

Just 4.6% of never smokers used an e-cigarette in the past 30 days, and 59% of them did so just 1-2 days.

Frequent smokers were 84 times more likely than never smokers to vape daily (16.9% v 0.2%), and infrequent smokers were 36 times more likely (7.3% v 0.2%).

Frequent smokers were 73 times more likely than never smokers to vape frequently (21.8% v 0.3%), and infrequent smokers were 41 times more likely (12.2% vs 0.3%).

Frequent smokers were 14 times more likely than never smokers to vape in past 30 days (64.7% v 4.6%), and infrequent smokers were 11 times more likely (50.4% v 4.6%).

<https://www.sciencedirect.com/science/article/pii/S074937971831626X>

Villanti et al revealed the 2014 NYTS found <0.1% of never tobacco users in 6th-12th grades reported vaping on 10+ of the past 30 days.

<http://ntr.oxfordjournals.org/content/early/2016/12/24/ntr.ntw388>

But CDC's press release headline (for 2014 NYTS findings) stated E-cigarette use triples among middle and high school students in just one year, and included:

“In today's rapidly evolving tobacco marketplace, the surge in youth use of novel products like e-cigarettes forces us to confront the reality that the progress we have made in reducing youth cigarette smoking rates is being threatened,” said Mitch Zeller, J.D., director of FDA's Center for Tobacco Products.

<https://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html>

“This is another generation being hooked by the tobacco industry. It makes me angry.” CDC Director Tom Frieden

<http://www.nytimes.com/2015/04/17/health/use-of-e-cigarettes-rises-sharply-among-teenagers-report-says.html>

NYTS found huge declines in cigarette smoking by 6th-12th graders from 2011-2017, including **daily smoking (-64%), frequent smoking (-63%), past 30 day smoking (-52%), and ever smoking (-43%)** as e-cigarette use increased.

https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html

Days	2011	2012	2013	2014	2015	2016	2017	2018
0	86.6	88.8	89.6	91.8	91.8	93.3	93.4	?
1+	10.6	9.3	8.2	6.1	6.0	5.8	5.6	?
3+	7.3	6.2	5.6	3.8	3.8	3.7	3.3	?
6+	5.8	4.9	4.5	3.0	2.8	3.0	2.4	?
10+	4.8	4.1	3.7	2.4	2.3	2.5	1.9	?
20+	3.5	3.0	2.7	1.8	1.7	1.8	1.3	?
All 30	2.5	2.1	2.0	1.3	1.2	1.3	0.9	?

CDC's NHIS found a 48% decline in cigarette smoking by 18-24 year olds from 2010-2017, similar to the decline by 9th-12th graders (as increasingly more smokers switched to vaping).

Year	Total	18-24 years	25-44 years	45-64 years	65+ years
2010	19.3	20.1	22.0	21.1	9.5
2011	19.0	18.9	22.1	21.4	7.9
2012	18.1	17.3	21.6	19.5	8.9
2013	17.8	18.7	20.1	19.9	8.8
2014	16.8	16.7	20.0	18.0	8.5
2015	15.1	13.0	17.7	17.0	8.4
2016	15.5	13.1	17.6	18.0	8.8
2017	14.0	10.4	16.1	16.1	8.2
Change	-27%	-48%	-27%	-24%	-14%

Public Health England: E-cigarettes around 95% less harmful than tobacco estimates landmark review

Key findings of the review include:

- the current best estimate is that e-cigarettes are around 95% less harmful than smoking
- nearly half the population (44.8%) don't realise e-cigarettes are much less harmful than smoking
- there is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers

<https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>

<https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

There is no evidence daily nicotine use increases disease risks (which was why FDA approved NRT for long term use).

There is no evidence youth nicotine use increases risk of brain damage (as CDC and FDA now claim), as rodents are NOT humans.

Nicotine is very similar to caffeine

- Nicotine and caffeine temporarily increase BP and heart rate.
- Nicotine and caffeine can create daily dependence.
- No evidence daily nicotine or caffeine use increase disease risks.
- **Nicotine “no more harmful to health than caffeine”**

Source: Royal Society for Public Health

<https://www.rsph.org.uk/about-us/news/nicotine--no-more-harmful-to-health-than-caffeine-.html>

Chantix poses more harm to humans than does nicotine

- **IMPORTANT SAFETY INFORMATION AND INDICATION**

- When you try to quit smoking, with or without CHANTIX® (varenicline), you may have symptoms that may be due to nicotine withdrawal, including **urge to smoke, depressed mood, trouble sleeping, irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased heart rate, and increased appetite or weight gain.**
- Some people have had new or **worse mental health problems**, such as changes in behavior or thinking, **aggression, hostility, agitation, depressed mood, or suicidal thoughts or actions while taking or after stopping CHANTIX.** These symptoms happened more often in people who had a history of mental health problems. Stop taking CHANTIX and call your healthcare provider right away if you, your family, or caregiver notice any of these symptoms. Before starting CHANTIX, tell your healthcare provider if you ever had depression or other mental health problems.
- Some people have had **seizures** during treatment with CHANTIX. Tell your healthcare provider if you have a history of seizures. If you have a seizure, stop taking CHANTIX and contact your healthcare provider right away.
- **New or worse heart or blood vessel problems can happen with CHANTIX.** Tell your healthcare provider if you have heart or blood vessel problems or experience any symptoms during treatment. Get emergency medical help right away if you have symptoms of a heart attack or stroke.

<https://www.chantix.com/>

Zyban poses more harm to humans than nicotine

- **Precautions**
- Before using this [medication](#), tell your doctor or pharmacist your medical history, especially of: [seizures](#) or conditions that increase your risk of seizures (including [brain/head injury](#), [brain tumors](#), [arteriovenous malformation](#), [eating disorders](#) such as [bulimia/anorexia nervosa](#)), alcohol/drug dependence, [diabetes](#), [heart disease](#) (e.g., [congestive heart failure](#), recent [heart attack](#)), [high blood pressure](#), [kidney](#) problems, [liver](#) problems (e.g., [cirrhosis](#)), mental/[mood disorders](#) (e.g., [bipolar disorder](#), thoughts of [suicide](#)), personal or family history of [glaucoma](#)(angle-closure type).
- This medication should not be used if you are suddenly stopping regular use of sedatives (including [benzodiazepines](#) such as [lorazepam](#)), drugs used to treat seizures, or alcohol. Doing so may increase your risk of seizures.
- This drug may make you dizzy or drowsy or blur your [vision](#). Alcohol or [marijuana](#) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness or clear [vision](#) until you can do it safely. Avoid [alcoholic](#) beverages. Talk to your doctor if you are using marijuana. Alcohol may also increase your risk of seizures.

<https://www.webmd.com/drugs/2/drug-1609/zyban-oral/details>

High School students engage in far more harmful behaviors than vaping and nicotine use (according to CDC's 2017 YRBS)

<https://www.cdc.gov/mmwr/volumes/67/ss/ss6708a1.htm>

- 39.2% texted or e-mailed while driving in past 30 days
- 5.9% rarely or never used a seat belt when riding in a car
- 5.5% drank alcohol and drove in past 30 days
- 16.5% rode in a vehicle in past 30 days driven by someone who had drank alcohol
- 13.5% binge drank alcohol (i.e. 4+ drinks) in past 30 days
- 14.0% ever used prescription pain medicine without a doctor's prescription
- 23.6% were in a physical fight in past year
- 7.4% were forced to have sexual intercourse when they did not want to
- 7.4% attempted suicide in past year
- 17.2% seriously considered attempting suicide in past year
- 14.8% were obese

According to DHHS data and scientific evidence

- Many/most youth who vape are NOT vaping nicotine.
- Many high school students who vape are 18 year old adults.
- Very few never smoking youth vape daily or frequently.
- Youth smoking has sharply declined as youth vaping increased.
- Vaping is far less harmful than cigarette smoking.
- No evidence daily nicotine use increases human disease risk.
- Nicotine is very similar to caffeine.
- Chantix and Zyban pose more risks than nicotine.
- Youth engage in many far more harmful behaviors than nicotine use.

Tobacco Cessation for Adolescents

**Eliminating Youth Electronic Cigarette and Other
Tobacco Product Use: The Role for Drug Therapies**

Food and Drug Administration Public Meeting

Susanne Tanski, MD, MPH, FAAP
American Academy of Pediatrics Tobacco Consortium

December 5, 2018

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



YOUTH E-CIGARETTE USE: TROUBLING TRENDS NECESSITATE URGENT ACTION

- Dramatic increases in current e-cigarette use among middle and high school students are of grave concern
- Insufficient action brings the threat of long-term nicotine dependence and negative health consequences for a new generation
- FDA's recognition of the youth e-cigarette epidemic is important, and FDA must now act urgently to encourage new models of cessation for adolescents given the current paucity of effective interventions



CURRENT STATE OF THE EVIDENCE ON YOUTH CESSATION

- Conclusive evidence about effective adolescent e-cigarette cessation is nonexistent
- The body of evidence for adolescent cessation of combustible cigarettes is limited
 - Research into adolescent tobacco cessation for combustible cigarettes suggests behavioral and psychosocial interventions are somewhat effective at helping youth abstain from smoking
 - Limited studies into drug therapies, including nicotine replacement therapy (NRT) and bupropion, indicate these treatment options are not particularly effective for youth cessation from combustible cigarettes

YOUTH CESSATION: WHAT WE NEED TO KNOW

- Effective interventions for adolescent e-cigarette users
 - Drug therapies, behavioral interventions, combination therapies
- Efficacy of currently approved NRT in treating adolescents dependent on e-cigarettes and potential modifications to NRT product characteristics to improve the performance of these products for adolescents
- Level of dependence among adolescents using e-cigarettes to better target treatment paradigms based on the severity of dependence
- Trajectory of nicotine dependence among teens who use e-cigarettes as compared to those who use traditional combustible products

RECOMMENDED ACTION

- We encourage FDA to use its authorities under law to increase the study of cessation drug therapies in adolescents, including under the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA)
- We encourage FDA to urgently fund studies that evaluate behavioral, pharmacological and combination interventions for adolescent e-cigarette users, based on evidence from combustible cigarette cessation, that can be implemented and tested in real time
- We encourage FDA to fund studies into outstanding questions around adolescent e-cigarette addiction, trajectories and nicotine dependence





Incorporated Village
Population: 26,000
3.36 Square miles

SEPTEMBER 2015

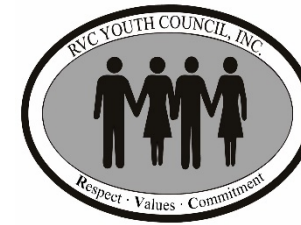


**Rockville Centre group to
receive grant to fight
drug abuse**

"The most effective efforts to prevent alcohol and drug use among young people happen on the ground in our communities, and supporting those efforts is the best investment our government can make," Rice (D-Garden City) said in a news release. The federal funding "will allow the Rockville Centre Coalition for Youth to continue building a strong grassroots movement that will empower kids with the knowledge and support they need to make smart, healthy choices," she said.



Rockville Centre Coalition for Youth



Mercy Medical Center
Catholic Health Services
At the heart of health



The Rockville Centre Coalition for Youth has as its principal mission the reduction of substance abuse, with a primary focus on reducing youth substance abuse. Its mission is to plan and implement strategies to prevent and reduce youth substance use and its associated consequences.



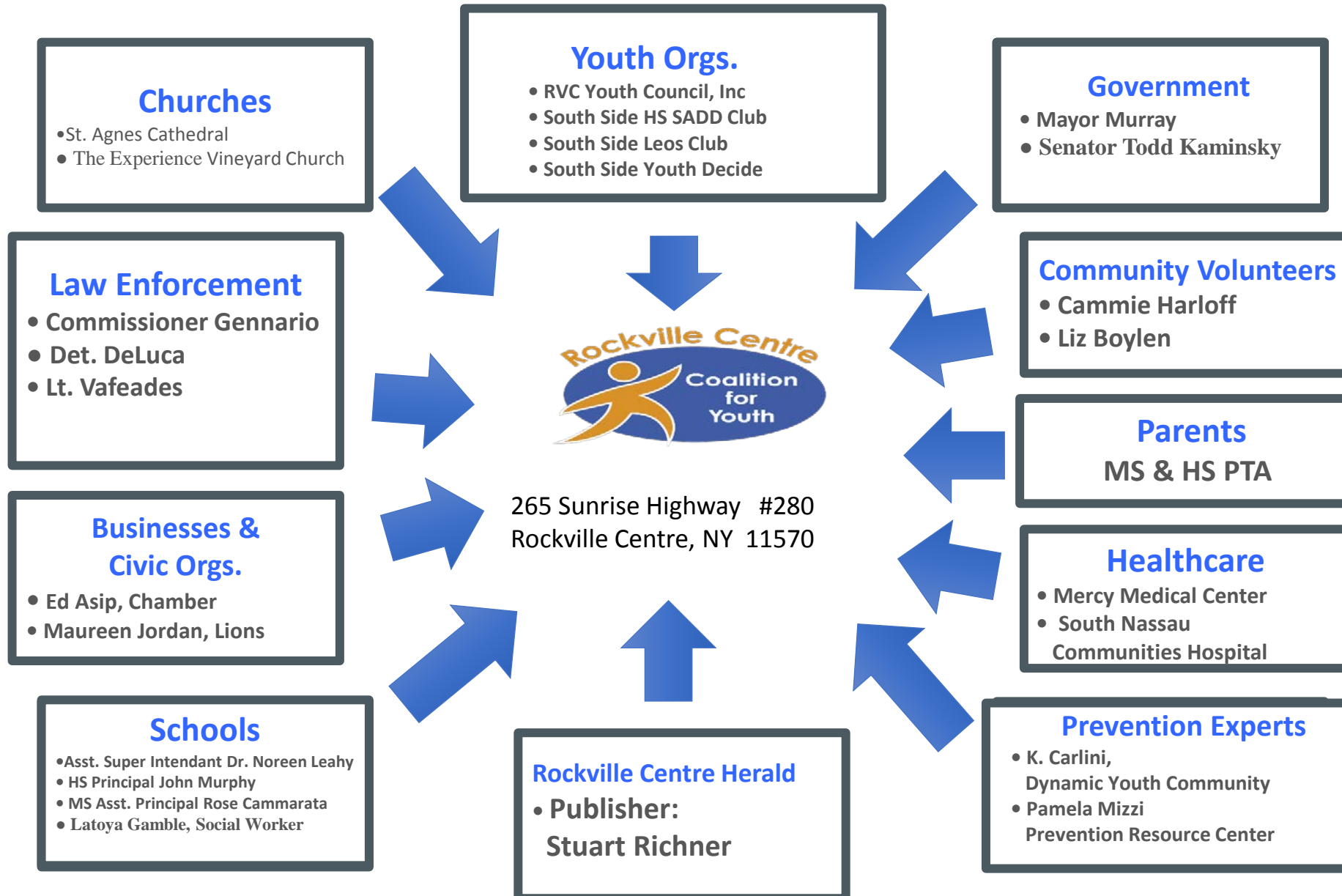
DON'T PRESS SEND



Lions Clubs International



COALITION SECTOR REPRESENTATIVES





Think using **Fake ID** is a good Idea?

THINK AGAIN!

**Do not use forged or altered driver's licenses
or someone else's real ID, you may pay the price!**

The following criminal charges may apply if a person manufactures,
alters and/or possesses a false or fraudulent identification:

Forgery or Criminal Possession of a Forged Instrument

Both are Class D Felonies which could land you up to 7 years in jail.



False Personation:

When someone tells police his/her name, date of birth, or address is something other than what is true.

This is a Class B Misdemeanor. A sentence of up to 1 year in jail can be issued.



**Criminal Impersonation
2nd Degree:**

When someone uses a fake id or another person's real id to obtain a benefit like purchasing alcohol or getting into a bar.

This is a Class A Misdemeanor. A sentence of up to 1 year in jail can be issued.



**Endangering the
welfare of a child:**

If you are 16 years old or older and give someone who is 15 or younger a beer or an alcohol drink, you are endangering the welfare of a child.

This is a Class A Misdemeanor. A sentence of up to 1 year in jail can be issued.

Rockville Centre Police Department - 34 Maple Ave. Rockville Centre, NY 11570 - 516-766-1500



Rockville Centre Police Department

Underage Drinking

Parent accountability
is the key to the fight against
underage drinking.

The Rockville Centre Police Department is cracking down on underage drinking. The consumption of alcohol by underage persons, whether at a party or a smaller gathering, poses an immediate threat to the safety and welfare of the residents of Rockville Centre, often leading to alcohol abuse by minors, physical altercations, accidental injuries, neighborhood vandalism, excessive noise disturbances requiring the intervention of local law enforcement and the commission of violent crimes including sexual offenses and serious assaults. The Social Host law is intended to deter the consumption of alcoholic beverages by minors by holding those responsible when they permit the consumption of alcoholic beverages by minors.

Social Host Law Penalties for Offenses in a 12 Month Time:

- First Offense:** Village Fine of \$250 plus New York State Penal Law charges below.
Second Offense: Village Fine of \$500 - \$750 plus New York State Penal Law charges below.
Third Offense: Village Fine of \$750 - \$1000 plus New York State Penal Law charges below.

Penal Law Charges:

260.20 Unlawfully dealing with a child in the first degree: Class A misdemeanor.

A person is guilty of unlawfully dealing with a child in the first degree when: **He gives or sells or causes to be given or sold** any alcoholic beverage to a person less than twenty-one years old.

260.10 Endangering the welfare of a child: Class A misdemeanor.

A person is guilty of endangering the welfare of a child when: He or she knowingly acts in a manner likely to be injurious to the physical, mental or moral welfare of a child less than seventeen years old or directs or authorizes such child to engage in an occupation involving a substantial risk of danger to his or her life or health.

Fines for both charges:

An amount fixed by the court not exceeding \$1,000 and/or a term of imprisonment in excess of fifteen days may be imposed, but for which a sentence to a term of imprisonment in excess of one year cannot be imposed.

Forged or Altered Driver's Licenses: The following criminal charges may apply if an underage person manufactures, alters and/or possess a false or fraudulent identification :

Forgery in the 2nd Degree or Criminal Possession of a Forged Instrument in the 2nd Degree.
(both a Class D Felony)

Criminal Impersonation in the 2nd Degree
(a Class A Misdemeanor)
False Personation (a Class B Misdemeanor)

For any questions or information related to underage drinking or any other police-related youth activity, please contact our Youth Officer: PO Nick DeLuca at 516-766-1577 or YouthOfficer@rvcny.us

DRUG TAKE-BACK EVENT

**EVERYDAY IS
DRUG TAKE BACK DAY**

The Rockville Centre Police Department has a permanent drug drop box located at:
34 Maple Ave. Rockville Centre NY 11570. Drop off your drugs, no questions asked.

Turn in your unused or expired medication for safe disposal.

We will accept:

- ✓ Prescriptions
- ✓ Over the counter pills
- ✓ Liquid medications
- ✓ Vitamins
- ✓ Pet medicine

We cannot accept:

- ✗ Needles and sharps
- ✗ Mercury (thermometers)
- ✗ Chemotherapy/radioactive substances
- ✗ Oxygen containers
- ✗ Pressurized containers/inhalers
- ✗ Illicit drugs

Sponsored By:



516-766-1500 - www.RockvilleCentrePolice.us

Athletes vs Alcohol



Athletes
VS.
Alcohol

Staying on the Winning Team

See how alcohol impacts each part of the body by matching the letters to the information on the back

Rockville Centre Coalition for Youth
rvcccoalitionforyouth.org

Texans Standing Tall
TexansStandingTall.org | TST@TexansStandingTall.org
512-442-7501

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The image features two anatomical diagrams of a human body, one on the left and one on the right. The left diagram is of a football player in a helmet and jersey, and the right diagram is of a baseball player in a uniform. Both diagrams show the internal organs and circulatory system. Letters A through H are placed on various organs: A on the brain, B on the lungs, C on the heart, D on the liver, E on the stomach, F on the pancreas, G on the kidneys, and H on the bladder. The diagrams are used to illustrate the impact of alcohol on the body.

**Parents who Host,
Lose the Most:
Don't be a party to
teenage drinking**

Sponsored by



**RVC Social Host Law:
Real Penalties, Real Prevention**

**RVC Students
Refuse to Use**

Sponsored by



RVC: Power of Prevention

**Drugs Kill.
Period.**

Sponsored by



RVC: Power of Prevention



JUUL
starter kit





JUUL
Kick-Off
Party in
NYC ,
July 2015

How an E-cigarette Works

E-cigarettes create an aerosol by using a battery to heat up liquid that usually contains nicotine, flavorings, and other additives. Users inhale this aerosol into their lungs. E-cigarettes can also be used to deliver cannabinoids such as marijuana, and other drugs.



What's Trending? JUULing

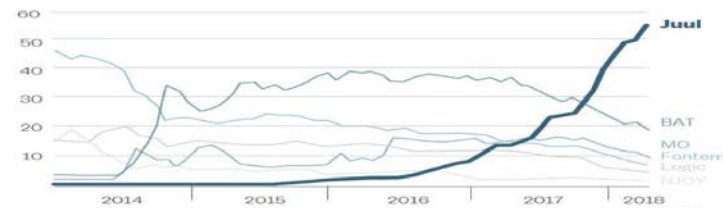
The Juul is a vape, or Electronic Nicotine Delivery System (ENDS) whose sleek design and odorless vapor made it a hot trend with teens.



63% 15-24 yr-olds report being unaware JUULs always contained nicotine

1/5 Youth (ages 12-17) surveyed reported having seen JUULs used in their school

Dollar share percentage of the e-cigarette traditional retail market, as of March 2018



Source: Nielsen Total US xAOC/Convenience Database and Wells Fargo Securities, LLC

JUUL's unit sales increased more than 600% in 2017. As a result, JUUL is now more popular than the e-cigarette brands manufactured by the major tobacco companies representing 68% of the market share.



Each JUUL cartridge contains as much nicotine as a pack of cigarettes

What communities can do

Assess the problem in your community:
Where is it happening?
Why here? What does it look like?



DATA



KNOWLEDGE



ACTION



Educate yourself, the community and youth about the risks



Advocate for school policy around vaping
Advocate for regulation and enforcement in your community

Questions? Email: training@cadca.org



facebook.com/CADCA



twitter.com/CADCA

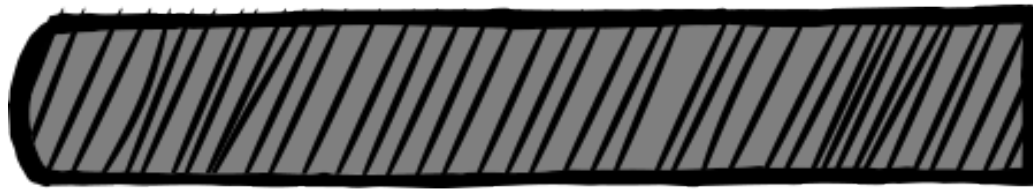


instagram.com/CADCAcoalitions

cadca.org

Battery

Powers
the
device.



Atomizer
Heats the
e-liquid into
an aerosol.

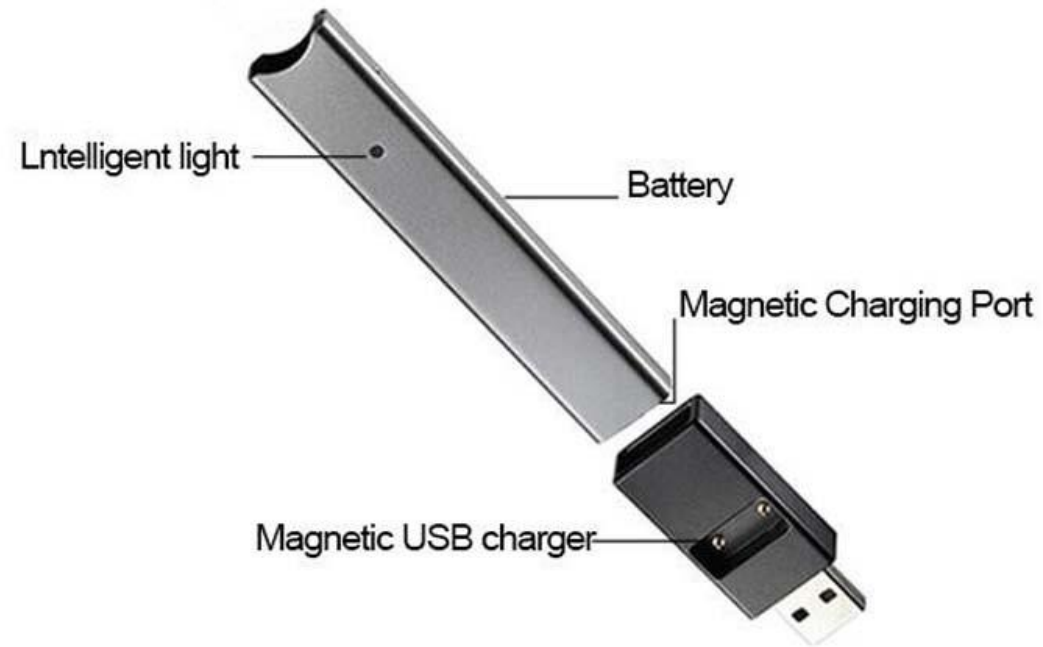


Cartridge
Stores the
e-liquid.

Mouthpiece

Allows user to
inhale the
aerosol.





JUUL looks like a USB And Is Charged Using a Computer





VAPING BILLBOARD



- **2 million U.S. teens are vaping marijuana**
- **One liquid vape cartridge has as much Nicotine as a pack of cigarettes. Most youth vape 2 cartridges at a time.**
- **Teens that start Vaping in middle school are addicted to Nicotine by the time they enter high school.**
- **Vaping increased nearly 80 percent among high schoolers and 50 percent among middle schoolers since last year (from roughly 1.5 million to 3.6 million kids).**

Behavior Risks

- E-cigarette use among youth and young adults is strongly linked to the use of other tobacco products, such as regular cigarettes, cigars, hookah, and smokeless tobacco.
- Some evidence suggests that e-cigarette use is linked to alcohol use and other substance use, such as marijuana. And certain e-cigarette products can be used to deliver other drugs like marijuana.

Significant Health Risk

E-cigarette use poses a significant – and avoidable – health risk to young people in the United States. Besides increasing the possibility of addiction and long-term harm to brain development and respiratory health, e-cigarette use is associated with the use of other tobacco products that can do even more damage to the body. Even breathing e-cigarette aerosol that someone else has exhaled poses potential health risks.

Long Term Affects of Vaping

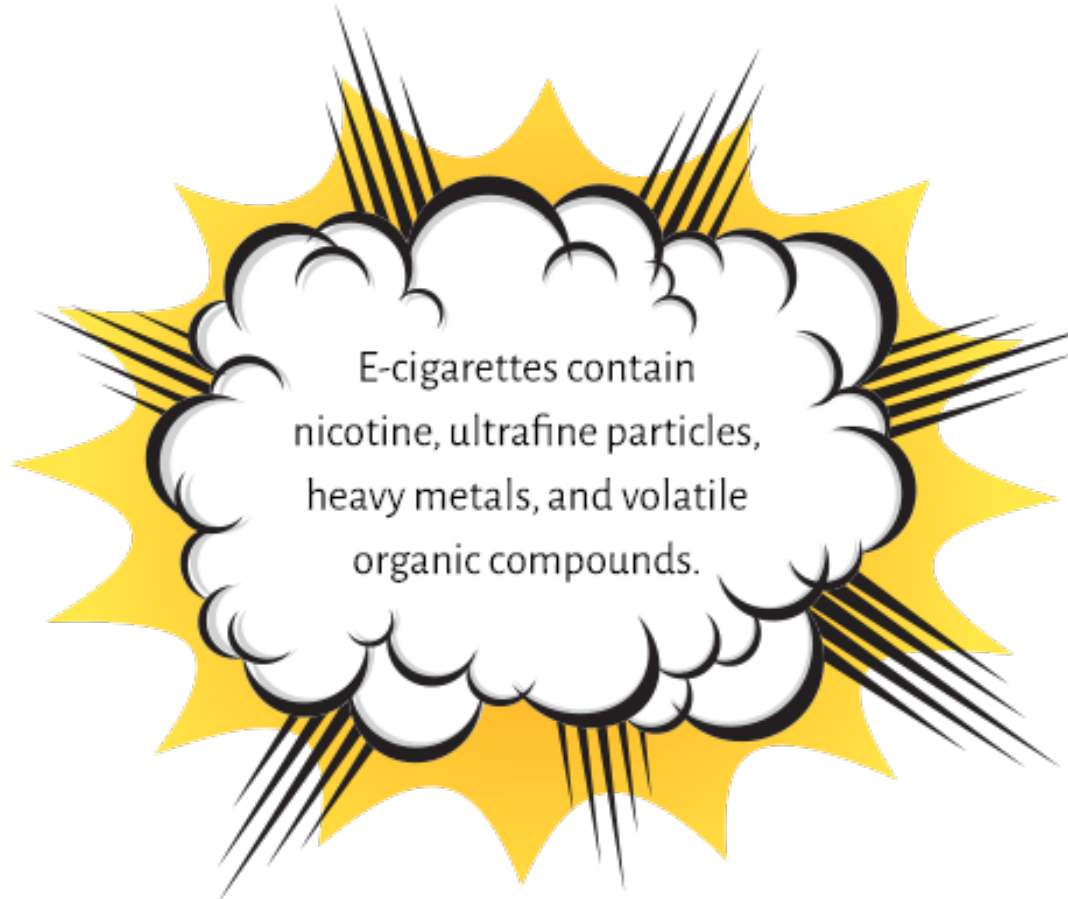
- Scientists are still learning more about how e-cigarettes affect health. However, there is already enough evidence to justify efforts to prevent e-cigarette use by young people.
- Because most tobacco use starts during adolescence, actions to protect our nation's young people from a lifetime of nicotine addiction are critical.
- Working together, we can keep America's youth and young adults safe from the dangers associated with tobacco use and nicotine addiction.

The Teenage Brain

How does the nicotine in e-cigarettes affect the brain?

Until about age 25, the brain is still growing. Each time a new memory is created, or a new skill is learned, stronger connections – or synapses – are built between brain cells. Young people's brains build synapses faster than adult brains. Because addiction is a form of learning, adolescents can get addicted more easily than adults. The nicotine in e-cigarettes and other tobacco products can also prime the adolescent brain for addiction to other drugs such as cocaine.

Aerosol & Other Risks

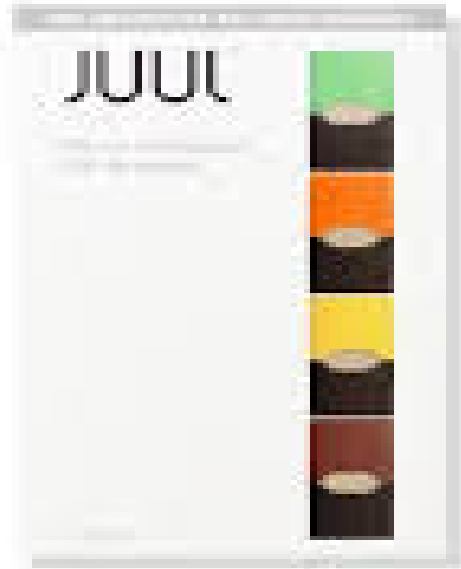


The aerosol from e-cigarettes is not harmless. It can contain harmful and potentially harmful chemicals, including nicotine; ultrafine particles that can be inhaled deep into the lungs; flavoring such as diacetyl, a chemical linked to a serious lung disease; volatile organic compounds such as benzene, which is found in car exhaust; and heavy metals, such as nickel, tin, and lead. Scientists are still working to understand more fully the health effects and harmful doses of e-cigarette contents when they are heated and turned into an aerosol, both for active users who inhale from a device and for those who are exposed to the aerosol secondhand. Another risk to consider involves defective e-cigarette batteries that have been known to cause fires and explosions, some of which have resulted in serious injuries. Most of the explosions happened when the e-cigarette batteries were being charged.

Explosions can happen causing severe injury



Youth are Attracted to the Flavors



MIXED FLAVORS:

***COOL MINT**

***MANGO**

***CREME BRULEE**

***VIRGINIA TOBACCO**

What Is JUUL Doing?

- JUUL has removed their social media presence
- JUUL will stop selling fruity flavors like mango and cucumber from brick-and-mortar stores.
- Juul has implemented stricter online purchasing age verification.
- To complete an order at JUUL.com, users are asked to provide their name, date of birth, permanent address, and the last four digits of their social security number. This information is verified by a third-party and cross-referenced with publicly-available records to confirm the person is at least 21 years of age. If a user's public records fail to match or they do not wish to provide their social security number, they must upload a valid government-issued I.D. for review by a member of the company's compliance team.

What can parents do?

It is important to talk with kids about the dangers of vaping. Youth see e-cigarette advertisements from many sources, including retail stores, the internet, TV, movies, magazines, and newspapers. They can also see posts or photos about vaping on social media. Parents should monitor screen time use and talk to their youth about what they may have seen or heard about vaping. Parents can also be role models and set a positive example by being tobacco free.

Rockville Centre Coalition for Youth

Contact Information:

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www.rvccoalitionforyouth.org

The Rockville Centre Coalition for Youth has as its principal mission the reduction of substance abuse, with a primary focus on reducing youth substance abuse. Its mission is to plan and implement strategies to prevent and reduce youth substance use and its associated consequences.



Reducing Addiction to Nicotine: Strategies Hidden in Plain Sight

Daniel A. Hussar, Ph.D.
Pharmacist and Dean Emeritus
Philadelphia College of Pharmacy
University of the Sciences
Philadelphia, PA

The Need for Non-Drug Therapies In Reducing Teen Vaping

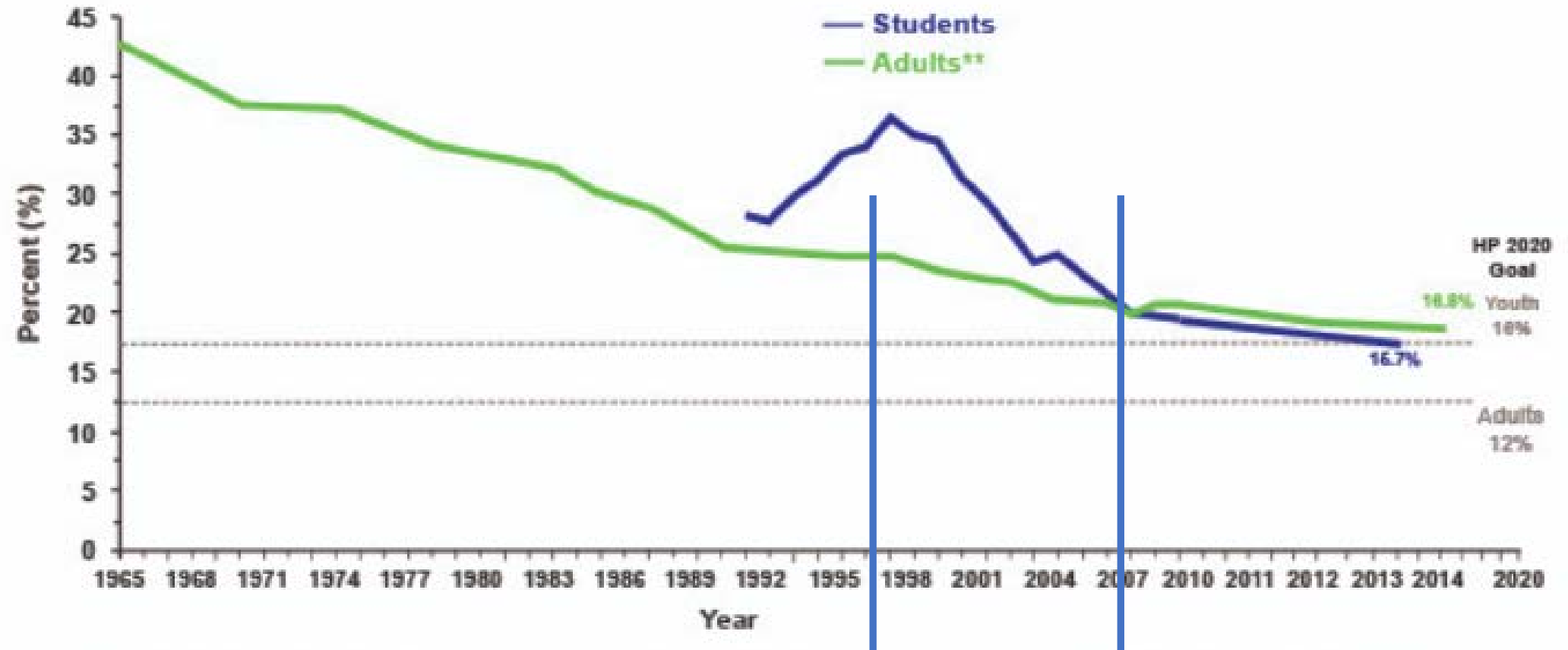
Don Seibert
SMOKENDERS™
Birmingham, AL

SMOKENDERS™

A Behavioral Approach to Smoking Cessation

- Taught in Hotels & Corporate meeting rooms from 1969 until 2012
- Taught via Online course since 2012
- 7 week course (1-2 hrs. per week) along 4 threads
 - Physical - nicotine dependency
 - Psychological – conditioned responses
 - Cultural – factors in smokers environment
 - Social – Shared experiences with linkages to food, caffeine and alcohol
- Video classes and Daily Action Step exercises
- **We guarantee smoker will quit or their money back!**

Trends in Current Cigarette Smoking by High School Students* and Adults** — United States, 1965-2014



*Percentage of high school students who smoked cigarettes on 1 or more of the 30 days preceding the survey (Youth Risk Behavior Survey, 1991-2013).

**Percentage of adults who are current cigarette smokers (National Health Interview Survey, 1965-2014).

Nicotine Replacement Therapies

- The Harvard School of Public Health study of NRT's in 2012, Concluded:
“ Nicotine Replacement Therapies are no more effective in smoking cessation than quitting on one's own”
- Other studies may indicate differently however, all seem to suggest, NRT's are effective only 7-10% of the time

Drug Therapies

- Risks
 - Potential high risk side effects for Adult Cigarette Smokers
 - Not recommended for Teen Cigarette Smokers and Teen Vape Users
- Side Effects require constant self monitoring
- At best, they are only 15-20% effective on their own

Behavioral Approach

- Participants continue to smoke while learning “How to Quit”
 - Physical - Handles Nicotine withdrawal via step down in nicotine content of cigarettes smoked over 4 week period.
 - Psychological - Breaks the psychological dependency on smoking
 - Social - Breaks the Linkages to Food, Caffeine & Alcohol
 - Cultural - Addresses the smokers adaptation to culture of quitting
- **Requires** - A Commitment to the process
- **Requires** - “Skin in the Game” Studies have shown, without a financial commitment positive outcomes suffer.
- Effective >60% of the time

VAPENDERS©

- Initial planning began in Feb, 2018
- Based on the Legendary SMOKENDERS™ course
- Cigarette-specific issues removed
- Vaping issues added
- Release 1
 - Oriented exclusively for teens who have not smoked cigarettes
 - Pilot Testing underway
 - Commercial availability in Spring of 2019
- Release 2
 - Oriented for adult vape users who desire to quit completely
 - Commercially available in Summer-Fall of 2019

Addressing the Teen Vaping Market

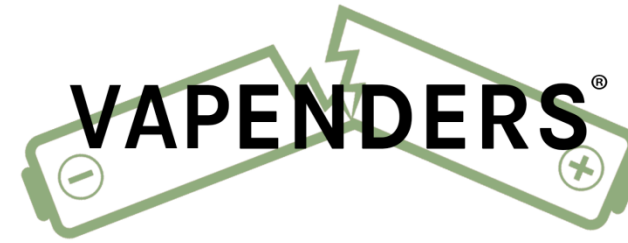
- Must market through parents & mentors
 - To provide support in teen education and motivation
 - To provide awareness of the risks and dangers (Parents & Teens)
 - To obtain commitment to quitting – as a “Family Team”
 - Accountability
 - Support
 - Open Communications
- Only provide course where commitment exists
 - \$250 up front - (\$200 refund available during first 2 weeks if teen is not participating)
 - \$100 “Crush Vaping” reward to Teen on successful completion of program
 - Or, donated to “Drug Free Clubs of America” if teen fails to quit vaping

Biggest Marketing Obstacles

- Gaining Market Awareness of VAPENDERS® Program – Parents & Teens
- Educating Parents of the Vaping epidemic and its issues/risks
- Educating Teens
 - Who Consider themselves “invulnerable” to health issues
 - Who Live in and for the moment and have little interest in the future
- Getting Parents & Teens to unemotionally discuss teen vaping
- **Achieving a Commitment from all parties, to “Crush Vaping”**

VAPENDERS® compared to SMOKENDERS™

- Nicotine is Nicotine – whether ingested by smoking or vaping
- Psychological Dependencies
 - Most are the same – perhaps not as strong “Conditioned Responses”
- Cultural Issues
 - Dealing with Teen issues of immaturity and secret vaping
- Dealing with Social vaping issues
 - Handling the issue of peer pressure
- We feel certain that VAPENDERS® can effectively address teen vaping, but only when we have a committed parent-teen team with “skin in the game”



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Dr. Jennifer M. Ossege, PsyD
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FDA is asking the wrong questions to help eliminate youth e-cigarette use

Lauren Kass Lempert, JD, MPH
UCSF, Center for Tobacco Control Research & Education

FDA Public Meeting
January 18, 2019

E-cigarettes are recreational products, not drugs

- **Not** medicines approved by FDA's drug authorities
- **Not** administered under clinical supervision
- **Not** interventions for smoking cessation



Our review did not find any eligible studies that used electronic cigarettes as an intervention for tobacco smoking cessation in adolescents.

Fanshawe TR, Halliwell W, Lindson N, et al. Tobacco cessation interventions for young people. Cochrane Review 2017.

FDA statements may mislead kids

- E-cigarettes can help quit smoking
- E-cigarettes are safe
- Unsubstantiated, illegal MRTP claims!
- Intended for adults, used in ads, heard by kids
- Reflected in FDA's questions



For example, our plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources. To that end, the agency's regulation of both novel nicotine delivery products such as e-cigarettes and traditional tobacco products will encourage the innovation of less harmful products while still ensuring that all tobacco products are put through an appropriate series of regulatory gates to maximize any public health benefits and

Questions FDA should be asking...

1. Do messages promoting e-cigs for adults attract kids?

- Messages suggest e-cigs are harmless
- “Adults only” messages attract kids
- Truth campaign denormalizing the industry works better



Journal of Adolescent Health 63 (2018) 401–406

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www.jahonline.org

Original article

Estimating the Pathways of an Antitobacco Campaign

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Article History: Received October 25, 2017; Accepted April 18, 2018
Keywords: Prevention; Youth tobacco use; Mass media campaign; Intervention

ABSTRACT

Purpose: This study examined mechanisms through which the truth campaign, a national mass media antismoking campaign, influences smoking-related attitudes, and progression of tobacco use over time in youth and young adults.

Methods: Structural equation modeling tested causal pathways derived from formative research and behavioral theory with a nationally representative longitudinal sample of 15–21-year-olds (n = 8747) over 24 months. Data were collected from 2014 to 2016, and analyses were conducted in 2017.

Results: Greater ad awareness predicted strengthening of attitudes targeted by the campaign (i.e., feelings of independence from tobacco, antitobacco industry sentiment, decreasing acceptance of social smoking, and decreasing acceptance of smoking imagery), and attitude changes were significantly associated with greater support for an antitobacco social movement (e.g., agreement to the item “I would be part of a movement to end smoking”). Greater social movement support predicted a slower rate of progression on smoking intensity after two years of the campaign.

Conclusions: Findings suggest that engaging youth and young adults in a cause-based social movement for promoting health can be a powerful strategy to drive positive behavior change. Messages targeting attitudes that resonate with values important to this age group, including independence and connectedness, are particularly effective. Investments in national antitobacco public education campaigns are key policy interventions which continue to help prevent tobacco use among youth and young adults.

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IMPLICATIONS AND CONTRIBUTION

Study findings highlight the importance of using messages based on the values and culture of the target audience. Further, findings suggest that engaging youth and young adults in a cause-based social movement for promoting health can be a powerful strategy to drive positive behavior and prevent tobacco use.

2. Why are e-cigarettes so attractive to kids?

- Kids think they're safe
- Flavors target kids
- Nicotine addicts kids
- Ads target kids
- Kids can get them easily



The Price of Cool: A Teenager, a Juul and Nicotine Addiction

E-cigarettes may help tobacco smokers quit. But the alluring devices can swiftly induce a nicotine habit in teenagers who never smoked. This is the tale of one person's struggle.

Matt Murphy, of Reading, Mass., developed a painful nicotine addiction from vaping that made him so dependent he called his device his "11th finger." Joshua Bright for The New York Times

3. What regulatory levers can FDA use to make e-cigarettes less attractive to kids?

- Pre-market review – TCA 910
- Modified risk claims – TCA 911
- Tobacco product standards – TCA 907
- Marketing restrictions – TCA 906(d)

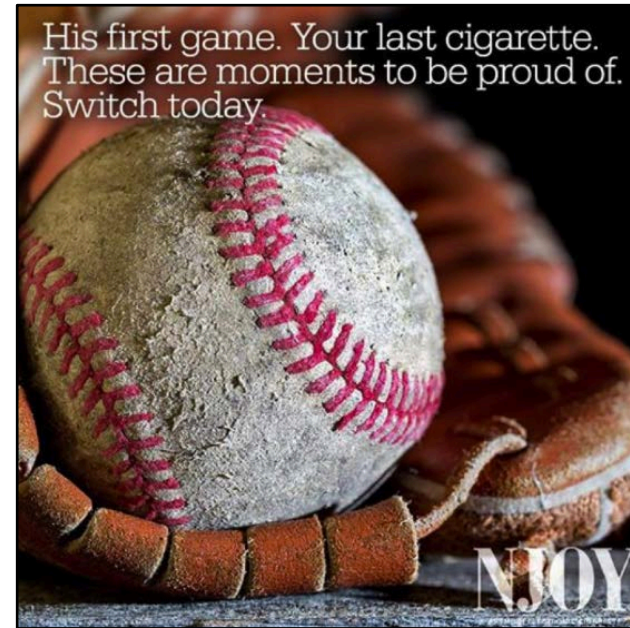
E-cigs must get FDA pre-market review and authorization under TCA section 910!!!

- Companies must demonstrate public health benefit
- FDA delayed e-cig reviews by extending compliance date
- Thousands of unreviewed e-cigs remain on market
- FDA reconsidering policy, but only for some e-cigs
- **All** unauthorized e-cigs should be removed from market including mint, menthol, and tobacco-flavored products

Unauthorized cessation, health, and MRTP claims

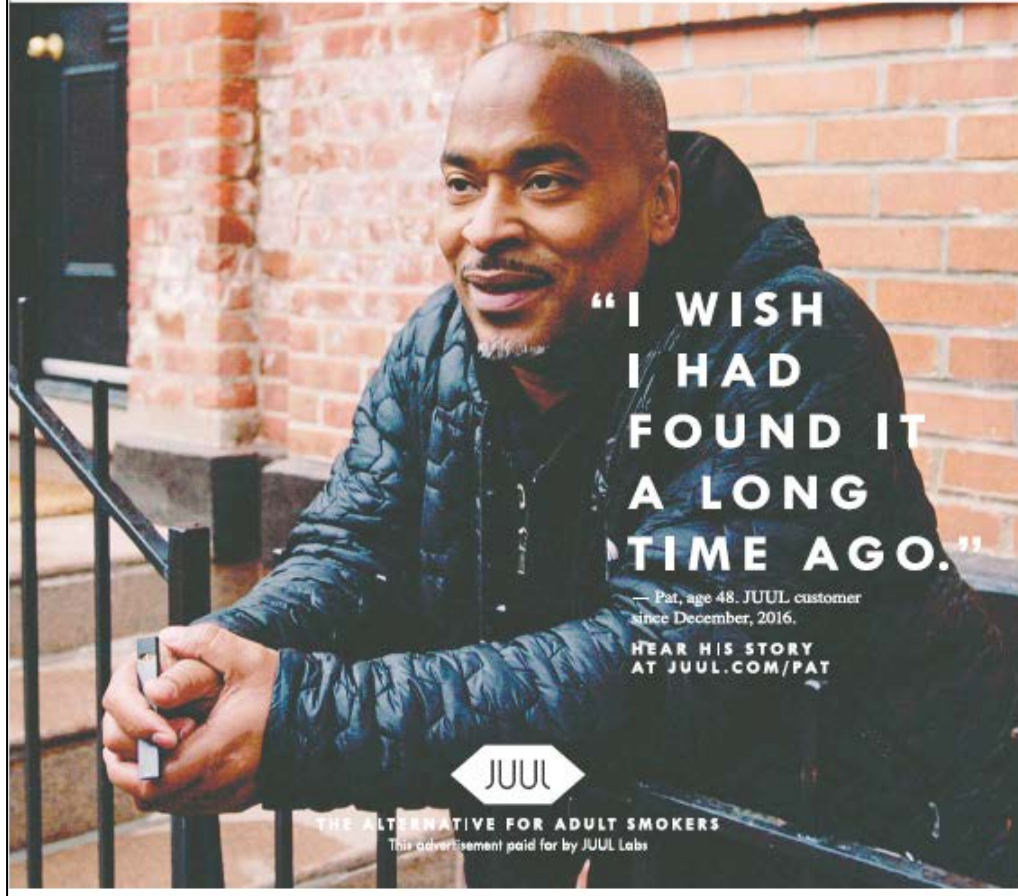
TCA section 911

- No FDA authorization to market e-cigs as cessation or therapeutic aids
- No FDA authorization to market e-cigs as modified risk products
- FDA should prohibit companies from marketing products with these claims



Implicit cessation claims

**WARNING: This product contains nicotine.
Nicotine is an addictive chemical.**



**"I WISH
I HAD
FOUND IT
A LONG
TIME AGO."**

— Pat, age 48. JUUL customer
since December, 2016.

**HEAR HIS STORY
AT [JUUL.COM/PAT](https://juul.com/pat)**

JUUL

THE ALTERNATIVE FOR ADULT SMOKERS
This advertisement paid for by JUUL Labs

(503) 961 - 4692 | info@VineVapors.com

Another ex-Smoker Turned to Vaping Success Story!

by Charles Montgomery | Jul 1, 2015 | Vape Shop Owners | 0 comments

Vaping Testimonials Are Flying In!

Read the story of Jerry Lozzo

We can't and won't ever claim that Vaping is HEALTHY, however, it is most certainly a significantly safer alternative to smoking, as the vaping science shows. The testimonials of former smokers are flying in all over the country and they won't ever quit because of its significance to their lives.

Here are what most ex-smoking vapers say:

- They couldn't exercise for long as a smoker
- Now they can exercise just like they had never smoked
- Couldn't quit smoking with traditional smoking cessation products
- Quit smoking in one day with vaping

You want to know who's the most excited?

- The ex-smoker themselves
- The ex-smoker's family
- The ex-smoker's coworkers

Tobacco product standards – flavors

TCA section 907

- Prohibit **all** flavors, including mint and menthol



Marketing restrictions – TCA section 906(d)

- Prohibit internet sales
- Prohibit ads targeting kids
- Prohibit e-cig ads on TV
- Prohibit false and misleading advertising
- Prohibit brand name sponsorships
- Prohibit self-service displays

A poster for the Freedom Project by Live Nation. The poster features the Manchester Orchestra and the text "presented by blu featuring". It lists tour dates and locations for the 2014 tour. The poster also includes the text "WITH BALANCE AND COMPOSURE AND KEVIN DEVINE + THE GODDAMN BAND" and "blu ELECTRONIC CIGARETTES TAKE BACK YOUR FREEDOM".

2014 TOUR DATES

Thursday, April 17
Tampa, FL
The Ritz

Friday, April 18
Ft. Lauderdale, FL
Revolution

Monday, April 21
Houston, TX
House of Blues

Wednesday, April 23
Dallas, TX
House of Blues

Thursday, April 24
Lawrence, KS
Granada

Monday, April 28
Spokane, WA
Knitting Factory

Tuesday, April 29
Seattle, WA
Neptune

Saturday, May 03
Los Angeles, CA
House of Blues

Tuesday, May 06
San Diego, CA
House of Blues

Friday, May 09
Colorado Springs, CO
Black Sheep

Sunday, May 11
St. Louis, MO
The Pageant

Wednesday, May 14
Minneapolis, MN
Skyway Theater

Friday, May 16
Grand Rapids, MI
Intersection

Saturday, May 17
Cincinnati, OH
Bogart's

Saturday, May 24
Philadelphia, PA
Theatre of Living Arts

Sunday, May 25
Philadelphia, PA
Theatre of Living Arts

Tuesday, May 27
Washington, DC
Fillmore

Wednesday, May 28
Norfolk, VA
The Norva

Thursday, May 29
Charlotte, NC
Fillmore

Friday, May 30
Atlanta, GA
Tabernacle

Saturday, May 31
Nashville, TN
Cannery

presented by **blu** featuring

MANCHESTER ORCHESTRA

WITH BALANCE AND COMPOSURE AND
KEVIN DEVINE + THE GODDAMN BAND

blu ELECTRONIC CIGARETTES **TAKE BACK YOUR FREEDOM**

NOT FOR SALE TO MINORS. blu eCigs® electronic cigarettes are not a smoking cessation product and have not been evaluated by the Food and Drug Administration, nor are they intended to treat, prevent or cure any disease or condition. ©2014 LOEC, Inc. blu™ and blu eCigs® are trademarks of Lorillard Technologies, Inc.

Summary: what FDA can do now

1. Use existing regulatory authority to tackle youth epidemic
2. Require premarket review demonstrating public health benefit
3. Enforce against unauthorized cessation and modified risk claims
4. Prohibit ***all*** flavors in e-cigs, including mint and menthol
5. Impose marketing and advertising restrictions
 - Prohibit internet sales
 - Prohibit ads targeting kids



Reducing Youth Access to Vapor Products

Mark Anton
Executive Director

January 18, 2019



Youth Prevention Efforts

- Smoke-Free Alternatives Trade Association was the First to Require Age Verification 2014
- Age to Vape was a program our members were required to follow before any state or federal laws were enacted to restrict access to minors
- The program mimicked the current tobacco laws of the state where the member was retailing the product
- SFATA realized the need to protect the youth acted to prevent access

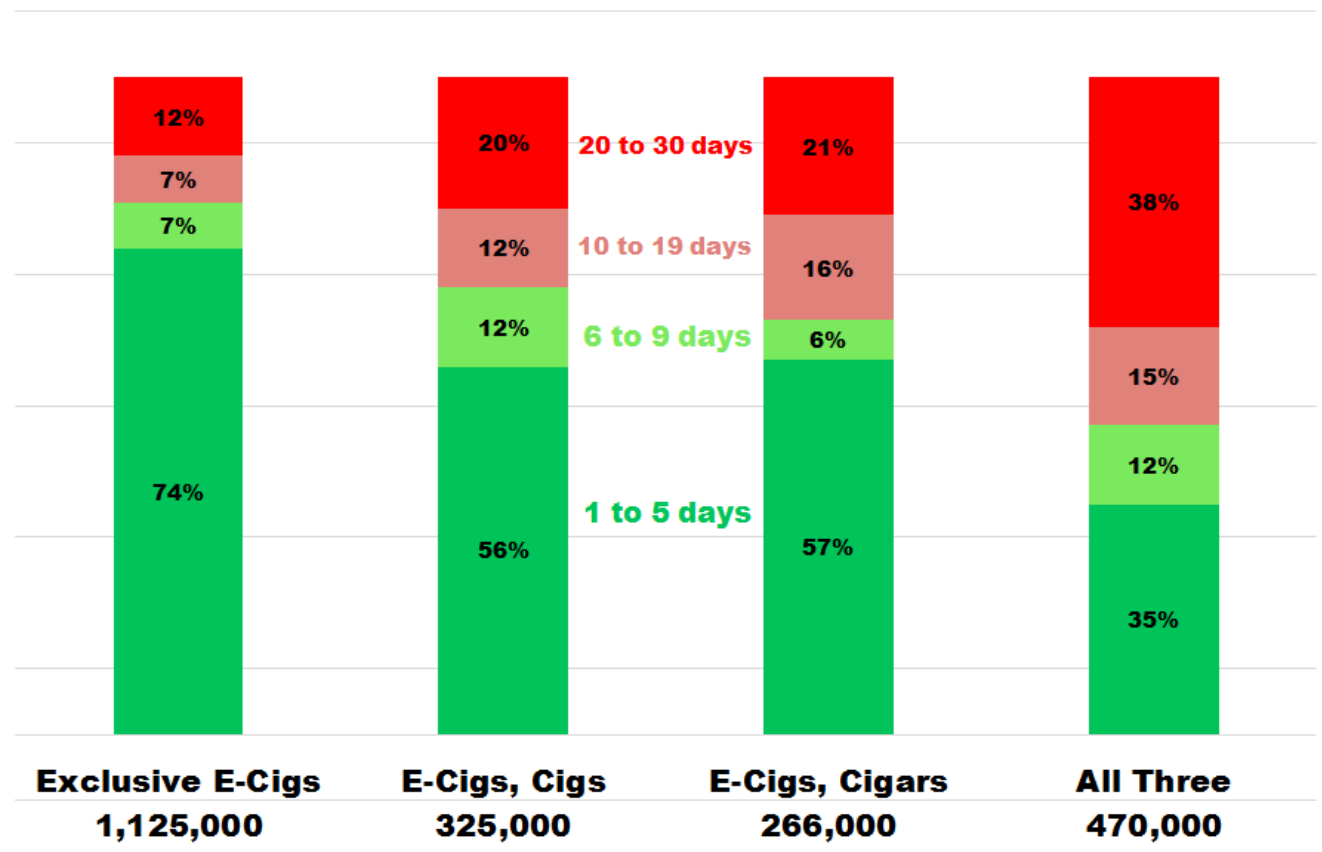


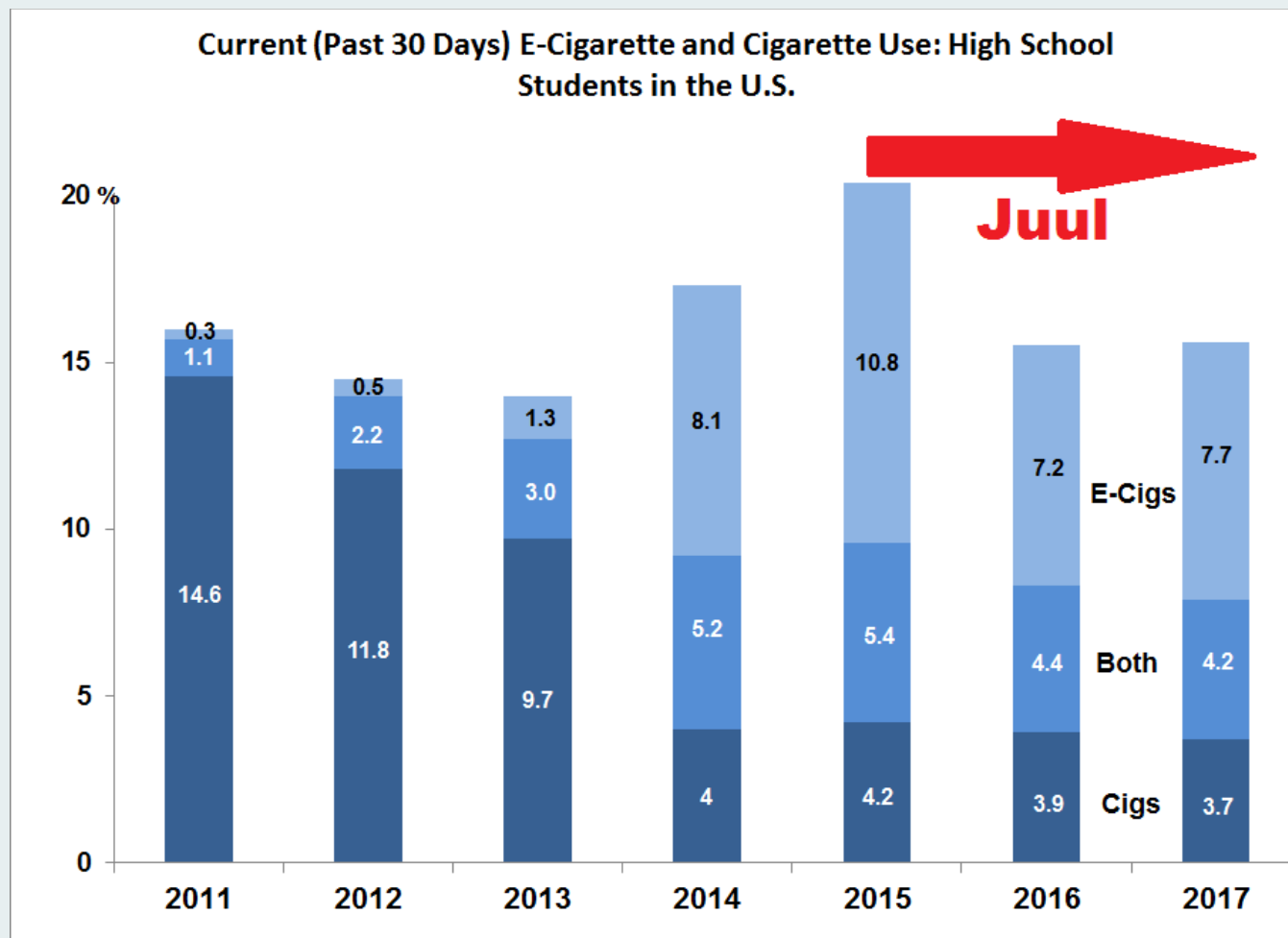
- ▶ Daily (1.1%) and frequent (1.6%) e-cigarette use by 6th-12th graders remained virtually unchanged from 2014 to 2017, while experimental use declined from 2015 to 2017, 2018?

Days	2014	2015	2016	2017	2018
0	89.3	87.4	90	90.6	?
1+	8.8	11.2	8.4	8.2	13.8
3+	4.5	6.2	4.9	4.8	?
6+	3	4.2	3.1	3.2	?
10+	2.3	2.8	2.2	2.5	?
20+	1.4	1.7	1.4	1.6	3.4
All 30	0.9	1.1	1.1	1.1	?



Frequency of Past-Month E-Cigarette Use Among Middle and High School Students, NYTS 2017







- ▶ The majority of High School students under age 18 (74%) obtained e-cigarettes from family members, friends and others.

E-Cigarettes Sources for High School Users < 18, 2017	
Source	
Friend	64.00%
Family member	5.80%
Other person	4.00%
Combined	72.80%
All Retailers	27.20%



The Risks of Selling Vape Products Today...

In September, 2018 The Food and Drug Administration (FDA) announced that it issued 1,300 warnings and fines against e-cigarette manufacturers and retailers for selling products to minors. FDA Commissioner Scott Gottlieb warned during a speech at FDA headquarters that the agency is prepared to take additional "significant" steps to curb use of e-cigarettes among minors.

Civil Money Penalty (CMP) Complaints:

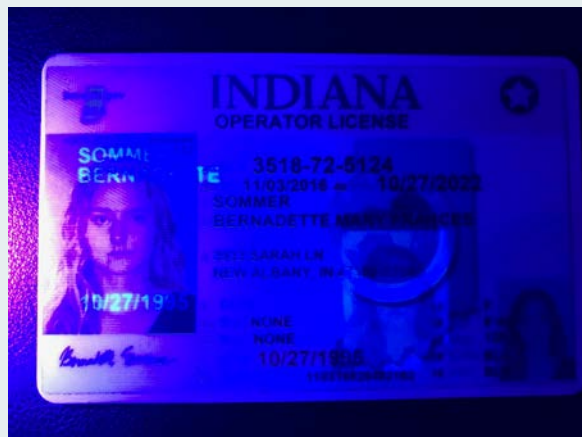
<u>Number of Regulation Violations</u>	<u>CMP Amount</u>
1st violation	\$0 (CTP will send a Warning Letter)
2 within a 12-month period	\$285
3 within a 24-month period	\$570
4 within a 24-month period	\$2,282
5 within a 36-month period	\$5,705
6 within a 48-month period	\$11,410

Under the law, the FDA may pursue a No-Tobacco-Sale Order (NTSO) against retailers that have a total of five or more repeated violations of certain restrictions within 36 months. Retailers are prohibited from selling regulated tobacco products at the specified location during the period of the NTSO.



Fake IDs Flooding The Market Today...

- ▶ Fake IDs are easily available from multiple sources on the web.
- ▶ Selling fake IDs is a lucrative business... up to \$1M in annual revenue for some operators who brag online of over a 1,000+ inquiries per day.
- ▶ Minors easily and **anonymously** purchase these Fake IDs by ordering through international eCommerce sites without a **trace** of the transaction or payment.
- ▶ These sites sell high quality fakes from all states that will pass all normal security checks... holograms, UV, Microprint and machine readable data in the barcode.
- ▶ Fake IDs are easy to buy and easy to create, and the fake IDs flooding the market today are so sophisticated that they are fooling even law enforcement.





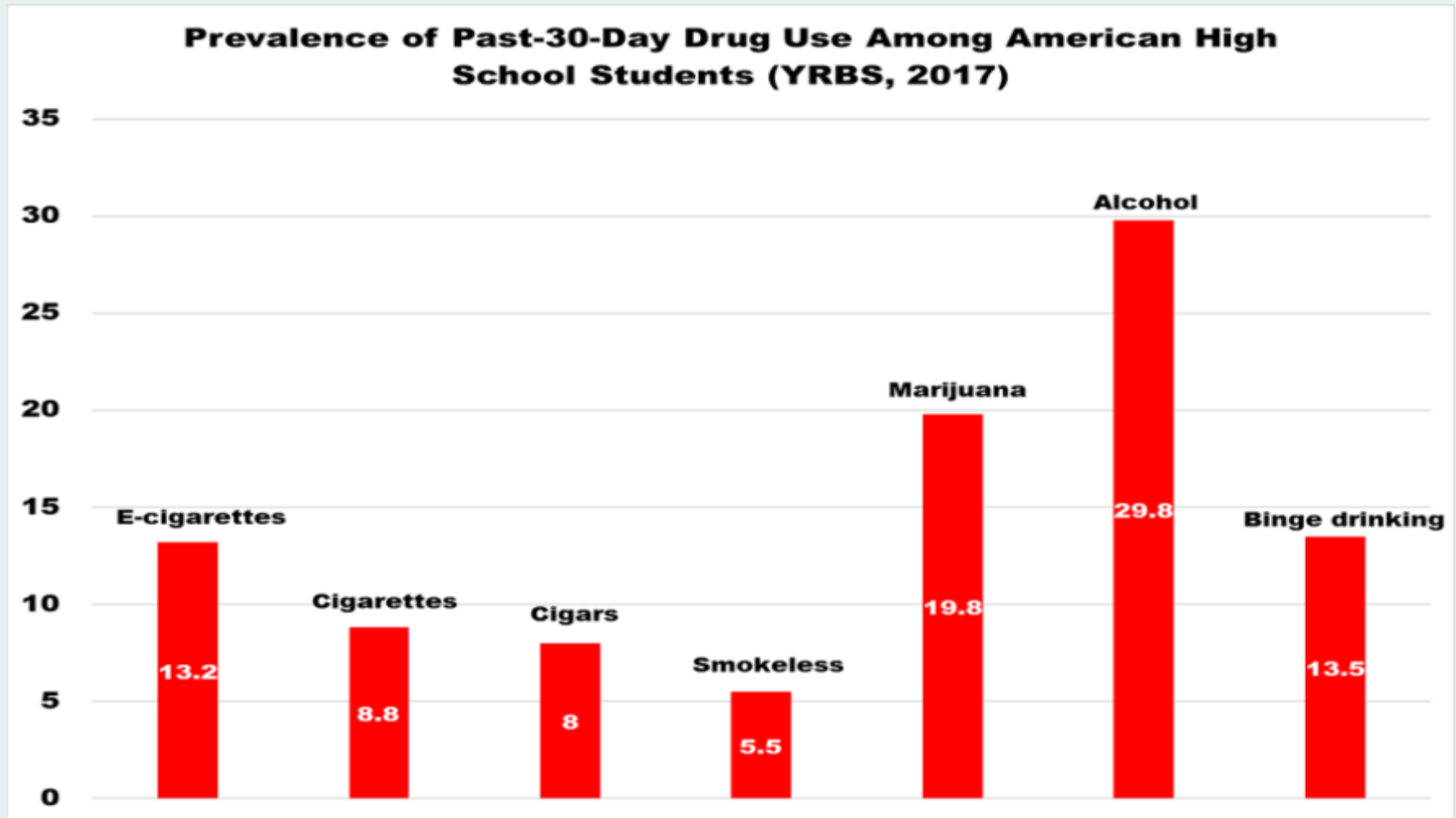
Why is ID Authentication Needed?

- ▶ High quality fake IDs are flooding the market everywhere.
- ▶ The recent FDA crackdown on the Vape industry puts all retailers at high risk.
- ▶ *Scan statistics showed that **3.85% of all IDs scanned** in 2018 for age-regulated products were determined to be fraudulent.*





How to Address the Access Issue?



Courtesy: <https://rodutobaccotruth.blogspot.com/2018/10/cdc-data-reveal-many-far-more-dangerous.html>



SFATA INTRODUCES A SOLUTION



YOUTH EDUCATION
PROTECTION &
PREVENTION



Who Does Educate?

YOUTH EDUCATION
PROTECTION &
PREVENTION

We Understand That Youth Prevention Has to Occur At All Levels:
We Are The Front Line Of Prevention



Education For Youth:
Nicotine and Addiction
Prevention, Addressing
Peer Pressure



Education For
Parents: Identifying
Components,
Suggested
Conversation Starters



Education For Schools:
PowerPoint
Presentations, Posters,
Literature



Program For
Convenience Stores
and Vape Shops:
Minor Identification





**Effective Detection of Vaping as a Method of Reducing Youth Use
– December 2018**

**Jack O'Toole – jack@FreshAirSensor.com
FreshAirSensor.com**

Improving Lives Through Novel Sensor Technology

Teens have Limited Unsupervised Opportunities to Vape

Adults control their own time and can vape whenever they choose

Teens have limited unsupervised free time when they can vape

Decreasing unsupervised opportunities to vape will reduce nicotine consumption and make cessation easier

Teens Time Scheduled in Supervised Activities

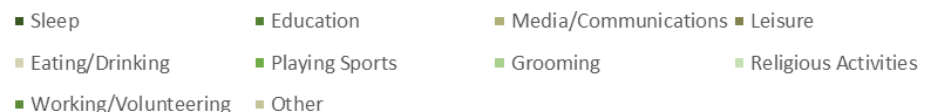
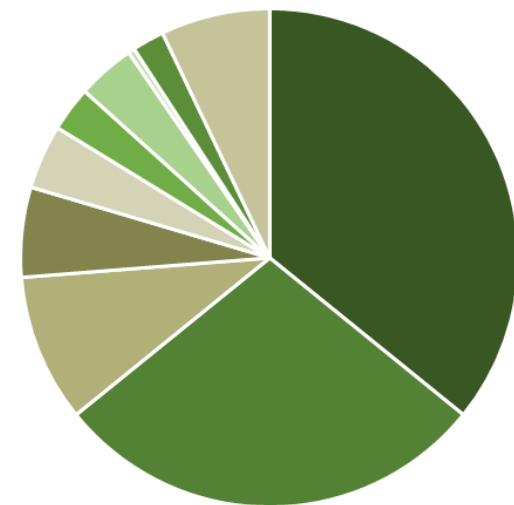
Most of a typical teen's day is in supervised activities (green). The remaining activities (tan) may be supervised

Teens have relatively small windows available to vape without risk of supervision

School bathrooms and locker rooms are a common place to vape

Sleep	8.6
Education	6.8
Communications	2.3
Leisure	1.4
Eating/Drinking	1
Playing Sports	0.7
Grooming	0.9
Religious Activities	0.1
Working/Volunteering	0.5
Other	1.7

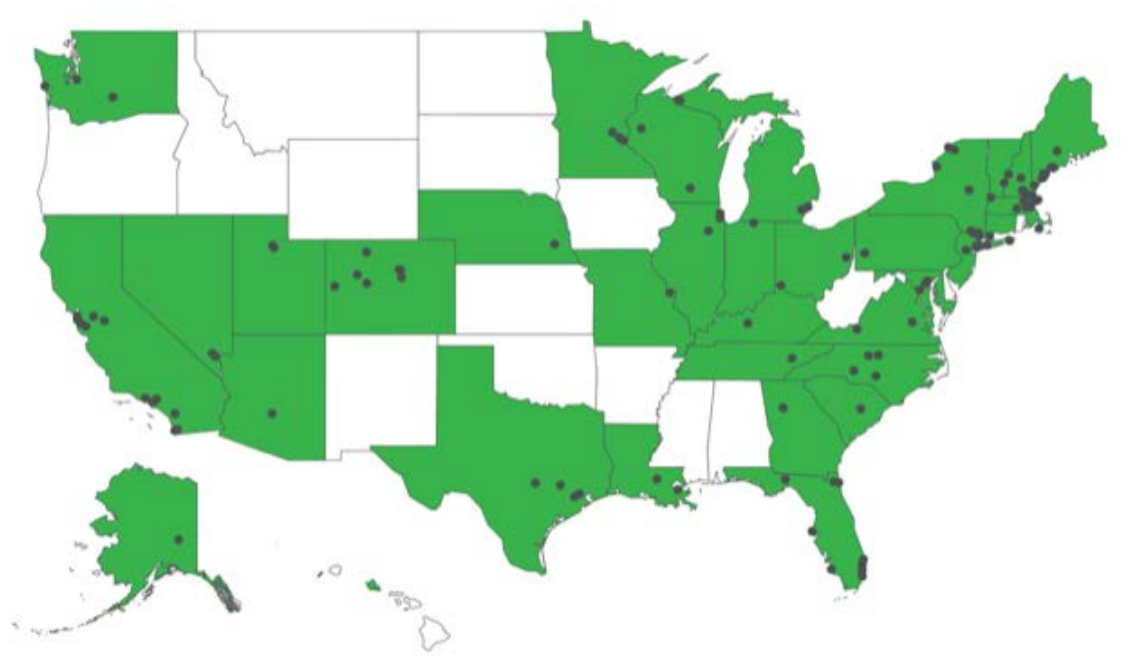
Typical Teen Weekday



FreshAir has a Proven Technology to Detect Smoking

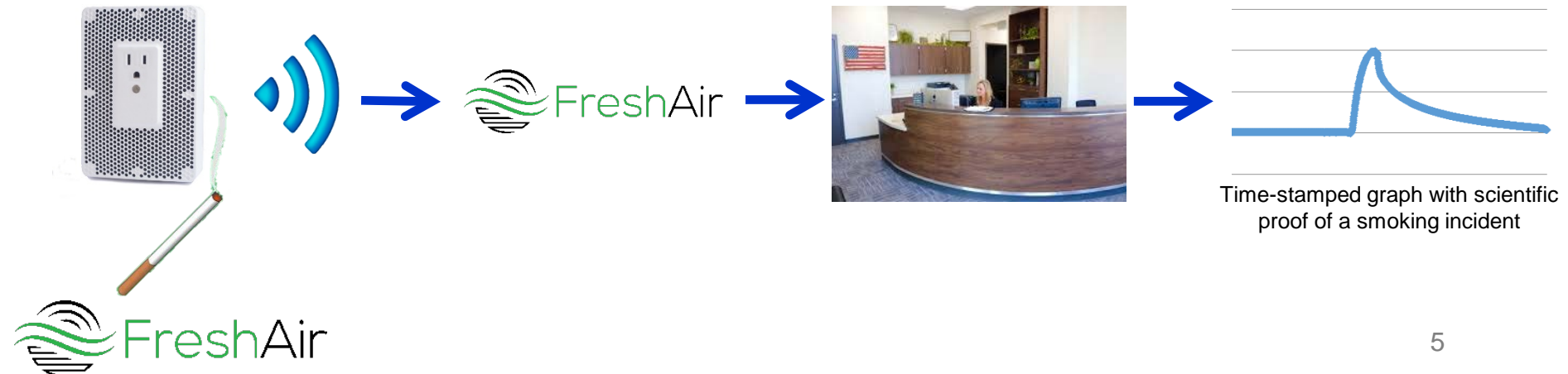
FreshAir Sensor develops and commercializes novel sensors for a wide range of substances.

Widely deployed in schools, hotels, and property management companies, FreshAir Sensor's patented sensors are the only technology that can specifically detect airborne cigarette and marijuana smoke



FreshAir Monitors for and Detects Smoking

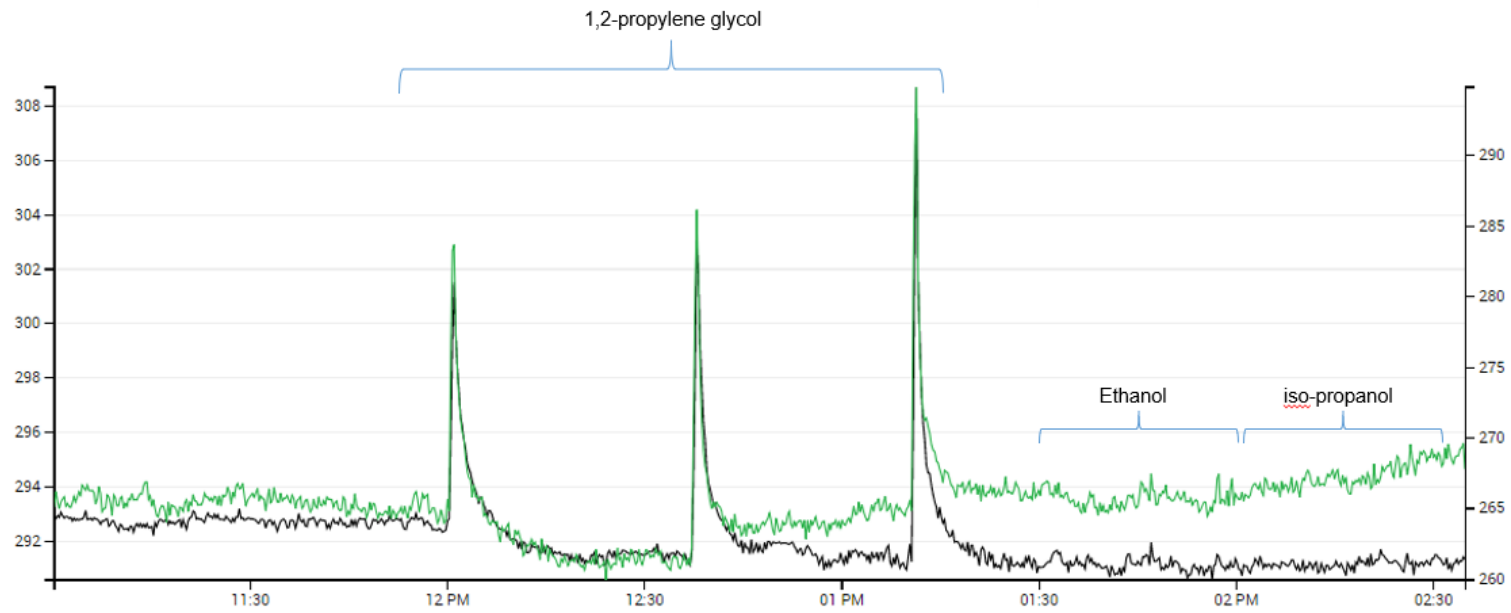
- Sensors detect small increases in ambient tobacco or marijuana smoke and send an alert signal to the FreshAir monitoring platform
- The FreshAir platform receives the signal and sends the alert to the client
- The client receives scientific proof of the incident in a detailed, time-stamped chart
- FreshAir devices enable confirmation of smoking with certainty and beyond reasonable doubt



FreshAir has Developed a Vaping Sensor

FreshAir has developed a new sensor to specifically detect vaping.

The vaping sensor is a laboratory version and will take significant development before commercialization



Reducing Opportunities to Vape Reduces Harm

Teens have limited opportunities to vape without adult supervision

The FreshAir vaping sensor, combined with FreshAir's current sensors, would detect and prevent all forms of cigarette smoking, marijuana smoking, and e-cigarette vaping during school hours and in school buildings, reducing overall vaping.

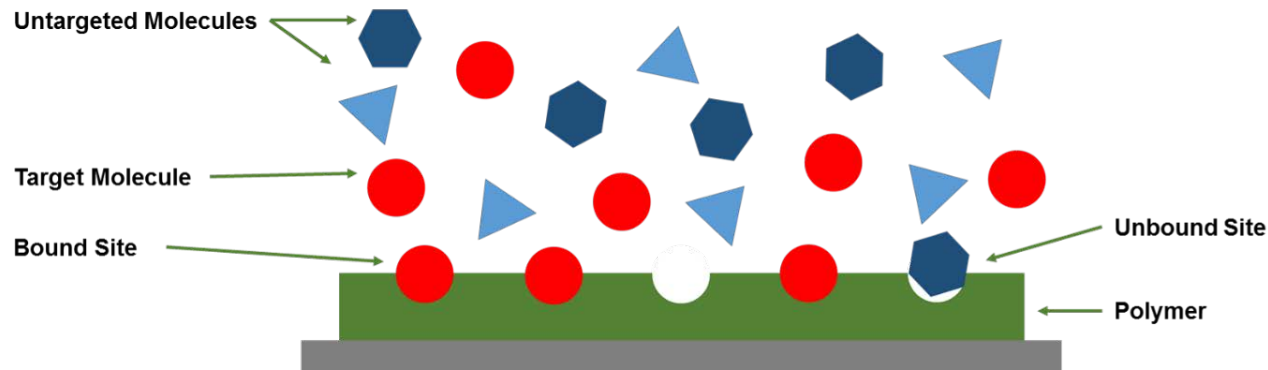


Questions



Sensors with Specific Sensitivity for Secondhand Smoke

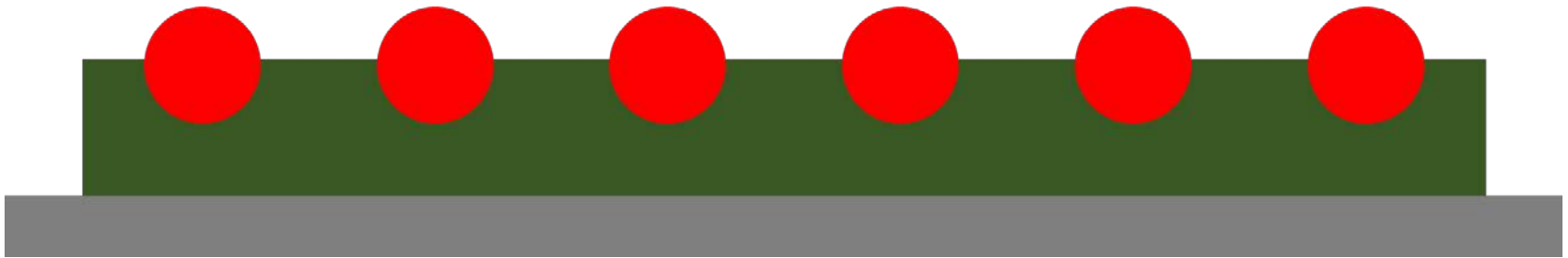
Our sensors are similar to biological receptors in the body. They have binding sites which bind the target molecule.



- The sensors measure the concentration of the target molecule by the change in electrical properties across the sensor.
- When the external concentration decreases, the sensors release the target molecule and return to original state, enabling them to remain active and detect multiple incidents.
- They do not send alerts due to smoke from candles, fireplaces, food preparation, incense or other burned items.

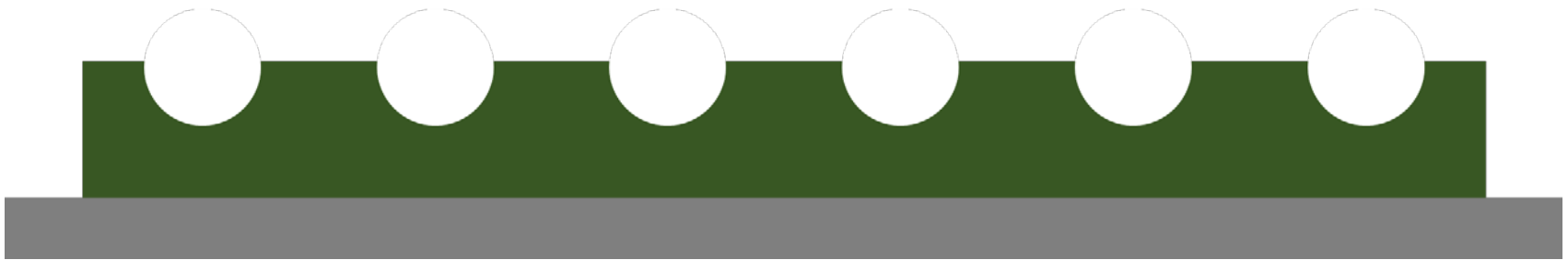
Molecularly Imprinted Polymers

Molecularly imprinted polymers (MIPs) start with the target molecule being contained in the polymer



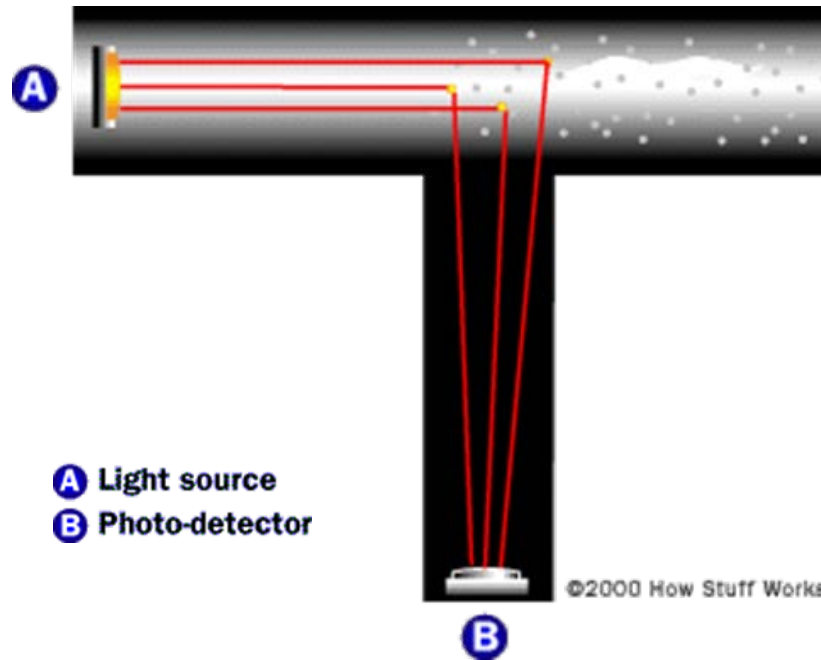
Molecularly Imprinted Polymers

Once the polymer has hardened the target molecule is removed from the MIP.



Different from a Normal Smoke Detector

Normal smoke detectors alarm when something – anything – reflects the light from one side to the other.



- As an optical photoelectric device, smoke detectors alarm when enough particles (any particles) reflect the light to the sensor.
- A large number of particles is required.
- The detector does not indicate what particles were present.

Patents

- FreshAir has four patents allowed and several patents and CIPs pending
- Patents cover a very broad range of methods for creating sensors
- Patents cover numerous substances
- Dartmouth patents are exclusive to FreshAir and royalty free

Patents Awarded

US 9,228,988	Molecularly Imprinted Polymers For Detection Of Contaminants (05-Jan-16) *
US 9,034,262	Molecularly Imprinted Polymer Sensor Systems and Related Methods (19-May-15) *
US 9,429,536	Airborne Contaminant Sensor Device and Method for Using the Same (30-Aug-16) *
US 10,024,814	Molecularly Imprinted Polymers Sensors and Methods for Manufacturing the Same (17-Jul-18) *

Patents Pending

14/624,813	Molecularly Imprinted Polymer Sensors (18-Feb-15)
14/065,990	Molecularly Imprinted Polymer-Based Passive Sensor (29-Oct-13)
14/554,634	Devices for Detecting Airborne Contaminants and Associated Methods (26-Nov-14) *
14/407,860	Systems, Sensing Devices and Methods for Detection (02-Dec-14) *
62/318,700	Molecularly-Imprinted-Polymer Coated Conductive Nanoparticle Cotinine Detection (05-Apr-16) *
16/004,297	Molecularly Imprinted Polymers Sensors (08-Jun-18) *
62/747,590	Polymer Vapor Sensors (18-Oct-18)

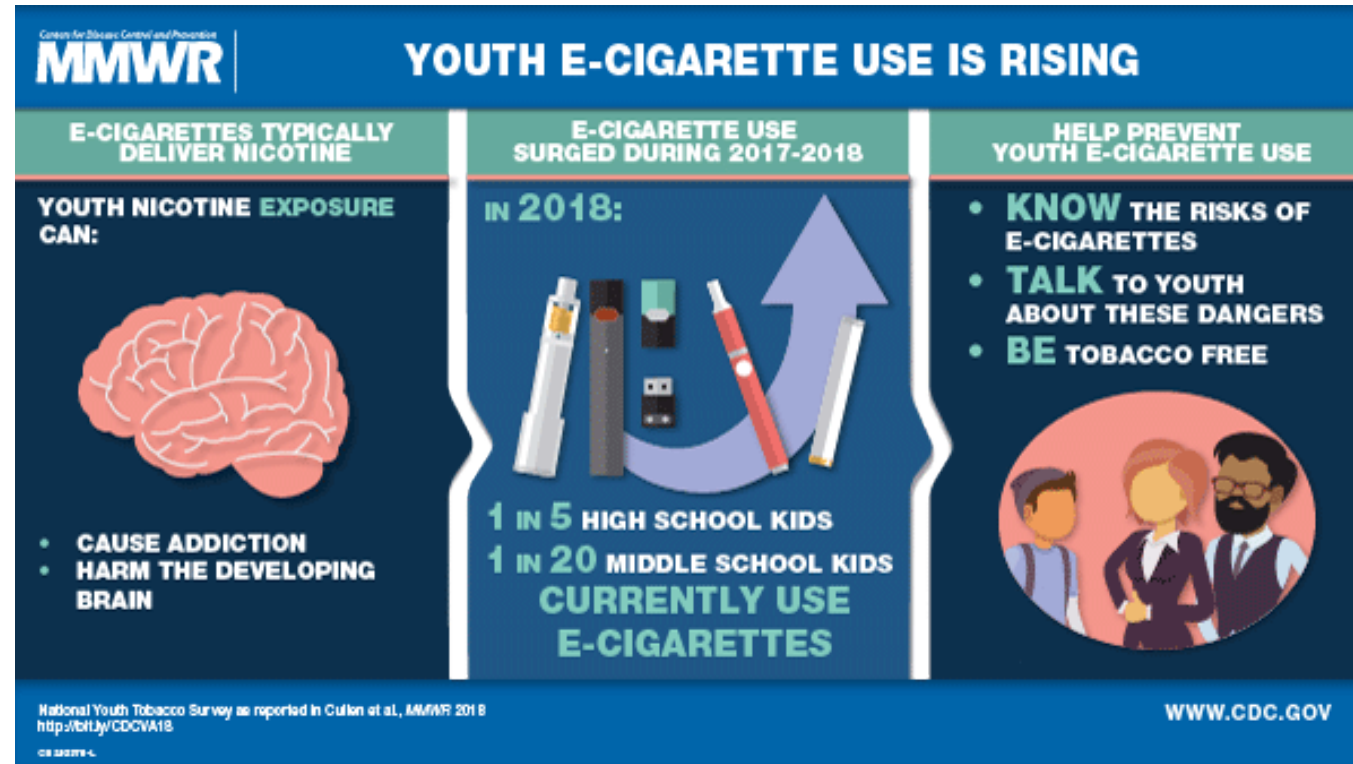
* Dartmouth patents

All patents are represented by Lathrop & Gage LLP

Steps FDA Can Take to Eliminate Youth E-Cigarette Use

January 18, 2019

E-Cigarette Use Among Youth is an Epidemic



Prevention Must Come First

Prevention Must Come First

- **FDA must enforce pre-market review.** FDA must actively enforce the legal requirement preventing products that were not commercially marketed as of August 8, 2016, or that were modified after that date, from being sold without premarket review. FDA must also rescind the four-year suspension of premarket review for newly deemed products on the market as of that date.
- **FDA needs to require the immediate removal of all flavored tobacco products** that have not been thoroughly vetted in advance by FDA to assess their public health impact.
- **FDA needs to institute restrictions on e-cigarette marketing**, including on social media, that are at least as stringent as those applied to cigarettes.
- **FDA needs to restrict internet sales of these products** and continue to aggressively enforce the law against sales to minors.

Immediate vs. Long-Term Strategies



Youth Cessation Counseling Works

Youth Cessation Counseling Works



Tobacco Cessation Resources



TEEN PROGRAMS

Not On Tobacco®

The Not On Tobacco® group (N-O-T) is the American Lung Association's voluntary smoking cessation program for teens ages 14 – 19. Over the 10-week program, participants learn to identify their reasons for smoking, healthy alternatives to tobacco use and people who will support them in their efforts to quit. Visit lung.org or call 1-800-LUNGUSA to learn more or contact your local chapter at 717-541-5864 for a list of available classes.

Smokefree Teen

Smokefree Teen is a web-based program designed and run by the National Cancer Institute to help you understand the decisions you make - especially the decision to quit smoking - and how those decisions fit into your life. Visit teen.smokefree.gov to learn more or sign up for this free program.

Smokefree TXT

Smokefree TXT is a mobile text messaging program that provides 24/7 tips, advice and encouragement to help you quit smoking. To sign up for SmokeyfreeTXT, simply text QUIT to IQUIT (47848). This free program is designed and run by the National Cancer Institute.

1-800-QUIT-NOW

The quitline is a free service that offers one-on-one immediate support. It is staffed by quit smoking coaches who can provide you with helpful information, advice and support as they walk you through a step by step plan to quit. To sign up or for more information, call 1-800-QUIT-NOW (1-800-784-8669).

QuitSTART App

This QuitSTART is a free app made for teens who want to quit smoking. This app takes the information you provide about your smoking history and gives you tailored tips, inspiration and challenges to help you become smokefree and live a healthier life. This app is free for download on iTunes and Android. This free program is designed and run by the National Cancer Institute. For more information, visit teen.smokefree.gov.

Taking Down Tobacco

Taking Down Tobacco is a comprehensive youth advocacy training program created by the Campaign for Tobacco-Free Kids in partnership with the CVS Health Foundation. This initiative educates and engages youth through free online and in-person trainings. It provides introductory training for youth new to the fight against tobacco and advanced training to help young leaders take their advocacy to the next level. For more information, visit takingdowntobacco.org

1-800-LUNGUSA | LUNG.org

- Not On Tobacco®
- Smokefree Teen
- Smokefree TXT
- 1-800-QUIT-NOW
- QuitSTART App

Youth Cessation Counseling Works

N-O-T Overview

- Developed by American Lung Association and West Virginia University in 1997
- Based on solid research and developed for teens
- Recognized by several federal agencies:
 - National Registry of Effective Programs
 - Substance Abuse and Mental Health Service Administration (SAMHSA): “evidenced-based model program”
 - National Cancer Institute: “research-tested intervention program”
 - US Office of Juvenile Justice and Delinquency Prevention: “model program”



Youth Cessation Counseling Works

The N-O-T Approach

- Standardized Training for Facilitators (Including On-going Technical Assistance)
- Establishes a Team Approach to Quitting
- Youth-Centered
- Voluntary
- Gender-Sensitive
- Multiple Learning Strategies (small group discussion, journal activities, role playing, and handouts)
- Tailored for Smokers
- Based on Theories of Behavioral Change



Youth Cessation Counseling Works

N-O-T Program Objectives

Not On Tobacco is designed to provide a total-health approach to helping adolescents:

- Quit smoking
- Reduce the # of cigarettes smoked per day by those who are unable to quit.
- Increase healthy lifestyle behaviors in the areas of physical activity and nutrition.
- Enhance their sense of self-control.
- Improve life skills such as stress management, decision making, coping and interpersonal skills.



Youth Cessation Counseling Works

N-O-T Nationwide Evaluation

- 90% of N-O-T teens quit or reduce smoking
- N-O-T female teens 4x more likely to be smoke-free 6 months post-program than those who received a brief intervention (BI)
- Nicotine Dependence:
 - Brief intervention only effective with teens with a low nicotine dependence
 - N-O-T is effective with a broad spectrum of dependence



Youth Cessation Counseling Works

N-O-T Evaluation Results

- Better grades
- Higher motivation
- Fewer absences
- Better relationships with teachers
- Fewer school smoking violations
- Positive recognition for schools/facility



Conclusion

Steps FDA Can Take to Eliminate Youth E-Cigarette Use

FDA must take meaningful action to prevent initiation that goes well beyond sales restrictions.

Youth cessation medication is a long-term strategy, not an answer to the immediate epidemic.

Counseling can work. FDA should coordinate with other public health agencies on youth cessation programming, taking the lessons learned from proven programs.



Thank You!

Jennifer Folkenroth
Certified Tobacco Treatment Specialist
National Senior Director, Tobacco Programs
Jennifer.Folkenroth@lung.org



Youth Vaping: ENDS Regulation Should Not Differentiate Based on Flavors

Larry Flick

AEMSA Executive Director

FDA Public Hearing, December 5, 2018





Who is AEMSA?

- AEMSA is the first and only Manufacturers' trade association originally dedicated to creating responsible and sustainable standards for the safe manufacturing of “e-liquids” used in e-vapor products.
- AEMSA now develops standards for all aspects of the ENDS industry including marketing and youth prevention standards and practices.
- AEMSA is an all-volunteer organization, formed by American manufacturers of e-liquids, to promote safety and responsibility through self-regulation.
- Our members believe we have a responsibility to self-regulate the e-liquid manufacturing process based on professional criteria.



For FDA Commissioner Gottlieb, understandably, it's ALL about the Youth:

- No one can argue that youth must not have access to ENDS products.
- AEMSA's position is that ENDS products should be marketed and sold *only to adult smokers*.
- AEMSA also believes that the ENDS industry, through responsible pro-active self regulation, should lead the effort to prevent youth access.



For FDA Commissioner Gottlieb, understandably, it's ALL about the Youth:

- According to Commissioner Gottlieb, the latest data shows a 78 percent increase in e-cigarette use among high school students in 2018, compared with 2017.
- Again, we all agree that we must take whatever necessary and reasonable steps are required to prevent youth vaping, and AEMSA shares Commissioner Gottlieb's concerns and objectives. But we also need to be honest and clear about what the landscape of youth vaping really looks like.
- For that we need to dive deeply into the 2018 National Youth Tobacco Survey data. However, the CDC and FDA have not publicly released the full set of the data from the NYTS.
- If public policy is based on data, that data should be made public!



One needs the full set of NYTS detailed data to understand what is happening with our youth.

- For example, the Commissioner states that there are 1.5 million more middle and high school kids in 2018 that are “current vapers”. That is defined as vaping once in the last 30 days. So if a kid takes one puff off a Juul in the last 30 days he is considered a current vaper. If that’s the case, we need to be clear about that.
- Gottlieb goes on to say that 27.7% of the 1.5 million have used e-cigarettes 20 or more days in the last 30 days. That’s 451K youth. Historical data embedded in the NYTS itself shows that more than half of those regular vapers are vaping marijuana or CBD, not nicotine, and more than 1/3 of the 451K youth are 18 years old (seniors) that are counted as youth in the NYTS but are of legal age. If that’s the case, we need to be clear about that.
- The number of kids that vape nicotine daily (which is the definition of nicotine addiction) has remained constant and is about 1%. FDA hasn’t said what that number is in the current survey, and that’s the number to be most concerned about, and only youth that are truly addicted to e-cigarettes should be the focus of this hearing.



An Ounce of Prevention is Worth a Pound of Cure

- When it comes to tobacco and ENDS addiction, nicotine is the issue.
- Most tobacco cessation therapies contain nicotine which is no better for youth if the concern is the effect of nicotine on a developing brain.
- Only 1% of youth that vape, vape everyday and are truly addicted.
- AEMSA believes that prevention through marketing and sales restrictions, and education aimed at getting kids that vape to stop without drug therapies is the best policy.



So What about Flavors?

The FDA Crackdown – No Flavored E-Cigarettes can be sold in Convenience Stores

- In the Commissioner's statement, he says "it's clear we must do more -- specifically, several policy changes to target *what appear to be the central problems -- youth appeal and youth access to flavored tobacco products*".
- This statement is based on a false premise: *that flavors are what prompt youth to experiment with vapor products. That is not the case.*
- Before vapor products existed, history has proven that youth will experiment with tobacco products that are not flavored.
- Adults need flavored e-vapor products to successfully transition off of combustible cigarettes. *Restricting flavored e-cigarette products to adults lessens the chance that they will transition off combustibles to ENDS and save their life by doing so.*



We Don't Have to Chose Between Flavors for Adults and Youth Prevention

- Commissioner Gottlieb has acknowledged that some adults might get hurt by a crackdown on flavored e-cigarettes. But “the youth risk is paramount,” he said. “In closing the on-ramp to kids, we’re going to have to narrow the off-ramp for adults who want to migrate off combustible tobacco and onto e-cigs.”
- So FDA appears willing to choose to reduce the number of adult lives saved by transitioning off combustible cigarettes to vaping products in order to prevent youth dependence on nicotine. This is a false choice: both adult harm reduction and youth e-vapor uptake prevention are achievable.
- Currently, the deadliest consumer product in history – combustible cigarettes – are available and will continue to be available, after the November 15 FDA announcement, at convenience stores and gas stations. FDA seems satisfied that these “c-stores” can effectively prohibit the sale of these deadly cigarettes to minors. Why, then, are these c-stores unable to sell far less harmful flavored e-cigarettes to adults while prohibiting their sales to minors? This policy does not, upon close examination, make sense.



How Do We Achieve Both Adult Harm Reduction and Prevent Youth E-Vapor Uptake?

- Strong and realistic steps must be taken to address the problem of youth retail sales.
- Marketing standards should be in place and agreed upon by a collaboration between front line industry stakeholders and federal regulators.
- Youth education campaigns are also needed, but they must be fact-based and directed to youth as well as to parents.



What is AEMSA Doing In Response to FDA's Recent Activities? YEPP! That's What! Youth Education, Protection, and Prevention

Youth Education, Protection, and Prevention

- We will work with Commissioner Gottlieb and FDA as we implement this campaign.
- YEPP is a 501 (c) 3 non profit; contributions will be tax deductible.
- We will fundraise from across the industry.
- The model we are following is M.A.D.D.
- YEPP will undertake a national Public Relations Campaign that includes educational material to every store that sells vapor products; every high school in the nation; PTAs across the nation; billboards across the nation; and a national speaking tour.



What is AEMSA Doing In Response to FDA's Recent Activities? YEPP! That's What! Youth Education, Protection, and Prevention

The premise behind YEPP is simple. The industry needs to take the lead in ensuring our products do not get in the hands of underage minors. For more information on YEPP please visit www.YeppWeID.org. The youth problem Commissioner Gottlieb points to – regardless of what the data shows – is solvable. It is in industry's best interest to make sure Commissioner Gottlieb knows that we are committed to solving it.

The YEPP campaign will be an industry-sponsored campaign that:

1. Educates youth on the dangers of vaping and nicotine addiction and encourage young people to make better choices than experimenting with nicotine products, including outreach directly to high schools around the nation.
2. Educates parents on what vaping is, as well as what to look for in their homes, so parents can readily identify vapor products that their minors may be experimenting with. YEPP also offers suggestions on how to open a dialogue with their minors about vaping.
3. Thirdly, YEPP will address retailers and provides an array of methods to identify minors to avoid unintentional sales to minors. YEPP also includes a "WeCare" program that retailers will subscribe to for on-going newly developed strategies on youth protection and prevention.

Mr. Robert Diaz



Comment on “Eliminating Youth Electronic Cigarette Use: The Role for Drug Therapies”

Amanda L. Graham, PhD

SVP, Innovations Center

Docket No. FDA-2018-N-3952

Brief background

Largest public health foundation in the U.S. dedicated to tobacco control

1. Education
2. Tobacco control research and policy studies
3. Community activism and engagement
4. Digital programs for tobacco cessation



Truth Initiative

SVP, Innovations Center
2008 – present

Georgetown University Medical Center

Professor, Oncology
2006 – present

Brown Medical Center

Centers for Behavioral &
Preventive Medicine
1999 – 2006

Central premise

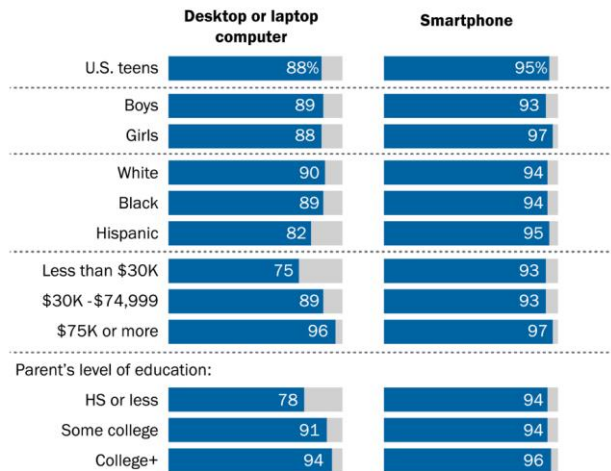
As the FDA pursues drug therapies to help youth quit vaping,
it should not lose sight of the importance of
behavioral and social factors
in e-cigarette and other tobacco product use
and the power of **digital cessation approaches**
to address this epidemic – today



Smartphones are ubiquitous

Smartphone access nearly ubiquitous among teens, while having a home computer varies by income

% of U.S. teens who say they have or have access to a ____ at home



Note: Whites and blacks include only non-Hispanics. Hispanics are of any race. Parent's level of education based on highest level of education associated with a teen's parent.

Source: Survey conducted March 7-April 10, 2018.

"Teens, Social Media & Technology 2018"

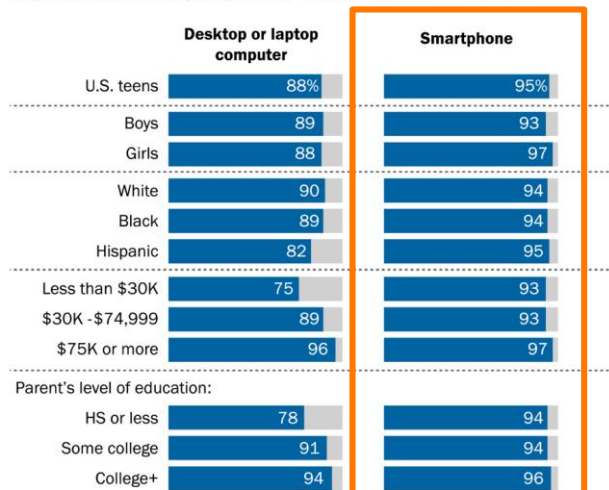
PEW RESEARCH CENTER

Source: Anderson & Jiang. *Teens, Social Media & Technology* 2018. Pew Research Center.

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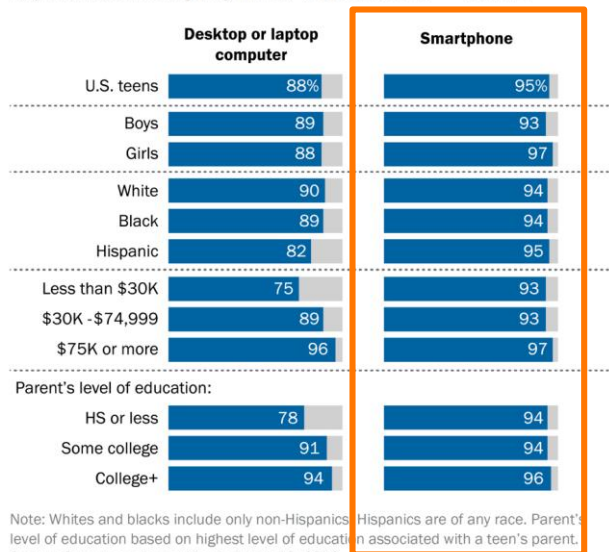
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PEW RESEARCH CENTER

Source: Anderson & Jiang. *Teens, Social Media & Technology* 2018. Pew Research Center.



Who owns cellphones and smartphones

A substantial majority of Americans are cellphone owners across a wide range of demographic groups. By contrast, smartphone ownership exhibits greater variation based on age, household income and educational attainment.

% of U.S. adults who own the following devices

	Any cellphone	Smartphone	Cellphone, but not smartphone
Total	95%	77%	17%
Ages 18-29	100%	94%	6%
30-49	98%	89%	9%
50-64	94%	73%	21%
65+	85%	46%	40%

Source: Survey conducted Jan. 3-10, 2018.

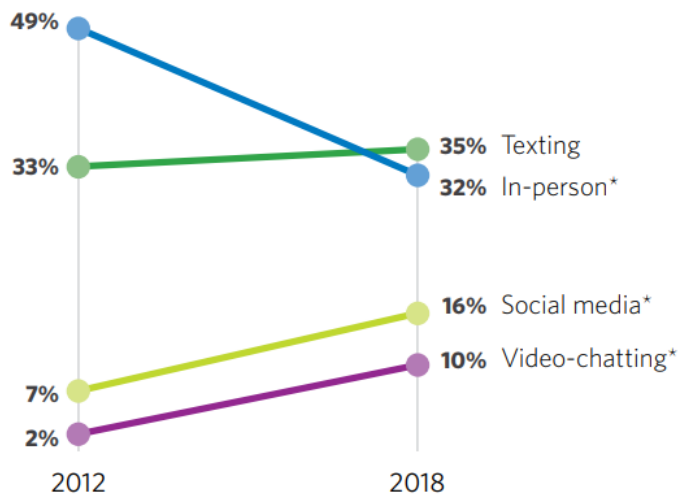
PEW RESEARCH CENTER

Source: *Mobile Fact Sheet*. <http://www.pewinternet.org/fact-sheet/mobile/>

Texting is preferred communication channel

FIGURE F. Preferred Method of Communication, 2012 vs. 2018

Among 13- to 17-year-olds, percent who say the following is their favorite way to communicate with friends:

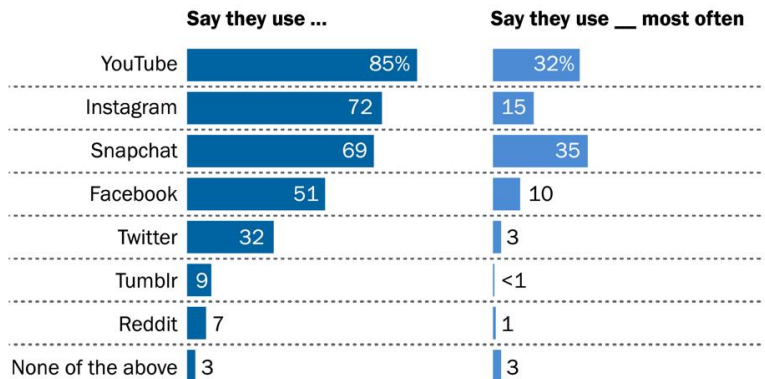


*Differences over time are statistically significant at $p < .05$.

Social media use is “almost constant”

YouTube, Instagram and Snapchat are the most popular online platforms among teens

% of U.S. teens who ...



Note: Figures in first column add to more than 100% because multiple responses were allowed. Question about most-used site was asked only of respondents who use multiple sites; results have been recalculated to include those who use only one site. Respondents who did not give an answer are not shown.

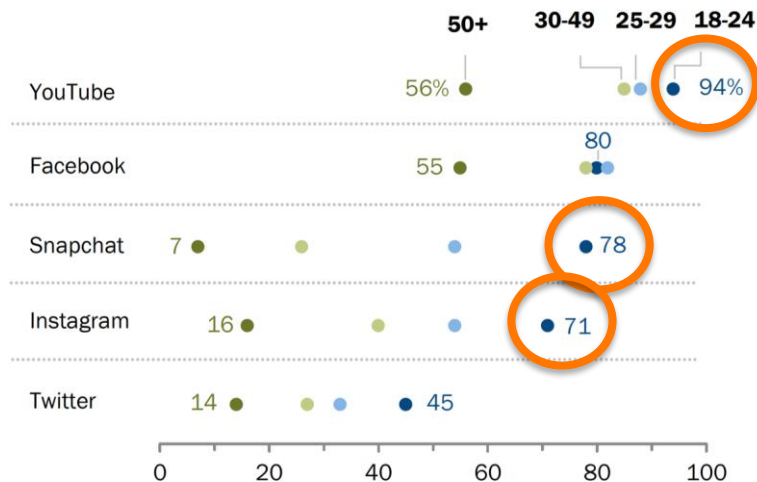
Source: Survey conducted March 7-April 10, 2018.

“Teens, Social Media & Technology 2018”

PEW RESEARCH CENTER

Social platforms like Snapchat and Instagram are especially popular among those ages 18 to 24

% of U.S. adults in each age group who say they use ...



Source: Survey conducted Jan. 3-10, 2018.

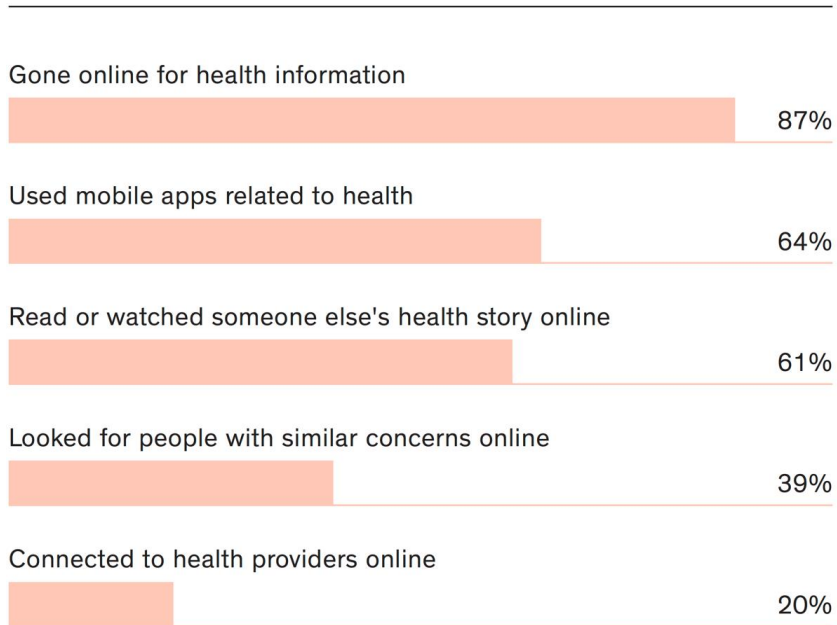
“Social Media Use in 2018”

PEW RESEARCH CENTER

Young people use technology for health.. and quitting

Figure 1. Reported use of online health resources

Percent of 14- to 22-year-olds who say they have:



... on Reddit



Prediction for the future: give it
10 years and people will be
using cigarettes to quit juuling

... on Reddit

“

Prediction for the future: give it 10 years and people will be using cigarettes to quit juuling

“

I quit juuling a little over a month ago and I'm still feeling withdrawal

... on Reddit

“

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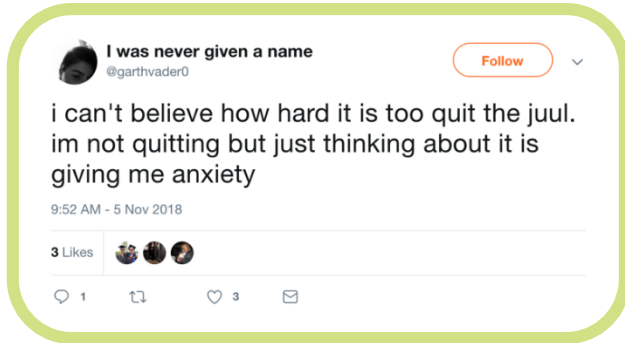
“

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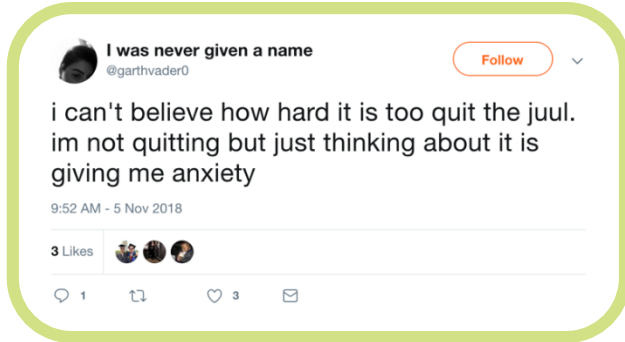
“

I was smoking off and on for 4 years, not feeling good about it at all, and was able to completely phase out cigs after I started the Juul. It felt like an achievement until I realized I was way more addicted to the vape than I was to the cigarettes.

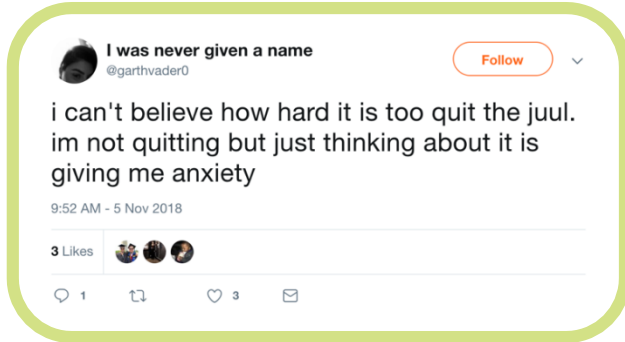
... on Twitter



... on Twitter



... on Twitter



... on Twitter

 **I was never given a name**
@garthvader0

Follow

i can't believe how hard it is too quit the juul.
im not quitting but just thinking about it is
giving me anxiety

9:52 AM - 5 Nov 2018

3 Likes



1 3

 **Sasha Sloan** ✓
@sadgirlsloan

Follow

i quit juul and i just wanted to let everyone
know cause it was hard lol

6:50 PM - 5 Nov 2018

16 Retweets 394 Likes



23 16 394

 **boink**
@ultraball

Follow

it's hard to quit the juul when every person
on campus fucking has one and juuls in your
face

1:33 PM - 23 Oct 2018

3 Retweets 15 Likes



1 3 15

 **goblin king**
@distastefulboy

Follow

someone needs to get me to quit smoking
bc, between my juul and regular cigs, i can
feel the end of my life when i extend my arm
out

4:11 PM - 26 Aug 2018

1 Retweet 36 Likes



3 1 36

... on Instagram



oliviafriedes • Follow

oliviafriedes I finally quit. I decided that I didn't want to be addicted to a little stick anymore. I have a lost voice in this video from a sore throat that I got after not juuling for three days. I knew I would have to stop at some point, but I really didn't want to. It's so easy to juul and to not know how much your doing, you just pop out the old pod and put a new one in, it's like a bottomless pit. It was the first thing I did when I woke up and the last thing I did before I went to sleep. Even throughout headaches, nausea, and the pure panic I experienced when I would pat my pocket and my juul wasn't in there. I kept going, telling myself I could stop whenever. Then I went on a 3 day trip and decided not to bring, just to see what would happen. I got pretty bad headaches, and my throat was attacking me, every time I saw something



335 views

DECEMBER 31, 2018

Add a comment...

#quitjuul

#quit

#juul

#quitsmoking

#destroyjuul

#quitvape

#vape

... on BecomeAnEX.org



ShyButterfly95
Age 21

How do you not smoke when smoking is all you do?

Question asked by [ShyButterfly95](#) on Aug 26, 2017

Latest reply on May 28, 2018 by [elvan](#)

Like • 0

Comment • 29

For clarity: I am quitting both smoking and vaping. I mainly vape, and would "treat" myself to cigarettes every now and then. I am quitting on September 10th.

For background: I'm disabled. I'm not working or going to school right now. I'm 21. I don't have any close friends. I have a boyfriend I see once or twice a week. Otherwise, all I do is smoke and vape and browse my phone. I have clinical depression and have lost all interest in other things. I also have anxiety, which is another trigger for smoking and vaping.

So I do nothing all day... have no interest or motivation to do anything... but at the same time I want to quit because of my health and because I'm sick of being controlled by nicotine.

I'm so conflicted. My life is fat full of nothing and nicotine. But then what the heck do I do all day instead of vaping and browsing my phone? I'm thinking to start I can replace the hand to mouth habit with a different (healthy) hand to mouth habit and still browse my phone. Then slowly introduce old hobbies back into my life.

Oh, I will be using the lozenge. Can't use the patch, I'm allergic. I'm already on bupropion for depression.

... on BecomeAnEX.org



ShyButterfly95
Age 21

How do you not smoke when smoking is all you do?

Question asked by [ShyButterfly95](#) on Aug 26, 2017

Latest reply on May 28, 2018 by [elvan](#)



Like • 0



Comment • 29

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And they get good advice!



MePlus3
Age 18-24

Vaping vs ecigs

 Blog Post created by [MePlus3](#) on Mar 26, 2017

 Like • 0  Comment • 7

Is it considered a relapse here to use a vape or ecig?

Im not thinking about doing it because I understand thats only dropping one habit for another im just curious



[jonescarp.aka.dale.Jan_2007](#)

Mar 26, 2017 6:19 AM

You certainly can not unlearn the hand to mouth connection.

And they get good advice!



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Thomas3.20.2010
Mar 26, 2017 6:49 AM

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freeneasy
Mar 26, 2017 12:04 PM

It would be better to use an NRT which is approved by the FDA for the purpose of helping you to quit smoking when used as directed. Ecigs are not an approved quit therapy.



Quitting e-cigarettes:

Published research & available programs

CASE REPORT

Successful use of nicotine replacement therapy to quit e-cigarettes: lack of treatment protocol highlights need for guidelines

Barbara Silver, Carol Ripley-Moffitt, Jennifer Greyber & Adam O. Goldstein

Department of Family Medicine, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina

Correspondence

Adam O. Goldstein, Department of Family Medicine, University of North Carolina at Chapel Hill, 590 Manning Drive, CB #7595, Chapel Hill, NC 27599.

Tel: 919 966 4090; Fax: 919 966 6125;

E-mail: adam_goldstein@med.unc.edu

Funding Information

The UNC Department of Family Medicine's Wellness@Work initiative provided program funding, and the Lineberger Comprehensive Cancer Center Innovation Fund provided funding for the manuscript preparation.

Received: 17 July 2015; Accepted: 19 November 2015

Clinical Case Reports 2016; 4(4): 409–411

doi: 10.1002/ccr3.477

Key Clinical Message

Although use of electronic nicotine delivery system devices, such as e-cigarettes and vapor pens, is on the rise, no treatment protocols exist to help such users quit. We report the case of a 24-year-old patient in a tobacco treatment program who successfully quit e-cigarette use by using nicotine replacement therapy.

Keywords

Cessation, e-cigarettes, nicotine replacement therapy, smoking, vape.

Clinical Case Reports

Open Access

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<https://www.wikihow.com/Quit-E-Cigarettes>

wikiHow to do anything...

Article Edit Discuss Home - Categories - Health - Medicines and Drugs - Recreational Drugs - Smoking - Smoking and Health Effects


How to Quit E Cigarettes

Expert Co-Authored

In this Article: [Quitting Smoking](#) [Reducing Nicotine Dependency](#) [Stopping Before You Start](#)
[Community Q&A](#)

Electronic cigarettes (also called "e-cigs," "vapes," "vape pens," and "electronic nicotine delivery systems") are devices that vaporize nicotine and additives into an aerosol which is inhaled by the user. E-cigarettes are not safe for kids, teens, young adults, pregnant women, or adults who do not currently use tobacco products. They are often marketed as healthier alternatives to cigarettes, because e-cigarettes do not require burning tobacco, so they reduce a user's exposure to toxicants. Despite this, there is not enough scientific evidence to support or contradict this claim.^{[1][2][3][4]}

People can become addicted to nicotine withdrawal easier. There is a same approach

Co-Authored By:  Klare Heston, LICSW
Clinical Social Worker

Co-authors: 7
Updated: 10 weeks ago
Views: 14,389

20 votes - 71%
Click a star to vote

Allen Carr's
Easyway

Vaping

Quit Vaping

Get started

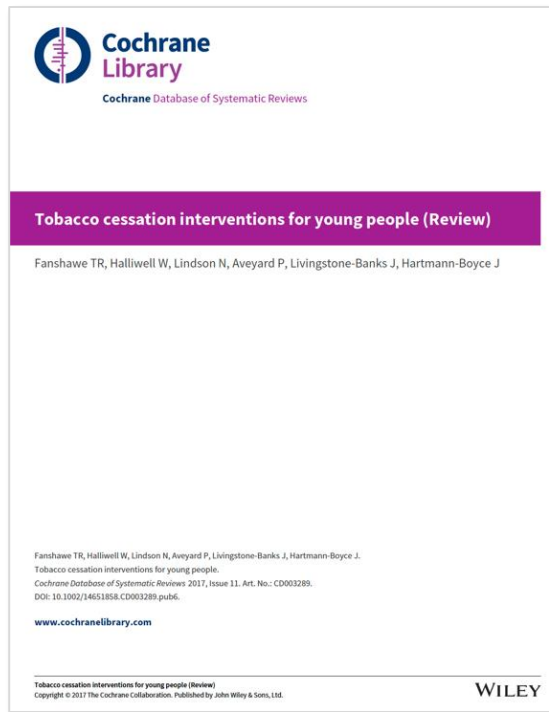
Top 10 Tips on How to Quit Vaping – Allen Carr's Easyway

Many people think Allen Carr's Easyway is simply a series of tips on how to quit vaping to help vapers quit. It isn't. It's as if vapers are lost in a maze. They want to escape vaping and smoking but they don't know the correct directions.

[Allen Carr's Easyway method](#) provides a map of the maze and simple instructions to help any vaper get free. However, if you try to follow the instructions without first understanding the map, or you fail to follow all the instructions, you may never find the exit.

Once you've got it clearly into your mind that there are no advantages to vaping, then the instructions below will help you get free but if you are serious about quitting, we strongly recommend you [attend your nearest Allen Carr center](#) or have an [online seminar](#) from the comfort of your own home:

What does youth/YA cessation literature tell us?



What does youth/YA cessation literature tell us?



Tobacco cessation interventions for young people (Review)

Fanshawe TR, Halliwell W, Lindson N, Aveyard P, Livingstone-Banks J, Hartmann-Boyce J

Fanshawe TR, Halliwell W, Lindson N, Aveyard P, Livingstone-Banks J, Hartmann-Boyce J.
Tobacco cessation interventions for young people.
Cochrane Database of Systematic Reviews 2017, Issue 11. Art. No.: CD003289.
DOI: 10.1002/14651858.CD003289.pub6.

www.cochranelibrary.com

Tobacco cessation interventions for young people (Review)
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WILEY

Smoking-Cessation Interventions for U.S. Young Adults A Systematic Review

Andrea C. Villanti, PhD, Heather S. McKay, MPH, David B. Abrams, PhD,
David R. Holtgrave, PhD, Janice V. Bowie, PhD

Context: Studies have demonstrated the importance of quitting smoking before age 30 years to avoid tobacco-related mortality but little attention has been paid to developing evidence-based smoking-cessation interventions for young adults, as distinct from adolescents and older-aged adults. The objective of this study was to conduct a systematic review of smoking-cessation interventions for U.S. young adults (aged 18–24 years).

Evidence acquisition: Electronic searches were conducted in CINAHL, the Cochrane Library, EMBASE, PsycINFO, PubMed, Scopus, and Sociological Abstracts to identify eligible interventions **through August 31, 2009**. Two independent coders critically evaluated the methodology and findings of all retrieved articles. Data analysis was conducted in 2010.

Evidence synthesis: Twelve RCTs and two nonrandomized studies met the inclusion criteria; these studies varied with respect to sample size, intervention, outcomes assessed, and smoking measures. Pooled results for two studies based on social cognitive theory indicated that they were effective in promoting short-term abstinence at 1–3-month follow-up and 4–6-month follow-up. Four studies had a significant positive impact on smoking cessation: two in the short term and two at 6 months or more.

Conclusions: **There is limited evidence demonstrating efficacy of smoking-cessation interventions for U.S. young adults. There were no pharmacologic interventions included in this review. Promising interventions were brief, with extended support via telephone and electronic media.** Further high-quality studies using standardized smoking measures and additional studies outside the college setting are needed to identify and tailor effective smoking-cessation interventions for at-risk young adults in the U.S.

(Am J Prev Med 2010;39(6):564–574) © 2010 American Journal of Preventive Medicine

Smoking Cessation Interventions for U.S. Young Adults A Systematic Review 2018 Update (in progress) Villanti et al.

Several studies demonstrate short-term efficacy of tech-based interventions for young adult smokers in the U.S.

Evidence in this area is growing; text messaging interventions seem promising.

Continued heterogeneity limits comparisons across studies.



**KEEP
CALM
AND
TAKE
ACTION**

Why Text Messaging?

- Evidence-based method
- Tailored to quitting progress
- On-demand support
- Supports quitters of all ages and SES
- Easy opt-in via existing tobacco cessation services
- Long enrollment period
- Combines the best of what we know engages and supports users from EX and TIQ



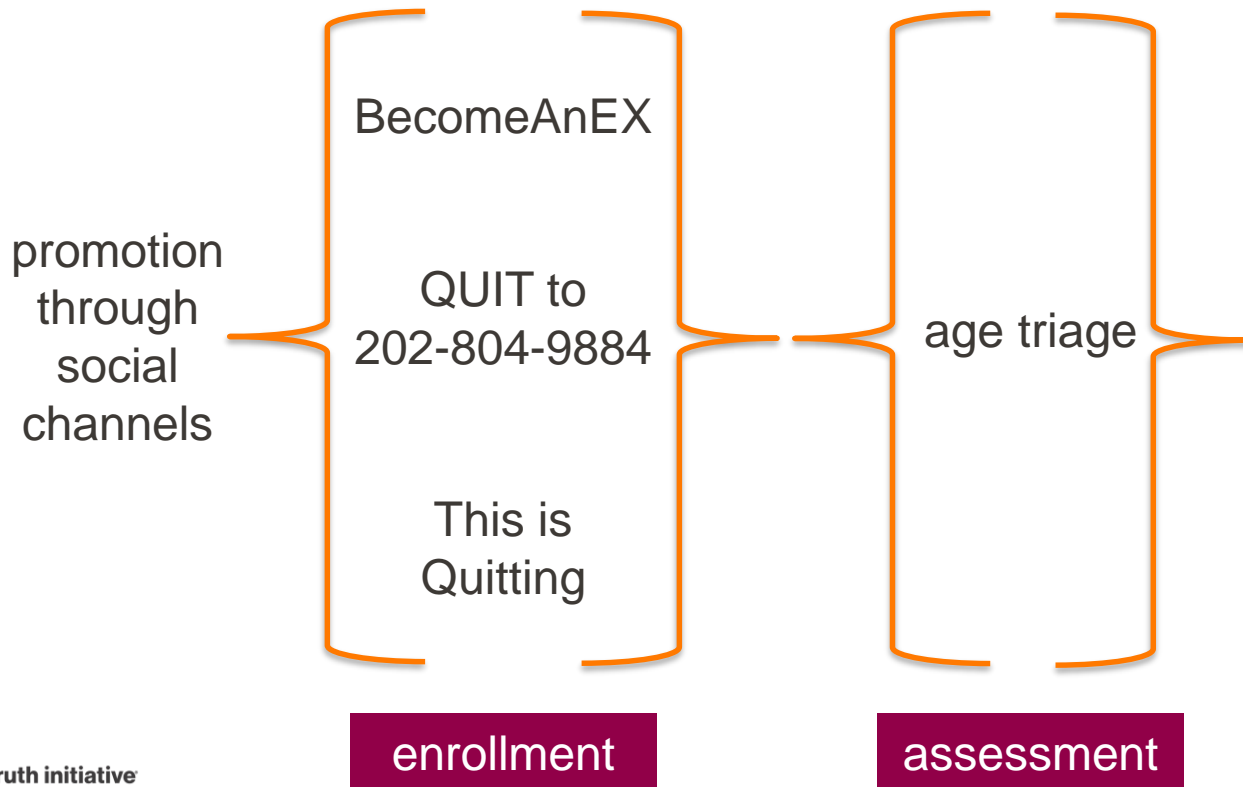
QUITTING
THIS IS QUITTING



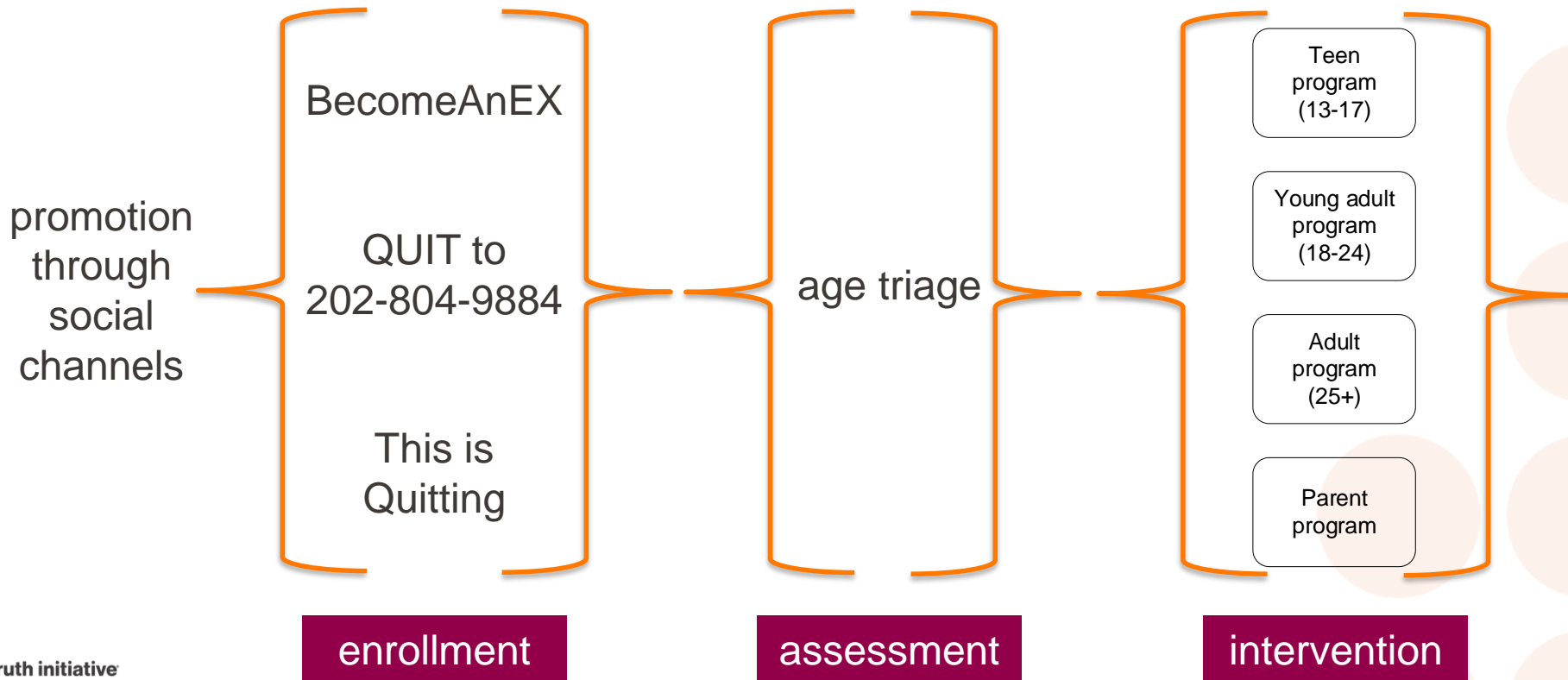
E-cig cessation program overview



E-cig cessation program overview



E-cig cessation program overview



Program features

Teens

- Context-specific language about school, social norms, and family
- Refers to product as JUUL

Young Adults

- Context-specific language about school, work, social norms, and family
- Refers to product as e-cigarettes generically, interspersed with vape

Adults

- Context-specific language about work, social norms, and family
- Refers to product as e-cigarettes generically, interspersed with vape

Parents

- Support for parents trying to help a child quit vaping
- Empathy and encouragement, practical advice and quitting strategies

Clinically sound information about quitting abruptly and cutting down

Age appropriate guidance and support for NRT

Social support and social norms around quitting

Behavioral activation tips and strategies

thank you

truthinitiative.org

