

Robert C. McMillen, PhD

Food and Drug Administration
Tobacco Products Scientific Advisory Committee
April 30, 2013

Conflict of Interest Statement

 I have no relevant financial relationships to disclose.

American Academy of Pediatrics

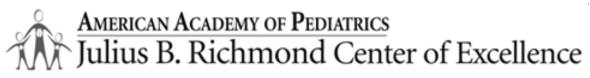
- Non-profit professional organization
- Over 62,000 member primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists
- Dedicated to the health, safety, and wellbeing of infants, children, adolescents, and young adults.

Julius B. Richmond Center of Excellence

- Improve child health by eliminating children's exposure to tobacco and secondhand smoke
- Changing the practice of pediatrics through:
 - the development and dissemination of practice tools;
 - research;
 - and improvement of community health.
- Healthy environment for children through public education and the promotion of public health policies to eliminate tobacco



Minh-Tri V., 17, Wichita, KS 1st Place, Grades 9-12 2010 Art Contest



Background

- A Content Analysis of Electronic Cigarette Website Marketing (unpublished data)
- Examples provided by Rachel Grana,
 Postdoctoral Scholar, Center for Tobacco Control
 Research and Education, UCSF
- Funding sources: NCI R25T 113710; California TRDRP 21FT-0040

Health claims

- "no carcinogens"
- product emits a "harmless water vapor"

Benefits of Electronic Cigarettes by LUCI



Without the Bad

Contains no tar, second-hand smoke, or burning substances.

www.myluci.com; accessed 5/22/12



Presence of doctors





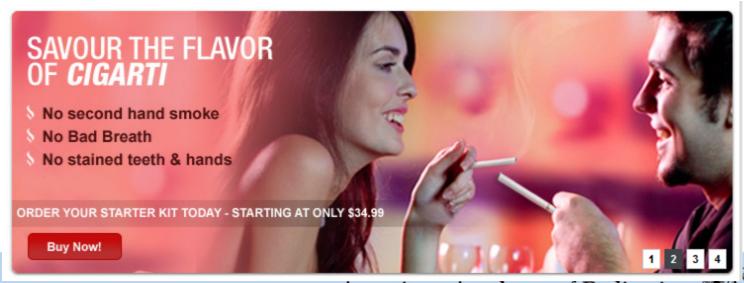
<u>Videos from www.smokestik.com</u> Image from <u>www.ecigaretteschoice.com;</u> <u>www.v2cigs.com;</u> Accessed 5/25/2012 American Academy of Pediatrics

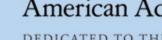
Dedicated to the health of all children

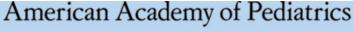
Dr. Matthew Huebner, M.D.

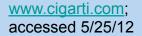
Cleaner than tobacco cigarettes

"The E cig provides a clean and comfortable smoking alternative. With our smoking products there is no more stale tobacco smell on your hands, clothes, hair, or furnishings. Everything—including your car, home and office—can be free of ashes, dirty cigarette butts, and that lingering tobacco smell; thanks to the Ecig and electronic cigarette cartridge."

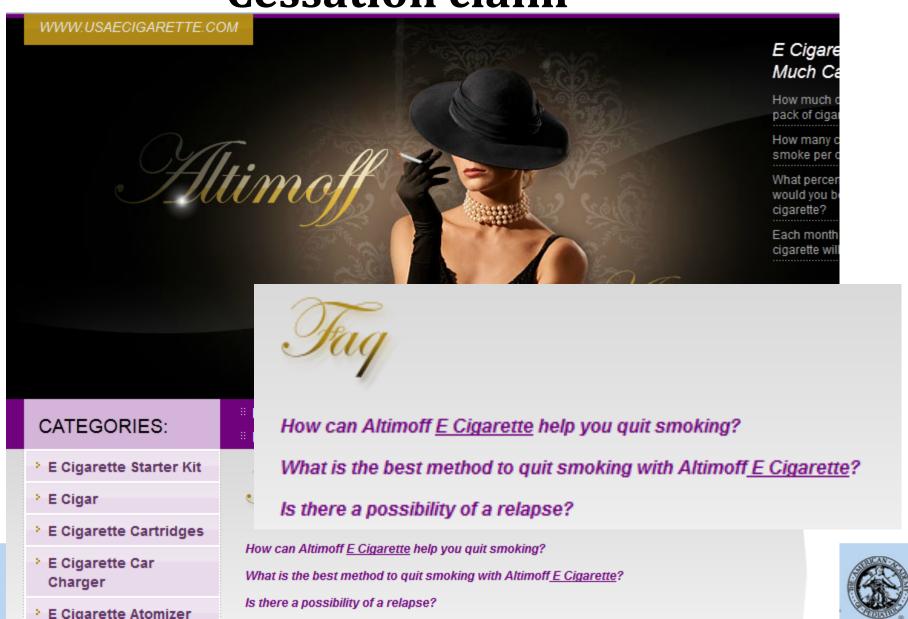








Cessation claim



Marketed for Cessation



Previous Studies

- Lifetime Prevalence of Electronic Cigarette Use, 2010
- Comparability Study of Self-Reported smoking prevalence estimates

Social Climate Survey of Tobacco Control

- Funding provided by:
 - American Legacy Foundation
 - Flight Attendant Medical Research Institute
- Annual cross-sectional survey on attitudes toward tobacco and tobacco regulation
- Dual-Frame
- 2012 sample:
 - 3,101 in sample

Electronic Cigarettes, 2010¹

Lifetime Prevalence

N=3,204

Overall Sample, n = 3,240

1.8%

Nondaily Smokers, n = 146

8.2%

Daily Smokers, n = 434

6.2%

Current Smoking, 2010²

2010 SCS-TC % (95% CI)

2010 NHIS % (95% CI) 2009/10 NHANES % (95% CI)

18.3

19.4

20.3 (17.0-19.6) (18.8-20.1) (18.7-22.1)

Three Year Trend – Lifetime Prevalence of Electronic Cigarette Use

2010 n = 3,240 **% (95% CI)**

2011 n = 3,059 % (95% CI) 2012 N=3,101 % (95% CI)

1.8 (1.3-2.3) 7.3

(6.4-8.2)

(9.5-11.7)

10.6

Predictors of Electronic Cigarette Use

Race: White, 13.2%; African American, 5.8%

Education: High School or less, 13.4%; Some college or more, 10.1%

Smoking status: Never smoker, 2.5%; Former smoker, 12.5%; Non-daily smoker, 27.8%, Daily smoker, 45.0%

Believe that thirdhand smoke is harmful: Yes, 8.9%; No, 25.7%



Predictors of Electronic Cigarette Use

Advised to quit smoking by PCP: Yes, 48.0%, No, 26.0%

Quit attempt in past year (Current smokers): Yes, 46.0%; No, 36.8%

In the Absence of FDA Regulation

- Over the past two years, lifetime prevalence of electronic cigarette use has increase by 489%
- Companies have been marketing e-cigarette products with both claims of reduced health risks and harms compared to tobacco cigarettes and with therapeutic smoking cessation claims.
- These claims may long influence consumer beliefs even if e-cigarettes are regulated as "new" rather than MRTPs.

In the Absence of FDA Regulation

- Raises question whether manufacturers that marketed as MRTPs should be required to seek MRTP approval even if they no longer intend to make such marketing claims.
- Current reduced risk marketing claims may foster a climate favorable to never-smoker youth experimentation.
- Such experimentation may, ultimately, result in youth becoming new nicotine-dependent cigarette smokers.

References

- 1. McMillen, R., Maduka, J., & Winickoff, J. P. (2012). Use of emerging tobacco products in the United States. <u>Journal of Environmental and Public Health</u>. doi:10.1155/2012/989474. Available at http://www.hindawi.com/journals/jeph/2012/989474/.
- 2. McMillen R, Winickoff J, Wilson K, Tanski S, Klein J (2013). A dual-frame methodology to address landline replacement in tobacco control research. Tobacco Control, doi:10.1136/tobaccocontrol-2012-050727