



Newly Emerging Tobacco Products and FDA Center for Tobacco Products: What You and Your Patients Need to Know



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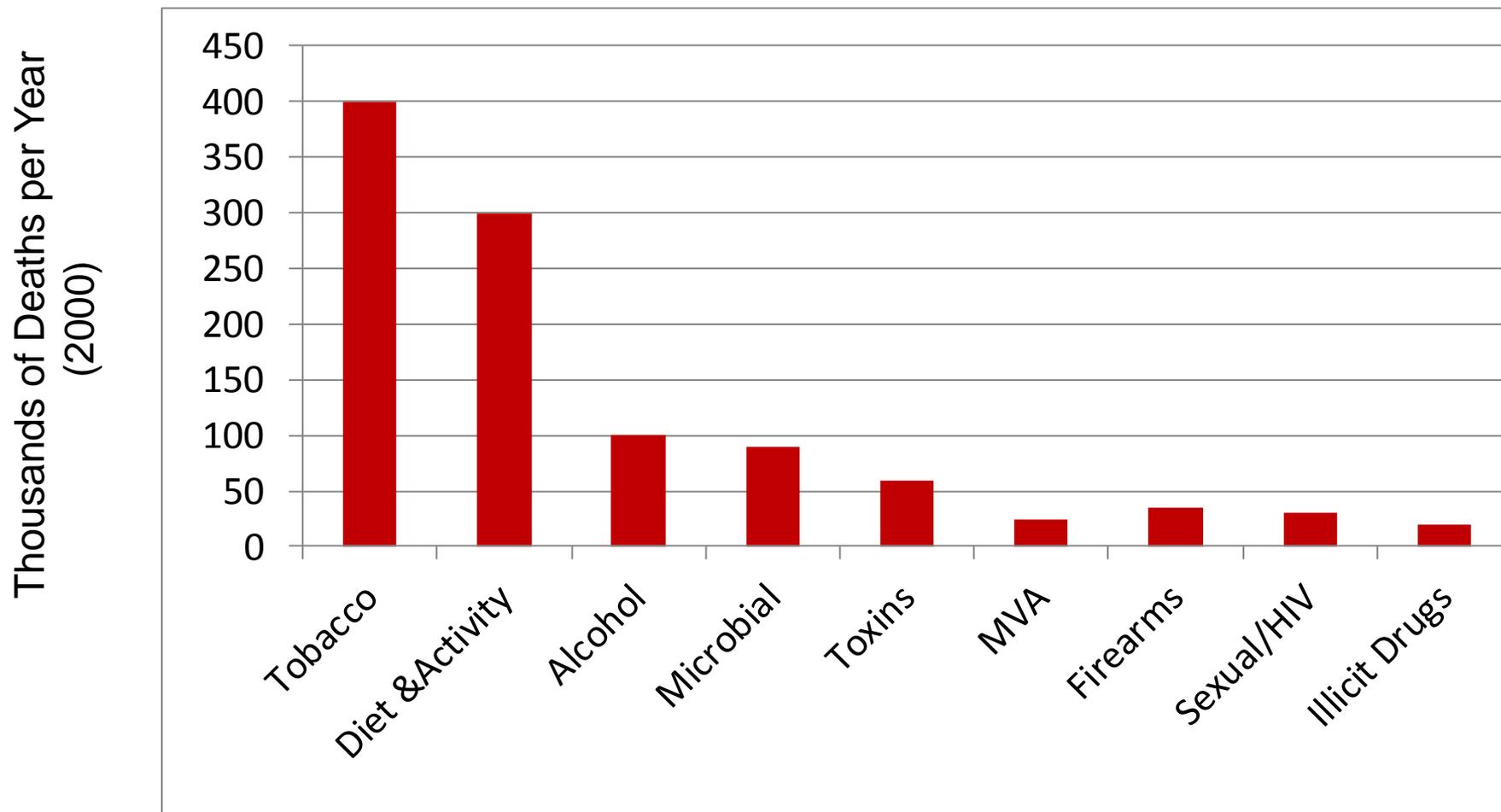
Disclosure

- No financial conflicts of interest
- No other conflicts of interest





Tobacco is Deadly



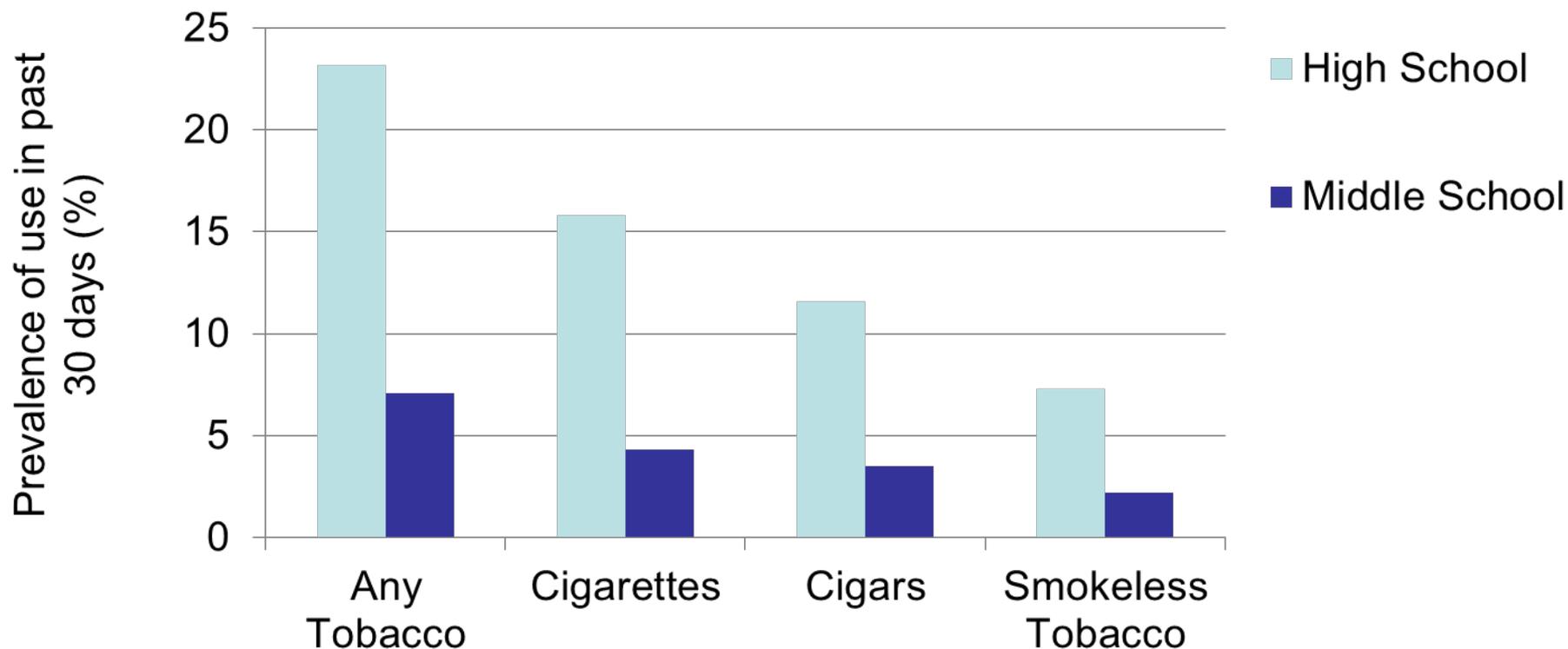
(McGinnis, Foege, 1993²³)

Tobacco Use Begins In Youth



(From Highlights from the 2012 Surgeon General's Report¹⁴)

Tobacco Use in Past 30 Days



(From 2011 National Youth Tobacco Survey (NYTS) Data⁵)

Factors in Youth Tobacco Use



(From Independent Web site¹⁶)

(Youth Risk Behavior Surveillance-United States, 2011⁷)



Tobacco Marketing

PM USA Research Center - Young Smokers Prevalence, Trends, Implications and Related Demographic Trends - March 31, 1981 by Myron E. Johnston

Related Demographic Trends - March 31, 1981 by Myron E. Johnston

1. For over fifteen years certain demographic and social trends have been moving in directions favorable to industry growth. Now, one by one, these powerful social and demographic factors are turning against us, and by 1985 all will be operating against us.

The trends are:

1. After increasing for over a decade, the prevalence of teenage smoking is now declining sharply.
2. After increasing for over a decade, the average daily consumption of teenage

It is important to know as much as possible about teenage smoking patterns and attitudes. Today's teenage is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens. In addition the ten years following the teenage years is the period during which average daily consumption per smoker increases to the average adult level. The smoking patterns of teenagers are particularly important to Philip Morris:

This report deals with only one of these trends -- teenage smoking and attitudes toward smoking, together with related demographics. Subsequent reports will cover the social, economic and psychographic characteristics of teenage smokers and the demographics of other significant age groups.

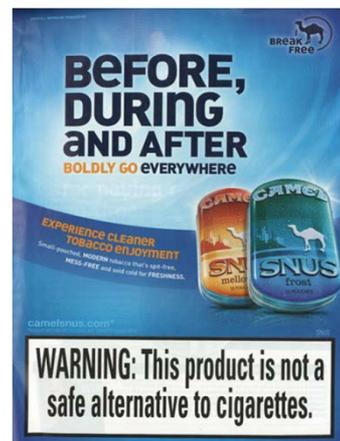
Because the major data sources have just become available, and because of the importance of these data to the company, I have elected to report the data in a series of memoranda rather than wait and issue all of the material at once.

2. See Entire Summary, pp 1-2. It is important to know as much as possible about teenage smoking patterns and attitudes. Today's teenage is tomorrow's potential regular customer, and the overwhelming majority of smokers first begin to smoke while still in their teens. In addition the ten years following the teenage years is the period during which average daily consumption per smoker increases to the average adult level. The smoking patterns of teenagers are particularly important to Philip Morris: Of the eleven packings of which the median age of smokers is under age 30, seven are Philip Morris packings, and the share index is highest in the youngest age group for all Marlboro and Virginia Slims packings and for B&H Lights and Menthol.

Philip Morris (1981)

Influences on Tobacco Use

(Photo Courtesy of Suzanne Tanski)



(From Tobacco Free Kids Web site³²)



(From Metrolic Web site²⁴)

What Can Pediatricians Do?





Don't Just Ask About Cigarettes...



Ask About ALL Forms of Tobacco Use



Non Traditional and Newly Emerging Products

- Cigars/Little Cigars
- Hookah
- Smokeless Tobacco Products
 - Dissolvable Tobacco Products
- Electronic Cigarettes



Cigars

- Cured tobacco wrapped in substance with tobacco
- Variety of sizes
- Taxed differently than cigarettes
- Not currently FDA regulated



Cigar Images Courtesy of Legacy®

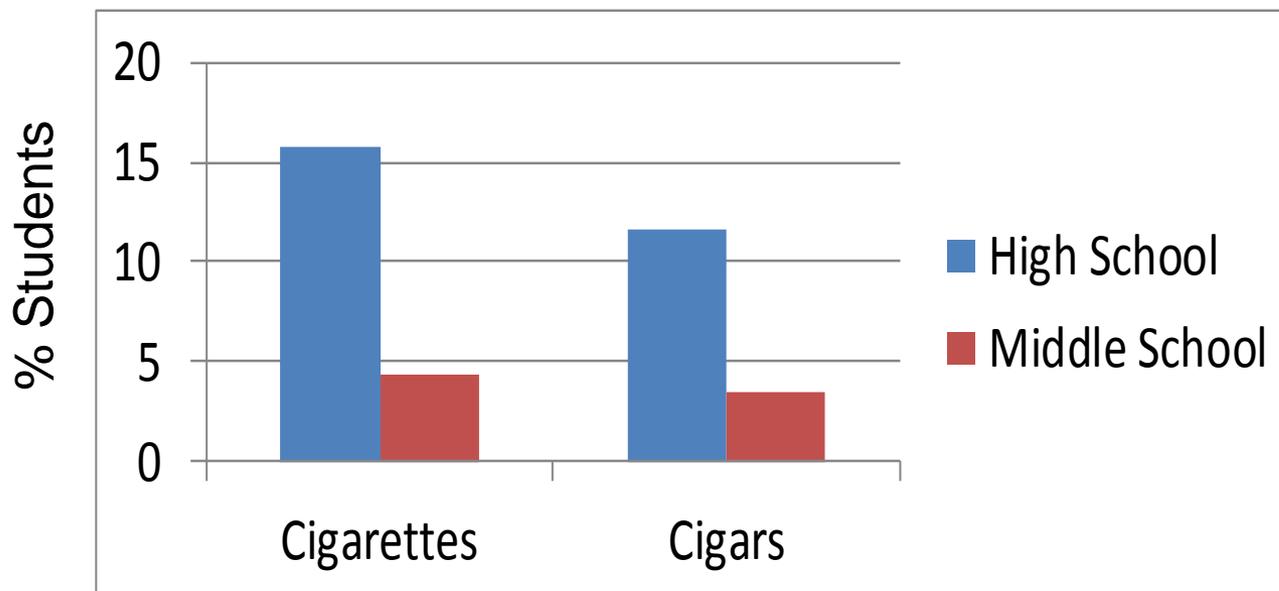
“Not Your Grandfather’s Cigar”



(From Campaign for Tobacco Free Kids 2013⁴)

Cigar Use and Effects

- Cigar sales more than doubled in 10 years
- Use



(From NYTS 2011 Data⁵)

- Health effects

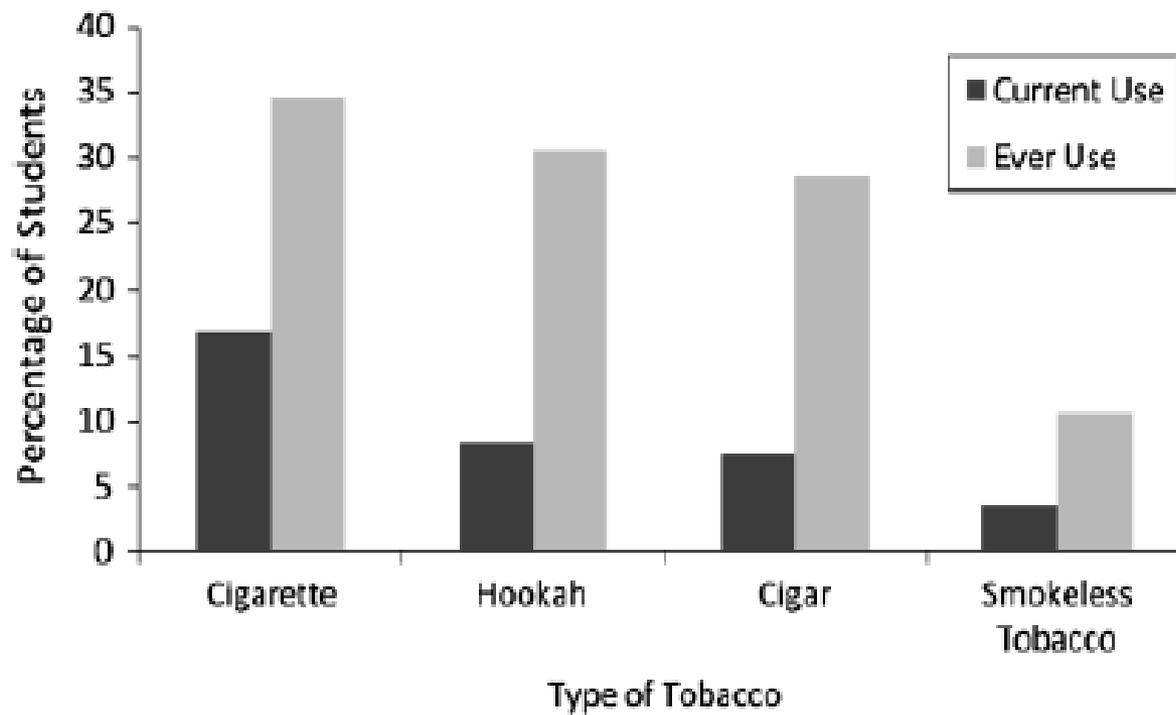
Hookah

- Flavored Tobacco
- Social Context
- Greater Exposures
 - 40-45 X tar
 - 6.5-10 X CO
 - 30 X PAHs*
 - 1.7-2 X nicotine

**polycyclic aromatic hydrocarbons*



Hookah in College Students



(From Primack et al, 2012²⁹)₁₇

Smokeless Tobacco Products



Snuff

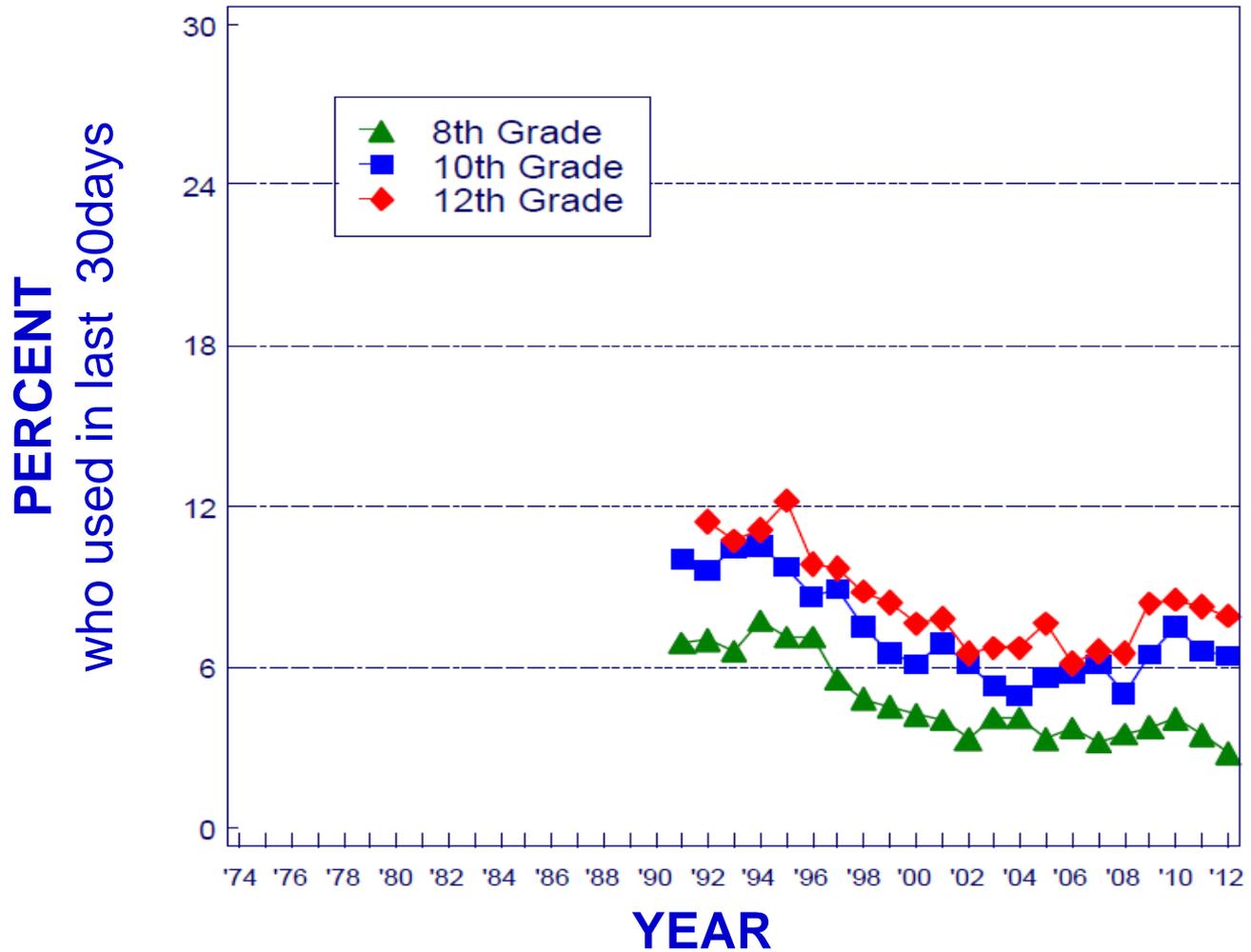


Chewing tobacco



Snus

Smokeless Tobacco Use Trends



(From Monitoring the Future 2012 Data¹⁸)

Dissolvable Tobacco Products



Electronic Nicotine Delivery



(From Johnson Creek Web site¹⁷)

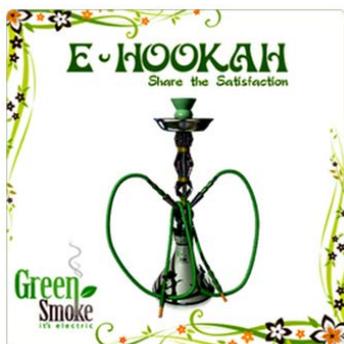
EPUFFER™ D1500
DISPOSABLE ELECTRONIC CIGAR



(From EPUFFER Web site¹²)



(From Blu Web site³)



(From Androgeek Web site²)



(From The Electronic Cigarette Shop Web site³¹)



E-Cigarettes

(From Polosa et al, 2011²⁸)



Who is “vaping”?



(From The Huffington Post 5/8/12¹⁵)

What do we know about e-cigs?



Vari-Volt-Vaping at it's finest!

(From Volcano Web site³⁴)

Tobacco Control Act (2009)

- Authorizes FDA to regulate “tobacco products”
- Defines Tobacco Product
 - any product made or derived from tobacco
(not “drug”, “device” or combination)
- CTP currently has jurisdiction over all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco





FDA Center for Tobacco Products

- Vision:
 - To make tobacco-related death and disease part of America's past, not America's future and, by doing so, ensure a healthier life for every family
- Mission:
 - To protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others

Tobacco Control Act - Limitations

In general, CTP's regulatory authorities do not extend to:

- Ban certain specified classes of tobacco products
- Require the reduction of nicotine levels to zero

FDA is generally not involved with:

- Setting tax rates for tobacco products
- Regulating the farming of tobacco leaf
- Setting smoke free policies



Public / Population Health Regulatory Standard in CTP



Tobacco products cannot be regulated using FDA's traditional "safe and effective" standard

The Tobacco Control Act mandates the use of a population health standard taking into account both users and non-users of tobacco products

FDA and Youth

FDA Tobacco Product Regulation

September 2009



Banned flavored cigarettes making them less appealing to kids

March 2010



Restricted youth access to tobacco products

June 2010



Banned misleading advertising to avoid misperception that products are safer

June 2010



Established new smokeless tobacco warnings to communicate health risks

March 2012



Established list of harmful and potentially harmful constituents

March 2012

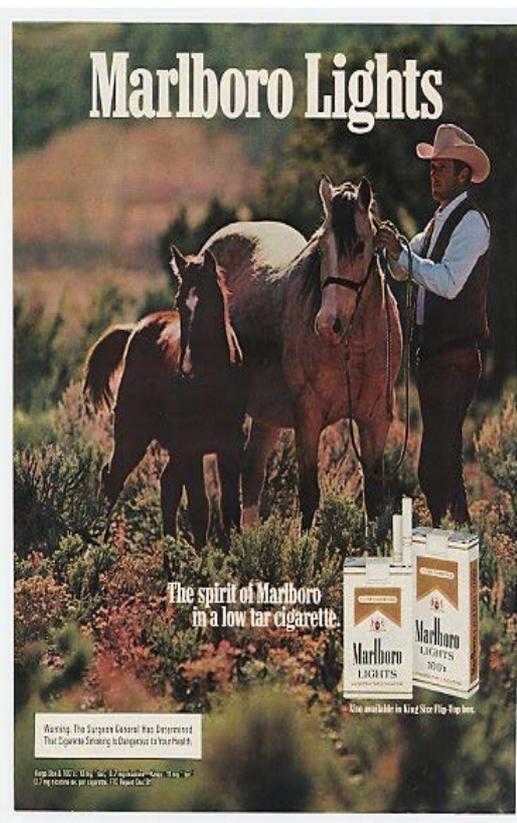


Issued draft guidance on submitting a Modified Risk Tobacco Product Application

Restrict Marketing and Distribution

- To reduce youth initiation FDA restricts access and marketing of regulated products. Since June 2010, FDA prohibits:
 - Sales to people younger than 18
 - Sales of cigarette packs with fewer than 20 cigarettes
 - Distribution of free samples of cigarettes and restricts distribution of free samples of smokeless tobacco products
 - Tobacco brand name sponsorship of athletic, musical, or other social events and of teams
 - Hats and tee shirts, etc., with brand names or logos
 - Sales in vending machines or self-service displays except in adult-only facilities

Prevent False & Misleading Claims that State or Imply Reduced Risk





What is FDA Doing Now Specific to Youth?

- Education
 - for youth and young adults to prevent initiation and encourage cessation
- Research
 - to inform regulation



Education Campaigns

At-risk youth ages 12-15 in the following audience segments:

- African American
- Hispanic
- Asian/Pacific Islander
- American Indian/Alaskan Native
- Youth who identify as LGBT
- Youth who reside in rural communities

Youth ages 12-17 who:

- Have not tried FDA-regulated tobacco products
- Are intermittent users of FDA-regulated tobacco products



The Population Assessment of Tobacco and Health Study

- The PATH Study is a **large, national, representative longitudinal cohort study of tobacco use and health in the United States** which will measure tobacco use behaviors and related health effects
- Baseline data collection, **N ~ 60,000**, is scheduled for the **Fall of 2013** with a cohort of never, current, and former users of tobacco products in the U.S. **ages 12 and over**
- The cohort will then be followed annually for at least two additional data collection waves.



PATH

Population Assessment
of Tobacco and Health

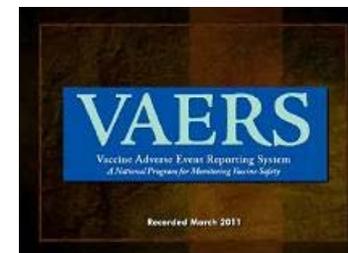
A collaboration between the NIH and FDA

Ensure Industry Compliance – Retailers

- **Undercover Buy Inspections**
 - Minor attempts to purchase regulated tobacco product (cigarettes, smokeless tobacco, or cigarette tobacco)
- **Inspectors also check that retailers:**
 - Sell regulated tobacco products in a direct, face-to-face exchange (i.e., no more vending machine sales) unless in a qualified adult-only facility
 - Do not sell cigarette packages containing fewer than 20 cigarettes
 - Do not sell single cigarettes - “loosies”
 - Do not sell cigarettes or cigarette tobacco with characterizing flavors (other than menthol).



Tobacco Product Adverse Event & Product Problem Reporting



Safety Reporting Portal





Why Track & Evaluate Adverse Events & Product Problems?

- To assess trends and signals indicating the need for regulatory action to protect public health



Adverse Event (AE) Definitions

FD&C Act

- **AE** = any adverse health-related event associated with the use of a product
- **SAE** = Serious AE is an AE that results in death, a life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, congenital anomaly / birth defect or requires a medical or surgical intervention
- Expected vs. Unexpected; Frequency; Attribution



Product Problems also of Interest

- Contamination
- Malfunction or defective component
- User errors
- Package breaches
- Labeling concerns
- Product mix-ups
- Poor quality
- Suspected counterfeit product

Current Voluntary Reporting Mechanisms

- MedWatch (Clinicians & Consumers)
 - Voluntary reporting of AEs, Product problems & product use errors
 - Form 3500 paper or online via <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
- CTP
 - AskCTP@fda.hhs.gov or 1-877-CTP-1373

CTPs Tobacco Adverse Event Reporting System (TAERS)

- Report unexpected adverse health effects associated with the use of tobacco products
- Report tobacco product, packaging and labeling problems





Create Account

Safety Reporting Portal

ABOUT THE PORTAL SAFETY REPORT DIRECTORY FAQs RELATED LINKS

Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whether you are a manufacturer, health care professional, researcher, public health official, or concerned citizen, when you submit a safety report through the SRP, you make a vital contribution to the safety of America's food supply, drugs, and other products that touch us all.

Begin Reporting Here

1. Login

EMAIL

PASSWORD

Or

[Forgot your password?](#)

Remember me

[Log In](#)

2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

[Report as Guest](#)

Account Benefits

- Save a draft
- Easier follow-up
- View submission history
- Faster data entry

[Create Account](#)

Who Should Submit a Safety Report?

Certain manufacturers and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances.

- Food and Drug Manufacturers, Processors, Packers, and Holders
- Researchers
- Drug Manufacturers

Other individuals, including concerned citizens, health professionals, and public health officials, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects.

Reports You Can Submit Through this Portal

FDA safety issues involving:

- Human or animal reportable foods
- Animal drugs
- Pet foods

NIH safety issues involving:

- NIH gene-transfer research

For other issues, [find out where to submit your report.](#)

How can you help CTP?

- Submit comments on draft guidances or special topics to the FDA docket:
 - Find guidance documents at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm>
 - Provide comments via
 - www.regulations.gov
 - <http://www.fda.gov/RegulatoryInformation/Dockets/FR/ucm290145.htm>
- Submit tobacco product adverse event reports
- Educate patients to submit tobacco product adverse events
- Report potential tobacco product violations

What have we learned?

- Tobacco use starts in youth and young adults
- Healthcare providers
 - should inquire about all forms of tobacco use
 - are a critical resource to patients and to CTP/FDA in decreasing the morbidity and mortality due to tobacco use



(From CDC Office on Smoking and Health)

FDA Resources

- Potential Tobacco Product Violations Form:
<http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm330160.htm>
- Web Site: www.fda.gov/tobacco
 - Find more information
 - Order materials
 - Sign up for email subscriptions, like “This Week in CTP”
 - Join us on Twitter



Other Resources

- 1-800-QUIT NOW (784-8669)
- Be Tobacco Free Web Site:
<http://betobaccofree.hhs.gov/index.html>
- CDC Web Site: <http://www.cdc.gov/tobacco/index.htm>
- NIH Web Site: <http://teen.smokefree.gov/Default.aspx>

Acknowledgements

- David Ashley, PhD
- Cathy Backinger, PhD, MPH
- Corinne Husten, MD, MPH
- Lucinda Miner, PhD
- Susan Rudy, MSN, CRNP
- Lester Jao Lacorte, MD, PhD



Thank You



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