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

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Disclaimer: The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy.
Disclosure

• No financial conflicts of interest
• No other conflicts of interest
Tobacco is Deadly

Thousands of Deaths per Year (2000)

(McGinnis, Foege, 199323)
Tobacco Use Begins In Youth

(From Highlights from the 2012 Surgeon General's Report)
Tobacco Use in Past 30 Days

(From 2011 National Youth Tobacco Survey (NYTS) Data)
Factors in Youth Tobacco Use

(Youth Risk Behavior Surveillance-United States, 2011)
Tobacco Marketing

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

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&M Lights and Menthol.
Influences on Tobacco Use

(Photo Courtesy of Suzanne Tanski)

(From Tobacco Free Kids Web site)

(From Metrolic Web site)
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
“Not Your Grandfather’s Cigar”

(From Campaign for Tobacco Free Kids 2013)
Cigar Use and Effects

• Cigar sales more than doubled in 10 years

• Use

• Health effects

(From NYTS 2011 Data5)
Hookah

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

*poly cyclic aromatic hydrocarbons
Hookah in College Students

(From Primack et al, 2012)
Smokeless Tobacco Products

Snuff  
Chewing tobacco  
Snus
Smokeless Tobacco Use Trends

(From Monitoring the Future 2012 Data)
Dissolvable Tobacco Products
Electronic Nicotine Delivery

(From Johnson Creek Web site\textsuperscript{17})

(From EPUFFER Web site\textsuperscript{12})

(From Androgeek Web site\textsuperscript{2})

(From The Electronic Cigarette Shop Web site\textsuperscript{31})

(From Blu Web site\textsuperscript{3})
E-Cigarettes

(From Polosa et al., 2011)
Who is “vaping”? 

(From The Huffington Post 5/8/12)
What do we know about e-cigs?

(From Volcano Web site)
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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>September 2009</td>
<td>Banned flavored cigarettes making them less appealing to kids</td>
</tr>
<tr>
<td>March 2010</td>
<td>Restricted youth access to tobacco products</td>
</tr>
<tr>
<td>June 2010</td>
<td>Banned misleading advertising to avoid misperception that products are safer</td>
</tr>
<tr>
<td>June 2010</td>
<td>Established new smokeless tobacco warnings to communicate health risks</td>
</tr>
<tr>
<td>March 2012</td>
<td>Established list of harmful and potentially harmful constituents</td>
</tr>
<tr>
<td>March 2012</td>
<td>Issued draft guidance on submitting a Modified Risk Tobacco Product Application</td>
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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, $N \sim 60,000$, 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.
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
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
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).

Your role, (manufacturer, health care professional, researcher, public 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, 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

Create Account

Should Submit a Safety Report?

Individuals and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances:
- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- Drug Manufacturers

Including concerned citizens, health professionals, and public officials, may voluntarily submit reports if they encounter issues with a product and/or unanticipated harmful effects related to related to it or use.

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

• 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
WE CAN
MAKE THE NEXT GENERATION TOBACCO-FREE

(From CDC Office on Smoking and Health)
FDA Resources

- Potential Tobacco Product Violations Form: [http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm330160.htm](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
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References


References, cont.


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