Grand Rounds

The Public Health Grand Rounds is a monthly series created to further strengthen CDC’s common scientific culture and foster discussion and debate on major public health issues. Each session of the Public Health Grand Rounds will focus on key issues and challenges related to a specific health topic, including cutting-edge scientific evidence and potential impact of different interventions. The sessions will also highlight how CDC is already addressing these challenges and discuss the recommendations for future research and practice.

Grand Rounds sessions are typically held on the third Thursday of every month at Roybal’s Global Communications Center, Auditorium A, between 9-10 a.m. For those unable to attend, the sessions will be available on CDC IPTV.
PUBLIC HEALTH GRAND ROUNDS

The Public Health Grand Rounds is a monthly series created to further strengthen CDC’s common scientific culture and foster discussion and debate on major public health issues. Each session of the Public Health Grand Rounds will focus on key issues and challenges related to a specific health topic, including cutting-edge scientific evidence and potential impact of different interventions. The sessions will also highlight how CDC is already addressing these challenges and discuss the recommendations for future research and practice.
PUBLIC HEALTH GRAND ROUNDS Access

IPTV link also available on Grand Rounds intranet site:
http://intranet.cdc.gov/od/odweb/about/directorGrandRounds.htm

For those outside of CDC, a broadband link is available at:
http://www.cdc.gov/about/grand-rounds (Grand Rounds internet site)
Starting in January 2010 Credit Hours will be available for:

- Physicians (CME)
- Non-Physicians (CME)
- Nurses (CNE)
- Certified Health Education Specialists (CECH)
- Other Professionals (CEU)
- Veterinarians (AAVSB/RACE)
- Pharmacist (CPE)
CME Planning Committee

- John Iskander, MD, MPH, Chair
  *Office of the Chief Science Officer*
- Sharon Hall, RN, PhD
  *Office of Workforce and Career Development*
- Elaine Miller, RN, MPH
  *National Center for Prevention, Detection and Control of Infectious Diseases*
- Patricia Thomas, M(ASP), MPH, CHES
  *Office of Workforce and Career Development*
- Nadine Shehab, PharmD, MPH
  *National Center for Prevention, Detection and Control of Infectious Diseases*
- Jennifer Wright, BS, DVM, MPH
  *National Center for Prevention, Detection and Control of Infectious Diseases*
We Welcome Any Feedback!

For information about the Grand Rounds or to suggest future topics, please contact Dr. Tanja Popovic at tpopovic@cdc.gov.

If you have specific questions about the broadband link and other connectivity issues, or if interested in receiving future CDC Public Health Grand Rounds announcements, please contact Shane Joiner at sjoiner@cdc.gov.
Public Health Impact of Tobacco Product and Advertising Regulation

Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
NCCDPHP
On June 22, 2009, President Obama signed legislation granting the FDA the authority to regulate:

- CONTENT of tobacco products
- MARKETING of tobacco products
- SALES of tobacco products
Centers for Disease Control and Prevention

- Lead federal agency for comprehensive tobacco prevention and control

- FY 09 Tobacco Control funding - $106.2 M
  - $85 M – National Tobacco Control Program (NTCP) to support all 50 states, D.C., U.S. territories, and national organizations

- Goals
  - Preventing young people from starting to smoke
  - Eliminating exposure to secondhand smoke
  - Promoting quitting among young people and adults
  - Identifying and eliminating tobacco-related health disparities
Roles for CDC in Tobacco Product Regulation

- Provide technical assistance and guidance to FDA
  - Laboratory (NCEH)
  - General tobacco control (OSH)

- Maintain comprehensive tobacco control programs
  - Coordinate national and state regulation efforts

- Conduct post-marketing surveillance of effects of the tobacco product regulation
Outline

- **Terry Pechacek, PhD**, Office on Smoking and Health
  - Overview of Tobacco Control in the United States

- **CAPT Matthew McKenna, MD, MPH**, Office on Smoking and Health
  - International Advances in Tobacco Control through Policy and Regulation

- **CAPT David Ashley, PhD**, National Center for Environmental Health
  - Product Regulation – Does it Fit into Tobacco Control?

- **Lawrence Deyton, MD, MSPH**, Food and Drug Administration
  - Overview of the Family Smoking Prevention and Tobacco Control Act
OVERVIEW OF TOBACCO CONTROL IN THE UNITED STATES

Terry F. Pechacek, PhD
Associate Director for Science
Office on Smoking and Health, NCCDPHP
About 443,000 U.S. Deaths Per Year Attributable to Cigarette Smoking

- Lung cancer: 128,900
- Ischemic Heart Disease: 126,000
- Chronic Obstructive Pulmonary Disease: 92,900
- Other cancers: 35,500
- Stroke: 15,900
- Other diagnoses: 44,000

*Average number of deaths, 2000-2004.

Source: MMWR 2008;57(45):1226-1228.

Every year:
- $96 billion in medical costs
- $97 billion in lost productivity
Trends in Current Cigarette Smoking by High School Students and Adults—United States, 1965-2007

- **High school students** who smoked on 1 > of the 30 days preceding the survey—United States, CDC. Youth Risk Behavior Survey, 1991-2007.

- **Total population adults** who were current cigarette smokers, National Health Interview Surveys, 1965-2006.

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* High school students who smoked on 1 > of the 30 days preceding the survey—United States, CDC. Youth Risk Behavior Survey, 1991-2007.

** Total population adults who were current cigarette smokers, National Health Interview Surveys, 1965-2006.
Evidence-Based Interventions

- Sustained funding of comprehensive programs
- Excise tax increases
- 100% smoke-free policies
- Comprehensive ad restrictions
- Aggressive media campaigns
- Cessation access
Total Funding for State Programs
Adjusted to FY2008 Dollars

- State Funding (adjusted to 2008)
- % High School Smoking

Best Practices released

Source: Project ImpacTEEN; CDC/Office on Smoking and Health; Campaign for Tobacco Free Kids; Research Triangle Institute; University of Illinois at Chicago; University at Buffalo, State University of New York

*High school students who smoked on 1 >/ of the 30 days preceding the survey—United States, CDC. Youth Risk Behavior Survey, 1993-2007.
State Status Toward Reaching CDC-Recommended Funding Levels — FY2009

Source: CDC, Office on Smoking and Health.
Cigarette Sales and Cigarette Prices
United States, 1970-2007

Sales (in millions of packs)

Price (in April 2008 dollars)

Year

Source: ImpacTeen Chartbook: Cigarette Smoking Prevalence and Polices in the 50 States.
State Cigarette Excise Tax Rates - 2000

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2001

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2002

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2003

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
Map showing state cigarette excise tax rates in 2004. The map indicates different tax rates across states with color coding:

- Dark green: $2.00+ per pack
- Medium green: $1.50-$1.99 per pack
- Light green: $1.00-$1.49 per pack
- Lighter green: 50-99 cents per pack
- Pale green: <50 cents per pack

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2005

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2006

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2007

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2008

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2009

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
State Cigarette Excise Tax Rates - 2009

Source: CDC, Office on Smoking and Health. State Tobacco Activities Tracking and Evaluation (STATE) System.
Indoor Air Quality Before and After Implementing a Smoke-Free Law

The outdoor ambient air quality standard for small particulate matter (PM 2.5) is 35 µg/m3. There is no indoor standard.

Smoke-Free Policies Reduce Hospitalizations for Acute Myocardial Infarctions

19% average reduction in hospitalizations

Institute of Medicine Report: Secondhand Smoke Exposure & Cardiovascular Effects

- **Purpose**
  - To assess the relationship between secondhand smoke exposure and acute coronary events

- **Conclusions**
  - Secondhand smoke causes heart attacks
  - Even brief secondhand smoke exposure could trigger a heart attack
  - Smoke-free laws prevent heart attacks and save lives

- **Concurred with 2006 Surgeon General’s Report**
  - Secondhand smoke exposure increases the risk of coronary heart disease by 25-30 %
Proportion of U.S. Population Covered by Local and State Smoke-Free Laws, 2000-2009

Population figures are as of December 31 of each given year, and October for 2009. All population figures are from the United States Census. Source: American Nonsmokers’ Rights Foundation.
Aggressive Media Campaigns

- Media campaigns
  - Reduce youth initiation
  - Encourage cessation
  - Increase negative attitudes toward tobacco use
The Impact of Cessation

- Presently: 46 million U.S. smokers
  - 70% of smokers want to quit
  - 40% try to quit each year
  - Only 2% call state or national quitlines

- Tobacco cessation works best when combined with
  - Significant tax and price increases
  - Comprehensive smoke-free policies
  - Advertising, promotion and sponsorship bans
  - Aggressive counter-advertising
Quitline Counseling Alone or with Medication Significantly Increases 6-Month Abstinence Rates

Adult and Youth Smoking Prevalence in New York City

Source: CDC. Decline in Smoking Prevalence -- New York City, 2002—2006. MMWR. 2007. 56(24);604-608; and New York City Department of Health and Mental Hygiene.
Opportunities Moving Forward
INTERNATIONAL ADVANCES IN TOBACCO CONTROL THROUGH POLICY AND REGULATION

CAPT Matthew T. McKenna, MD, MPH
Acting Director
Office on Smoking and Health, NCCDPHP
Tobacco Is Now the World’s Leading Preventable Cause of Death

Unchecked, worldwide deaths will exceed 8 million a year by 2030

Global Deaths per Year (millions)

- Tobacco: 5.4
- Acute Resp Infect: 3.9
- AIDS: 2.2
- Diarrheal Disease: 2.1
- TB: 1.7
- Traffic Injuries: 1.3
- Malaria: 1.1
- Measles: 0.8

Source: World Health Organization
Projected Deaths Attributable to Tobacco
Unless Effective Programs Are Implemented

Nearly 2/3 of the World’s Smokers Live in Just 10 Countries

More than 40% live in just 2 countries

There ARE Effective and Proven Strategies

- 100,000,000 global deaths can be prevented by the end of the century through a group of policy and regulatory interventions.

- This number of lives saved is possible through a modest prevalence decline (from 25% to 20%), using the assumption that 1/3 of users will die from smoking-related diseases.


Monitor tobacco use and prevention policies

Protect people from tobacco smoke

Offer help to quit tobacco use

Warn about the dangers of tobacco

Enforce bans on tobacco advertising, promotion and sponsorship

Raise taxes on tobacco
Smoke-Free Areas

Public Support for Comprehensive Smoking Bans in Bars and Restaurants after Implementation

Impact of Pictorial Warnings on Brazilian Smokers

80%

60%

40%

20%

0%

Changed their opinion about health consequences of smoking
Want to quit as a result
Approve of health warnings

Source: Datafolha Instituto de Pesquisas, 2002.
Health Warning Labels

Size of Health Warnings on Cigarettes*  2008

- 50% and above
- 30 - 49%
- Less than 30%
- No requirement
- No Data
- Countries requiring pictorial health warnings

Marketing Bans

* Direct and indirect advertising bans, 2007.
** Four, five or six direct bans and at least one indirect ban.
***One, two or three direct bans or at least one indirect ban.

Comprehensive Advertising Bans Amplify Other Interventions

Average change in cigarette consumption 10 years after introduction of advertising bans in two groups of countries

<table>
<thead>
<tr>
<th>Change in cigarette consumption</th>
<th>14 countries with a comprehensive ban</th>
<th>78 countries without a ban</th>
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<tbody>
<tr>
<td>-10%</td>
<td>-9%</td>
<td>-1%</td>
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<td>-8%</td>
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<td>0%</td>
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Tobacco Prices and Consumption

Source: Aloui O. 2003. Analysis of the economics of tobacco in Morocco. (right graph)
No More Than 8% of the World’s People Are Covered by Even One Effective Tobacco Control Policy

Share of world population

- Smoke-free environments: 5%
- Cessation programmes: 7%
- Health warnings: 8%
- Advertising bans: 8%
- Taxation: 6%

8% or fewer benefit from effective interventions to reduce use

Global Tobacco Surveillance System, 1999-2009

- GYTS Completed Regionally
- GYTS Completed Regionally + GATS
- GYTS Completed Nationally
- GYTS Completed Nationally + GATS

GYTS in 163 countries
GATS in 14 countries

GYTS = Global Youth Tobacco Survey
GATS = Global Adult Tobacco Survey
CAPT David L. Ashley, Ph.D.
Chief, Emergency Response and Air Toxicants Branch
Division of Laboratory Sciences
National Center for Environmental Health, NCEH
Product Regulation

- Why are differences in the design, packaging and marketing of the product important?
- How can product regulation reduce morbidity and mortality from tobacco use?
- How do we make sure that changes to the product benefit public health?
Some Tobacco Products Are Designed to Appeal to Youth

- Flavoring
- Nicotine control
- Marketing of sophistication
- Image of smoking
Targeted Engineering of Tobacco Products

- Modifying the product (ventilation) to appear to lower delivery
- Developing complex sensory properties that encourage continued use
- Developing nicotine in a form that is more addictive
- Providing false promises to health conscious smokers
- Producing products that can be used when smokers cannot smoke to provide ways to keep smoking
Tobacco Product Complexity

- Many different forms of tobacco products
- Approximately 1,500 cigarette brand variants
- More than 4,000 chemicals in tobacco smoke
Design of Tobacco Products Determines Levels of Toxic Compounds

Nitrosamines in cigarette tobacco vary by more than a factor of 20.
Design of Tobacco Products Determines Levels of Addictive Compounds
Marlboro Sales and Smoke pH: 1964 through 1972

How Can Product Regulation Reduce Morbidity and Mortality from Tobacco Use?

- Use product standards to make the products less appealing to youth
- Prevent changes to the products that make them more addictive or toxic
- Use product standards to reduce exposure to toxic and addictive emissions of people who continue to use the products
Remove Low Free-Nicotine Smokeless Tobacco Starter Brands
Help Block This Pathway to Addiction

Youth start with low free nicotine products, then graduate to higher levels

Prevent Changes in Critical Properties without Assessing the Public Health Impact

Free Nicotine (mg/g)

- Skoal Bandits WinterGreen
- Skoal Bandits Mint

January 1999
2000
Before 2002
August 2004
December 2006
May 2007
Set Effective Product Standards to Reduce Exposure to Carcinogenic Nitrosamines: Higher Lung Cancer Rates Are Associated with Higher Levels of NNAL

Source: Ashley DL, et al. Impact of differing levels of tobacco-specific nitrosamines in cigarette smoke on the levels of biomarkers in smokers, in CDC clearance.
How do We Make Sure that Changes to the Product Benefit Public Health?

- Monitor the impact of product regulation
- Develop clear messages and communicate about product risk
- Prevent use of product messages to imply safety without scientific validation
### NHANES Serum Cotinine Trend in Nonsmokers by Age Group Geometric Mean (95% CI)

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<tr>
<td>Ages 4-11</td>
<td>0.35</td>
<td>0.25</td>
<td>0.15</td>
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<tr>
<td>Ages 12-19</td>
<td>0.35</td>
<td>0.25</td>
<td>0.15</td>
<td>0.05</td>
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<tr>
<td>Ages 20+</td>
<td>0.35</td>
<td>0.25</td>
<td>0.15</td>
<td>0.05</td>
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Totals: Age 4-11 = 9,797  Age 12-19 = 10,617  Age 20+ = 27,936
Product Regulation: Next Steps

- Expand surveillance to collect baseline data on smokers
- Monitor for changes to the product which may be altered to circumvent product regulations
- Develop clear messages regarding the meaning of meeting these standards, particularly that it does not mean the product is now safe
- Develop ways to prevent product standards from being used to promote tobacco use
OVERVIEW OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Lawrence Deyton, MD, MSPH
Director
The Center for Tobacco Products
Food and Drug Administration
“This legislation is a victory for bipartisanship, and it was passed overwhelmingly in both Houses of Congress. It's a victory for health care reform, as it will reduce some of the billions we spend on tobacco-related health care costs in this country. It's a law that will reduce the number of American children who pick up a cigarette and become adult smokers. And most importantly, it is a law that will save American lives and make Americans healthier.”

Passage of the FSPTCA is a significant new component of the larger goal of tobacco control.

Still a lot of work ahead of all of us.

Presents opportunities for all of us in public health to increase action on tobacco control at every level.

FSPTCA established a new standard for FDA: to regulate tobacco products based on a public health and population health standard.
FDA Tobacco Control Goals

- Prevent youth tobacco use
- Help adults who use tobacco to quit
- Promote public understanding of contents and consequences of use of tobacco products
- Develop science base and begin meaningful product regulation to reduce the toll of tobacco-related disease, disability, and death
Authority Granted Under FSPTCA

SEC. 102. FINAL RULE.

- Requires Secretary to issue a final rule (on first Federal Register publication date six months after enactment) regarding advertising of, and access to, tobacco products.
- Requires that the rule become effective one year after enactment.
- Requires the final rule to be identical to the advertising and access regulations promulgated by FDA in 1996, except as specifically provided.
- Authorizes the Secretary to modify the final rule, but provides that such modification shall be through the normal rule making process.
SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

- Requires manufacturers or importers to submit information to the Secretary, under various timeframes, on—
  - tobacco product ingredients;
  - nicotine content;
  - research on the health and physiological effects of tobacco product use; and
  - marketing practices and effectiveness.
SEC. 905. ANNUAL REGISTRATION.

- Requires annual registration, with the Secretary, of each establishment in the U.S. engaged in the manufacture, preparation, compounding, or processing of tobacco products. FDA must inspect registered establishments at least every two years.

- "Substantial equivalence." Any registered establishment planning to introduce a new tobacco product (not commercially marketed in the U.S. as of February 15, 2007) must report to the Secretary how the product is "substantially equivalent" to a tobacco product marketed as of such date, or to a product marketed after such date which meets applicable requirements.

- If not "substantially equivalent", product must undergo premarket review as a new tobacco product, under section 910.
SEC. 907. TOBACCO PRODUCT STANDARDS.

- Artificial and natural flavors banned. Prohibits, three months after enactment, any cigarette from containing characterizing fruit flavors, herbs or spices (including clove). Menthol is expressly excepted from the prohibition, but still subject to Secretarial action.

- Secretary can restrict flavors not specifically identified. The Secretary may take action under this or other sections against menthol or any other flavoring, herb, or spice not included in the prohibited list.

- Other standards possible. The Secretary can adopt other tobacco product standards as the Secretary determines appropriate for protecting public health, including for nicotine yields and reduction or elimination of other constituents.

- Menthol cigarettes and dissolvable tobacco products. The Secretary must refer the issues of menthol in cigarettes and dissolvable tobacco products to the Tobacco Products Scientific Advisory Committee for report and recommendations within one year (with respect to menthol) and within two years (with respect to dissolvable tobacco products).
SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

- Premarket review required for new tobacco products (i.e., not commercially marketed as of February 15, 2007, or modified after that date);

- Substantial equivalence. Premarket review NOT required for new tobacco products "substantially equivalent" to products on market as of February 15, 2007, or exempt from "substantial equivalence" requirements by regulation;
SEC. 911. MODIFIED RISK PRODUCTS.

- **Described.** Modified risk products are tobacco products characterized as `light,' `mild,' or `low,' or otherwise for use to reduce harm or the risk of tobacco-related disease associated with other tobacco products.

- **Conditions for marketing.** Modified risk products can only be marketed if the Secretary, after reviewing a product application, determines that the product:
  - will significantly reduce harm and the risk of tobacco-related disease to individual users (compared to other tobacco products), and
  - benefit the health of the population as a whole, taking into account the impact on both users and nonusers of tobacco products.

- **Not "modified risk products".** “Smokeless” tobacco products are not modified risk products, nor are products approved by FDA as drugs or devices for treatment of tobacco dependence.
Requires the Secretary, within 6 months after enactment, to establish the Tobacco Products Scientific Advisory Committee.

The Committee will submit reports or recommendations on:

- The impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities
- The nature and impact of the use of dissolvable tobacco products on the public health, including such use on children
- The effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved
- Any application submitted by a manufacturer for a modified risk tobacco product
SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

- Amends the Federal Cigarette Labeling and Advertising Act to specify nine new required warning labels, one of which must appear on cigarette packages and advertisements within 1 year of enactment.

- The warnings must comprise the top 50% of the front and rear panels of the package and at least 20% of the related advertisements.

- Requires the Secretary to issue regulations requiring color graphics depicting the negative health effects of smoking, to accompany the written warnings.
The Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.

State and local activities. Requires the Secretary, within three months of enactment, to inform State, local, and tribal governments of their authorities with respect to tobacco products as provided under this Act.

Community Assistance. Permits communities to seek assistance from the Secretary to prevent underage tobacco use.
State and Local Involvement & Coordination

- FDA bridge to state tobacco control programs
- The tobacco control efforts in place in states and localities are crucial
- FDA will seek opportunities to support state activities related to the FSPTCA
Intra-HHS Coordination

- Assistant Secretary for Health
- CDC: Surveillance, epidemiology, product analysis
  - Office on Smoking and Health
  - National Center for Environmental Health
- SAMHSA: Tobacco outreach and surveillance
- NIH: Tobacco Research Topics
### Major Accomplishments To Date

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<th><strong>June</strong></th>
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<td>FSPTCA signed into law</td>
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<th><strong>July</strong></th>
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<tr>
<td>Listening session with State and local officials</td>
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<th><strong>August</strong></th>
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<tr>
<td>Established the Center for Tobacco Products</td>
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<td>Established the Scientific Advisory Committee</td>
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<td>Created the User Fee Program</td>
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<td>Listening sessions with public health advocates and tobacco industry</td>
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<tr>
<td>Hired and introduced Center Director</td>
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<td>Enacted the ban on flavored cigarettes</td>
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<th><strong>October/November</strong></th>
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<td>Issued Final Guidance on Registration and Listing (section 905)</td>
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<tr>
<td>Issued Draft Guidance on Ingredient Submission (section 904)</td>
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Regulatory Deadlines: Next Steps

- **January 2010**: Industry ingredient submission
- **April 2010**: Reissuance of 1996 Rule
- **July 2010**: Ban on misleading marketing terms
- **July 2010**: Smokeless tobacco warning labels
- **October 2012**: Cigarette warning labels
Challenges and Opportunities

- FDA regulatory authority new to this industry
- Creating a major new regulatory organization
- Meeting aggressive statutory deadlines
- Striving to meet diverse expectations from stakeholders
- Collaborating with state and local agencies on tobacco control
- Establishing effective and interactive channels for public communication, education and outreach with all stakeholders