U.S. Food and Drug Administration Center for Tobacco Products

2009-2010:
INAUGURAL YEAR IN REVIEW


FDA


DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

MESSAGE FROM THE DIRECTOR

To help reduce tobacco's impact on the nation's health, President Barack Obama on June 22, 2009 signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which gives the Food and Drug Administration (FDA) authority to regulate tobacco products. FDA established the Center for Tobacco Products in August 2009 to implement this new regulatory authority and to work with other federal, state, territory and tribal authorities to develop effective public health strategies to reduce tobacco-related illness and death nationwide.

Our priorities at the Center include preventing America's children and adolescents from initiating tobacco use; helping adults who use tobacco to quit; providing accurate information to the public about the contents of tobacco and consequences of tobacco use; and using regulatory tools, including setting tobacco product standards, to reduce the public health burden of tobacco in the United States.

For example, research has found that children are especially attracted to and begin using tobacco products very early because of all kinds of pressures and motivations, including access to cigarettes that have candy-like characterizing flavors, such as mint, chocolate, cinnamon, coconut, and strawberry. The Tobacco Control Act prohibits the manufacture, distribution, and sale of those cigarettes in order to protect our kids and gives FDA broad authorities to take many other science-based regulatory actions to protect the public health.

In the short time since President Obama signed the Tobacco Control Act, the Center for Tobacco Products has taken the initial steps outlined in the law and begun to regulate tobacco products.

Here, we present updates regarding the steps we have taken to initiate tobacco product regulation and to implement this new law. We will also describe some of what is expected in the coming year, including restrictions on potentially misleading marketing terms for tobacco products and mandatory new warning labels for smokeless tobacco products. The Center will continue working to further the goals of the Tobacco Control Act, and we will work closely with our stakeholders in doing our work. I look forward to sharing our future accomplishments.

Lawrence R. Deyton, M.S.P.H., M.D.
Director, Center for Tobacco Products

INTRODUCTION

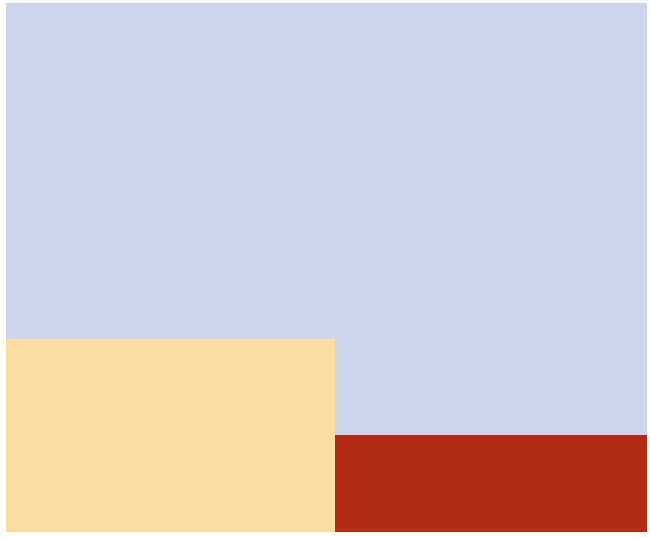
In 2005, the tobacco industry spent more than $13 billion to attract and retain users of tobacco products, increase consumption of tobacco products, and encourage people to think favorably about smoking and tobacco use. With such great expenditures mirrored in many countries, tobacco control and regulation has become a worldwide concern. A growing number of countries have enacted total bans on tobacco marketing, including South Africa, Thailand, Norway, and Finland. In addition, legislation passed in the European Union in the past 10 years has granted member countries the option of adding pictures to mandatory warning labels. Australia, Poland, South Africa, and Thailand also have stringent labeling requirements.

Although FDA has for many years regulated consumer products, such as food and drugs, tobacco products have not been similarly regulated. Partial or full smoking bans for workplaces, restaurants, bars, and other public spaces exist in at least 27 states, but states have had no legal right to regulate marketing of tobacco products.

Passage of the Family Smoking Prevention and Tobacco Control Act, and the subsequent creation of the Center for Tobacco Products, has helped address the gap by creating a national uniform standard for the regulation of tobacco products. Across the past year, the Center has worked to implement the Tobacco Control Act and regulate the manufacture, sale, and distribution of tobacco products to protect public health and to reduce tobacco use by minors.

BACKGROUND

On June 22, 2009, President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act. This historic legislation granted FDA the authority to regulate tobacco products. The law put special emphasis on youth because research has shown that most tobacco users become addicted at a young age, before they are old enough to understand the risks. Under the Tobacco Control Act, FDA has been granted broad authority over tobacco products, including the ability to set and enforce standards for tobacco product ingredients and design, establish good manufacturing practices, institute product labeling and health warnings, and regulate the promotion and marketing of tobacco products. The Tobacco Control Act also requires FDA pre-market approval for certain new products and the reporting by industry to FDA on a number of subjects. These authorities will assist FDA with the regulation of tobacco products in an effort to protect the public health, while taking into consideration tobacco product users and non-users alike.



2009–2010: INAUGURAL YEAR IN REVIEW

ABOUT THE CENTER FOR TOBACCO PRODUCTS

The mission of the Center for Tobacco Products is to protect public health by issuing and enforcing tobacco product regulations and educating the public about the dangers of tobacco use. Tobacco is the leading cause of preventable disease, disability, and death in the United States. Tobacco products, including cigarettes and smokeless tobacco, are responsible for approximately 443,000 deaths and $193 billion in medical expenditures and lost productivity each year in the United States.

The Center strives to translate the best available science into effective public health regulatory action. These actions and educational efforts aim to reduce the number of tobacco-related diseases and deaths in the United States, with the ultimate goal of improving the health of the nation.

"We're addressing a larger public health effort to prevent our children from becoming the next generation of Americans to die early from tobacco-related disease. This is a great step toward a healthier America."

— HHS Secretary Kathleen Sebelius

HOW FDA REGULATION IS MAKING A DIFFERENCE

The Center for Tobacco Products is making progress in a wide range of areas, including:

- Building a science base for tobacco product regulation.
- Issuing and enforcing tobacco regulations to protect the nation's health.
- Publishing guidance to help industry comply with regulations.
- Creating the Center's Tobacco Products Scientific Advisory Committee, which will offer advice to the Center on scientific issues.
- Opening public dockets to receive public input.
- Partnering with stakeholders, such as states, local communities, public health advocates, tobacco manufacturers, retailers and industry organizations, medical and scientific experts, and federal agencies.
- Producing public information and education campaigns and materials.
- Building a highly-capable Center workforce.

The Center's top priorities include:

- Preventing youth from using tobacco.
- Helping those who use tobacco quit.
- Providing accurate information about tobacco ingredients and the consequences of tobacco use.
- Building the science base for tobacco product regulation.
- Using regulatory tools to reduce the public health burden of tobacco in the United States.

FDA'S MAJOR ACCOMPLISHMENTS ON TOBACCO

Since the passage of the Tobacco Control Act on June 22, 2009, the Center has completed several key activities to reduce the public health burden of tobacco products:

PROTECTING KIDS: Every day, nearly 4,000 kids younger than age 18 try their first cigarette and 1,000 kids younger than age 18 become daily smokers. Many of these kids will become addicted before they are old enough to understand the risks and will ultimately die too young of tobacco-related diseases. FDA is working to protect the health of America's children and ultimately reduce the burden of illness and death caused by tobacco use. Therefore, FDA, as directed by the law, has taken several actions this past year designed to significantly curb access to and the appeal of cigarettes and smokeless tobacco products to children and adolescents in the United States. In particular, the Center:

- Announced and enforced the ban on cigarettes with characterizing fruit, candy or clove flavors and issued guidance on implementation (September 2009). FDA followed this with the issuance of several warning letters to companies in violation of this ban.
- Reissued final 1996 Rule: "Regulation Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents" (March 2010). FDA is contracting with states, territories, and tribal nations to enforce the regulations. Maine and Massachusetts were the first states to receive the award.

Among other provisions, these regulations:

- Set a national minimum age of 18 for sale of cigarettes and smokeless tobacco.
- Prohibit sale of cigarette packs with fewer than 20 cigarettes.
- Prohibit distribution of free samples of cigarettes and restrict free samples of smokeless tobacco products.
- Prohibit tobacco brand name sponsorship of athletic, musical, or other social events.
- Prohibit sale of tobacco products in vending machines except in limited adult-only venues.

ESTABLISHING A SCIENCE BASE: There exists a substantial scientific base for each of the areas FDA has been empowered to act. FDA will build on this base to guide key decisions in tobacco regulation. One of FDA's main priorities is to use the best available science to develop and put into action effective public health strategies to reduce the enormous toll of illness and death caused by tobacco products. Therefore, FDA, as directed by the law, has taken several actions this past year designed to enhance the scientific foundation of the Center. In particular, the Center:

- Issued Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 2009).
- Issued Guidance for Industry: Listing of Ingredients in Tobacco Products (November 2009).
- Established the Tobacco Products Scientific Advisory Committee (TPSAC) (March 2010). TPSAC is tasked with providing advice, information, and recommendations to the Commissioner of Food and Drugs on health and other issues relating to tobacco products.

2009–2010: INAUGURAL YEAR IN REVIEW

The first meeting of the TPSAC focused on the public health impact of the use of menthol in cigarettes (March 2010). The first Tobacco Constituents Subcommittee meeting focused on harmful and potentially harmful constituents of tobacco products, and how best to develop and publish a list of such constituents, as directed by the Tobacco Control Act (June 2010).

- Appointed Captain David Ashley as the first Director, Office of Science (June 2010). Capt. Ashley comes to the Center with 27 years of experience at the Centers for Disease Control and Prevention (CDC), where he served as a bench scientist and chief of one of the largest branches in the agency, the Emergency Response and Air Toxicants Branch, Division of Laboratory Sciences, National Center for Environmental Health at CDC. For the past decade, he has overseen research relating to tobacco products, focusing on the relationship between tobacco product design, contents, and emissions, and looking for biomarkers to measure the impact of tobacco product use and exposure to second-hand smoke

REGULATING TOBACCO PRODUCTS: In the short time since President Barack Obama signed the Tobacco Control Act, FDA has taken several steps to implement the law and begun to regulate tobacco products to reduce their public health burden in the United States. Here is a sample of some key actions:

- Announced the ban on cigarettes with characterizing fruit, candy, or clove flavors and issued guidance on implementation. FDA also issued warning letters to several companies that were in violation of this ban during the fall of 2009. This ban is expected to help reduce the number of children who start to smoke and who become addicted to tobacco products.
- Issued final guidance on the Tobacco Control Act requirement that tobacco product manufacturers and importers inform FDA of the ingredients and additives in their tobacco products, by quantity, in each brand and sub-brand. This information will inform the Center's regulation of the manufacture, marketing, and distribution of tobacco products to protect the public health generally.
- Issued final guidance on the Tobacco Control Act requirements for the registration of tobacco product manufacturing establishments and products. These requirements will provide FDA with a registry of U.S. establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products.
- Issued final guidance on the Tobacco Control Act requirement that manufacturers and importers submit documents to FDA that relate to the health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.
- Issued letters to industry requesting information about the perception and use of dissolvable tobacco products, especially among young people, to gain a better understanding of the intended use and marketing of these products.
- Issued draft guidance for industry regarding FDA's proposed enforcement policy for the regulations restricting the sale and distribution of cigarettes and smokeless tobacco to youth. The regulations become legally enforceable on June 22, 2010.

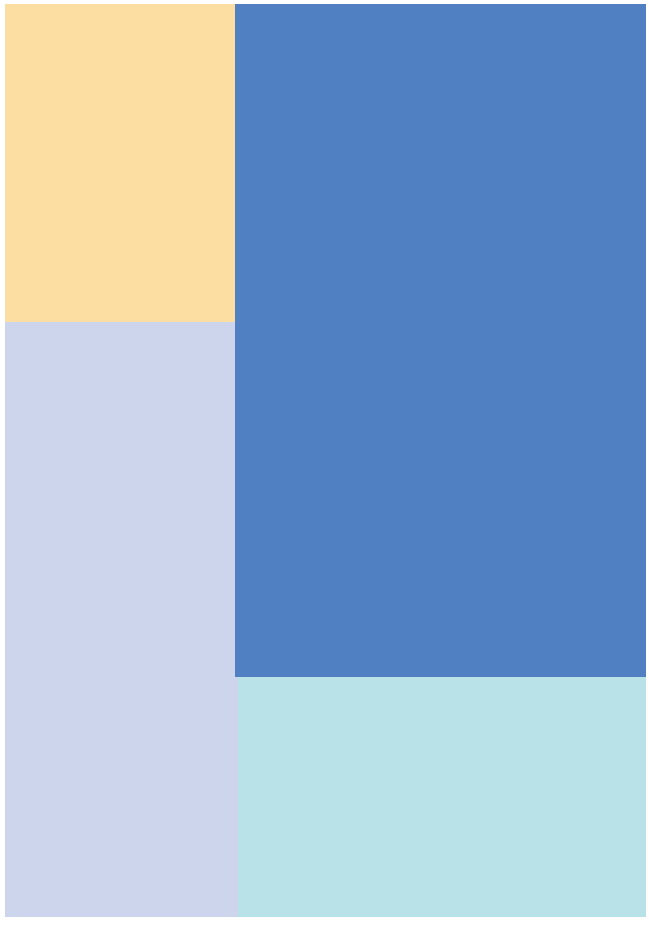
- Began to review industry plans for the rotation and equal display of the new health warning labels that the Tobacco Control Act requires for smokeless tobacco product labels and advertising. These new warning labels must begin to rotate quarterly in advertising for smokeless tobacco products beginning on June 22, 2010, and must be randomly and equally distributed and displayed on the packaging of smokeless tobacco products.
- Issued Guidance for Industry and FDA Staff: Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products. The Tobacco Control Act restricts the use of such descriptors to help protect the public from unsubstantiated claims that tobacco products have a reduced risk, for example, claims that they have less of some ingredient or constituent.
- Issued Guidance for Industry and FDA Staff: Harmful and Potentially Harmful Constituents in Tobacco Products to provide FDA interpretation of this provision and solicit public comment. FDA is required to develop and publish a list of harmful and potentially harmful constituents to better inform the public about tobacco products.

COMMUNICATIONS WITH STAKEHOLDERS AND THE AMERICAN PUBLIC: As FDA implements the Tobacco Control Act, the Center is committed to ensuring that our actions are grounded in sound science, that we are open and transparent, and that we give stakeholders the opportunity to comment and participate in the regulatory process. To promote the public health, it is crucial that we communicate with the tobacco industry, retailers, state and local officials, public health advocates, and the public at large about the new law and our efforts to implement it.
To this end, FDA:

- Held seven listening sessions in fall 2009 with various groups, including public health advocates, state and local governments, tobacco industry representatives, and distributors to introduce the Center and hear their views on implementation.
- Created a Center Web site in order to have one place all audiences could come to get up-to-date information on Center actions.
- Established a Small Business office, and a small-business section of the Web site, to better serve the needs of small tobacco businesses.
- Launched a call center for consumers and stakeholders, which will be the central point of contact for any inquiry into the Center and about the Center's actions.
- Reached out to key tobacco journalists and publications to begin educating them about the statute and FDA's public health role.

2009–2010: INAUGURAL YEAR IN REVIEW

- Opened several public dockets to provide an opportunity for the public to share information, research, and ideas regarding certain tobacco products that raise important public health issues, including modified risk tobacco products, dissolvables, and menthol cigarettes, and regarding advertising and promotion designed to appeal to youth or to racial and ethnic minority populations.
- Presented at a wide variety of public health, tobacco control, scientific, retailer, and tobacco industry conferences to learn more about our stakeholders and provide information about the Center.
- Began developing a comprehensive retailer education campaign about new restrictions on advertising and sales to youth to educate retailers about their obligations and get feedback about how to improve compliance. As part of this campaign, the Center:
  - Created a Web area dedicated to retailers.
  - Held its first Web Dialogue to solicit input from state and local officials and industry on the channels and tactics to effectively communicate with tobacco retailers and receive information from FDA on actions and activities.
  - Launched its first ideation tool (voting mechanism) to directly involve those most affected by FDA regulatory actions.
- Announced the Center's Stakeholder Discussion Series, which is designed to leverage the knowledge, ideas, feedback, and suggestions from communities interested in and affected by tobacco product regulation. This will be done through moderated discussions held across the United States during the next 12-18 months. To enhance transparency, FDA will publish summaries of the results of each session.



2009~2010

INAUGURAL YEAR AT A GLANCE

Since President Barack Obama signed the Family Smoking Preventing Tobacco Control Act in 2009, FDA has made great strides to initiate tobacco product regulation.

JUN
- Family Smoking Prevention and Tobacco Control Act signed by President Obama

JUL
- Established the Collection of User Fees from Industry

AUG
- Created the Tobacco Products Scientific Advisory Committee
- Selected the Director of the Center for Tobacco Products

SEP
- Announced and Began Enforcing the Flavored Cigarette Ban

OCT
- Issued Guidance on Registration and Product Listing

FEB
- Announced Request for Proposals to Enforce Provisions of the Tobacco Control Act

MAR
- Issued Final Rule Restricting Access and Marketing of Cigarettes and Smokeless Tobacco Products to Youth
- Launched Call Center for Tobacco Product Inquiries: 1-877-CTP-1373

APR
- Announced Stakeholder Discussion Series

JUN
- Issued Prohibition on Misleading Marketing Terms ("Light," "Low," and "Mild") for Tobacco Products
- Required Warning Labels for Smokeless Tobacco Products

2009–2010: INAUGURAL YEAR IN REVIEW

SPEAKING OUT

Passage of the Family Smoking Prevention and Tobacco Control Act represents the hard work and dedication of many individuals across diverse sectors. Here are some of their statements regarding the bill's passage and its potential to reduce smoking incidence and improve the overall health of Americans:

"What Americans once regarded as a bad habit or, at worst, a vice, we came to recognize as an addiction with deadly consequences. With implementation of the Tobacco Control Act, the best available science drives our regulation of tobacco products. So today, and into the future, tobacco control is being driven by regulatory science; not political science. It's an historic advance and one that presents new challenges, and, in a very real sense, defines new opportunities and responsibilities for the nicotine and tobacco research community."

— Lawrence R. Deyton, Director, Center for Tobacco Products

"Passage of this legislation represents an important break from the past, as it signifies broad acceptance that nicotine is a drug harmful to people's health."

— Nancy N. Nielson, President, American Medical Association

"Tobacco use is a contributing factor to dozens of diseases and conditions that impact Americans and accounts for $96 billion each year in health care costs. This groundbreaking legislation is a big investment in prevention that will help all Americans lead healthier lives."

— Risa Lavizzo-Mourey, President and CEO, Robert Wood Johnson Foundation

"This bill has the power to finally break the dangerous chain of addiction for millions of Americans and save them from a lifetime of dependence, disease, and premature death that comes with tobacco use."

— John R. Seffrin, CEO, Cancer Action Network, American Cancer Society

"Effectively implemented, this legislation will significantly reduce the number of children who start to use tobacco, the number of adults who continue to use tobacco, and the number of people who suffer and die as a result."

— Matthew L. Meyers, President, Campaign for Tobacco-Free Kids

CENTER STAFF

The Center is led by Dr. Lawrence R. Deyton, a physician and an expert on public health, tobacco use, and veterans' health issues. Center staff members include a diverse group of dedicated professionals working together to improve the public's health. The staff includes experts in tobacco control, law, medicine, public health, public policy, management, social science, and health communications.

The Center is comprised of seven offices, each with a particular focus.

- Office of the Director,
  Lawrence R. Deyton, M.S.P.H., M.D.
- Office of Health Communication and Education,
  Acting Director, Kathleen K. Quinn, M.P.H.
- Office of Management,
  Acting Director, Erik P. Mettler, M.P.A., M.P.H.
- Office of Regulations,
  Director, Beverly Chernaik, J.D.
- Office of Compliance,
  Acting Director, Ann Simoneau, J.D.
- Office of Policy,
  Acting Director, Lawrence R. Deyton, M.S.P.H., M.D.
- Office of Science,
  David Ashley, Ph.D.

CENTER CONTACT INFO

CONTACT INFORMATION

Center for Tobacco Products
9200 Corporate Blvd.
Rockville, MD 20850

Main Phone Number:
1-877-CTP-1373

For General Consumer Inquiries:
AskCTP@fda.hhs.gov

For Tobacco Industry Questions:
TobaccoIndustryQuestions@fda.hhs.gov


DEPARTMENT OF HEALTH & HUMAN SERVICES · USA