DEPARTMENT OF HEALTH AND HUMAN SERVICES

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STATEMENT

OF

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BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS

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"PROGRESS AND CHALLENGES: THE STATE OF TOBACCO USE AND REGULATION IN THE U.S."

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Introduction

Mr. Chairman and Members of the Committee, I am Mitch Zeller, Director of the Center for Tobacco Products (CTP) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss FDA's activities in implementing the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act), since it was signed into law on June 22, 2009.

This January we marked 50 years since the first Surgeon General's Report on Smoking and Health, and how we've learned so much about tobacco use as the leading cause of preventable disease and death in this country. We've shifted the perception of smoking from an accepted national pastime to a discouraged threat to health—and more than halved smoking rates in this country. This year's Surgeon General's Report highlighted 50 years of progress in tobacco control and prevention, presented new data on the health consequences of tobacco use, and detailed initiatives that can end the tobacco epidemic in the United States.

But the fact of the matter is, for all the progress we've made over these past five decades, tobacco-use remains the leading cause of avoidable death here in the United States and also around the world. Each year, more than 480,000 Americans lose their lives to tobacco-related illness. This recent Surgeon General's Report also added new diseases to the list of those known to be caused by smoking: liver cancer, colorectal cancer, diabetes, and rheumatoid arthritis, as well as adding strokes caused by exposure to secondhand smoke. And each day in

the United States, more than 3,200 youth under age 18 try their first cigarette and more than 700 youth under age 18 become daily smokers. If we fail to reverse these trends, 5.6 million American children who are alive today, will die prematurely due to smoking later in life.

The Tobacco Control Act

In 2009, the Congress passed, and the President signed, the Tobacco Control Act, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to oversee the manufacture, marketing, distribution, and sale of regulated tobacco products and protect the public from the harmful effects of tobacco product use. This new authority gave FDA comprehensive tools to protect the public from the harmful effects of tobacco use through science-based tobacco product regulation.

FDA's traditional "safe and effective" standard for evaluating medical products does not apply to tobacco products. With limited exceptions, FDA evaluates new tobacco products based on a public health standard that considers the risks and benefits of the tobacco product to the population as a whole, including users and non-users. Similarly, when developing regulations, the law generally requires FDA to apply a public health approach that considers the effect of the regulatory action on the population as a whole, not just on individual users, taking into account initiation and cessation of tobacco use.

Under the statute, FDA had immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act also authorized FDA to deem other tobacco products to be subject to the Agency's regulatory authority in Chapter IX

of the FD&C Act. On April 24, 2014, FDA issued a proposed rule (the "proposed deeming rule") to deem additional products that meet the statutory definition of a "tobacco product" (which includes "any product made or derived from tobacco that is intended for human consumption" that is not a drug, device, or combination product under the FD&C Act) to be subject to FDA's regulatory authority.[1] Under the proposed rule, products that would be "deemed" to be subject to FDA regulation, include currently unregulated marketed products, such as electronic cigarettes (e-cigarettes), cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and dissolvables not already under the FDA's authority. Manufacturers of newly deemed tobacco products would be required, among other things, to:

- Register their establishments with FDA, report product and ingredient listings, and report harmful and potentially harmful constituents;
- Market new tobacco products only after FDA review;
- Make direct and implied claims of reduced risk only if FDA confirms that scientific evidence supports the claim and that marketing the product will promote public health; and
- Not distribute free samples.

In addition, under the proposed rule, the following provisions would apply to newly "deemed" tobacco products:

- Minimum age and identification restrictions to prevent sales to underage youth;
- Requirements to bear certain health warnings; and
- Prohibition of vending machine sales, unless in a facility that never admits youth.

[1] *See* FDA, "News Release: FDA proposes to extend its tobacco authority to additional tobacco products, including e-cigarettes" (April 24, 2014), available at *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm394667.htm.*

Issuing the proposed deeming rule was an important step forward in regulating these products, and finalizing the rule after a thorough review of comments is a priority for the Agency. Products that are marketed for therapeutic purposes will continue to be regulated as medical products under the FDA's existing drug and device authorities in the FD&C Act.

Between 2008 and 2010, FDA had previously attempted to address electronic cigarettes (e-cigarettes) as unapproved drug/device combination products. FDA's action was challenged, and ultimately the U.S. Court of Appeals for the D.C. Circuit ruled that while FDA could choose to regulate e-cigarettes and other products "made or derived from tobacco" under its new tobacco authorities, it could not regulate these products under FDA's drug and device authority. *Sottera, Inc. v. Food and Drug Administration,* 627 F.3d 891 (D.C. Cir. 2010). Finalizing the proposed deeming rule would bring these tobacco products under FDA's regulatory authority.

FDA welcomes comment on all aspects of the proposed rule. We asked for comment on a number of specific issues, on which we look forward to receiving input, research, data and other information from the public to help inform the development of the Final Rule.

Accomplishments Since Enactment of the Tobacco Control Act

In the nearly five years since enactment of the Tobacco Control Act, FDA has made significant progress toward establishing a comprehensive, effective, and sustainable framework for tobacco product regulation that is designed to reduce the impact of tobacco on public health, to keep people, especially our nation's youth, from starting to use tobacco, and to encourage consumers to quit. These major strides include, among other things:

- Establishing an initial framework for industry registration, product listing, and submission of information on ingredients and harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke;
- Requiring cigarette, roll-your-own, and smokeless tobacco product manufacturers to seek FDA authorization before marketing a new product or making changes to existing products;
- Implementing and enforcing the FD&C Act's prohibition on the use of marketing terms for regulated tobacco products that imply reduced risk (such as "light," "mild," or "low") without FDA authorization;
- Developing a process for the review and evaluation of applications for new, modified risk claims, and substantially equivalent (SE) tobacco products;
- Implementing and enforcing the statutory ban on cigarettes with certain characterizing flavors;
- Increasing regulatory science capabilities through research to better understand regulated products and patterns of tobacco use;
- Restricting access and marketing of cigarettes and smokeless tobacco products to youth;
- Implementing a compliance and enforcement program to ensure industry compliance with regulatory requirements; and
- Establishing public education campaigns about the dangers of regulated tobacco products.

These accomplishments demonstrate FDA's commitment to effectively regulate the manufacture, marketing, and distribution of tobacco products and to advance tobacco product regulations appropriate for the protection of public health.

Establishing the Center for Tobacco Products

FDA's first priority following the enactment of the Tobacco Control Act was creating the Center for Tobacco Products (CTP or the Center), FDA's first new center in 21 years. CTP oversees the implementation of the FDA tobacco program, and has been tasked with developing the scientific, regulatory, and public education infrastructure necessary to implement and track FDA's goals for meaningful product regulation that will help reduce the harms associated with tobacco products and prevent initiation of tobacco use (particularly among youth).

From a handful of employees in the fall of 2009, the Center has grown to nearly 500 employees, including regulatory counsels, policy analysts, scientists, researchers, management officers, communications specialists, and other professionals who are designing and implementing a comprehensive program of tobacco product regulation. Key objectives involved in launching CTP have included recruiting management officials to lead the Center, hiring skilled staff, setting up necessary infrastructure and technology resources, and putting in place processes to meet statutory deadlines and directives.

During its start-up phase, FDA quickly established the foundation for meeting the many mandatory statutory deadlines included in the Tobacco Control Act. The law contains more

than 20 statutory deadlines by which FDA was required to issue certain regulations, guidance documents, Reports to Congress, and a list of harmful and potentially harmful constituents, among other things. Most of these deadlines were in the first three years after the law went into effect. Therefore, even as the Center was establishing itself, creating infrastructure, and hiring appropriate personnel, it was required to develop a significant number of regulations and guidance documents on precedent-setting, complex issues. In addition, the Center was required to assess user fees, establish the Tobacco Products Scientific Advisory Committee (TPSAC), and refer to TPSAC the issue of the impact of the use of menthol in cigarettes on the public health, within its first year. The Center met nearly all of the more than 20 statutory deadlines.

CTP undertakes four broad categories of activities in carrying out its responsibilities and authorities under the Tobacco Control Act:

- reviewing submissions for marketing new tobacco products and developing the science base for product regulation;
- enforcing statutory and regulatory requirements to ensure regulated industry and tobacco products are in compliance with the law;
- developing and issuing regulations and guidance for industry; and
- engaging in public education and outreach activities about the risks associated with tobacco product use, and promoting awareness of and compliance with the Tobacco Control Act.

I will briefly describe some of CTP's accomplishments in each of these areas over the last five years, as well as note some of the challenges that we have faced in carrying out our responsibilities and authorities under the Tobacco Control Act.

The Tobacco Product Review Process

The Tobacco Control Act requires manufacturers to seek FDA authorization before marketing a new tobacco product, including when modifying an existing product; the FD&C Act defines a "new" tobacco product as a product not commercially marketed in the United States as of February 15, 2007, or a product already on the market that is modified after that date. Products that were on the market on February 15, 2007, and which have not been modified, can continue to be marketed without FDA authorization. This review process gives FDA the ability to help ensure that the marketing of any new product, including a modified product, is appropriate for the protection of public health and allows for greater awareness and understanding of the changes being made to tobacco products. There are three ways a new tobacco product, including an existing product that is modified, can obtain FDA authorization for distribution or retail sale: a premarket tobacco product application; an application demonstrating substantial equivalence (SE) to certain commercially marketed products; or an application for exemption from demonstrating SE.

- Premarket tobacco product applications: One pathway for a new tobacco product to receive market authorization is through the Premarket Tobacco Product Application (PMTA) process.[2]

[2] In September 2011, FDA issued a draft guidance document describing what the FD&C Act requires to be submitted in a new tobacco product application. The draft guidance also sought comment on the information to be included in the application that the agency would use to determine whether the marketing of a new tobacco

- Demonstrating substantial equivalence to certain commercially marketed products: Demonstrating SE to a product already on the market is a second pathway to marketing authorization under specific circumstances. Under the SE pathway, whenever an existing tobacco product is modified, the manufacturer must submit a report with sufficient scientific data and information to FDA to demonstrate either that the product characteristics, as compared to the predicate product, are the same or that the tobacco product has different characteristics but does not raise different questions of public health.[3] This means that products brought to market through this pathway should not present more harm to public health than a valid predicate tobacco product.
- Exemption from demonstrating substantial equivalence: The third pathway for new tobacco products is a request for an exemption from the SE requirements. This pathway is available for products modified by the addition or deletion of an additive or a change in the quantity of an existing additive, if FDA finds the modification of the product to be minor; FDA determines an SE report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; and an exemption is otherwise appropriate.[4]

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product is appropriate for the protection of the public health, as determined with respect to the risks and benefits to the population as a whole, including users and non-users of tobacco products, and taking into account the impact on cessation and initiation.

[3] Products that were first introduced or delivered for introduction into interstate commerce for commercial distribution between February 15, 2007, and March 22, 2011, and for which SE reports were submitted prior to March 23, 2011, can remain on the market unless FDA issues an order that they are "not substantially equivalent (NSE)." FDA refers to these SE reports as "provisional." An SE report for a tobacco product submitted after March 22, 2011 is considered a "regular" report and the product covered by the application cannot be marketed unless FDA first issues an order finding the product substantially equivalent and in compliance with the FD&C Act. FDA issued a guidance document in January 2011 describing the content and data to be included in the report and the process for its review.

[4] In July 2011, FDA issued a final rule on "Exemptions from Substantial Equivalence Requirements" that established the procedures for requesting an SE exemption.

In addition to creating the pathways for marketing of new tobacco products, the statute directs FDA to evaluate and authorize marketing of modified risk tobacco products (MRTPs). MRTPs are tobacco products sold or distributed for use to reduce harm or the risk of tobacco-related disease. These include products whose labeling or advertising represents (explicitly or implicitly) that the product is less harmful or presents a lower risk of tobacco-related disease than commercially marketed tobacco products, or that the product or its smoke contains a reduced level of, presents a reduced exposure to, or does not contain or is free of a substance.

In order for a tobacco product to make claims that the product "presents a lower risk of disease," an applicant must show that the product will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users and non-users of tobacco products.

There is also a "Special Rule" for certain MRTPs, such as those that claim to "present a reduced exposure to a substance." FDA may issue an order for such products if, among other things, the order would be appropriate to promote the public health; the claims for the product are limited to claims that the product does not contain or is free of a substance, contains a reduced level of a substance, or presents a reduced exposure to a substance; scientific evidence to satisfy the lower disease risk standards cannot be made available without conducting long-term epidemiological studies; and the available scientific evidence demonstrates that a measurable and substantial reduction in morbidity/mortality among individual users is reasonably likely in subsequent studies.

FDA review of a new product, including a modified product, requires scientific and technical expertise in order to assess how the product design, ingredients, and other characteristics impact the public health.

Substantial equivalence is one pathway manufacturers can use to seek permission to market a new tobacco product. The primary pathway, however, is through the filing of a new tobacco product application. As of May 1, 2014, FDA had not received any complete premarket applications for new tobacco products for which we can commence a scientific review.

As of May 1, 2014, FDA had received a total of 4,580 submissions seeking to demonstrate SE to a predicate product, including 3,578 "provisional" submissions that were received before March 23, 2011, and apply SE to products currently marketed in the United States. The remaining 1,002 applications are "regular" submissions for products not currently on the market.

FDA is committed to carefully and thoroughly reviewing all submissions in order to protect the public health as required by the FD&C Act. FDA is also committed to a consistent, transparent, and predictable review process and to completing reviews of all new product applications in a timely manner.

CTP has prioritized the review of regular SE submissions and has made progress in each of the three key steps in the SE review process: (1) jurisdiction review; (2) administrative

review; and (3) scientific review. As of May 1, 2014, CTP has completed the jurisdiction review of 4,559 SE submissions and completed administrative review of 4,384 SE submissions and provided acknowledgment and, where appropriate, administrative advice and information letters to the applicants seeking information required for review. On March 24, 2014, CTP announced that we no longer have a backlog of regular SE reports awaiting review. CTP is starting review on regular SE reports as they are received. As of May 12, 2014, 257, or 25 percent of regular SE submissions have been resolved, either because CTP issued a determination (34 submissions) or because the submission was withdrawn (223 submissions). Fifty-seven percent of the Regular SE Report withdrawals reported to FDA were withdrawn after CTP issued an action letter which identified deficiencies in the submission.

CTP has completed an initial evaluation of the 3,559 provisional SE reports to guide the order of review so that those products that remain on the market and present the highest likelihood of raising a different question of public health will be reviewed first. CTP has begun review of provisional SE reports and issued the first decisions on these reports on February 21, 2014. These decisions marked the first time that FDA used its authority under the Tobacco Control Act to order a manufacturer of currently-available tobacco products to stop selling and distributing them.[5] The products were found to be not substantially equivalent to predicate tobacco products, therefore under the Tobacco Control Act, they can no longer be sold or distributed in interstate commerce or imported into the United States.

[5] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm386707.htm

FDA has received 59 requests to consider certain products to be exempt from the SE requirements. To be considered for an exemption, requests must meet the requirements in the statute and regulations. CTP published a final regulation on the SE exemption pathway on July 5, 2011. FDA has refused to accept 35 requests for SE exemption because they did not meet the statutory and regulatory requirements. The remaining 24 requests are under administrative, eligibility, or scientific review.

There are many factors that can affect the timing of a determination by FDA, including the completeness of an application or whether there is a need for manufacturers to submit more information or provide an additional explanation so that FDA can complete its assessment. It is important to note that there was a wide range of quality in SE reports submitted thus far by the tobacco industry. In almost all cases, reports that have been submitted lack both information referenced in FDA guidance documents to facilitate FDA review and information required by statute for FDA to make its determination. Examples of some of the general issues that FDA is observing across multiple applicants include:

- Reports containing contradictory statements, particularly about whether the product characteristics were the same or different;
- Reports identifying a predicate product that does not meet the statutory requirement;
- Reports lacking information to completely understand product composition, including information about the tobacco blend used in the product;
- Reports missing specifications on components used in the manufacture of the finished product;

- Reports with HPHC measurements that were scientifically inadequate or did not include information needed to evaluate data quality; and
- Reports in which information on product design was incomplete, preventing a scientific assessment.

In response to industry feedback, where possible, FDA has been taking steps that would streamline the SE review process, by:

- increasing opportunities for communication with industry by encouraging teleconferences between the assigned FDA regulatory project manager and the submitter;
- taking steps to facilitate quicker responses to questions;
- modifying the initial review for completeness to focus only on administrative issues, so that applicants can be notified more quickly about submission deficiencies;
- hosting webinars for tobacco manufacturers specifically to discuss the types of information that the Agency needs to complete the review of SE reports;
- issuing a September 2011 draft guidance document for public comment with responses to frequently asked questions about demonstrating SE of a new tobacco product; and
- launching a new section on the Agency's website, providing comprehensive information on the pathways available to legally market new tobacco products, including SE.

In addition to streamlining the SE review process, FDA is taking other steps to improve the timeliness of product reviews. In FY 2013, CTP increased the number of scientific staff by

38 percent, mostly to perform reviews. CTP plans to continue to hire many more scientists and expects the time required for review of SE submissions to get substantially shorter as CTP continues to improve the efficiency of its review process and as the quality of reports received from industry improves.

In addition to hiring more scientific staff to perform reviews, last month, the Center established four performance measures that include time frames for review of regular SE Reports, review of Exemption from SE Requests, review of MRTP Applications, and for responding to meeting requests. Beginning on October 1, 2014, all four measures will be implemented. The interim time between now and October 1, 2014, will be used to develop tracking systems for monitoring progress in meeting the performance goals. As FDA gains more experience with reviewing provisional SE Reports, we intend to identify and implement performance standards for these submissions as well.

Tobacco Regulatory Science

CTP relies on the most current science to make regulatory decisions on tobacco products. The Center funds and uses scientific research to better understand tobacco products, how the differences in products change the behavior of users and non-users, how they cause death and disease, and how to best reduce the harm from these products.

CTP has identified seven categories of research priorities:

- ***Product diversity*** – understanding the types of tobacco products and how their specific characteristics affect people's use of these products, as well as their attitudes, beliefs, and perceptions about these products.

- ***Addiction*** – understanding what effect different levels of nicotine and other factors have on addiction.
- ***Toxicity and carcinogenicity*** – understanding how changes in tobacco products affect their potential for harm and ways to reduce that harm.
- ***Health consequences*** – understanding the risks of different tobacco products.
- ***Communication*** – finding ways to effectively convey information about the risks of using tobacco and about CTP's role in regulating tobacco products.
- ***Marketing*** – understanding the impact of tobacco product marketing and public education on people's attitudes, beliefs, perceptions, and use.
- ***Economics and policy*** – estimating the economic impact of CTP's regulations; also understanding how CTP's actions change tobacco use and illness and death from tobacco use.

CTP partners with other agencies, such as the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), as well as with FDA's National Center for Toxicological Research, to continue to advance the regulatory science base. For example, CTP is partnering with NIH to support important research efforts, including:

- ***The Population Assessment of Tobacco and Health (PATH) Study:*** The PATH Study will help scientists learn how and why people start using tobacco, switch products, quit using tobacco, and start using it again after they've quit. By monitoring and assessing the behavioral and adverse health impacts of tobacco use in the United States, the PATH Study will add to the evidence base to inform regulatory decisions about the marketing, manufacture, and distribution of tobacco products. Because this

is a longitudinal study following the same individuals, with appropriate consent, over years, FDA will be able to draw scientific conclusions on how users transition from the use of one product to another and from experimentation to regular use and how these choices impact the ultimate death and disease resulting from their use. The PATH survey went into the field in September 2013, the data will be available in the fall of 2015 for researchers by request, and the publicly-available baseline survey dataset is expected in spring 2016. Any publicly-released data will protect the identity of the participants.

- ***Tobacco Centers of Regulatory Science (TCORS):*** TCORS is a new research program designed to generate research to inform the regulation of tobacco products to protect public health. The program was initially funded in 2013 and will run up to five years. Essential elements of these centers include an overall focus on the high-priority tobacco regulatory program needs for CTP; three or more theoretically grounded, strong research projects with an integrative theme; the ability to respond quickly to emerging research questions through pilot projects; and a program for career development to train future generations of researchers in tobacco regulatory science.

In addition, in response to the Court of Appeals decision on FDA's rule requiring that all cigarette packages bear one of nine new textual warnings and include color graphics depicting the negative health consequences of smoking, FDA is undertaking research to support a new rulemaking consistent with the Tobacco Control Act and actively working to move forward on this important issue.

Compliance and Enforcement Activities

Vigorous enforcement of the Tobacco Control Act and implementing regulations is carried out through tobacco retail compliance check inspections, inspections of domestic manufacturers and imported tobacco products, and surveillance and review of tobacco promotions, advertising, and labeling. CTP also provides compliance education and training to regulated industry.

The FD&C Act instructs FDA to contract, where feasible, with the states, to carry out inspections of retailers in connection with the enforcement of the Tobacco Control Act; the retail inspection program provides a framework for a nationwide FDA enforcement strategy through the credentialing of more than 1,100 state and territorial officials and a comprehensive training program for these FDA-commissioned inspectors and program coordinators. CTP has awarded contracts for tobacco retail inspections in 48 states and territories, with awards totaling more than $93 million since the program began. Measurable accomplishments in the retail inspection program from 2009 through May 1, 2014, include:

- Conducting more than 289,000 compliance check inspections of regulated tobacco retailers utilizing state and territorial contractors;
- Issuing over 14,800 warning letters to retail establishments where violations were found during compliance check inspections;
- Issuing over 1,430 CMP administrative actions to retail establishments where subsequent violations were found during follow-up compliance check inspections; and

- Developing an online searchable database of retail compliance check inspection results.[6]

Active and effective enforcement of tobacco laws and regulations governing the promotion, advertising, and labeling of tobacco products can help to protect the public health by preventing the sale and distribution of misbranded and adulterated tobacco products, including those with marketing and advertising materials that violate the requirements of the Tobacco Control Act. In this regard, FDA reviews and evaluates regulatory submissions that include tobacco product labeling, representative advertising, and consumer information materials; conducts routine monitoring of websites and publications that sell, distribute, promote, or advertise regulated tobacco products; and conducts surveillance of event promotion and sponsorship by tobacco manufacturers, distributors, or retailers.

CTP has issued a number of letters to manufacturers requesting information regarding their marketing and advertising practices. For example, FDA has requested information on events that include the distribution of free samples of smokeless tobacco products, internet marketing activities, and other relevant information to determine compliance. From 2009 through May 1, 2014, FDA's promotion, advertising, and labeling compliance and enforcement program has:

- Monitored approximately 3,000 websites and more than 74,000 publication issues where regulated tobacco products might be sold, distributed or advertised.

[6] *See* FDA, "Compliance Check Inspections of Tobacco Product Retailers," available at *http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm*.

- Issued over 150 Warning Letters as a result of CTP's monitoring and surveillance of tobacco advertising, labeling, and other promotional activities; and
- Reviewed 38 smokeless tobacco warning plans and 13 smokeless tobacco warning plan supplements.

FDA conducts biennial inspections of registered tobacco product establishments that manufacture regulated tobacco products in the U.S. market. These inspections are designed to determine compliance with requirements of the FD&C Act, including establishment registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products. In the area of manufacturing compliance and enforcement, through May 1, 2014, FDA has:

- Conducted more than 120 inspections of registered tobacco product facilities;
- Conducted more than 20 investigations that included sponsorship events and distribution of free sample events; and
- Reviewed over 77,500 lines of imported tobacco products, completing over 1,100 field exams and more than 1,900 label exams, and refusing more than 70 entries, in collaboration with U.S. Customs and Border Patrol (CBP). We have also issued four import alerts that directed many of these reviews and exams.

CTP also provides compliance education and training to regulated industry to ensure that those who must understand the law and regulations have the resources to do so. In 2011, FDA started hosting live webinars to help educate regulated industry and encourage compliance with Federal tobacco laws and regulations. Public webinars allow retailers and

small businesses to watch and ask live questions. Each webinar addresses a specific subject, including published guidance, and many of the webinars are archived on the Center's website for future viewing. Industry can also suggest topics for future webinars.

In addition, one of FDA's initial activities was to establish the Office of Small Business Assistance within CTP to assist small tobacco product manufacturers and retailers in complying with the Tobacco Control Act. The office has a dedicated webpage, e-mail address, and staff to assist small businesses with their questions, comments, and concerns.

"The Real Cost" and Other Public Education Campaigns

The Tobacco Control Act gives FDA the authority to educate the public about the dangers of regulated tobacco product use. To advance efforts to protect the public from the harmful effects of tobacco use, FDA is developing integrated, far-reaching, and evidence-based public education campaigns related to FDA's regulatory activities, including informing consumers about risks from tobacco use and preventing youth tobacco initiation, and promoting tobacco use cessation among youth.

FDA has awarded multiple contracts for public education campaigns to conduct sustained, multi-media efforts that will enable FDA to educate the public, and vulnerable youth populations in particular, about the harms and risks of regulated tobacco products in order to help prevent youth initiation and encourage cessation. Specifically, these campaigns will equip the public with important facts about the health risks and addictiveness of regulated tobacco products and the HPHCs in regulated tobacco products.

In February, we launched a national public education campaign to prevent youth tobacco use and reduce the number of kids ages 12 to 17 who become regular smokers. "The Real Cost" campaign is the first of several planned tobacco education campaigns[7]; it targets the 10 million young people ages 12-17 who have never smoked a cigarette but are open to it as well as youth who are already experimenting with cigarettes and are at risk of escalating their use. "The Real Cost" campaign uses a comprehensive multimedia approach with compelling facts and vivid imagery designed to change beliefs and behaviors over time,[8] educate youth about the dangers of tobacco use and to encourage them to be tobacco-free.[9] Supported by the best available science, "The Real Cost" campaign will be evaluated to measure its effectiveness over time.

In addition, FDA is overseeing a variety of research and analytic activities to strengthen and inform public education initiatives and efforts. This includes awarding a contract to conduct rigorous outcome evaluations on the effectiveness of individual FDA tobacco-related public education campaigns, overall messaging, and related communications activities. This combination of establishing and evaluating evidence-based public education campaigns will enable the Agency to implement effective models for educating the public about the risks and dangers of regulated products, and will also complement public education initiatives by our partner agencies, including CDC, on tobacco-related issues.

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[9] See http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/PublicEducationCampaigns/TheRealCostCampaign/ucm384305.htm

Addressing Challenges and Advancing the Tobacco Control Act

Some of the challenges that we have faced in these early years are the growing pains inherent in building a regulatory body from the ground up. FDA has worked through the logistical challenges of creating a new organizational structure, recruiting and hiring qualified staff with applicable experience in a short time frame, and developing the processes, procedures and dedicated information technology resources to carry out CTP's important regulatory functions.

There are challenges intrinsic to the regulation of tobacco products, which are markedly different from other products traditionally regulated by FDA. For example, FDA has created and validated entirely new scientific testing procedures for the measurement of HPHCs in tobacco products and tobacco smoke, and developed metrics for the evaluation of product applications, including the SE applications now under review. The responsibility given to FDA's Center for Tobacco Products for the premarket public health review of tobacco product applications and reports is unprecedented. No other country's regulatory agency has been given the responsibility to evaluate new tobacco products before they are marketed and determine which products will be authorized for marketing based on public health criteria. FDA also established and implemented a tobacco retail compliance program that is unique even within the Agency. Tobacco product regulation also involves the regulation of an industry that is new to Federal product regulation and often unfamiliar with and continuing to learn what is expected in the regulatory process.

Conclusion

Moving forward, FDA will sustain the momentum needed to achieve its goals for reducing the harms and risks associated with tobacco product use. Despite the common misperception that decades of program and policy efforts have solved this problem, the reality is that tobacco use continues to be the leading cause of preventable death and disease in the United States. The total economic burden of cigarette smoking is estimated to be nearly $300 billion in annual health care and productivity costs. FDA will work to finalize the proposed deeming rule in a timely manner; expand the tobacco regulatory science base; continue to improve product review processes to enable the Center to make timely decisions; expand the compliance program to conduct enforcement in additional states; and develop and implement additional public education campaigns.

In addition to the activities described above, FDA plans to explore the potential for tobacco product standards and is investing in research to support potential product standards to reduce product addictiveness, toxicity, and/or appeal.

Roughly one in five adults still smoke. Those numbers are even higher in states like Kentucky and West Virginia, where smoking rates greatly exceed the national average.[10] FDA cares greatly about the 43 million addicted smokers, and one of our core goals is to reduce the harmfulness of tobacco products. We will explore all available regulatory science to do that.

[10] *See* CDC, "Behavioral Risk Factor Surveillance System," at *http://apps.nccd.cdc.gov/brfss/list.asp?cat=TU&yr=2012&qkey=8161&state=All*

Perhaps the greatest opportunity FDA has to overcome this pressing public health problem is to dramatically decrease the access and appeal of tobacco products to youth. Ninety percent of smokers start smoking by age 18, and 99 percent start by age 26; and despite years of steady progress, declines in the use of tobacco by youth and young adults have slowed for cigarette smoking and stalled for smokeless tobacco use.[11] FDA intends to use the many tools at its disposal to continue the decline in tobacco use and to reinvigorate public determination to arrest the epidemic by making the next generation tobacco-free. The Agency remains committed to making tobacco-related death and disease part of America's past, not its future.

Thank you for the opportunity to testify today about FDA's accomplishments and challenges in the five years since enactment of the Tobacco Control Act. I am happy to answer questions you may have.

[11] U.S. Surgeon General, "Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General" (2012), available at *http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/exec-summary.pdf*.