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PROGRESS AND CHALLENGES: THE STATE OF TOBACCO USE AND REGULATION IN THE UNITED STATES

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE STATE OF TOBACCO USE AND REGULATION IN THE UNITED STATES, FOCUSING ON PROGRESS AND CHALLENGES

MAY 15, 2014

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C O N T E N T S

STATEMENTS

THURSDAY, MAY 15, 2014

PROGRESS AND CHALLENGES: THE STATE OF TOBACCO USE AND REGULATION IN THE UNITED STATES

THURSDAY, MAY 15, 2014

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 3:35 p.m. in room SD–430, Dirksen Senate Office Building, Hon. Tom Harkin, chairman of the committee, presiding.

Present: Senators Harkin, Alexander, Whitehouse, and Burr.

OPENING STATEMENT OF SENATOR HARKIN

The CHAIRMAN. The committee on Health, Education, Labor, and Pensions will come to order.

I thank everyone for their patience. We just had a whole lot of votes on the Senate floor.

We have convened this hearing to examine the State of tobacco use and regulation in the United States, both the extraordinary public health efforts that have driven down tobacco use, and the enormous challenges that remain.

Our Nation has made remarkable progress in the 50 years since the first Surgeon General's Report on Smoking and Health. In that time, the smoking rate has been cut by more than half, from 42 percent to 18 percent. We have learned what works, from smoke-free workplaces to access to free cessation services; from meaningful tobacco taxes to robust regulation; from media campaigns like the wildly successful Tips from a Former Smoker to commonsense marketing restrictions. So, we know what works.

Yet, despite all these efforts and successes, tobacco use remains the leading preventable cause of death in the United States. Let me repeat that. Tobacco use remains the No. 1 preventable cause of death in the United States.

Right now, 16 million Americans are suffering from smoking-caused illness, and 5.6 million kids alive today will ultimately die from smoking. Today, nearly 1 in 4 high school seniors smoke and, sadly, most young smokers become adult smokers.

The problem is not just cigarettes. Last fall, the Centers for Disease Control and Prevention reported that the use of electronic cigarettes, or e-cigarettes—and I am going to have more to say about those after a bit because I have an array of them up here—among middle and high school students more than doubled in 1 year.

It is because of statistics like these that public health efforts to combat tobacco have been among my top priorities since I came here. In responding to the hundreds of thousands who die every year due to tobacco use, in 1998 I introduced the first comprehensive, bipartisan bill—it was bipartisan—to give the FDA authority to regulate tobacco. It took a while, but that goal finally became a reality 5 years ago with passage of the Family Smoking Prevention and Tobacco Control Act. Today, we want to examine the implementation of that law to date.

More recently, in light of the fact that some 3,500 children try smoking for the first time each day, I authored provisions in the Affordable Care Act that ensure every American has access to tobacco cessation services without co-pays or deductibles. Also, due to the provisions that I put in on the Prevention and Public Health Fund, we have invested more than $300 million in community-based public health efforts to curb tobacco use.

And last month, confronted with the bleak prospect of a whole new generation becoming addicted to nicotine by way of e-cigarettes, I joined with 10 of my colleagues to release an investigative report revealing that manufacturers are devoting massive resources to the marketing of e-cigarettes and their marketing strategies are expressly designed to appeal to kids. So I urge everyone to read that report.

I want to just share one example of the many graphics it contains. That is this chart you see up here. It is an animated cartoon video game through which players earn e-cigarette coupons to redeem on Facebook. Kids play these games, then they get on Facebook and they can redeem coupons.

Cartoons, video games, social media, candy flavors. The ones I have here, let us see, I have Gummy Bear, that is one; that appeals to adults, right, gummy bear? Then there is one, Rocket Pop that has a popsicle on the front of it; cotton candy concentrated nicotine. Now, I have another one here is Cran-Apple, and I have a strawberry too. I did not want to leave out strawberry.

It is the same thing we used to see with flavored cigarettes; same thing. So again, they are pulling out their stops to target children. It is absolutely shameful. Again, a throwback, a disgusting throwback, to Big Tobacco's playbook to promote traditional cigarettes to kids before restrictions were in place.

I know that some believe that e-cigarettes are a promising alternative to cigarettes, but hopefully, we can all agree these products do not belong in the hands of kids. Keep in mind, this is a drug delivery device. It delivers nicotine. Nicotine is an addictive drug.

I look forward to hearing more today from FDA about their new proposal to regulate these e-cigarettes and other tobacco products under the authority of the Family Smoking and Prevention Control Act.

What is this one called? Cherry crush; I did not mean to leave that out either. Cherry crush, that is for the refillables. You can refill them.

The e-cigarette phenomenon has created a regulatory black hole that has gone on too long. Today's hearing is Congress' first examination of that proposal, which has extraordinary consequences for public health.

We are pleased today to have Dr. Tim McAfee of CDC's Office on Smoking and Health, and Mr. Mitch Zeller of FDA's Center for Tobacco Products to talk about the ongoing public health challenge posed by tobacco. They will also report on the important community-based and regulatory work in which those agencies are engaged.

And now, I will turn to Senator Alexander for his opening statement.

OPENING STATEMENT OF SENATOR ALEXANDER

Senator ALEXANDER. Thanks, Mr. Chairman.

Welcome to the witnesses.

Congress passed the law to which Senator Harkin referred, the Family Smoking Prevention and Tobacco Control Act almost 5 years ago, and it clearly was taking a position to discourage the use of tobacco products. What has happened since then, around 18 percent of adults still smoke cigarettes, but that is down from 20 percent in 2010. Smoking among youth continues to decline.

Electronic cigarettes have grown rapidly. The number of adult smokers who tried e-cigarettes doubled between 2010 and 2011. I am going to focus mostly on the so-called Deeming Regulation proposed 2 weeks ago by the FDA, but I did want to, first, read some statistics about the Center for Tobacco Products.

FDA spent nearly 80 percent of the $1.8 billion in user fees collected, more than half of the spending, $868 million, occurred during fiscal year 2013.

FDA has received only four premarket tobacco product applications, which would have to be filed for any novel product put on the market after February 2007 if deeming is finalized as it is. All four were rejected as incomplete. There are over 4,000 substantial equivalence applications pending for tobacco products. FDA has decided on 34 of the over 4,500 that the Agency received. I believe these statistics reflect a poor performance, and I think it is important to call that to your attention.

Now, I appreciated being informed about the proposed regulation. I want to articulate my strong support for the alternative, exempting premium cigars from FDA regulation. I have some concerns about that, but I will followup with questions on how that works. The FDA regulations should fit the product and risk proposed by that product.

Throughout the proposed regulations, FDA talks about a somewhat controversial idea of harm reduction. For the 42 million Americans who currently smoke, FDA should enable companies to find creative ways to reduce the negative health effects of nicotine addiction, not regulate that innovation out of existence.

Most of the discussion around the Deeming Regulation in tobacco seems to be about e-cigarettes, and I am here to listen. I understand there are competing points of view.

Now, some public health experts, such as David Abrams at American Legacy Foundation, the largest nonprofit public health charity in the Nation devoted specifically to tobacco control, has said, "This could be the single biggest opportunity that has come along in a century to make the cigarette obsolete." That is one view.

On the other hand, CDC Director, Dr. Frieden, has been quoted as stating that, "Many kids are starting out with e-cigarettes and then going on to smoke conventional cigarettes."

So what I would like to understand is what research have we done to answer those questions. There are reports from countries overseas that some of these new products do not seem to be a gateway to traditional cigarette use, but we do not know that. We do not know that yet.

The purpose of a hearing such as this, and I thank the chairman for calling this, is not to presuppose an answer, but to find from experts in our Government what their opinion is. And what I would like to know is which of those points of view you subscribe to.

Here is what I think we all have agreement on. The regulations should be based on data and sound science. No. 2, no sales to anyone under 18. Any child beginning to use a tobacco or nicotine product is bad for public health. And No. 3, manufacturers should register and list the products they make and ingredients they use with the FDA.

After that, I think what we need to focus on is what is the research and what does it tell us?

I look forward to the testimony. Thank you.

The CHAIRMAN. Thank you, Senator Alexander.

I know that Senator Whitehouse has to leave shortly and maybe Senator Burr; I do not know, but you wanted to make a short statement. I will recognize Senator Whitehouse.

STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. I appreciate the chairman recognizing me for 1 minute.

We have two wonderful witnesses here from the FDA and from the CDC. But I wanted to make the point, as a Senator from Rhode Island, that there has been some very important corporate leadership in this area of reducing access to the No. 1 cause of preventable deaths, which is tobacco. And that comes from CVS Caremark, a company headquartered in Woonsocket, RI. They are a very significant pharmacy chain across the country.

Larry Merlo, the CEO, and his management team, has made the decision to phaseout the sales of tobacco products by October 1st of this year, and I think that is an important and commendable step. And I just wanted to have that be a part of the record of this hearing.

The CHAIRMAN. Thank you very much, Senator Whitehouse.

Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Mr. Chairman, I never miss an opportunity to say something when given the opportunity, and since I feel like I have lived with this issue as long as anybody in Congress, now 20 years.

And Mr. Zeller, thank you for the job you are doing over there. A newly created agency. Very, very tough to get up and run it.

But Mr. Chairman. I can remember when opportunities for harm reduction were the goal, and it could not be achieved because the technology did not allow us to get there. I remember when R.J.

Reynolds spent several decades and came out with a product that, I guess, was a precursor to some degree of the electronic cigarette, even though it operated differently, and Mr. Zeller, you might remember that.

And there became a real opportunity for individuals to use a product that got what they were looking for without a combustible. And how quickly we have moved to a point where now harm reduction is no longer a goal and technology now allows us to get there. It allows us to field products, and trust me, Mr. Chairman, we can work out these things about flavors and all of this.

But for God's sakes, let us not say we are not going to let technology play part of the process of taking more Americans off of using combustible tobacco products. And I look at the pool that was available to us when gum came out. We were ecstatic because this gave the ability for some people to break the cycle of combustible tobacco products for them.

Then the patch came out. Not everybody could do the gum. Not everybody can do the patch. And now, we have electronic cigarettes. Rather than kill this before we know what we have got, and I am right with the chairman, let us do the science. I think Mr. Zeller is attempting to do that. I know the job that is in front. I know the statutory requirements. Let us let him do it.

But let us not condemn where the technology has gone before we ever had an opportunity to see, in fact, what effect this can have on pulling people off of combustible tobacco products.

So I hope the committee and I hope the FDA puts as much stock in harm reduction in how we get people off of something that is not as safe to a product that is safer. This is, for some people, not eliminating access. It is eliminating a product category. It has been for 20 years and nothing has changed today, and that is fine.

But as long as I am a member of the committee, Mr. Chairman, I am going to fight for the American people to have a right to make a choice, and for Mr. Zeller to determine what those choices are going to be within reason. And I encourage you to continue the job you are doing.

I hope that our policies reflect an opportunity for the American people to make a decision based upon what technology is available to choose a reduced harm product which, I think, many of the categories we see today are beginning to move toward.

I thank the chairman.

The CHAIRMAN. Thank you, Senator Burr.

We will start with our first witness, Dr. Tim McAfee. He is the Director of CDC's Office on Smoking and Health within the National Center for Chronic Disease Prevention and Health Promotion. He directs all science, policy, and programming on tobacco control and prevention.

Dr. McAfee is a family physician who practiced for more than a decade and served as a clinical faculty member at the University of Washington Family Medicine and School of Public Health.

And Dr. McAfee also authored the World Health Organization's Tobacco Quit-Line Manual for low- and middle-income countries. Thank you for being here, Dr. McAfee.

And then after Dr. McAfee, we will recognize Mr. Mitch Zeller, who is the Director of the Center for Tobacco Products where he

leads the FDA's efforts to reduce disease and death from tobacco use and to develop regulations for a variety of tobacco products.

Mr. Zeller has been working on FDA issues for more than 30 years. He served as Associate Commissioner and Director of FDA's first office of Tobacco Programs. And prior to rejoining the FDA in 2013, Mr. Zeller worked on tobacco control as executive vice president of the American Legacy Foundation, and as senior vice president at Pinney Associates. And we thank you for being here also, Mr. Zeller.

Both of your statements will be made a part of the record in its entirety. And we would ask if you could just sum it up in just 5 minutes or so, we would appreciate it, and then we can get into a discussion.

Dr. McAfee, welcome. Please proceed.

STATEMENT OF TIM McAFEE, M.D., MPH, DIRECTOR, OFFICE ON SMOKING AND HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. MCAFEE. Thank you very much, Chairman Harkin and Ranking Member Alexander, and members of the committee for their statements previously.

It is an honor to provide this statement to you. I want to thank Chairman Harkin for his leadership and also recognize this committee's bipartisan history of support on tobacco control.

As noted, my name is Dr. Tim McAfee, and I serve as the Director of the Office on Smoking and Health at the Centers for Disease Control and Prevention, and I am also a physician.

Today, I will discuss, briefly, the past, present, and future of tobacco control drawing on findings and recommendations, primarily from the 50th Anniversary Surgeon General's Report on Tobacco and Health.

Fifty years ago, half of the men and one-third of the women in this country smoked cigarettes. Tobacco companies could advertise everywhere, including TV, and school children carried lunch boxes with cigarette logos. Smoking was common in public places.

Today, the landscape is already dramatically different. Adult cigarette smoking has fallen from 42 percent in 1965 down to 18 percent today. And tobacco prevention and control measures saved 8 million lives over the last 50 years.

Today, half of our States prohibit smoking in worksites, restaurants, and bars. And on TV, we now see the real consequences of smoking through CDC's Tips from Former Smokers campaign. These hard-hitting ads show real people fighting serious disease and disability from smoking. In their first year, the ads led 1.6 million Americans to make a quit attempt, and over 100,000 to quit for good.

Now, despite enormous progress, every day, over 3,000 children under age 18 smoke their first cigarette. Smoking-related deaths approach half a million a year in the United States, and another 16 million Americans suffer from serious smoking-related disease.

The 2014 Surgeon General's report concluded that,

> "The tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which deliberately misled the public on the risks of smoking."

In addition to making their products powerfully addictive, the tobacco industry spends nearly $1 million an hour on promotions. They are developing products such as the fruit- and candy-flavored little cigars and electronic cigarettes. Little cigars, which are similar in size and shape to cigarettes, appeal even more to youth than adults because of their flavors and lower prices.

Responses to our surveys showed cigar use among non-Hispanic black students in 2012 is nearly double the rate observed in 2009. And cigarette use among all twelfth graders surged in recent years to levels that we have not seen in over a decade.

And e-cigarettes are heavily marketed on TV and radio, and some marketing includes unproven health claims and themes proven to appeal to youth. As a result, nearly 1.8 million students in grade 6 through 12 reported trying an e-cigarette in 2012.

There are now hundreds of e-cigarette products ranging from disposables that look like cigarettes to tank devices that are refillable, adjustable, and they allow for use of other drugs besides nicotine.

FDA's deeming proposal could establish important regulatory requirements and allow for more comprehensive protections as we move forward. However, FDA regulation alone is insufficient and this process will take time. That is why many States and cities across the country are folding e-cigarettes into clean indoor air policies and enacting bans on e-cigarette sales to minors.

Now, what are the many risks with e-cigarettes? The fact that e-cigarettes exist and are being marketed by some tobacco companies as being the same as cigarettes, but safer, is a dramatic shift. According to the Surgeon General's report, e-cigarettes could be beneficial if they are completely substituted for burned tobacco and could assist in a rapid transition to a society with little or no use of burned tobacco products.

As we consider these issues, we must not forget that burned tobacco products are overwhelmingly responsible for tobacco-related death and disease. Yet today, cigarettes remain cheap, ubiquitous, and heavily marketed. They appeal to children, kill half of longtime users, and are addictive by design. If current rates of smoking continue 5.6 million American children under the age of 18 will die early because of smoking.

Now, the good news is we know a great deal about what works and we also have a regulatory framework to accelerate our progress. The bad new is we are not doing enough of what works, like 100 percent smoke-free policies, higher prices, access to cessation treatments, hard-hitting media, and State-based tobacco control programs.

The progress we have made is due to efforts from across our society including, as noted, from companies like CVS, which stopped selling tobacco products in October and the thousands of businesses that are helping their employees quit smoking.

Working together, we can help Americans live longer, healthier lives. We can prevent 1 in 3 cancer deaths, save our economy $300 billion annually, and prevent half a million premature deaths a year.

Thank you for the committee's attention to this important matter, and I am happy to answer any questions you may have.

[The prepared statement of Dr. McAfee follows:]

PREPARED STATEMENT OF TIM MCAFEE, M.D., MPH

SUMMARY

Fifty years ago, half of the men and a third of the women in this country smoked cigarettes. Tobacco companies advertised everywhere and smoking was common in almost all public places, including hospitals. Today, however, the landscape is different. Tobacco prevention and control measures have saved an estimated eight million lives over the last half-century.* In fact, the success of the tobacco-control movement constitutes one of the greatest public health achievements of the 20th century.

Despite enormous progress, the tobacco epidemic still rages on—in every community and in every corner of our country. The Surgeon General has concluded that combusted—or burned—tobacco products, such as cigarettes, cigars, and pipes, are overwhelmingly responsible for the burden of death and disease from tobacco use in the United States.† And new, novel tobacco products pose challenges to research, surveillance, health policy, and regulation because they vary so widely in form, mode of use, contents, designs and emissions, potential health effects, and marketing claims.2

To accelerate declines in tobacco use, the 2014 Surgeon General's Report emphasizes the effectiveness of comprehensive approaches to tobacco control that apply a mix of educational, clinical, regulatory, economic, and social strategies to: prevent initiation of tobacco among youth and young adults; promote quitting among adults and youth; eliminate exposure to secondhand smoke, and identify and eliminate tobacco-related disparities among population groups. While these evidence-based strategies are currently underutilized, CDC along with other Federal agencies, States and communities are taking steps to change that dynamic. Real progress in tobacco control will require commitment and effort across all sectors of our society including the business sector.

If we end the tobacco-use epidemic, we can prevent one out of three cancer deaths in this country and save our economy nearly $300 billion a year in medical costs and economic losses.‡

Chairman Harkin, Ranking Member Alexander, and members of the committee, it is an honor to provide this statement for today's hearing on progress in tobacco prevention and control. Fifty years ago, half of the men and a third of the women in this country smoked cigarettes. Tobacco companies advertised everywhere, and school children carried lunch boxes and wore baseball caps branded with cigarette logos. Except for churches and grade school classrooms, smoking was common in almost all public places, including hospitals.

Today the landscape is different. Tobacco prevention and control measures have saved an estimated eight million lives over the last half-century.[1] In fact, the success of the tobacco-control movement constitutes one of the greatest public health achievements of the 20th century. Adult smoking rates have fallen from about 43 percent in 1965 to about 18 percent today.[2] The latest surveys show that cigarette smoking rates among high school students are at the lowest in our history of measuring them. Most indoor workplaces are smoke-free and over half of States prohibit smoking in other indoor areas of public places such as restaurants, bars, and airports.[2] Colleges and universities have embraced these policies, and many have adopted smoke-free and tobacco-free campuses, indoors and out. Instead of images of glamorous people enjoying a cigarette, today we see the real health consequences of smoking through *Tips from Former Smokers*, the first federally funded anti-smoking national media campaign in the United States, which was initially established through the Prevention and Public Health Fund. These hard-hitting ads pull back the curtain to reveal real people fighting serious diseases and disabilities because they smoked, and in their first year led 1.6 million Americans to make a quit attempt and 100,000 quit for good.[3]

However, we are far from the finish line. Despite enormous progress, the tobacco epidemic still rages on—in every community and in every corner of our country.

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* Holford TR, Meza R, Warner KE, Meernik C, Jeon J, Moolgavkar SH, Levy DT. Tobacco control and the reduction in smoking-related premature deaths in the United States, 1964–2012. *JAMA: the Journal of the American Medical Association* 2014.

† Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta (GA), Centers for Disease Control and Prevention (U.S.).

‡ U.S. Department of Health and Human Services (2014). Let's Make the Next Generation Tobacco-Free: Your Guide to the 50th Anniversary Surgeon General's Report on Smoking and Health. Available at: *http://www.surgeongeneral.gov/library/reports/50-years-of-progress/*. Accessed May 5, 2014.

Every day, more than 3,200 children under age 18 smoke their first cigarette, and another 2,100 youth and young adults who are occasional smokers become daily smokers.[2] Smoking-related deaths now approach half a million a year in the United States, and another 16 million Americans have at least one serious smoking-related disease.[2] One-third of all cancer deaths are caused by smoking, including the vast majority of lung cancers—the leading cause of cancer death in our Nation for both men and women.[2]

Progress in reducing the disease and death caused by the tobacco epidemic has not been consistent across all populations. The burden of smoking now falls disproportionately on some of our most vulnerable populations—the poor, some racial and ethnic minorities, some members of the gay and lesbian community, and those living with mental illness and substance use disorders.[2]

This entirely preventable public health tragedy did not occur by accident. The Surgeon General concluded that "the tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which deliberately misled the public on the risks of smoking cigarettes."[2] Today's cigarettes contain over 7,000 chemicals and chemical compounds—over 70 of which are known to cause cancer.[4] They are designed to addict their users quickly and heavily, speeding a jolt of nicotine to receptors in the brain in as little as 10 seconds after the smoke is inhaled.[5] The adolescent brain is especially sensitive to nicotine and teens become dependent on nicotine more quickly than adults.[6] In fact, nicotine will cause three out of four teen smokers to become adult smokers—even though most say they plan to quit in a few years.[2] Prevention and intervention in the teen and youth years is important because nearly 90 percent of adult smokers say they started before they were 18 years old.[2]

In addition to making their products powerfully addictive, the tobacco industry spends $8 billion annually—nearly a million dollars an hour—to advertise and market cigarettes and smokeless tobacco.[2] They outspend current State tobacco-control programs by a factor of 18-to-1.[7] In the United States, the tobacco industry recruits customers to consume over 14 billion packs of cigarettes a year.[8] Marketing and glamorization of tobacco products remains widespread. Despite causal evidence that depictions of smoking in the movies lead to smoking initiation among young people, movies remain one of the largest unrestricted traditional media channels promoting smoking and tobacco use to youth. In fact, tobacco incidents in PG–13 rated top-grossing U.S. movies surged 98 percent from 2010 to 2012.[2]

The Surgeon General concluded that combusted—or burned—tobacco products, such as cigarettes, cigars, and pipes, are overwhelmingly responsible for the burden of death and disease from tobacco use in the United States.[2] Cigarettes carry the highest risk of addiction following initiation.[2] This is due to cigarette designs that facilitate efficient and tolerable inhalation of nicotine-laden toxic smoke deep into the lung.[2] In addition to cigarettes, there is an increasing array of combustible and noncombustible tobacco products on the market. New, novel tobacco products pose challenges to research, surveillance, health policy, and regulation because they vary so widely in form, mode of use, contents, designs and emissions, potential health effects, and marketing claims.[2] Combustible product lines include fruit- and candy-flavored little cigars and cigarillos, which are about the same size and shape as cigarettes. These are of particular concern because their flavors and low pricing relative to cigarettes (largely attributable to differential tax treatment) are appealing to young people. In fact, research surveys have found that high school boys are smoking cigars at the same rate as cigarettes.[2]

Noncombustible product lines include smokeless tobacco, dissolvable tobacco products, and the increasingly prevalent electronic nicotine delivery systems (ENDS). ENDS, including e-cigarettes, e-hookahs, hookah pens, vape pens, e-cigars, and others, are battery-powered devices that provide doses of nicotine and other constituents to the user in an aerosol. ENDS contain nicotine, which is addictive, toxic to developing fetuses, and may have lasting consequences for adolescent brain development.[2] Potentially harmful constituents also have been documented in some ENDS, including: irritants, toxicants that can change genes, and other ingredients that have been shown to cause cancer in animals.[9] ENDS are not "safe," and because of the known risks associated with nicotine, the Surgeon General specifically cautions against their use by young people and pregnant women.[2] ENDS could be less dangerous for the smoker to use than conventional cigarettes or other combusted tobacco products if and when used by established adult smokers as a complete substitution for cigarettes[2] However, the consequences of long-term use of ENDS are unknown.

In 1971, the tobacco companies stopped advertising cigarette and smokeless tobacco products on television and radio. This had a lasting impact on deglamorizing smoking.[10] But now, electronic nicotine delivery systems are being heavily marketed

on television and radio. The 2014 Surgeon General's Report observed that ENDS marketing "has included claims of safety, use for smoking cessation, and statements that they are exempt from clean air policies that restrict smoking." Moreover, some ENDS marketing uses tactics which the Surgeon General has found lead to youth smoking:[5] candy-flavored products; youth-resonant themes such as rebellion, glamour, and sex; and celebrity endorsements and sports and music sponsorships. This is of concern because the Surgeon General has found that "many changes in tobacco product form and marketing have been documented as efforts by the tobacco industry to contribute to tobacco use and addiction by fostering initiation among young people; making products easier and more acceptable to use; making and marketing products so as to address health concerns; and making and marketing products to perpetuate addiction through the use of alternate products, when smoking is not allowed or is socially unacceptable." [2]

These actions appear to be successfully recruiting adult and youth ENDS users. Results from the HealthStyles survey suggest that adult e-cigarette experimentation nearly doubled from 2010 (3.3 percent) to 2011 (6.2 percent)[2] In 2012, approximately 1.8 million students in grades 6–12 reported ever trying an e-cigarette.[11] We do not yet know the long-term health effects that may result from use of ENDS, or the consequences of exposure to secondhand aerosol for bystanders. The recent Surgeon General's Report on smoking and health says that ENDS will cause harm if they:

- Encourage nonsmoking youth or adult non-smokers to start using them and become addicted to nicotine,
- Entice former smokers to relapse,
- Delay current smokers from trying to break their nicotine addiction altogether, or
- Encourage dual use of combustible tobacco products and electronic devices.[2]

Additional risks include:

- The potential for ENDS to expose bystanders involuntarily to aerosolized nicotine, and
- Accidental poisonings resulting from ingestion or absorption through the skin of liquids containing high concentrations of nicotine.

While we respond to the new challenges and opportunities presented by ENDS, we must remember that cigarettes and other combusted tobacco products are overwhelmingly responsible for the burden of tobacco-related death and disease in the United States. Cigarettes remain cheap; ubiquitous; heavily marketed; appealing to children; "unreasonably dangerous, killing half of long-term users; and addictive by design." [2] Every adult who dies prematurely from smoking in this country is replaced by two younger smokers who have been recruited to sustain the epidemic.[2] In fact, if current rates of smoking by youth and young adults continue, 5.6 million American children under age 18 will ultimately die early because of smoking.[2]

How do we accelerate the decline in the use of these deadly products? The good news is that we know a great deal about what works. The 2014 Surgeon General's Report emphasizes the effectiveness of comprehensive approaches to tobacco control that apply a mix of educational, clinical, regulatory, economic, and social strategies to:

(1) prevent initiation of tobacco among youth and young adults,
(2) promote quitting among adults and youth,
(3) eliminate exposure to secondhand smoke, and
(4) identify and eliminate tobacco-related disparities among population groups.

Unfortunately, the Surgeon General concluded that these evidence-based strategies are currently underutilized, but we are taking steps to change that dynamic:

- We know that a 10 percent increase in cigarette prices cuts consumption by 4 percent in adults, and by even more for youth.[6] Yet many States have excise taxes of less than a dollar on a pack of cigarettes—and as a result, have higher smoking rates and higher medical costs to treat smoking-related disease relative to States with lower excise taxes. The fiscal year 2014 and fiscal year 2015 President's Budgets propose a 94 cent per-pack increase in the Federal excise tax on cigarettes, which has the potential to prevent at least 450,000 premature deaths of children alive today.
- We know that over half of current cigarette smokers want to quit and at least half will try to quit this year—the Affordable Care Act expanded access to smoking-cessation services and requires most insurance companies to cover cessation interventions. Integrating cessation help into behavioral health treatment will improve cessation rates, treatment retention, and outcomes for individuals with mental illness—a group disproportionately affected by tobacco use.

• We know that hard-hitting media campaigns such as CDC's *Tips from Former Smokers* have the potential to motivate even more smokers to quit successfully if they are sustained, as the Surgeon General recommends, at a high frequency for 10 years or more. The Affordable Care Act's Prevention and Public Health Fund supported the creation of this innovative campaign, which already has helped tens of thousands to quit smoking.

• We know that smoke-free policies protect nonsmokers from the dangers of secondhand smoke without harming businesses. Through the Office of the Assistant Secretary for Health's Tobacco-Free College Campus Initiative, the number of smoke-free campuses increased 73 percent from 772 in 2012 to 1,343 in 2014. More work remains, as close to 90 million non-smokers, including over half of children between ages 3 and 11—continue to be exposed to this known carcinogen. This year, 41,000 Americans will die from a disease caused by this exposure.[2]

• We know that adequately funded, comprehensive, statewide tobacco control programs help inform tobacco-free social norms throughout communities and lower smoking rates and health care costs. CDC continues to invest in these State-based efforts through the National Tobacco Control Program. Yet States will spend less than 2 percent of the more than $25 billion they receive in tobacco revenues this fiscal year on tobacco control.[5]

At the Federal level, the work at the Food and Drug Administration to implement the landmark Family Smoking Prevention and Tobacco Control Act of 2009 is critical to further progress, and we are pleased to work in close partnership with FDA on the work described in its testimony today. CDC, FDA, and the National Institutes of Health are also partnering to fill critical research gaps.

We also know that States and cities are taking action—implementing smoke-free indoor air policies, raising minimum age requirements for tobacco purchases, and putting policies into place to minimize potential harms of e-cigarettes. For example:

• Over half of States already prohibit e-cigarette sales to minors, as FDA is proposing in its deeming rule. Some are enforcing those policies through licensing requirements and penalties for violations.

• Three States prohibiting e-cigarette use in places where smoking is prohibited such as restaurants, bars, and worksites.

As part of the National Prevention Council, agencies across the Federal Government are undertaking important commitments to promote tobacco-free living. For example, the Department of Housing and Urban Development is increasing access to smoke-free multi-unit housing for residents.[12] Within the Department of Defense, efforts are underway to prevent and reduce tobacco use on DOD installations to promote health and mission readiness, help tobacco users quit, and lead by example for all workplaces. In addition, the U.S. Department of Veterans Affairs health care system provides evidence-based tobacco cessation counseling and FDA-approved medications for Veterans enrolled in care, including a national smoking cessation quitline and a mobile texting program, in collaboration with the National Cancer Institute. These and other initiatives have extended the reach of tobacco use treatment to Veterans nationally.

CDC and the Department of Health and Human Services are committed to providing agencies with technical assistance and support as they implement these critical, but often challenging commitments. As resources permit, CDC is also committed to increasing the frequency of its high-impact *Tips from Former Smokers* campaign; conducting cutting-edge research and surveillance to monitor the rapidly changing landscape of tobacco control; powering comprehensive tobacco control programs in States, tribes, and territories with resources and technical assistance, and expanding access to barrier-free tobacco-cessation treatment, including through 1-800-QUIT-NOW.

Real progress in tobacco control will require commitment and effort across all sectors of our society—not just local, State, and Federal agencies. One important partner will be the business community, and we are seeing some important movement in this sector. A striking example is the decision by CVS pharmacies to stop selling tobacco products in all their stores. Employee well-being and productivity also serve as motivators for business engagement. In addition to providing insurance coverage for smoking cessation, many large companies offer their employees free help to quit on the job, with cessation classes and support groups available throughout the work day. And smoking cessation as an important part of corporate wellness programs is spreading to smaller companies as well. Public health and tobacco-control stakeholders are working together with business leaders around the country to identify other opportunities for progress.

If we end the tobacco-use epidemic, we can prevent one out of three cancer deaths in this country.[13] We can prevent 480,000 premature deaths a year from smoking-

related illnesses.[13] We can prevent a third of heart disease cases, 80 percent of chronic obstructive pulmonary disease cases, and over 90 percent of lung cancer cases.[13] We can keep 400,000 babies every year from being exposed to the chemicals in cigarette smoke before they are even born.[13] We can save our economy nearly $300 billion a year in medical costs and economic losses.[13] And we can help individual men and women live longer, healthier lives and avoid the pain and suffering that are a part of preventable diseases caused by smoking.

Thank you.

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The CHAIRMAN. Thank you very much, Dr. McAfee.

Mr. Zeller, please proceed.

STATEMENT OF MITCH ZELLER, J.D., DIRECTOR, CENTER FOR TOBACCO PRODUCTS, U.S. FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Mr. ZELLER. Thank you, Chairman Harkin, Ranking Member Alexander, Senator Burr, other members of the committee for the opportunity to testify today.

I am Mitch Zeller, Director of FDA Center for Tobacco Products, or CTP as we call it, and I am honored to be here today to discuss FDA's activities in implementing the Family Smoking Prevention and Tobacco Control Act since it was signed into law in June 2009.

Next month, marks the 5-year anniversary of the Tobacco Control Act, a law that gave FDA comprehensive tools to protect the public from the harmful effects of tobacco use through science-based tobacco product regulation.

Since the Act became law in 2009, we have made significant progress toward establishing a comprehensive, effective, and sustainable framework for tobacco product regulation.

Our first priority was the creation of the Center for Tobacco Products, the first new center at FDA in 21 years. CTP has grown from a handful of employees in the fall of 2009 to nearly 500 employees today.

During our startup phase, even as the Center was establishing itself, creating infrastructure, hiring appropriate personnel, we were required by law to meet more than 20 mandatory, statutory deadlines. We were also required to assess user fees, establish the Tobacco Products Scientific Advisory Committee, known as TPSAC, and refer initially issues to TPSAC for consideration, and the Center met nearly all of these many deadlines.

CTP's main responsibilities include reviewing new product submissions, developing the science base for product regulation, enforcing the law, issuing regulations and guidance for industry, and educating the public about the risks associated with tobacco product use. And I would like to briefly touch on each of these.

CTP is committed to carefully and thoroughly reviewing all tobacco product submissions in a consistent, transparent, predictable, and timely way. And we recently established performance measures that include timeframes for review of many of the submissions we receive.

As a regulatory agency, we can only go as far as the regulatory science will take us. CTP funds and uses scientific research to better understand tobacco products, how the differences in products change the behavior of users and nonusers, and how to best reduce the harm from these products.

We partner with the National Institutes of Health and the Centers for Disease Control and Prevention, as well as with FDA's own National Center for Toxicological Research to advance the regulatory science base.

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 review of tobacco promotions, advertising, and labeling. CTP also provides compliance education and training to regulated industry.

In February, we launched a national public education campaign called the Real Cost to prevent youth tobacco use and reduce the number of teens who become regular smokers. The campaign uses compelling facts and vivid imagery designed to change beliefs and behaviors over time, to educate youth about the dangers of tobacco use, and to encourage them to be tobacco-free.

We have faced some challenges in the 5 years since CTP was created including the growing pains inherent in building a regulatory body from the ground up. We have worked through the logistical challenges of creating a brand new organizational structure, hiring qualified staff, developing the processes, procedures, and even the dedicated IT resources to carry out CTP's important regulatory functions.

Regulating tobacco products is markedly different from other products traditionally regulated by FDA. Now, our responsibility is unprecedented. No other country has tasked a regulatory agency to evaluate new tobacco products before marketing based on public health criteria. And we have also had to create a tobacco retail compliance program that is unique even within FDA.

Moving forward, we intend to sustain the momentum needed to achieve our goal of reducing the harms and risks associated with tobacco product use.

I would like to close on a more personal note. After 13 years out of Government, I returned to public service in March of last year to direct the Center for Tobacco Products. The main reason I returned to FDA was the public health opportunity to help use the product regulation tools Congress and the President granted the Agency in the Tobacco Control Act to help reduce the death and disease from tobacco use.

The reality is that roughly 1 in 5 adults still smoke, and we will explore all available regulatory options to reduce the harm caused by tobacco products.

But perhaps our greatest opportunity to overcome this pressing public health problem is to dramatically decrease the access and appeal of tobacco products to youth. We intend to use the many tools at our disposal to help make the next generation tobacco-free.

I thank the committee for its efforts and I am pleased to answer any questions.

Thank you.

[The prepared statement of Mr. Zeller follows:]

PREPARED STATEMENT OF MITCHELL ZELLER, J.D.

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 nonusers. 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.

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.

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[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*.

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 5 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 startup 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 3 years after the law went into effect. Therefore, even as the Cen-

ter 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 5 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]
- *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

[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 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.

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]

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 nonusers 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

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

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.

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 Web site, 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 fiscal year 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 timeframes 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.

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

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 5 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 terri-

torial 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 followup compliance check inspections; and
- Developing an online searchable data base 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 Web sites 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 Web sites and more than 74,000 publication issues where regulated tobacco products might be sold, distributed or advertised.
- 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 Web site 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 Web page, e-mail address, and staff to assist small businesses with their questions, comments, and concerns.

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

"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.

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 timeframe, 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 prob-

[7] Was not supplied.
[8] Was not supplied.
[9] See *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/PublicEducationCampaigns/TheRealCostCampaign/ucm384305.htm*.

lem, 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.

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 5 years since enactment of the Tobacco Control Act. I am happy to answer questions you may have.

The CHAIRMAN. Thank you very much, Mr. Zeller.

Now, we will open rounds of 5 minute questions.

Dr. McAfee, I will start with you. We both already mentioned the hard-hitting and incredibly effective Tips from a Former Smoker campaign created using resources from the Affordable Care Act's Prevention and Public Health Fund; I mentioned that in my statement.

The outcomes of this campaign, at least what I have seen, have been extraordinary. You mentioned more calls to the quit lines. I think you said 1.6 million calls. More quit attempts mean ultimately more long-term quitters.

Can you, again, just elaborate on CDC's work on this campaign? How did they decide on messages? What evidence do you have that your message is effective? And then last, is there a difference between the CDC media campaign, Tips from a Former Smoker, and FDA's media campaign, the Real Cost?

Dr. MCAFEE. Thank you very much, and please feel free to, if I do not remember each one of the ones that you asked about, to refresh my memory.

As you noted, Chairman Harkin, the campaign has been remarkably successful. The 1.6 million figure was actually the number of people who made a quit attempt because of the campaign just in the first year of the campaign. We also saw concurrently, we are now in our third year now, and we have also seen doublings in calls to the national 1-800-QUIT-NOW telephone number. And as much as fivefold increases in visits to the website of the campaign. So we are very excited by this. We are particularly excited about

[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*.

[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*.

the very specific information about quit attempts that we saw with the campaign.

We also saw increases in nonsmokers, millions of whom said that they had actually talked to a loved one who smoked and encouraged them to get help quitting.

I think one of the reasons, however, that we were not surprised by these results is that we put a lot of work in up front. First, reviewing all the information from other countries' and other States' experiences that had done campaigns.

And then working with literally thousands of smokers asking them, "What would be most helpful to you to make a quit attempt a successful quit attempt?" And we designed the campaign through several cycles of trying out our ideas and then checking back with smokers to see what they said. And they were very firm that this was the type of campaign that they wanted.

We have also seen, 80 to 90 percent of smokers say that they have seen the ads. So we are feeling very, very strong about the response that we have had. I would just also mention that Terrie Hall from North Carolina, who died in September at 53, was our real poster child. Of the 30 people, Americans, that stepped up, very difficult step to show, to put a face on what the harms of smoking will cause.

In terms of your question about FDA and CDC.

The CHAIRMAN. Yes, the two different approaches.

Dr. MCAFEE. Yes. We are really in different swim lanes because the CDC program is focusing on adult smokers and encouraging them to quit. That is its laser focus. And the FDA's campaign, which Mr. Zeller can talk more about, but we are actually quite excited about the work that they have been doing, is also laser focused on youth in initiation and trying to keep experimenters from consolidating. So we are doing very different things.

And the other thing to keep in mind is both campaigns combined represent, in terms of the amount of promotional effort that we are able to make, represents about 5 days out of a year of what the tobacco companies are spending, $8.5 billion.

The CHAIRMAN. You are talking about both combined?

Dr. MCAFEE. Yes, both ours combined, both the FDA and CDC's campaign. Ours is——

The CHAIRMAN. About 5 days out of——

Dr. MCAFEE. Three hundred and sixty-five.

The CHAIRMAN. Three hundred and sixty-five that would be funded by the tobacco companies.

Dr. MCAFEE. Right.

The CHAIRMAN. Mr. Zeller, in my brief time, again, just elaborate a little bit on the Real Cost.

Mr. ZELLER. Sure. Unfortunately, too many kids experiment with cigarettes each day for the first time, over 3,000 and over 700——

The CHAIRMAN. A day?

Mr. ZELLER. Each day and each day, over 700 kids make the progression from experimentation to becoming regular smokers.

The good news is compared to 20 years ago, those numbers are down. The bad news is those numbers are still unconscionably high from a public health perspective.

There are 25 million 12- to 17-year-olds in our entire country and from the research that we did and we spent 2 years doing research before we launched the Real Cost campaign in February.

What we came to understand is that there is about 10 million of those 25 million teens who are at-risk. We call them being, literally, one party away from taking that first puff or they have already started to smoke a few cigarettes, and they are on that trajectory to becoming regular smokers. And from our research, we developed insights into how to communicate to these kids in ways that will breakthrough.

The initial launch of the campaign is focused on the health consequences of smoking and addiction, but we do not talk to them like an adult lecturing a child about, "Do not smoke and here are the long term risks."

It turns out that if you talk to at-risk kids about premature skin wrinkling or gum disease and tooth loss. And if—instead of talking to them about nicotine and addiction—you talk to them about loss of control if they become addicted to cigarettes, that enables them to hit the pause button; that enables them to rethink their relationship with the cigarette. We also made a major investment in evaluation, so we will see how we are doing over time.

It starts with building awareness. That will lead to changes in attitudes and belief, and then ultimately changes in behavioral intent and behavior. And we have made the investment in the evaluation to follow 8,000 of our target over the next couple of years to see how we are doing.

The CHAIRMAN. Very good. Thank you both very much.

Senator Alexander.

Senator ALEXANDER. Mr. Zeller, on one point, I think you are correct that premium cigars should be treated differently. I support the option and the regulation that would exempt premium cigars from FDA regulation. I introduced legislation like that some time ago. I believe people ought—adults—ought to be able to make their own choices.

And I had a couple of questions, how would this price of $10 at retail work? What if one retailer sold a cigar at $9.99? What would that do?

Mr. ZELLER. Let me just clarify one thing, Senator. We have proposed regulatory options on cigars.

Senator ALEXANDER. Yes.

Mr. ZELLER. And one of the options is to exempt premium cigars.

Senator ALEXANDER. Right.

Mr. ZELLER. The other is to include them, and we are in a rulemaking period now, and we need to wait for all the comments to come in, and we will then consider our regulatory options, in large part, informed by the information that comes in.

Senator ALEXANDER. But you cannot comment on how it would work?

Mr. ZELLER. No. I just want to say, I do not want to prejudge what the outcome of the rulemaking would be.

Senator ALEXANDER. No, I was trying to prejudge it a little bit.

Mr. ZELLER. Which are free to do and I am not.

Senator ALEXANDER. Right. I understand.

Mr. ZELLER. But to your question about the price point, in the option that we laid out where premium cigars would be exempted, there would have to be a definition of premium cigars.

Senator ALEXANDER. Right.

Mr. ZELLER. So that we would know what is in.

Senator ALEXANDER. And if the price point seems to be, that might not work very well.

Mr. ZELLER. We have asked for comment on every aspect of the definition including the price point. And if people have a better way of us doing the price point than what we propose, which is $10 per cigar, we welcome information on the record. Absolutely.

Senator ALEXANDER. Are you open to considering extending the comment period?

Mr. ZELLER. We have received multiple requests——

Senator ALEXANDER. Yes.

Mr. ZELLER. For extensions of the comment period, which we are reviewing, literally, as we speak.

Senator ALEXANDER. I would encourage you to do that. I think it is more important to get this right, as you know very well, because of your background. This is an extensive, complex area.

Let me ask you a broader question. Where do you come down on this difference of opinion on e-cigarettes? David Abrams at the American Legacy Foundation, "The single biggest opportunity that has come along in a century to make the cigarette obsolete." That is one point of view.

Dr. Frieden, "Many kids are starting out with e-cigarettes and then going on to smoke conventional cigarettes."

Do we know enough to know yet what the impact of e-cigarettes is?

Mr. ZELLER. I need to answer as a regulator. We have proposed to extend our jurisdiction over electronic cigarettes that meet the statutory definition of a tobacco product.

We are also funding, literally, dozens of studies to answer all the questions that we have about e-cigarettes and right now, we have far more questions than answers about the safety of the product, about what is in the product, about what is in the vapor. We have questions about who is using the products and how they are being used. It is a very complicated subject.

Senator ALEXANDER. So you do not come down on either side yet as to whether it is tool; more important as a tool to help those who already smoke cigarettes to stop smoking or more dangerous as a tool to encourage kids to start smoking?

Mr. ZELLER. I think the only appropriate position for FDA to take at this point is they have the potential to do good and they have the potential to do harm. And we need answers to questions, which we are funding through research.

Senator ALEXANDER. When will you have enough answers to be able to make the kind of decisions that you are expected to make here?

Mr. ZELLER. The first step in the process is having regulatory authority over them. We do not need the answers to those questions to complete the deeming rulemaking that we launched several weeks ago.

But going forward, in terms of figuring out what regulatory policies and approaches should be applied to e-cigarettes, when they come within our regulatory reach, we need answers to those questions. Let me give you an example of one of the studies that we are funding.

We are spending a lot of money on what is called a longitudinal study following the same people over time. It is called the Population Assessment of Tobacco and Health and it is following, literally, tens of thousands of adolescents and adults. And over time, studies like that will begin to give us information that answers some of the behavioral questions: who is using the products, how they are being used.

We then need additional studies on the products themselves, product safety. There are a series of questions that have been raised about these liquid nicotine products and exposure to the nicotine in these liquid nicotine products.

When we have answers to those kinds of questions, we can figure out how to use the many regulatory tools that Congress has given the agency to figure out an appropriate regulatory framework to regulate e-cigarettes. But it starts with having the authority to regulate them, which is what the deeming proposal is all about.

Senator ALEXANDER. My time is up. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Alexander.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman.

Director Zeller, do you believe that some tobacco products present greater risks to individuals than other products?

Mr. ZELLER. Yes.

Senator BURR. OK. On the continuum of risk, do you believe that noncombustible tobacco products are more likely to reduce harm than a smoked form of tobacco for individuals who would otherwise be using a conventional cigarette?

Mr. ZELLER. The answer is that it depends upon who was using the product and how they are being used. You can take any noncombusting product, whether it is a smokeless tobacco product, an e-cigarette, and it really depends upon who is using them and how they are being used.

If we look at a subset of smokers who are otherwise unable or unwilling to quit, they are going to continue to smoke that pack of cigarettes. Half of them will die prematurely later in life from that decision. If we could get all of those people to completely switch all of their cigarettes for one of these noncombustible products, that would be good for public health.

But our job as the regulator is to figure out what is going on at the population level, and it includes the much larger group of smokers—not like the first group I defined—a much larger group of smokers who are concerned about their health, and who are interested in quitting. And what happens instead of those people completely substituting with a noncombustible product, they start using both. And then along the way, they wind up being less interested in quitting.

Then we would say, that might not be good for public health and our job is to figure out what the net is of all of those possible be-

haviors, including any initiation, which would not be good for public health, and then try to make regulatory policy on top of that.

Senator BURR. Mitch, for the adult that chose Nicorette 5 years ago, and they chewed the gum, and then they went out back and they had a cigarette. And they could not smoke at work, so they chewed the gum, and they went out back, and had a cigarette.

Does that mean that Nicorette is not a useful tool for that individual? It is only a useful tool if that individual uses it to quit?

Mr. ZELLER. Yes. I would absolutely concede that any of these products, at an individual level, can do good.

What is challenging for all of us dealing with the law that you gave us the responsibility to implement and enforce is the decisions that we have to make are not going to be made about what might be good for the theoretical individual. We have to have regulatory science to support decisions that inform what is happening at a population level.

So, we have to look at all possible behaviors.

Senator BURR. Yes, but if your trend line is this way, then the public health effect is better. You have less people using combustible products. You have more of those individuals that have either quit or they have gone to a reduced harm product that is good for public health.

And let me just say for the record, CVS eliminated their cigarettes. CVS still sells patches, Nicorette gum, probably all of the pharmaceutical products—Chantix and others—that aid in eliminating or reducing the rate of smoking. It is not like they threw out the whole category.

So take the retailer that sacrificed some large amount of sales, they still believe that risk reduction is an important thing for them to endorse. Would you agree?

Mr. ZELLER. I would answer it in this way, Senator. The products that you are referring to have been approved by FDA as safe and effective medications, and they have been on the market for over 30 years. There is a robust evidence base to know that those products work to help smokers stop smoking.

They are actually not approved for reduction. They are only approved for abrupt cessation, but there is a robust evidence base that shows that when marketed to help smokers quit, and when used properly, people can succeed.

By contrast, to go to the questions from Senator Alexander about what do you know and what you do not know, when it comes especially to e-cigarettes, there is a lot more that we need to know about the impact on reduction and the impact on cessation.

Senator BURR. I agree with you totally. But can you point to any new innovation where we know right at the beginning everything about it and that we could come to an assessment? Now, I am hopeful that through your studies, you find this product is safe. We do not want an unsafe product out there that contributes to a different problem.

But if you find that it is safe, are we going to say the same thing about e-cigarettes 10 years from now? "Jeez, the body of evidence says that this did a tremendous thing to moving people off of combustible tobacco products." Is that not a good thing?

Mr. ZELLER. If we are going to regulate them as tobacco products, which is what the Tobacco Center has proposed to do, we have to find the claims that the new products are appropriate for the protection of the public health. That is not the safety and efficacy standard.

Congress gave us a very different standard to use when using the tobacco authorities. And under the standard appropriate for the protection of the public health, it is that mix of behaviors that I was describing that we have to assess and then make regulatory policy based upon. It is complicated.

Senator BURR. I certainly look forward to the science that is produced on this. I just caution you and our friends at CDC that if we kill technology and innovation, which is, in essence, what some are attempting to do with electronic cigarettes right at the beginning. "Just stop it. No more. It should not be sold." Then innovation is not going to play a role in reducing the amount of Americans that smoke. It is just not.

I think it is safe to say that when I look at diabetes today, I look at other things that we would consider a public health epidemic, innovation is going to give us the ability to do it. I do not think it is going to be by going out and eliminating whether they can go to McDonald's and buy a double cheeseburger, and the CDC is not proposing that.

It is going to be innovation. It is going to be driving technology. It is going to be coming out with products that allow us to turn around the problem that they have.

I think that is what we are talking about here, and I look forward to the work you are doing.

Mr. ZELLER. Thank you.

Senator BURR. Thanks.

The CHAIRMAN. Thank you, Senator Burr. We will start another round.

Last month's proposal to expand FDA's authority to include more tobacco products marked an essential step forward. And while I was heartened by the release of this long-awaited proposal, I was also disappointed that the rule did not address some of the most egregious practices of e-cigarette manufacturers.

I mentioned in my opening statement that last month, along with 10 of my colleagues, I released the finding of our investigation into the marketing practices of nine commonly sold e-cigarette brands. To say those findings were disheartening, I think for me, is an understatement.

Among those findings, I know you will not be surprised to learn, that six of the companies reported that they market e-cigarettes in flavors that appeal to children and teens. Flavors like cherry crush, and chocolate treat, and peachy keen, and great mint.

Now, I would just say that anyone who claims that these products are not explicitly targeting kids is clearly blowing smoke. These are targeted to kids, not adults. I have some examples here.

Here is one I pointed out earlier: Rocket Pop. In fact, I have a chart. I had it blown up so you can take a look at it. Rocket Pop. It has got a popsicle on front. Now, can anybody say that they are trying to market that to adults?

The other one I have here, this is for that refill with pink spots is Gummy Bear. I do not think I have Gummy Bear, but it is there. Here is another one Cotton Candy. Here is for the refillables Cherry Crush. The one I had earlier was Apple Cranberry. Again, these are targeted to kids.

Congress knew what it was doing based upon, I think, evidence that we had that they were using flavors in cigarettes to go after kids. Forget about the prospect of whether e-cigarettes are good or bad for adults, and can this be a step towards cessation. We do not know all that yet, and that has got to be learned. But is it safe to say that, when you are talking about kids that maybe there ought to be some restriction on these to kids?

Dr. McAfee or Mr. Zeller, I guess, why did FDA feel it was important to hold off on restrictions on e-cigarette flavors and marketing when they are clearly targeting kids? Why did FDA hold off on that on the flavors?

Mr. ZELLER. I appreciate the question and the perspective, Mr. Chairman, and we share the concerns about any marketing of any of the currently unregulated products like e-cigarettes that would have an appeal to kids.

We need to have jurisdiction over them to do something about it, but in the preamble to the proposed deeming rule that would give us the authority to take regulatory action, we summed up all the evidence that we had about flavors. Then we asked a series of, what I think, are very profound and far-reaching questions that we want comment from, from all points of view on what role the presence of flavors like this should play as an influence on the regulatory policies that the Agency will be in a position to make when deeming is final, and we have the ability to use all manner of tools.

Technically, to ban flavors requires the issuance of something called a product standard under a different section of the statute; it is a separate rulemaking. But we need answers to the questions that we posed about what role should the flavors play in how these products are regulated.

The CHAIRMAN. Let me take a different line. Does FDA have authority to regulate drug delivery devices?

Mr. ZELLER. FDA first tried to regulate e-cigarettes as drug delivery devices and we were struck down by the courts in the absence of a cessation claim.

The very first action that FDA tried to take on e-cigarettes back in 2008 and 2009, before the Family Smoking Prevention and Tobacco Control Act passed, was an enforcement action to prohibit the importation of e-cigarettes as unapproved drugs and devices. We were sued by an importer and the importer won in court. And in 2011, we had to announce that we would create a regulatory framework for e-cigarettes under these tobacco authorities in the absence of a cessation claim.

The CHAIRMAN. I guess I do not understand it. Is nicotine generally recognized as a drug?

Mr. ZELLER. Yes.

The CHAIRMAN. It is an addictive drug, is it not?

Mr. ZELLER. It is.

The CHAIRMAN. Does not an e-cigarette deliver a nicotine vapor to your body?

Mr. ZELLER. We can make the assumption that it does. We need more information about that, but we can make the assumption that it does.

The CHAIRMAN. I mean, you puff on it and you get nicotine. I mean, what else would you do? You do not throw it on the ground. It is put in there and you inhale it.

Mr. ZELLER. I can only tell you what——

The CHAIRMAN. It is a delivery device.

Mr. ZELLER. I can only tell you what the courts ruled. We tried to regulate e-cigarettes in exactly that way and we were overruled by the courts.

In the absence of a claim, a medicinal claim, a therapeutic claim, the courts told FDA, the only way that we could regulate nicotine containing e-cigarettes was under the tobacco authorities, and that is because of a statutory definition of a tobacco product. It has two parts, something that is either made or derived from tobacco, and the nicotine in e-cigarettes is derived from tobacco.

The CHAIRMAN. Right.

Mr. ZELLER. And the courts said in the absence of a drug claim, the only way we could regulate tobacco-derived nicotine in these products was under the tobacco authorities.

The CHAIRMAN. The reason I had all these out here today, just to show the proliferation of the devices that are going to kids. Here is one that is 800 puffs, delivers something that is a can-apple.

It is interesting, they say on the back in fine print, it says—it is called an "electronic hookah",

> "Electric hookah" is not approved by the United States Food and Drug Administration. You must be of legal tobacco purchase age according to State law to purchase and use these products. This product has not been tested or proven to aid in smoking cessation and the product contains nicotine, which is an addictive and toxic substance and must not be used by pregnant or nursing women and nonsmokers. Keep this product out of reach of children."

But we know kids are getting them. They are buying them. They are proliferating among high school students. They are buying these fancy things here. They have a plug that goes into the wall. It looks like a computer plug. It has the little computer device that goes in there and you stick your thing in there and recharge it. They are rechargeable. I do not know what that costs. I am told this costs about $10 bucks and you get 800 puffs on $10 bucks. But these are all geared toward young people and I had that out just for show.

I heard you say we need a longer comment period. I do not know about that. Something has got to be done about this.

Mr. ZELLER. Let me tell you other parts of the proposal that would address the issue of youth use of these products. We proposed extending the minimum age of sale that currently exists for cigarettes, smokeless tobacco, and roll your own to e-cigarettes. And so retailers who sold e-cigarettes to minors, if this proposal goes final, would be violating our regulations and Federal law.

We have proposed to ban the sale of any of these products in vending machines to the degree that there are vending machine sales, unless it is in an adult-only establishment.

And on the issue of nicotine and addiction, we have proposed a warning label on all of these products that explains to the public that they contain nicotine and that nicotine is addictive. The comment period is the public's opportunity to make suggestions for additional things that we should be thinking of doing when our rule goes final.

The CHAIRMAN. That is interesting. This has a lot of that stuff I told you in fine print on the back, but none of this stuff does; nothing on it.

Mr. ZELLER. And that is because they are not currently regulated by FDA.

The CHAIRMAN. But it is concentrated nicotine, an addictive drug. I went way over my time. I will yield.

Senator ALEXANDER. Thank you, Mr. Chairman. I have no more questions, and I have an appointment that I have to go to. But I certainly have no objection to your continuing.

The CHAIRMAN. Do you mind if I continue?

Senator ALEXANDER. No, sir.

The CHAIRMAN. OK. Thank you very much. I want to change things here a little bit.

Dr. McAfee, one of the most startling findings of the recent Surgeon General's report was that cigarettes are more dangerous today than they were when the first Surgeon General's report on smoking was issued 50 years ago. That was startling.

The report indicates that cigarette smokers today have a higher risk for lung cancer than smokers in 1964 despite smoking fewer cigarettes. And that some, if not all, of this increased risk is likely caused by changes in the composition and design of cigarettes.

Can you explain ways in which these cigarettes are more dangerous?

Dr. MCAFEE. Sure. I would add that the other thing that I think we have found very disturbing around this, in some ways, unexpected finding, is that it does raise concerns about the ability of innovation to automatically lead to improvements in public health without regulation, because over the last 50 years, until the FDA got authority 4½ years ago, cigarettes were entirely unregulated.

The remarkable thing that happened was that the innovations that were put in place by—apparently some of the innovations that were put in place that affected composition and design of cigarettes did not lead to fewer deaths. Most of the innovations appear to have been more driven for other purposes.

And that the things that we have found, and a lot of this is basically driven by epidemiologic findings, is that despite the fact that we are smoking fewer cigarettes, a person who smokes in the United States is more likely to develop lung cancer than they were 30 or 40 years ago.

The CHAIRMAN. I am sorry. Excuse me.

Dr. MCAFEE. Sure. No problem. There has been a specific change that we absolutely think is related to changes in the design composition and that is that the type of cancer that people develop, the common lung cancer——

Way back when I was in medical school the most common form of lung cancer was squamous cell carcinoma, which was found close-in to the main branchings of the lung. And over the last few

decades, this has shifted to another kind of cancer called adenocarcinoma, which is located in the periphery of the lungs.

And we believe that this is due, essentially, to the fact that cigarettes, over the last 30 or 40 years, have become easier to inhale due to changes in their design and composition. That may range from everything from the light, low, mild changes in the nature of their composition to design changes like ventilation holes in filters.

We are not entirely sure what it was, but the Surgeon General determined that this change was related to design and composition changes.

The CHAIRMAN. So the technology was used to make a cigarette that was easier to inhale and contain substances that were more dangerous?

Dr. MCAFEE. Whether they contain more substances that were actually more dangerous or they literally just allowed the smoker to inhale them more deeply than they previously were inclined to do because the cigarettes 50 years ago were harsher.

What we are viewing, what we are seeing in terms of the numbers is very large increases in the risk of lung cancer; larger in women than in men, but very large in both. Cigarettes have actually become—at least the way that cigarettes are being used and smoked in the United States—have become more dangerous, not less dangerous.

The CHAIRMAN. Mr. Zeller, again, 5 years since we passed the Family Smoking Prevention and Tobacco Control Act. Again, I think a truly historic achievement for public health, but I know there have been some delays in implementing some provisions. But I also recognize that thanks to the ability of the FDA to regulate these products, strides have been made during that time. The Center for Tobacco Products has been, obviously, key. That is who is charged with this responsibility.

What have been some of the best accomplishments, perhaps some of the biggest challenges confronting the Center for Tobacco Products?

Mr. ZELLER. In terms of accomplishments, it was no small task to start with literally 2 full-time employees at the end of September 2009—two—accompanied by about 20 other people who were temporarily on loan to this brand new Center. So it was no small task to literally build the Center into what it is today.

It is a full-fledged, regulatory entity doing compliance and enforcement, doing public education, doing major work in terms of reviewing product applications, and overseeing investments in research because as I said in my remarks, we are a regulatory Agency. We can only go as far as the regulatory science will take us.

The regulatory science informs all the decisions that we make on product applications, all the policies, guidances, regulations that we could be issuing.

On the accomplishment side of the ledger, having a fully functioning Center that is doing all of that and that has launched the Real Cost campaign, and that is doing a massive nationwide enforcement of youth access laws, making a major investment in research, and making progress on the product review submissions, would be the short list of accomplishments.

There have been challenges for the very same reason that we literally started from nothing in 2009, there were challenges with the product submissions. No question.

We can look at it from both sides. There were problems with the submissions. Many of them were incomplete, but we have to own part of that as the regulator as well. It took us time to get up to speed. It took us time to hire all of the scientists, and especially chemists and engineers. We really needed some specialized science capability to do the best possible product reviews. But we have made extraordinary progress in dealing with the queue of applications.

On the challenges side, it is what comes with literally starting from nothing, inheriting, as I said, over 20 mandatory, statutory deadlines, and then doing the best possible job that we could with the product submissions.

I can report that we have made extraordinary progress on the product submissions. There is a concept known as substantial equivalence. It is one of the pathways to market that companies can submit applications for. And for the queue of substantial equivalence applications for products not currently on the market, review of new applications can begin as soon as an application is received, and we could not have said that a year ago, 2 years ago, 3 years ago. There is more progress to be made, but I think that we are meeting some of the greatest challenges that we have faced.

The CHAIRMAN. I appreciate that.

Then let us talk a little bit about warning labels. One of the key provisions was calling for larger warning labels on cigarettes and smokeless tobacco products. The smokeless warning labels requirement, I guess, has been implemented. However, the specific graphic warning labels proposed by FDA, again, were struck down by a court, the U.S. Court of Appeals here for the D.C. Circuit on First Amendment grounds.

After that decision, I wrote to Commissioner Hamburg urging FDA to move quickly to develop and implement a strong, new graphic warning labeling rule. Indeed, FDA's general authority to require graphic warning labels has been affirmed in the courts.

So given the evidence that graphic warning labels encourage smokers to quit and prevent nonsmokers from starting to smoke, I am hoping this is a high priority for FDA.

Is FDA going to propose a new set of cigarette warning labels that are designed to withstand a constitutional challenge?

Mr. ZELLER. The priority, and we are doing this, is getting the research done to inform our ability to write a new rule to survive the likely litigation that would come. Getting that research done is one of our highest priorities.

And armed with the results of that research, and with paying attention to the court decisions that have come in, in reviewing our first attempt, which was struck down, will require some careful deliberations. And we will do that, just as soon as we can complete the research. But getting the research done to support a new, graphic warning label rule is a very high priority of the Center and the Agency.

The CHAIRMAN. I wish we had some labels like I see in our neighboring country to the north in Canada. They have some pretty

graphic and strong labels; full package on it. I guess they do not have a Constitution like we have that they have to worry about, but they are great warning labels.

Does FDA plan to exercise its authority in the area of standards to require changes in cigarettes and other tobacco products, for example, limiting tar and nicotine levels to make them less addictive, less harmful, or less attractive?

Mr. ZELLER. Are you referring to the authority in the law known as Product Standards?

The CHAIRMAN. That is right, product standards.

Ms. ZELLER. Product standards is one of the most powerful tools that Congress gave the agency in the Tobacco Control Act. It is the power with one exception. It is the power to ban or restrict the allowable levels of ingredients, constituents in the finished product.

we have been saying publicly that we are investing in research to explore potential product standards in three areas, and this is as far as I can go publicly. We are supporting research to explore potential product standards in the areas of addiction, toxicity, and appeal. And armed with that information, we will then explore our regulatory options.

The CHAIRMAN. Good. Good, good.

My last question, Dr. McAfee, I want talk about cessation services. Last year, I wrote to Secretary Sebelius because I had a concern that many private health insurance plans were not covering tobacco cessation services that are recommended by the U.S. Preventive Services Task Force and required under provisions that I authored in the Affordable Care Act.

Earlier this month, the Department issued guidance clarifying for insurers exactly what evidenced-based tobacco cessation services must be covered without co-pays or deductibles as the law requires. We know that a combination of medication and counseling is most effective at helping tobacco users quit.

Could you elaborate on the role of cessation services in stemming the tide of tobacco use, and whether you expect this guidance to provide improved access to such services?

And second, do you have any suggestions on the best way to increase the number of doctors who talk to their patients about quitting and increase the number of smokers who are covered under the cessation services?

Dr. MCAFEE. Thank you very much, Chairman Harkin, for that question.

It is a question that is near and dear to me because one of the things that I did prior to coming to CDC was to work very, very hard as a primary care doctor within an integrated healthcare system basically to try to figure out how we could mobilize the engine of healthcare to help our patients quit smoking. And this has proven to be something that has lots of very strong potential, but also lots of very strong challenges.

And the potential is basically 75 percent of smokers see a doctor in a year, and doctors have a lot of respect, and they also are embedded in a system that increasingly knows how to adopt changes and influence behaviors.

But on the flip side, there have been prodigious obstacles to moving forward around this including the lack of training that medical

professionals get to help their patients, and then particularly the lack of coverage and capacity to be able to provide services without it seeming like something that they are doing just as, on top of everything else, as opposed to something that is integral to care.

The short story that I learned from my decade of trying to do this is, yes, it is possible. It takes a lot of work. You have to make services accessible so that clinicians can refer people out to get deeper levels of service.

We spent a lot of time trying to buildup services like the 1-800-QUIT-NOW as an option for clinicians. And, you have to figure out ways that they can have the time, get reimbursed for it, et cetera, and then it really does work. You can actually drop prevalence at a population level.

There were very, very exciting experiences in Massachusetts in Medicaid, for instance, where they were able to drop prevalence in just a few short years by major promotion of a good benefit.

The exciting elements associated with the Affordable Care Act are really that it has, as you noted, embedded in it requirements about barrier-free coverage. There has been a devil in the details challenge around how that actually gets translated into language and guidance to health plans so that they are able to do that, encouraged to do that, required to do that.

I do think that the guidance that HHS released last month gets a bit more specific around this. This is what the health plans actually were saying that would be helpful to them and that many of them will move. It will continue to be a process, but one that has hope.

We have tried to integrate this in with the Tips from Former Smokers campaign and have gotten a lot of interest from healthcare organizations.

The CHAIRMAN. I just guess I wish we had more emphasis, and I am going to be looking at this too, that people who are covered under the Affordable Care Act that see their doctors on prevention and wellness with no co-pays, no deductibles, they go in and get their annual checkup. That doctors have in their list of things that they do is to advise them on smoking if they smoke; to advise them on not only why they should quit, but how they should quit, what is available to them to help them; and refer them to the quit lines; refer them to other activities that they might do to cease. And then, if they need medication, or the patches, or the gum and stuff like that, to be able to advise them and get them on those. That is what I am hoping we do.

Dr. MCAFEE. I strongly agree. We have actually done a pretty good job over the last 15 years, say, of getting it so that people are asked about their tobacco use status and given brief advice by physicians.

But we still have a ways to go to try to make it so that particularly if people are interested, which most people are, that they can gain access to help everything from counseling right on the spot, to referral for counseling, or phone counseling, or Web counseling, and to medications. Just having it more embedded the way we treat hypertension, cholesterol, or the management of diabetes; having it just be part of service.

The CHAIRMAN. I want to just add one more thing before I close up here, and that is the issue was raised earlier about premium cigars.

Then I read somewhere about more and more kids are smoking, not what you think of as a cigar, but they are like little cigarettes, but they are cigars. They are wrapped in cigar paper and they are little, small cigars. And those are also, I think, being flavored too, if I am not mistaken. Yes, some of those are being flavored. So there is a clear distinction between that and premium cigars.

And you said to me as you are working on a rule and how you define what a premium cigar is. I do not know what it is either, but I just hope that there is a clear delineation between those. Between that, which kids do not use, and which they cannot afford to buy, and they are too expensive, and the ones which they do get hooked on, those little cigarillos or whatever they are called.

Mr. ZELLER. And to point on flavors, one of the elements of our proposed definition for a premium cigar is that the only flavor that is in there is tobacco.

The CHAIRMAN. Are there premium cigars with flavoring?

STAFF. Yes.

The CHAIRMAN. Oh, there are premium cigars with flavoring.

Mr. ZELLER. We are proposing that the only flavor that can be in a premium cigar is tobacco, but we will welcome to take comments on that.

The CHAIRMAN. Yes, I do not know that either. It is like that old saying, "I know it when I see it."

Mr. ZELLER. Right.

The CHAIRMAN. You know a premium cigar when you see it, but it is hard to define.

Mr. ZELLER. It is hard for a regulator to take that approach, though.

The CHAIRMAN. That is very true. I appreciate that.

Dr. MCAFEE. If I could just add a word or two around that, I would want to make sure that we emphasized the reality that all cigars are dangerous. They all contain most of the same toxic substances.

We are burning tobacco and that creates thousands of chemicals including around 70 or 80 carcinogens, most of those worrisome chemicals that are present in cigarettes are also present in cigars, including premium cigars. There may be some differences in how they are smoked, et cetera, but it is still a dangerous product and the question of how it should be regulated is different from the question of whether it should be regulated; whether they should be regulated.

The CHAIRMAN. Got that.

The other thing I just want to say is I had all this stuff on the e-cigarettes and, again, I'll just re-emphasize that the way they are being marketed, they are being marketed to kids and it is nicotine. Nicotine is an addictive drug. So they are marketing an addictive drug to kids, which gets them addicted on nicotine.

If they cannot get a hold of one of these or one of those when they are addicted, they will get a hold of cigarettes. It just almost seems to me like this is almost like a gateway kind of an approach to cigarette smoking. So I urge you, I hope that——

Again, I do not know about extending the comment period, whether that needs to be done, but I sure hope we do not kick this can down the road any more. We have got to get a handle on this one and start nipping this in the bud, this e-cigarettes stuff.

What you do on it with adults, I am a little less clear on that, but for kids, as far as I am concerned, pretty clear what is happening here and how they are marketing it.

Now, do either one of you have anything else that we have not asked, or covered that you would like to make for the record, or have us think about? Is there anything we have not asked or covered that you would like to add?

Dr. MCAFEE. I would actually just like to followup a little bit on one of the things that you had said about e-cigarettes.

I think one of the things that has been misunderstood about our findings last September at CDC is that there is some implication that we have to prove that children who use e-cigarettes will progress in some large, dramatic fashion automatically to cigarettes, and we think that is a red herring.

It is essentially related to what you just said. It is an important thing to find out, and we look forward to the findings from the pad, but the bottom line is for at least three reasons, children should not be using e-cigarettes.

And we, as a society, there is no necessity for us to require marketing, sales, and product characteristics that will result in millions of kids experimenting with e-cigarettes. As you noted, nicotine is addictive.

The other thing that we are worried about is even if kids were not to progress to cigarettes, we do not need to have e-cigarettes to get kids to not smoke. We have plenty of other societal tools that have proven to be very effective. We can get youth-use down into low single digits doing stuff.

It is egregious to suggest that somehow we need to have kids do this in order for adults to quit. And we are very worried because the Surgeon General's, this most recent Surgeon General's report, one of its findings around nicotine was that it is strongly suggestive that it has deleterious effects on the development of the adolescent brain. And this is not something that we need to, or should, fool around with.

And then the last issue is, in fact, we are not saying that it is a gateway, but we have ample reason to be anxious and concerned that one of the results of millions of kids, if it becomes millions, playing around with e-cigarettes, especially if the reason that they are fooling around with e-cigarettes is because they are watching advertising and promotions that are renormalizing tobacco use, by making it sexy, glamorous, and using celebrity endorsements on television.

This is a huge experiment and it is not fair to our children to ask them to pay a potential price around that for a hypothetical benefit to adult smokers. And we know the tactics that are being used in the process of marketing e-cigarettes, half a dozen characteristics of them that are very similar to the same things that a 2012 Surgeon General's report found, that the tobacco companies that had engaged in that caused kids to—that increased the chances that they would smoke cigarettes.

We do not think that we can afford to or that there is any necessity to literally spend 5 or 10 years proving that a 13-year-old using e-cigarettes will lead to them using cigarettes. It is just purely a bad idea.

The CHAIRMAN. You are saying, basically, they are dangerous in and of themselves, whether they are a gateway or not.

Dr. MCAFEE. Correct. Even the idea of a gateway, it is somewhat of a misnomer because a gateway in substance abuse treatment is that if you use one drug, it will lead to another drug. Like if you use marijuana, maybe it will cause you to use cocaine or heroin.

This is the same drug. It is nicotine. It is just a different delivery device and the drug itself is intrinsically of concern in adolescents.

The CHAIRMAN. Got it.

Mr. Zeller.

Mr. ZELLER. Just one closing thought. Absolutely understand the concerns that you and Dr. McAfee have expressed about e-cigarettes and especially the degree to which, any degree to which they are enticing kids.

I will just leave you with one big picture thought. Let us not lose sight of the fact that this remains the leading cause of preventable death and disease in our country principally because of combusting cigarettes. And the opportunity that Congress has given the Center for Tobacco Products with the authorities and the resources that you have given us is an opportunity to make a serious dent in that death and disease toll.

Now that we can add the tools of product regulation and the impact that product regulation can have to national comprehensive tobacco control efforts, let us not lose our focus on what that primary cause is for those now more than 480,000 avoidable deaths each year, and that is primarily burning combusting cigarettes. And we need to redouble our efforts to focus on that.

Dr. MCAFEE. And if I might just re-emphasize the very important point that Mitch Zeller made along these same lines, the Surgeon General's report really emphasized this point that we can argue, and we will, about how e-cigarettes should be regulated, velvet glove-iron fist, how should this happen, and which particular policies.

But the safest thing that we can do, the biggest way that we can minimize their dangers and potentially maximize any potential benefits they have is,

> "The impact of the noncombustible aerosolized forms of nicotine delivery on population health is much more likely to be beneficial in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced, especially among youth and young adults."

The CHAIRMAN. In other words, if e-cigarettes were marketed like the patch.

Dr. MCAFEE. Or if cigarettes, if the appeal, accessibility, and promotion, and use of cigarettes were thumb-screwed in a more dramatic fashion.

The CHAIRMAN. I am concerned about this approach now because I know there is a debate on whether e-cigarettes is a smoking ces-

sation device or does it lead to youth to become more addicted to nicotine. I have seen a lot of back and forth on this.

If you control the marketing so that e-cigarettes are simply marketed or sold under the same provisions like a patch or Nicorette gum, that is one thing. But that is not what is happening.

Mr. ZELLER. All I can say, Mr. Chairman, is that we tried that and the courts said no. We tried that.

The CHAIRMAN. You tried to regulate e-cigarettes?

Mr. ZELLER. We tried to regulate e-cigarettes as unapproved drugs and devices, and we took an enforcement action, and we were sued, and the courts sided with the company that sued us and said, "In the absence of a claim, a cessation claim," which would automatically make it subject to regulation by FDA under the safety and efficacy standard as a drug and device.

In the absence of a cessation claim, the courts ruled that the only way that we could regulate e-cigarettes is under the tobacco authorities because the nicotine in these products is derived from tobacco and that is the regulatory framework that we are trying to create starting with the deeming proposal.

The CHAIRMAN. I will have to think more about that. Just a moment.

[Pause.]

Yes, I guess you are right. The courts made a bad decision.

Anyway, thank you both for all your leadership in this area. We just cannot let up on our efforts, and we have to figure out some way of getting a handle on these e-cigarettes, especially as it pertains to kids.

I do not know whether I am for extending the deadline on it or not. I do not know. All I know is that there should be some really compelling reasons to extend the deadline beyond 75 days. I do not know if there are or not; I have not seen that yet. Thank you all very much.

I ask that the record be open for 10 days for other comments and suggestions from other members.

Thank you again, for being so patient, for being here, and thanks for your leadership.

Mr. ZELLER. Thank you, Mr. Chairman.

The CHAIRMAN. Appreciate it.

Dr. MCAFEE. Thank you.

The CHAIRMAN. Thank you. Thank you both.

[Additional material follows.]

ADDITIONAL MATERIAL

DEPARTMENT OF HEALTH & HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION,
SILVER SPRING, MD 20993,
March 27, 2015.

Hon. LAMAR ALEXANDER, *Chairman,*
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC. 20510–6300.

DEAR MR. CHAIRMAN: The Food and Drug Administration (FDA or the Agency) provided testimony at the May 15, 2014, hearing before the Committee on Health, Education, Labor, and Pensions entitled, "Progress and Challenges: The State of Tobacco Use and Regulation in the U.S." This is a response for the record to questions posed by several Committee Members to Mitchell Zeller, Director of FDA's Center for Tobacco Products.

Please let us know if you have further questions.

Sincerely,

THOMAS A. KRAUS,
ASSOCIATE COMMISSIONER FOR LEGISLATION.

RESPONSE OF THE FOOD AND DRUG ADMINISTRATION TO QUESTIONS OF SENATOR HARKIN, SENATOR ALEXANDER, SENATOR MIKULSKI, SENATOR MURKOWSKI, SENATOR ROBERTS, SENATOR BURR, AND SENATOR CASEY

SENATOR HARKIN

Deeming Rule

On April 24th, FDA issued a long awaited draft rule asserting agency jurisdiction over additional tobacco products, including e-cigarettes. This proposed "deeming" rule marked an essential step in FDA's implementation of the *Family Smoking Prevention and Tobacco Control Act*. While I know there have been a number of requests to lengthen the comment period and otherwise delay the issuance of a final rule, it is imperative to the public health that these regulations be finalized and strengthened. This is all the more important because, as drafted, the full force of the proposal would not come to bear for a full 2 years after it is finalized.

Question 1. What steps can FDA take now to ensure issuance of a final rule within a year?

Answer 1. The comment period for the proposed tobacco deeming rule closed on August 8, 2014. We are carefully considering all of the comments. FDA is also considering any data, research, and other information submitted to the docket. Finalizing the deeming rule is a priority for the Agency and we share your sense of urgency on this important matter.

Mislabeled Pipe Tobacco

We tax different tobacco products at dramatically different rates in this country—while roll-your-own tobacco is taxed at the same rate of cigarettes, pipe tobacco is taxed at a much lower rate. Over the course of the last 5 years, we've seen ill-intended manufacturers take advantage of this disparity by relabeling roll-your-own tobacco as pipe tobacco—while making it clear to consumers that the product is intended for rolling into cigarettes. As a result, in 2012 GAO reported that annual sales of so-called pipe tobacco increased 869 percent between 2008 and 2011. The same report concluded that between 2009 and 2011, the loss of tax revenues due to pipe tobacco masquerading as roll-your-own tobacco totaled as much as $492 million. I've authored legislation that would eliminate this problem by equalizing tax rates across tobacco products but FDA also has important tools.

Question 2. What has FDA done to address the issue of mislabeled roll your own tobacco? Does FDA plan to take enforcement action, in addition to the August 2013 warning letters that you sent, against these companies under the misbranding provision of the *Family Smoking Prevention and Tobacco Control Act*, through which Congress gave the agency authority to address this issue?

Answer 2. To ensure regulated industry and tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA conducts compliance check inspections of retailers; compliance reviews relating to tobacco product document submissions; routine surveillance of promotional activities of manufacturers, distributors, importers, and retailers; and inspections of manufacturers, among

other activities. During the course of these compliance activities, if a tobacco product is promoted and sold as a product that is currently under FDA's jurisdiction (i.e., cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, smokeless tobacco), FDA would determine whether the product complies with the requirements of the FD&C Act and would take an enforcement action if violations are found. Examples of violations contained in Warning Letters issued by FDA include violations of the prohibition on characterizing flavors other than tobacco or menthol and violations of the restrictions on modified-risk claims and descriptors. Even tobacco products that are labeled as pipe tobacco may be found to be in violation of the law, if the product, due to its labeling or promotion, meets the definition of cigarette tobacco or RYO tobacco in the FD&C Act.

Pipe tobacco that is not promoted or sold as cigarette tobacco or RYO tobacco is currently not subject to Chapter IX of the FD&C Act.[1]

As of September 30, 2014, FDA has issued 20 Warning Letters to firms for the sale and promotion of adulterated cigarette tobacco and RYO tobacco products labeled as pipe tobacco. FDA continues to take enforcement actions, as appropriate, to ensure continued compliance with the FD&C Act and FDA's implementing regulations. FDA's Warning Letters are available to the public on our Web site, *www.fda.gov*, which serves to educate the public and encourage voluntary compliance by regulated industry.

Tobacco Track and Trace

The *Family Smoking Prevention and Tobacco Control Act* authorized the Secretary to "require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system."

Question 3. What barriers do you see to the implementation of a Federal track and trace program for tobacco?

Answer 3. CTP is taking a number of actions on issues related to illicit trade and track and trace. For example, CTP has hosted a number of listening sessions on track and trace and illicit trade with members of the tobacco industry; has consulted with colleagues from the Alcohol and Tobacco Tax and Trade Bureau (TTB), the Bureau of Alcohol, Tobacco, Firearms, and Explosives (BATF), and other Federal agencies; has helped the Centers for Disease Control and Prevention (CDC) plan special meetings of experts on illicit trade and track and trace, "which included representatives from CTP and other Federal agencies; and has sponsored a major report from the Institute of Medicine (IOM), released in February 2015, on the characteristics of illicit trade markets throughout the world and the various initiatives that have been implemented to prevent and reduce illicit trade (including tracking-and-tracing systems).

Multiple agencies within HHS, including FDA and CDC, are working to address the issue of illicit trade at both the State and national levels. All of these actions will help to inform CTP's efforts to implement a track-and-trace system and to otherwise address illicit trade issues. The IOM report will be especially valuable by increasing our understanding of existing illicit trade characteristics and mechanisms and the effectiveness of various responses, and how an illicit trade in non-FDA-compliant tobacco products might differ, how track-and-trace technologies might prevent that type of illicit trade, and what other approaches are likely to be most effective. The IOM committee was also asked to identify research gaps and potential approaches to closing those gaps. Other challenges to implementing a new Federal track-and-trace system include making sure that it will work well with existing Federal, State, and local tobacco tax collection systems and with related recordkeeping and track-and-trace systems and procedures.

SENATOR ALEXANDER

Question 1a. To not be regulated by FDA, a premium cigar must have a price above $10 at retail—how does that work?

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[1] Currently only cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco are subject to Chapter IX of the FD&C Act. On April 25, 2014, the Agency published the proposed rule entitled "Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." Products that would be "deemed" to be subject to FDA regulation are those that meet the statutory definition of a tobacco product, including currently unregulated marketed products, such as e-cigarettes, cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and dissolvables not already under FDA's authority.

Answer 1a. In the proposed deeming rule, FDA included two options for the categories of cigars that would be covered by the rule. The first option proposes to regulate all products that meet the definition of a tobacco product (except accessories of newly deemed tobacco products), and would include all cigars. The second option proposes defining a category of premium cigars that would not be subject to FDA's regulatory authority. FDA has proposed several criteria for a cigar to be considered a premium cigar and, therefore, exempt from the deeming regulation, should FDA select option 2 for the final rule. One of these criteria is that the cigar has a retail price (after any discounts or coupons) of no less than $10. If a retailer sells a cigar for less than $10 per cigar, the cigar would not be considered a premium cigar and would not be exempt from the deeming regulation, even if FDA selects option 2 for the final rule. FDA encouraged comments on all aspects of the proposed rule, including the proposed criteria for a premium cigar.

Question 1b. If one retailer were to have a sale and sell cigars for $9.99,would that cigar manufacturer be in violation of the law and all cigars of that type be misbranded?

Answer 1b. Under option 2 of the proposed rule, one of the criteria that a cigar would have to meet to be considered a premium cigar would be to have a retail price (after any discounts or coupons) of no less than $10. If the retail price of the cigar were less than $10, it would not be considered a premium cigar under this proposal. Therefore, the cigar would not be exempt from the deeming regulation, even if FDA were to select option 2 for the final rule; the cigar would be subject to regulation and would have to comply with the FD&C Act's requirements. We note that FDA specifically requested comment on this $10 price point, and we will consider all comments when finalizing the rule.

Question 2. To avoid FDA regulation, a premium cigar must not have "characterizing flavors". What does that mean? There is flavor information on the box? If the tobacco is aged in a whiskey barrel, is that a characterizing flavor? If Cigar Aficionado were to describe flavors in a cigar, would that affect whether the product qualifies for the exemption?

Answer 2. The proposed criteria for a premium cigar under option 2 of the proposed rule is intended to capture those products that, because of how they are used, may have less of a public health impact than other types of cigars. The preamble does not otherwise further define "characterizing flavor" for the purposes of this criteria. However, FDA solicited comments on all aspects of the proposed rule, including the proposed criteria for a premium cigar.

Question 3. More broadly, given the thorough documentation of harms from smoking tobacco and addictive nature of nicotine in the proposed regulation, do you believe FDA can exempt any product that is made from or derived from tobacco from regulation given the mission of protecting the public health?

Answer 3. FDA recognizes that all cigars are harmful and potentially addictive. At the same time, it has been suggested that different kinds of cigars may have the potential for varying effects on public health, based on possible differences in their effects on youth initiation and frequency of use by youth and young adults, among other factors. We published the proposed rule with two options (option 1 to include all cigars; option 2 to exempt premium cigars) for public comment to solicit information regarding such issues as disease risk, nicotine addiction, how premium cigars are used, and an appropriate definition for premium cigars, if needed, in order to determine whether it is appropriate to exempt premium cigars from the regulation. FDA will examine all of the available information in order to make the best-informed decision.

Question 4. I'm here to learn about these new products, like electronic cigarettes, as they compare to products we know more about such as cigars, smokeless tobacco, and cigarettes. Mr. Zeller, you have written about the relative risks of different tobacco products for individuals. Could you share your thoughts about the continuum of risk related to tobacco products, and list some products such as traditional cigarettes, premium cigars, smokeless tobacco, and electronic cigarettes from most risky to least risky based on the data we have now?

Answer 4. While FDA acknowledges that there may be products that contain lower levels of toxicants than cigarettes, many provisions in the Tobacco Control Act require FDA to make decisions after considering the risks and benefits to the population as a whole, including both users and non-users of tobacco products. The risk continuum is a relevant consideration as regulatory policy is developed; however, the variety of potential patterns of use render this a challenging assessment.

There are distinctions in the hazards presented by various nicotine-delivering products. The view has been advanced by some that certain new non-combustible tobacco products (such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products, given the carcinogens in smoke and the dangers of secondhand smoke. The Department of Health and Human Services (HHS), including FDA, CDC, and NIH, are conducting studies that will assess addictiveness and the relative toxicities of e-cigarettes and other tobacco products. To the extent that scientific evidence demonstrates that certain products are indeed less harmful than others at an individual level, they could help reduce the overall death and disease toll from tobacco product use at a population level in the United States.

Cigarette smoking is the major contributor to the death and disease attributable to tobacco use. The challenge for FDA, in considering currently regulated products and any additional products that would be deemed to be subject to the FD&C Act, is that regulatory policy under the Tobacco Control Act (TCA) must account for the net public health impacts at the population level. This includes impacts on initiation and cessation, and an evaluation of product harm.

Ongoing research, both within HHS and elsewhere seeks to characterize whether emerging technologies, such as the e-cigarette, may have the potential to reduce the death and disease toll from overall tobacco product use, depending on who uses the products and how they are used.

Much remains to be learned about the risks of e-cigarettes to health, as well as their possible benefits. E-cigarettes could be a detriment to public health. e-cigarettes have the potential to re-normalize smoking, encourage youth to initiate smoking, and/or prompt users to continue or to escalate to cigarette use—in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, childhood poisoning events, and physical harm from defective products (such as exploding batteries). On the other hand, e-cigarettes could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use.

Question 5. There is currently a backlog of over 4,000 applications, and by some estimates, the deeming of cigars as tobacco products alone could lead to 5,000–10,000 additional applications being filed 2 years after the proposed regulation is finalized. How could you possibly handle such a workload?

Answer 5. FDA has made significant progress in reviewing substantial equivalence (SE) reports for currently regulated products, and the Agency believes that this momentum will continue. The Agency has increased staffing, taken steps to streamline the SE review process, and established performance goals that include timeframes for review of regular[2] SE reports and review of exemption from SE requests. We have been able to develop these performance goals because of increased capacity, efficiency, and knowledge of the scientific evidence needed to adequately review SE reports. As of September 30, 2014, 45 percent of regular SE reports had been resolved by a final decision,[3] either because FDA issued an Order letter (92 submissions), a Refuse-to-Accept letter (6 submissions), or because the submission was withdrawn (361 submissions). FDA has issued a Scientific Advice and Information Request Letter or a Preliminary Finding Letter for 81 percent of the regular SE reports that are pending.

FDA continues to move forward with additional improvements to the tobacco product review program. We continue to hire and train new staff, develop better IT systems for tracking submissions, and address the scientific policy issues that result from developing a new regulatory review program. We will continue to advance our efforts to review and act on provisional SE reports while also working to meet the performance goals for regular SE reports and modified-risk tobacco product applications. We are committed to completing the review of provisional tobacco products.[4]

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[2] SE reports received before March 23, 2011 for new products introduced to market between February 15, 2007, and March 22, 2011 are considered "provisional," and the products covered by those reports can remain on the market unless FDA finds that they are "not substantially equivalent.'" The other category is "regular" SE reports (reports received on or after March 23, 2011). Products covered by "regular" reports cannot be marketed unless FDA first issues an order finding the product substantially equivalent and in compliance with the FD&C Act.

[3] Final decisions include refuse-to-accept letters, withdrawals by an applicant, substantially equivalent (SE) orders, and not substantially equivalent (NSE) orders.

[4] If FDA issues an order that a tobacco product subject to a provisional SE report is NSE, the product may not be legally marketed and may be subject to enforcement action, including seizure.

We intend to continue to build on this experience as we review premarket applications for newly deemed products. CTP is committed to a consistent, transparent, and predictable review process and to completing reviews in a timely manner.

Question 6. FDA has tiered the 4,000 applications at the agency, which all are for products still in the market, into four tiers based on the potential risk to public health. For the product applications in the high-risk tier, representing the greatest potential risk to public health, can you provide a timeline for when the agency will complete its review and remove any products from the market if necessary?

Answer 6. In June 2012, CTP established four Public Health Impact Tiers for provisional SE submissions, and in August 2012, CTP began assigning submissions to these tiers to prioritize scientific reviews for those products with the greatest potential to raise different questions of public health. Tier 1 includes submissions for products that have high potential for raising different questions of public health; Tier 2 is for products with moderate potential; Tier 3 is for products with low potential, and Tier 4 is for products with the lowest potential. Because FDA has been prioritizing the review of those provisional SE reports that are most likely to raise different questions of public health, the initial reviews likely will be more complicated and will have less predictable review timeframes. On February 21, 2014, FDA issued the first "not substantially equivalent" (NSE) orders for four provisional tobacco products currently on the market. These products can no longer be legally marketed. We continue to review provisional products and will act on these as these reviews are completed.

Question 7. You propose not allowing electronic cigarettes to make claims that e-cigarettes may pose less risk than traditional cigarettes. A popular electronic cigarette company has a marketing campaign using phrases such as "Friends don't let friends smoke" and "Cigarettes, you've met your match."Would these campaigns be considered in violation of the proposed deeming regulation? Why would we not want companies to market their products to smokers as a less harmful alternative to smoking, rather than forcing marketing to appeal to the whole population?

Answer 7. The proposed deeming rule would extend FDA's tobacco product authorities (which currently apply to cigarettes, cigarette tobacco, RYO tobacco, and smokeless tobacco) to all other tobacco products, as defined in section 201(rr) of the FD&C Act, except the accessories of such other tobacco products, and potentially premium cigars (if FDA were to choose option 2 of the proposal). Such authorities include section 911 of the FD&C Act, which prohibits the introduction into interstate commerce of a "modified-risk tobacco product" without an FDA order in effect. A tobacco product is considered a modified-risk tobacco product under section 911(b) of the FD&C Act if its label, labeling, or advertising explicitly or implicitly represents that: (1) the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; (2) the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or (3) the product or its smoke does not contain, or is free of, a substance. In addition, a tobacco product is considered a modified-risk tobacco product if its manufacturer takes any action directed to consumers, other than by means of the product's label, labeling or advertising, respecting the product that would be reasonably expected to result in consumers believing that the product or its smoke may present a lower risk of disease or is less harmful than other commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance. Modified-risk tobacco products that are introduced into interstate commerce without an appropriate FDA order in effect are adulterated under the FD&C Act.

The modified-risk tobacco product provisions aim to ensure that modified-risk claims, including those about the relative harms of different products, are substantiated and supported by scientific evidence. As Congress found, unsubstantiated modified-risk claims are detrimental to the public health. We have seen this historically, with "light," "low," and "mild" descriptors leading consumers to incorrectly believe that those products were safer. If the deeming rule is finalized as proposed, e-cigarette manufacturers would be eligible to file applications seeking authorization from FDA to market their products as modified-risk products under section 911 of the FD&C Act. CTP's review of electronic cigarette modified-risk claims would help to ensure that those claims are substantiated and not misleading. CTP would be able to issue modified-risk tobacco product orders to applicants that meet the criteria described under section 911 (g) of the FD&C Act.

Question 8. I am concerned about the newly deemed products where substantial equivalence is not available because you believe that you cannot set a new grandfather date. All products, such as e-cigarettes, cigars, and water pipes will have to

submit premarket new tobacco applications. My understanding is that no one has submitted a complete premarket new tobacco application, and the guidance outlines requirements for randomized controlled trials to prove impact on the public health. What data and scientific evidence does the agency have that these newly deemed products should be held to a different standard than those that were able to use the substantial equivalence pathway?

Answer 8. Section 910 of the FD&C Act provides three pathways that new tobacco products can use to obtain marketing authorization: SE; premarket tobacco application (PMTA); or exemption from SE. The criteria for whether a product can use a particular pathway, and the standard for FDA authorization under each pathway, are set forth in the statute. With regard to those newly deemed products for which a PMTA is submitted, as noted in the preamble to the tobacco deeming proposed rule, it is possible that an applicant may not need to conduct any new nonclinical or clinical studies to support a PMTA application. FDA requested comments on this issue, as well as comments regarding the proposed compliance policy for substantial equivalence applications and PMTAs and other legal interpretations of the substantial equivalence grandfather provision that FDA should consider. FDA also requested comments as to what other information the Agency should consider to help expedite review of PMTAs for tobacco products that contain fewer or substantially lower levels of toxicants.

Question 9. Would FDA work with Congress and support a legislative solution to allow FDA to set different substantial equivalence dates for newly deemed products if necessary?

Answer 9. FDA is aware of new tobacco product categories that entered the marketplace after the February 15, 2007, reference date in the Tobacco Control Act, and that the SE pathway may not be available to these newer products. FDA included a question in the proposed deeming rule, requesting comment as to whether there are other legal interpretations of the SE reference date provision that FDA should consider.

To address concerns that such products would immediately be removed from the market, FDA is proposing a compliance period of 24 months, following the effective date of a final rule, for submitting a marketing application under this pathway. FDA is also proposing a 24-month compliance period for the submission of PMTAs. In addition, we proposed to continue the compliance policy, pending review of marketing applications, if those applications are submitted within the 24 months after the final rule's effective date. As a practical effect of these compliance periods, we would expect that most firms would continue marketing their tobacco products, pending FDA's review of their marketing applications.

Question 10. If an electronic cigarette manufacturer files premarket tobacco applications for its products, but then a change is made to those products, say a new supplier is used, would the manufacturer have to re-file all new premarket tobacco applications? What changes will result in new tobacco product applications being filed if the substantial equivalence pathway is not available?

Answer 10. All tobacco products that meet the definition of a "new tobacco product" under section 910 of the FD&C Act are required to undergo premarket review by FDA. However, FDA expects that not all PMTAs will require the same type or amount of data and information in order to satisfy the requirements of section 910 of the FD&C Act. In the proposed deeming regulation, we explain that we are seeking information as to how the Agency might streamline review of new product applications. We state in the proposed rule that in certain instances, we expect that FDA will be able to determine that a product meets the requirements of the FD&C Act using information that might be less burdensome for a manufacturer to gather and submit to FDA. For example, in some cases it is possible that an applicant may not need to conduct any new nonclinical or clinical studies. We are seeking comment on the types of information that manufacturers of certain categories of products could use to support their PMTAs.

Question 11. Can you provide the total number of inspections of retail facilities, including how many have occurred on Native American reservations and how many have occurred off-reservation?

Answer 11. As of September 30, 2014, over 346,000 FDA tobacco retail inspections have been conducted across 54 States and territories.

Working with federally recognized tribes requires careful consideration of the legal and political framework that the United States has established with respect to Indian tribal governments, including Executive orders. FDA also follows the HHS Tribal Consultation Policy, which directs FDA to consult with tribes before any action is taken that will significantly affect tribes.

CTP discussed its compliance and enforcement activities during a Tribal Consultation webinar held on June 16, 2014. Also on June 16, 2014, CTP issued a Request for Proposal (RFP) for contracts with federally Recognized Indian Tribe government agencies to assist with inspections of retail establishments on Tribal lands, similar to the tobacco retail inspection program utilizing contracts with U.S. States and territories. CTP provided a technical assistance webinar for tribes to learn about the requirements of this RFP and how to submit a proposal. As of September 30, 2014, FDA awarded two contracts to tribes to conduct tobacco retail inspections within their jurisdictions.

Question 12. Does the Center for Tobacco Products plan on approving one or more training programs for retailers so that retailers have a model to use to best comply with the law?

Answer 12. Retailers are encouraged to implement a training program for their staff and to tailor their program to meet the needs of their employees and business, taking into consideration the size of their business and the products that they sell.

FDA understands that some retailers have established various tobacco retailer training programs. The Agency does not currently approve any retailer training programs, however, FDA intends to promulgate regulations establishing standards for approved retailer training programs.

The TCA established two schedules for the maximum civil money penalties that can be assessed for violations of regulations issued under section 906(d) of the FD&C Act, including violations of FDA regulations at 21 CFR part 1140—one schedule for retailers that do not have an approved training program and another schedule, with lower penalties, for retailers with an approved training program. In determining the amount of penalty the Agency will seek, CTP will use the lower schedule for all retailers, whether or not the retailer has implemented a training program, until regulations are developed that establish standards for retailer training programs.

FDA has also issued a guidance entitled "Guidance for Industry: Tobacco Retailer Training Programs," which is available at *www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm218898.htm*. This guidance contains examples of recommended elements that may be helpful to retailers in designing and implementing a training program.

Currently, FDA develops compliance training materials for retailers, posts important information to its Web site, issues guidance documents, meets with and presents before stakeholders, and has established a comprehensive program for training on, and assistance with, the requirements of the TCA. In fiscal year 2014, CTP delivered five compliance training webinars for retailers and small businesses covering topics relevant to tobacco product businesses. In addition, FDA is developing a new retailer education campaign and will continue to provide easy-to-understand, free educational materials online and by direct mail that help tobacco retailers comply with the law. The campaign currently provides materials in English and Spanish and plans to expand to include additional languages in fiscal year 2015.

Question 13. How is FDA utilizing the "Minor Modification" exemption to allow companies to make certain changes without review? What types of changes qualify for these exemptions? Will you consider permitting changes that are beneficial to the public health, such as reducing harmful and potentially harmful constituents, through this fast track process?

Answer 13. Under section 905(j)(3)(A) of the FD&C Act "[t]he Secretary may exempt [a tobacco product] from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent . . ." In general, among other requirements, a new tobacco product may be found exempt from the requirements of SE, if the tobacco product is modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing additive, where that change constitutes a minor modification to the product. This requirement is found in section 903(j)(3) of the FD&C Act and at 21 CFR 1107.1(a). The term "additive" is defined in section 900(1) of the FD&C Act:

> "The term 'additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical."

Additionally, FD&C Act section 905(j)(3)(A)(ii) states that one of the criteria for finding a product exempt requires that the Secretary determine that "a report under

this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health . . .," and FD&C Act section 905(j)(3)(A)(iii) adds the requirement that the Secretary determine that an exemption is otherwise appropriate.

FDA has issued regulations implementing this SE Exemption Pathway. When a product change meets the requirements in the statute as described above, FDA can exempt the product from the requirement to demonstrate SE. In this event, the manufacturer can implement the change after notifying FDA in accordance with section 905(j)(1)(A)(ii) of the FD&C Act.

Question 14. FDA allows sampling of smokeless tobacco in age-restricted facilities. What scientific evidence exists to support restricting similar sampling of newly deemed products, such as e-cigarettes and cigars?

Answer 14. Congress, by law, provided an exception only for smokeless tobacco in age-restricted facilities from the general rule banning free sampling. FDA believes that the free sample prohibition, as applied to newly deemed products, would eliminate a pathway for youth to access tobacco products, reducing youth initiation and, therefore, short-term and long-term morbidity and mortality resulting from use of these products. The IOM has stated that free samples of cigarettes "*encourage experimentation by minors with a risk-free and cost-free way to satisfy their curiosity" (Institute of Medicine of the National Academies*, "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths," 1994). Although the IOM was speaking in the context of cigarettes, the same rationale would apply to the proposed deemed products. In addition, the U.S. Court of Appeals for the Sixth Circuit previously recognized that FDA has provided "extensive" evidence that free tobacco samples constitute an "easily accessible source" for youth (*Discount Tobacco City & Lottery, Inc.* v. *United States*, 674 F.3d 509, 541 (6th Cir. 2012) (citing 61 FR 44396 at 44460, August 28, 1996), *cert. denied*, 133 S. Ct. 1966 (2013)).

FDA solicited comments on all aspects of the tobacco deeming proposed rule, including data and information on how this restriction would reduce youth use of proposed deemed products.

SENATOR MIKULSKI

Question 1. It is currently estimated that one in five deaths can be directly attributed to tobacco use. Smoking reduces life expectancy by at least 10 years and the CDC has said that tobacco use results in at least $133 billion worth of direct medical care costs each year. We have tried imposing taxes and educating—even scaring—the public about the harmful effects of tobacco use—but more needs to be done. As Director of the FDA's Center for Tobacco Products, what do you propose could be done to reduce tobacco use and address the tragic loss of life and unnecessary costs to taxpayers that result? Are you ready to try new actions?

Answer 1. Despite decades of efforts by HHS to reduce tobacco use, it continues to be the leading cause of preventable disease and death in the United States. Since enactment of the TCA, FDA has made significant progress toward establishing a comprehensive, effective, and sustainable framework for tobacco product regulation. These accomplishments include:

- Establishing an initial framework for industry registration, product listing, and submission of information on ingredients and harmful and potentially harmful constituents in tobacco products and tobacco smoke;
- Implementing and enforcing the statutory ban on cigarettes with certain characterizing flavors;
- Restricting access and marketing of cigarettes and smokeless tobacco products to youth;
- Implementing and enforcing the requirement that cigarette, RYO, and smokeless tobacco product manufacturers seek FDA authorization before marketing a new product or making modifications 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 tobacco products and modified-risk claims;
- Utilizing a science-based approach that addresses the public health issues raised by menthol cigarettes. FDA has taken several actions related to menthol, including: issuing an advance notice of proposed rulemaking seeking comments that may inform regulatory actions by FDA; requesting comment on the Agency-prepared report entitled "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Non-Menthol Cigarettes"; investing in research, such as on

the effects of menthol in cigarettes and launching a youth education campaign that includes menthol-specific messages.

• Collaborating with CDC and NIH in pursuing a research agenda to better understand regulated products and patterns of tobacco use to inform the development of regulatory policy. This includes establishment of the Tobacco Centers of Regulatory Science, a program designed to generate research to inform the regulation of tobacco products, and the Population Assessment of Tobacco and Health study, or PATH, which is a collaborative study with NIH designed to measure tobacco use behaviors and health to inform product regulation. PATH is a longitudinal study that intends to follow tens of thousands of people age 12 and older in the United States, who use and do not use tobacco products.

• Implementing a compliance and enforcement program to ensure industry compliance with regulatory requirements, such as minimum age of sale in retail establishments throughout the United States; and

• Collaborating with CDC in establishing public education campaigns about the dangers of regulated tobacco products.

CTP is well-positioned to build on the work of its first 5 years. In June 2014, we announced five strategic priorities designed to use the authorities in the TCA to have the greatest impact on the public health. CTP's strategic priorities are:

• *Product Standards*—This tool enables FDA to require changes to product content or design, including banning or restricting the allowable levels of harmful compounds in finished tobacco products.

• *Comprehensive FDA-wide Nicotine Policy*—We will help establish an integrated, FDA policy on nicotine-containing products that is public health-based and recognizes that it is not the nicotine that kills half of all long-term smokers, but the carcinogens and other toxins in tobacco smoke.

• *Pre-and Post-Market Controls: Regulations and Product Reviews*—We are developing rules and guidance for industry and improving the timeliness of product reviews.

• *Compliance and Enforcement*—We will continue to build the compliance and enforcement program for tobacco products, including any products deemed under CTP's jurisdiction.

• *Public Education*—We will collaborate with CDC to maximize HHS' efforts to educate at-risk audiences on the dangers of tobacco use.

FDA shares your sense of urgency, and we are committed to taking bold and sustained action to reduce the death and disease caused by tobacco use.

Question 2. The 50th anniversary Surgeon General's report found,

> "The evidence is sufficient to conclude that the increased risk of adenocarcinoma of the lung in smokers results from changes in the design and composition of cigarettes since the 1950's."

FDA has had the authority since 2009 to require changes in all cigarettes to make them less deadly, make them less appealing to kids or to reduce the addictive levels in the product. What steps will FDA take to move forward with using this very important tool from the Tobacco Control Act to reduce the death and disease caused by cigarettes?

Answer 2. Section 907 of the FD&C Act gives FDA the authority to issue tobacco product standards that are appropriate for the protection of the public health, through rulemaking. For example, FDA could issue a product standard that would reduce the harm, addictiveness, and/or appeal of tobacco products, if appropriate for the protection of the public health.

CTP, with input from HHS, is exploring the potential for product standards in all three areas: addiction, toxicity, and appeal. CTP is also funding research to address issues related to potential product standards.

SENATOR MURKOWSKI

I am concerned about recent data published by CDC showing a huge spike in nicotine poisonings among small children related to e-cigarettes. I understand from the American Academy of Pediatrics that even a teaspoon of the liquid nicotine used to refill an e-cigarette could be fatal if ingested by a small child. Yet, liquid nicotine is not required to be sold in childproof packages, and the proposed rule you put out last month makes no recommendations on child-proofing.

Question 1. Is the FDA doing anything to prevent child nicotine poisoning? Is there a reason why the FDA did not include these precautions in its proposed rule?

Answer 1. In the preamble to the proposed deeming rule, FDA included discussion regarding the recent increased incidence of child nicotine poisoning and the Agency's

concerns regarding this issue. FDA considers the deeming rule to be a foundational regulation, which, when finalized, would allow the Agency to take further actions regarding critical issues, such as protecting children from liquid nicotine, related to the proposed deemed products. For example, FDA would have authority to issue tobacco product manufacturing practice regulations under section 906(e) of the FD&C Act. Such regulations could include requirements regarding the packaging and storage of a tobacco product such as liquid nicotine. In addition, under section 907 of the FD&C Act, FDA would have authority to issue a product standard with provisions related to components of tobacco products, such as liquid nicotine refill cartridges. Sections 906(d) and 907(a)(4)(B)(v) also afford FDA the authority to issue regulations restricting the sale and distribution of a tobacco product, if FDA determines that such a regulation would be appropriate for the protection of the public health.

FDA Commissioner Margaret Hamburg wrote in a *New York Times* op-ed on May 12, 2014, the following,

> "Much remains to be learned about the risks of e-cigarettes to health, as well as their possible benefits, particularly for those smokers who have not been able to quit using deadly conventional cigarettes."

Question 2. Mr. Zeller, can you share your views on the various levels of perceived risk and potential benefit related to various tobacco products currently on the market?

Answer 2. While FDA acknowledges that there may be products that contain lower levels of certain toxic chemicals than cigarettes, many provisions of the TCA require FDA to make decisions after considering the risks and benefits to the population as a whole, including both users and non-users. The risk continuum is a relevant consideration as we make regulatory policy. But the potential patterns of use make this a challenging assessment.

There are distinctions in the hazards presented by various nicotine-delivering products. The view has been advanced by some that certain new non-combustible tobacco products (such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products, given the carcinogens in smoke and the dangers of secondhand smoke. HHS including FDA, CDC, and NIH, are conducting studies that will assess the addictiveness and the relative toxicities of e-cigarettes and other tobacco products. To the extent that scientific evidence demonstrates that certain products are indeed less harmful than others at an individual level, they could help to reduce the overall death and disease toll from tobacco product use at a population level in the United States.

Cigarette smoking is the major contributor to the death and disease attributable to tobacco use. The challenge for FDA, in considering currently regulated products and any additional products that would be deemed to be subject to the FD&C Act, is that regulatory policy under the TCA must account for the net public health impacts at the population level. This includes impacts on initiation and cessation, and an evaluation of product harm.

Ongoing research, both within HHS and elsewhere, seeks to characterize whether emerging technologies such as the e-cigarette may have the potential to reduce the death and disease toll from overall tobacco product use, depending on who uses the products and how they are used. If such products result in minimal initiation by children and adolescents while significant numbers of smokers quit, then there is a potential for the net impact at the population level to be positive. If, on the other hand, there is significant initiation by young people, minimal quitting, or significant dual use of combustible and non-combustible products, then the public health impact could be negative.

SENATOR ROBERTS

Question 1. The Center for Tobacco Products is imposing fines for retailers that fail inspections, but they are imposing multiple fines and alleging multiple violations for a single inspection. This seems to be contrary to the provisions of the law establishing the Center for Tobacco Products which specifically states that retailers must be informed of all previous violations before being charged with an additional violation. In addition, it doesn't make sense with the penalty scale in the law that gradually increases fine amounts per violation. CTP's policy of counting one failed inspection as multiple violations could lead to a retailer losing his or her business or being hit with an unaffordable fine due to the actions of one bad employee without giving the retailer an opportunity to fix the problem. Can you explain how imposing multiple fines for a single inspection is consistent with the law?

Answer 1. FDA charges a person with a violation at a particular retail outlet only after providing notice to the retailer of all previous violations identified by FDA at that outlet, as required under section 103(q)(l)(D) of the TCA. Further, TCA section 103(q)(l)(E) states that the maximum civil money penalties (CMPs) for multiple violations shall increase from one violation to the next violation, pursuant to the penalty schedule provided in the law.

As noted in the June 2014 revised Guidance for Industry entitled "Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions," the first time FDA identifies violation(s) at a retail outlet, its policy is to send a Warning Letter. CTP counts only one violation from the first inspection that finds one or more violations at an outlet, regardless of the number of violations that were noted and included in a Warning Letter. For any subsequent inspections, CTP may count any or all violations, and its general policy is to count each of them individually.

If the respondent does not agree with the allegations in a CMP notice, wants to contest the amount of the CMP that FDA is seeking, or has other concerns related to the case, the party may file an answer. At that time, the respondent may request settlement discussions with FDA. Settlement discussions are often an efficient method of resolving a contested case. The respondent may present evidence and arguments as to why the party should not be liable for a CMP, or mitigating factors that should reduce the amount of the CMP. If the respondent and FDA do not agree on a settlement, the respondent may still have a hearing. If the respondent is not satisfied with the decision at a hearing, the respondent has a right to appeal the initial decision to the Departmental Appeals Board (DAB) by filing a notice of appeal with the DAB and the FDA Division of Dockets Management within 30 days of the relevant decision.

In an effort to provide information to retailers and other interested stakeholders regarding the issuance of CMPs for violations of the FD&C Act requirements relating to tobacco products in retail outlets, FDA has issued two guidance documents ("Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions" and "Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers") and has provided at least three compliance training webinars that covered the topic of CMPs.

Question 2. The Family Smoking Prevention legislation was set up to create incentives for voluntary compliance by retailers by, for example, providing for a smaller set of penalties for retailers that have compliance programs that include using an approved training program. However, it is my understanding that CTP has not yet approved a single training program. I'm hearing from retailers that without that approval it is hard for them to justify the investment in training that they would like to make. Can you tell me when CTP will approve one or more training programs so that retailers know which ones they should use to best comply with the law?

Answer 2. Retailers are encouraged to implement a training program for their staffs and to tailor their programs to meet the needs of their employees and businesses, taking into consideration the size of their businesses and the products they sell.

FDA understands that some retailers have established various tobacco retailer training programs. FDA does not currently approve any retailer training program. FDA intends to promulgate regulations establishing standards for approved retailer training programs. The TCA also establishes two schedules for the maximum civil money penalties that can be assessed for violations of regulations issued under section 906(d) of the FD&C Act, including violations of FDA regulations at 21 CFR part 1140—one schedule for retailers that do not have an approved training program, and another with lower penalties for retailers with an approved training program. In determining the amount of the penalty the Agency will seek, CTP will use the lower schedule for all retailers, whether or not the retailer has implemented a training program, until regulations are developed that establish standards for retailer training programs. FDA has also issued a guidance entitled "Guidance for Industry: Tobacco Retailer Training Programs," which is available at *www.fda.gov/TobaccoProducts/GuidanceCompliance Regulatory information/ucm218898.htm*. This guidance contains examples of recommended elements that may be helpful to retailers when designing and implementing a training program.

Currently, FDA develops compliance training materials for retailers, posts important information to its Web site, issues guidance documents, meets with and presents before stakeholders, and has established a comprehensive program for training on, and assistance with, the requirements of the Act. In fiscal year 2014, CTP delivered five compliance training webinars for retailers and small businesses covering topics relevant to tobacco product businesses. In addition, FDA is developing a new retailer education campaign and will continue to provide easy-to-understand,

free educational materials online and by direct mail that help tobacco retailers comply with the law. The campaign currently provides materials in English and Spanish and plans to expand to include additional languages in fiscal year 2015.

SENATOR BURR

Question 1. Do you believe that public health messaging with respect to tobacco products should be based on science and reflect the risk continuum of tobacco products?

Answer 1. Yes, to ensure that public health messaging is effective, it should be grounded in solid science. To that end, FDA continues to collaborate with CDC and NIH, and invests in research in the development and evaluation of its public education efforts. At the same time, scientific consensus is not required prior to disseminating public health information.

FDA also recognizes that there is a continuum of tobacco products with potential differences in risk, and the Agency will rely on sound science to demonstrate the public health impact of new FDA-regulated tobacco products. Many provisions of the TCA require FDA to make decisions after considering the risks and benefits to the population as a whole, including both users and non-users. A risk continuum is a relevant consideration as we make regulatory policy. But the potential patterns of use make this a challenging assessment. For example, in addition to understanding the adverse health impact of a particular product or regulatory action on tobacco product users, the Agency's actions include consideration of the impact on non-users (including youth) initiating tobacco use, the potential for delayed cessation, and the potential for former smokers to resume tobacco use.

Question 2. What are the potential health benefits for individuals moving from smoking conventional cigarettes to forms of non-combustible tobacco products, including those with the goal of cessation as well as those who would otherwise be using a combustible tobacco product?

Answer 2. FDA acknowledges that there may be products that contain lower levels of toxicants than cigarettes. HHS, including CDC, FDA, and NIH, are conducting studies that will assess the addictiveness and the relative toxicities of e-cigarettes and other tobacco products. However, under the TCA, FDA must make determinations about whether a particular regulatory action or the marketing of a particular product is appropriate for the protection of the public health based on a population health standard. This means that FDA must consider the risks and benefits to both users and non-users.

Thus, in addition to understanding the impact for smokers who completely switch to a non-combustible tobacco product, the Agency needs to understand the impact on youth and others initiating tobacco use, smokers continuing to smoke while using the non-combustible product, the potential for delayed cessation of smoking, and the potential for former smokers to resume tobacco use. Products marketed for therapeutic purposes, such as FDA-approved smoking cessation products, would continue to be regulated under the safety and efficacy standard that currently exists for drugs and devices. They would not be regulated as tobacco products.

Question 3. Will FDA take into consideration the scientific evidence comparing the health impact of vaping compared to combustible tobacco cigarettes? Please describe any scientific theory or current evidence that e-cigarettes are as hazardous as, or more hazardous than, combustible tobacco cigarettes.

Answer 3. The tobacco marketplace is changing rapidly, with new types and brands of tobacco products increasing at a faster pace than ever before. The resulting prospect of consumers exploring and adopting use of new products is prompting tobacco control experts, scientists, and regulators to consider how to best evaluate, monitor, regulate, and communicate to the public about these products in order to protect the public health.

E-cigarettes have become a significant source of nicotine in this new tobacco use environment. Awareness of e-cigarettes among U.S. adults doubled between 2009 and 2011. Adolescent use increased between 2011 and 2014. According to the University of Michigan's *Monitoring the Future* study, in 2014, 9 percent of 8th graders reported using an e-cigarette in the past 30 days, 16 percent of 10th graders, and 17 percent of 12th graders.

Much remains to be learned about the risks of e-cigarettes to health, as well as their possible benefits. E-cigarettes could be a detriment to public health. E-cigarettes have the potential to re-normalize smoking, encourage youth to initiate smoking, and/or prompt users to continue or to escalate to cigarette use—in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, childhood poisoning

events, and physical harm from defective products (such as exploding batteries). On the other hand, e-cigarettes could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use. Anecdotes illustrating both harms and benefits abound, but it is definitive scientific evidence that should drive the actions taken with respect to e-cigarettes.

CTP has identified e-cigarettes as an immediate research priority area, and since 2012 has funded 50 research projects to better understand e-cigarette initiation, use, perceptions, dependence, and toxicity. Research to address e-cigarette knowledge gaps is being funded by grants administered through NIH and through internal FDA research. This ongoing and funded research is likely to provide characterization of some e-cigarette devices, e-liquids, and aerosols, and a better understanding of e-cigarette users, reasons for use, abuse liability, user perceptions, health effects, and topography. CTP comprehensively assesses e-cigarette use among U.S. youth and adults via the national tobacco surveillance systems in collaboration with the CDC (National Youth Tobacco Survey (NYTS) and National Adult Tobacco Survey (NATS)). CTP has also partnered with CDC's Pregnancy Risk Factor Surveillance System (PRAMS) to track the prevalence of e-cigarette use before, during and shortly after pregnancy, among women who have recently given birth. An analysis of the totality of the data will be needed to assess the impact of e-cigarettes on the public health.

Question 4. Is there a potential public health benefit at the individual tobacco user level, as well as for the millions of individuals, who may be seeking to transition from tobacco products that present the greatest level of harm to products with a reduced or lesser level of harm?

Answer 4. FDA recognizes that there is a continuum of tobacco products with potentially different toxicity profiles, and will rely on sound science to demonstrate the public health impact of new FDA-regulated tobacco products. HHS, including CDC, FDA and NIH, are conducting studies that will assess the addictiveness and the relative toxicities of e-cigarettes and other tobacco products. Many provisions of the TCA require FDA to make decisions about what is appropriate for the protection of the public health after considering the risks and benefits to the population as a whole, including both users and non-users. A risk continuum is a relevant consideration as we make regulatory policy. But the potential patterns of use make this a challenging assessment. For example, in addition to understanding the adverse health impact of a particular product on tobacco product users, the Agency's actions include consideration of the likely impact on youth or others initiating tobacco use, smokers continuing to smoke while using the product, the potential for delayed cessation of smoking, and the potential for former smokers to resume tobacco use.

Much remains to be learned about the risks of e-cigarettes to health, as well as their possible benefits. E-cigarettes could be a detriment to public health. E-cigarettes have the potential to re-normalize smoking, encourage youth to initiate smoking, and/or prompt users to continue or to escalate to cigarette use—in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, childhood poisoning events, and physical harm from defective products (such as exploding batteries). On the other hand, e-cigarettes could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use.

Question 5. Is FDA committed to ensuring that the Agency's regulation of tobacco products will ensure that consumers have timely access to innovative products that present less harm to them than combustible tobacco cigarettes?

Answer 5. FDA's proposed rule to extend its tobacco product authorities to additional products that meet the statutory definition of "tobacco product" demonstrates the Agency's sensitivity to the importance of innovation. FDA has proposed an extended compliance period for manufacturers of newly deemed products to submit their marketing applications. In addition, for products with applications submitted in that compliance period, FDA has indicated the Agency 's intent to continue the compliance period and not initiate enforcement action against products on the market for failing to have marketing authorization, pending FDA's review of the application.

FDA has also specifically solicited suggestions on other actions/approaches that the Agency could take to address this issue. The proposed deeming rule also acknowledges that there exists a continuum of nicotine-delivering products that may

pose different levels of risk to the individual. We pose a series of questions in the rule, and sought comment on how this continuum should impact regulatory policy going forward, once the final rule is in effect.

Question 6. FDA received seven modified-risk tobacco product pathway applications, but it is my understanding that FDA refused to accept six of these applications. Please provide FDA's reasoning for refusing to accept each of these six applications. How is FDA ensuring that applicants have clear guidance with respect to the requirements that need to be met in order for FDA to accept these applications for review?

Answer 6. When FDA receives a modified-risk tobacco product (MRTP) application, it will first determine whether the application can be accepted and filed for substantive review. For example, if the application is for a product that is not a "tobacco product,"or is for a tobacco product that is not currently regulated by FDA, or FDA is unable to review and process the application, the Agency may refuse to accept it. If the application is accepted, FDA will conduct a filing review to determine whether the application is complete, i.e., whether it contains all the items required under Section 911(d) of the FD&C Act. If the application is incomplete, FDA may refuse to file it. If the application is complete, FDA will file the application and begin a substantive review.

As of September 30, 2014, FDA has received multiple MRTP applications. Ten of these applications have been filed by FDA and are currently undergoing scientific review. FDA issued refuse-to-accept letters for two applications and refuse-to-file letters for four applications, because they failed to include information required under the TCA and/or were about products that CTP does not currently regulate. One application was withdrawn by the applicant.

A draft guidance was released for public comment in March 2012, containing information about submitting applications for MRTPs. The draft guidance addresses topics such as how to organize and submit an application, what scientific studies and analyses could be submitted, and what information could be collected through post-market surveillance and studies.[5] FDA has also been meeting with individual manufacturers to discuss studies the manufacturers have proposed to demonstrate that marketing authorization for a product is appropriate under section 911 of the FD&C Act.

Question 7. By what date does FDA intend to finalize its draft guidance on modified-risk tobacco product requirements?

Answer 7. FDA is currently reviewing comments on the draft guidance on MRTP applications, but is not able to provide a specific date for finalization.[6] FDA is committed to helping industry better understand the tobacco product review process and the requirements in the law related to MRTP, and plans to continue meeting with stakeholders as needed to answer specific questions.

Question 8. Last fall, GAO issued a report that found that as of late June 2013, CTP had made a final decision on only 6 of the 3,788 substantial equivalent submissions, with the remaining submissions still undergoing CTP review. In this same report, GAO recommended that FDA establish performance measures that include timeframes for making decisions on new tobacco product submissions and monitor performance relative to those timeframes. Last month, GAO testified that as of December 31, 2013, CTP had made final decisions for only 30 of the 4,490 SE submissions the agency had received. Will CTP set a performance target for provisional SE submissions to mitigate the current backlog of submissions? If so, please provide the performance goals and targets for clearing CTP's current backlog. If not, please explain why the Agency will not apply any performance metrics to these submissions.

SE reports fall into two categories. One category is "provisional" SE reports that apply to new products introduced to market between February 15, 2007, and March 22, 2011, and for which SE reports were submitted to FDA by March 22, 2011. These products can remain on the market unless FDA finds they are NSE. The other category is "regular" SE reports (reports for new products submitted after March 22, 2011). Tobacco products subject to a regular SE report may not be marketed unless FDA issues an order that the tobacco product is substantially equiva-

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[5] "Draft Guidance for Industry: Modified Risk Tobacco Product Applications." 77 Fed. Reg. 20026 (published for comments on April 3, 2012).

[6] Section 911(1)(l) of the FD&C Act directs FDA to issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified-risk tobacco products. FDA issued this draft guidance in compliance with section 911(1)(l). See 77 FR 20026 at 20027 (April 3, 2012). *http:www.gpo.gov//dsys/pkg/FR-2012–04-03/pdf/2012-7908.pdf*.

lent and in compliance with the requirements of the FD&C Act. In April 2014, CTP established performance measures that include timeframes for review of regular SE reports. These performance measures were implemented on October 1, 2014.

CTP has begun review of provisional SE reports and issued the first decisions on these reports on February 21, 2014. As provisional SE reports were submitted very early in the history of the review process, they were submitted before applicants had the knowledge and experience gained over the last few years. Thus, provisional SE reports are likely to be less well-organized, have many more deficiencies, and require a more complicated review by FDA than SE reports for regular products that are now being submitted. The potential for both large numbers of deficiencies and varying quality of provisional SE reports prevents FDA from predicting the time necessary for completing the initial review and for making a final decision. While it is important that FDA makes review decisions about tobacco products in a timely manner, it is absolutely critical that these marketing decisions are sound, grounded in the best available science, and made in accordance with applicable public health standards. Once FDA has had more experience addressing provisional SE reports, we expect to better understand the time that will be needed to review individual reports. At that time, we intend to set performance goals for provisional SE reports.

Question 9. How does CTP propose to uphold its responsibility to review products in a timely manner given the potential impact the proposed deeming rule on CTP's current backlog of submissions? Will CTP establish performance goals and timelines to balance the current backlog of submissions with any additional workload as a result of the two options proposed with respect to cigars and other products under the proposed deeming rule? If so, please provide details.

Answer 9. On March 24, 2014, CTP announced that we no longer have a backlog of regular SE reports awaiting review and that the Center is starting review on regular SE reports as they are received. As of September 30, 2014, 45 percent of regular SE reports had been resolved by a final decision[7] either because FDA issued an Order letter, issued a Refuse-to-Accept letter or because the submission was withdrawn. FDA has issued a Scientific Advice and Information Request Letter or a Preliminary Finding Letter for 81 percent of the regular SE reports that are pending.

CTP established four performance goals that include timeframes for review of regular SE reports, review of Exemption from SE requests, and review of MRTP applications (see tables below). Beginning on October I, 2014, tracking of all goals was implemented.

Regulatory Performance Measures

Substantial Equivalence Reports for products currently regulated by FDA (cigarettes, cigarette tobacco, smokeless tobacco, roll-your-own tobacco)

Category	Performance goal	Submission cohort (In percent)
Regular SE Reports	Finalize jurisdiction and completeness review (and issue letter as appropriate) within 21 days of FDA receipt of SE Report.	Fiscal year 2015: 50 Fiscal year 2016: 60 Fiscal year 2017: 70 Fiscal year 2018: 80
	Review and act on an original SE Report within 90 days of FDA receipt.	Fiscal year 2015: 50 Fiscal year 2016: 60 Fiscal year 2017: 70 Fiscal year 2018: 80
Regular SE Report Resubmissions	Review and act on a SE Report resubmission within 90 days of FDA receipt.	Fiscal year 2015: 50 Fiscal year 2016: 60 Fiscal year 2017: 70 Fiscal year 2018: 80

Exemption from SE Requests for products currently regulated by FDA (cigarettes, cigarette tobacco, smokeless tobacco, roll-your-own tobacco)

[7] Final decisions include Refuse-to-Accept letters, withdrawals by an applicant, substantially equivalent (SE) orders, not substantially equivalent (NSE) orders.

Category	Performance goal	Submission cohort (In percent)
Exemption from SE	Review and act on a Request for Exemption from SE within 60 days of FDA receipt.	Fiscal year 2015: 50 Fiscal year 2016: 60 Fiscal year 2017: 70 Fiscal year 2018: 80

Modified-Risk Tobacco Product Applications (MRTPA) for products currently regulated by FDA (cigarettes, cigarette tobacco, smokeless tobacco, roll-your-own tobacco)

Category	Performance goal	Submission cohort (In percent)
MRTPA	Review and act on a complete MRTP application within 360 days of FDA receipt.	Fiscal year 2015: 50 Fiscal year 2016: 60 Fiscal year 2017: 70 Fiscal year 2018: 80

For purposes of the regulatory performance measures listed above:

• "Review and act on" means issuance of a letter (e.g., Scientific Advice and Information Letter, Preliminary Finding Letter, NSE or SE Order) after the review of an accepted regular SE report or resubmission; issuance of an order or letter after the review of an exemption from SE request; or the issuance of an order or letter after the complete review of a filed MRTP application. This timetable for MRTPs is FDA's best estimate, but it is based on limited information.

• "Issue letter as appropriate" means the issuance of an Acknowledgement Letter or Refuse-to-Accept Letter. If acknowledged, and the administrative review notes missing information, the information will be addressed during scientific review.

• Scientific Advice and Information Letter or Preliminary Finding Letter means a written communication, which lists deficiencies in an SE Report that precludes either further scientific review or issuance of an SE Order.

FDA has made significant progress in reviewing SE reports for currently regulated products and this momentum will continue. The Center has increased staffing, taken steps to streamline the SE review process, and established the performance measures above that include timeframes for review of regular SE reports and review of exemption from SE requests. We have been able to develop these performance goals because of increased capacity, efficiency, and knowledge of the scientific evidence needed to adequately review SE reports.

FDA plans to continue increasing staffing, strengthening our IT systems, and developing guidance and/or regulations to clarify submission requirements. As FDA and industry gain experience with submissions for these newly deemed products, we intend to identify and implement performance goals for these submissions.

CTP is committed to a consistent, transparent, and predictable review process and to completing reviews in a timely manner.

SENATOR CASEY

Question 1. There are an increasing number of cases of children who have been poisoned from electronic cigarette refill vials. In April, the CDC warned that the number of calls to poison control centers for nicotine poisoning from electronic cigarettes has increased dramatically. More than half of these calls involved children age 5 or under. What, if any, steps does the FDA feel would be appropriate to address this issue? Does the FDA plan to begin collecting data on this matter or propose a regulation to require childproof refill vials if the current deeming regulation is approved?

Answer 1. In the preamble to the proposed deeming rule, FDA included discussion regarding the recent increased incidence of child nicotine poisoning and the Agency's concerns regarding this issue. FDA considers the deeming rule to be a foundational regulation, which, when finalized, would allow the Agency to take further actions regarding critical issues, such as protecting children from liquid nicotine, related to the proposed deemed products. For example, FDA would have authority to issue tobacco product manufacturing practice regulations under section 906(e) of the FD&C Act. Such regulations could include requirements regarding the packaging and storage of tobacco product such as liquid nicotine. In addition, under section 907 of the FD&C Act, FDA would have authority to issue a product standard with provisions related to components of tobacco products, such as liquid nicotine refill cartridges.

Sections 906(d) and 907(a)(4)(B)(v) also afford FDA the authority to issue regulations restricting the sale and distribution of a tobacco product, if FDA determines that such a regulation would be appropriate for the protection of the public health.

Question 2. In your testimony, you discuss the partnerships the CTP has formed with organizations such as the NIH and the CDC to advance the regulatory science base for tobacco products. What, if any, impact did sequester cuts to institutions like the NIH and the CDC have on those efforts? Is there any research that is not being done or that is being delayed because of a lack of adequate funding?

Answer 2. Congress designed CTP's financial structure to depend, in part, on carryover funding, so it made CTP's tobacco fees available until expended. This made it possible for FDA to limit the impact of sequestration in fiscal year 2013 on the TCA. FDA successfully worked with institutions such as NIH and CDC to ensure that activities funded with tobacco user fees were able to continue.

[Whereupon, at 4:59 p.m., the hearing was adjourned.]

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