EXAMINING THE IMPLEMENTATION OF THE TOBACCO CONTROL ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

APRIL 8, 2014

Serial No. 113–139

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

90–906 PDF WASHINGTON : 2014

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C O N T E N T S

EXAMINING THE IMPLEMENTATION OF THE TOBACCO CONTROL ACT

TUESDAY, APRIL 8, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY AND COMMERCE,
COMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to call, at 10:17 a.m., in room 2322 of the Rayburn House Office Building, Hon. Joe Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Shimkus, Murphy, Lance, Cassidy, Guthrie, Griffith, Bilirakis, Ellmers, Upton (ex officio), Pallone, Engel, Capps, Green, Barrow, Christensen, Castor, and Waxman (ex officio).

Staff present: Gary Andres, Staff Director; Noelle Clemente, Press Secretary; Paul Edattel, Professional Staff Member, Health; Sydne Harwick, Legislative Clerk; Carly McWilliams, Professional Staff Member, Health; Charlotte Savercool, Legislative Coordinator; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Ziky Ababiya, Democratic Staff Assistant; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; Karen Nelson, Democratic Deputy Staff Director, Health; Anne Morris Reid, Democratic Senior Professional Staff Member; and Matt Siegler, Democratic Counsel.

Mr. PITTS. The subcommittee will come to order. Chair will recognize himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

The Tobacco Control Act, TCA, was signed into the law on June 22, 2009. The TCA established the Center for Tobacco Products, the CTP, within FDA, and gave FDA authority over the regulation of tobacco products, including restricting their sale, distribution, advertising and promotion. In addition, FDA has the authority to require changes in the design and characteristics of current and future tobacco products, such as the reduction or elimination of harmful ingredients and additives. The sole funding source for CTP is user fees assessed on tobacco manufacturers and importers.

GAO has conducted a comprehensive study on the law's implementation, and in September 2013, it released a report entitled "New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process." The report examines CTP's review of new tobacco product submissions, responses to meeting requests, and use of its

user fees. Among its findings, GAO reports that CTP lacks basic performance measures "like time frames for reviews of submissions" and that this "limits CTP's ability to evaluate policies, procedures and staffing resources in relation to CTP's submission review process, and in turn limits CTP's ability to reasonably assure efficient operations and effective results."

GAO concludes that "an entity that is limited in its ability to evaluate its performance will be hard-pressed to determine what adjustments it should make to its operations, or how to plan for the future." This report raises troubling concerns about CTP's performance, and its ability to effectively implement the Tobacco Control Act, and respond to the thousands of new product submissions it has received in a timely manner.

As the subcommittee with oversight of FDA and the Center for Tobacco Products, we were hoping to hear directly from the FDA, however, Dr. Marcia Crosse of GAO is here today to walk us through the report and GAO's ongoing efforts to oversee implementation of the act.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Tobacco Control Act (TCA) was signed into law on June 22, 2009.

The TCA established the Center for Tobacco Products (CTP) within FDA and gave FDA authority over the regulation of tobacco products, including restricting their sale, distribution, advertising, and promotion. In addition, FDA has the authority to require changes in the design and characteristics of current and future tobacco products, such as the reduction or elimination of harmful ingredients and additives.

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The report examines CTP's review of new tobacco product submissions, responses to meeting requests, and use of its user fees.

Among its findings, GAO reports that CTP lacks basic performance measures "like time frames for reviews of. . . submissions" and that this "limit[s] CTP's ability to evaluate policies, procedures, and staffing resources in relation to CTP's submission review process and, in turn, limit[s] CTP's ability to reasonably assure efficient operations and effective results."

GAO concludes that "[a]n entity that is limited in its ability to evaluate its performance will be hard-pressed to determine what adjustments it should make to its operations or how to plan for the future."

This report raises troubling concerns about CTP's performance and its ability to effectively implement the Tobacco Control Act and respond to the thousands of new product submissions it has received in a timely manner.

As the subcommittee with oversight of FDA and the Center for Tobacco Products, Dr. Marcia Crosse of GAO is here today to walk us through the report and GAO's ongoing efforts to oversee implementation of the act.

Thank you.

Mr. PITTS. Yield the balance of my time to the gentleman from Kentucky, Mr. Guthrie.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. GUTHRIE. Thank you, Mr. Chairman. Thank you for yielding and holding this hearing today.

Congress granted the Center for Tobacco Products the authority to regulate tobacco products, but unfortunately, the process has been fraught with problems. I have heard from many in the industry, including constituents, who have been stuck in the dysfunctional CTP approval process.

As a result of CTP's inaction, many reduced risk or harm reduction products are not being approved and are not available to consumers. There are examples of ingredients that could be potentially hazardous, and are removed from products sold in other international markets, but because of the burdensome process at the FDA, and the unlikelihood that their submission would even be reviewed, they have to leave the ingredient in their products sold in the U.S. So consumers overseas are offered a potentially less harmful product than American consumers have access to.

There are a number of examples like this, very minor tweaks that require substantial equivalence or SE submissions, and they just sit at CTP waiting approval. For March 2011 until June 2013, CTP did not rule on one single filing, and at that point, they ruled on six of nearly 4,000 submissions. To date, I believe they have made only 12 determinations. It appears that CTP is just not doing their job.

I have a bill, House Resolution 389, that would exercise oversight over CTP, and require they submit a report to Congress on their activity. It is a good-government, commonsense approach to ensure that this agency of government works, and is accountable to Congress and the committee that is vested with its authority.

Tobacco user fees are not subject to reauthorization, so there is little opportunity for the industry to enter into discussions with FDA the way pharmaceutical companies or device manufacturers can. As the oversight body, I believe we should be able to see how these funds are being used, the number of applications being reviewed or still pending, and get a clear picture of the division's work.

Mr. Chairman, my—by its inaction, CTP is blocking consumers from having access to less harmful products, with the little sign of improvement, I encourage my colleagues to support my bill, which would ensure we receive a clear picture of CTP's activities moving forward.

I yield back.

Mr. PITTS. Chair thanks the gentleman.

Now recognizes the ranking member of the subcommittee, Mr. Pallone, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman, and thank you for calling today's important hearing on the implementation of the Tobacco Control Act.

This year marks 5 years since the Tobacco Control Act became law, which, for the first time, provided FDA the authority to regulate tobacco products.

The Center for Tobacco Products was given an enormous but critically overdue task to protect the public health from the dan-

gers of tobacco use, and many members of this committee, including myself, led by Mr. Waxman, were proud to work on this groundbreaking law.

We have known for 50 years about the terrible health effects of smoking. Tobacco companies initiated and sustained the Nation's tobacco epidemic, and for decades deliberately misled the public about the risks of smoking. Meanwhile, new findings in the latest Surgeon General's report indicated cigarettes are even more hazardous and addictive than they previously were known. Each year, 480,000 Americans die from smoking-related causes, and smoking costs the country over $289 billion in health bills and lost productivity.

So I think we can all agree that the Center for Tobacco Products has a lofty task moving forward, but I wanted to highlight a few of the important benefits FDA has begun to execute.

They have restricted the sale of and marketing of tobacco products to children, they have set standards for companies who make claims about the harms on their products, they have implemented a new science-based public health standard for the review of tobacco products, and they have begun to review these new product applications. Of course, there is a lot more work to be done. There are a number of regulatory actions that I believe still need to occur to protect the public from the dangers of other tobacco products, and this includes banning candy-flavored cigars that appeal to our youth, and ending e-cigarette marketing practices that target kids. We should also raise taxes on all tobacco products, and close loopholes that let tobacco companies avoid Federal taxes. In addition, I believe we must remove barriers to quitting tobacco use by making certain that tobacco cessation coverage is available to all Americans through the Affordable Care Act.

Mr. Chairman, I hope this will be the first in a number of oversight hearings on the tobacco law. For the past few years, my colleagues and I have asked for tobacco hearings. In fact, the most recent request would have examined the recent alarming trends in the currently unregulated tobacco products like e-cigarettes. Just last week, we learned that about—some data came forward that reports of poisonings caused by accidental ingestion of e-liquids, and that is the liquid containing nicotine used to refill e-cigarette cartridges. That—the incidents tripled from 2012 to 2013. And while I appreciate the views of GAO and look forward to Ms. Crosse's testimony and comments, today's hearing should have included the FDA. It is important that we offer our administration some courteousness. That includes allowing for sufficient time in scheduling hearings. So I hope you will ensure that the Director of the Center for Tobacco Products and the FDA have a legitimate ability to update members on FDA's regulatory efforts.

I would like to yield the balance my time to the gentleman from New York, Mr. Engel, if he would like to use it.

OPENING STATEMENT OF HON. ELIOT L. ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. ENGEL. Well, I thank my friend for yielding to me, and I want to thank both the ranking member and the chairman for holding this hearing.

I want to echo the comments of Ranking Member Pallone, and then I also wish that this hearing could have been scheduled at a time that would have allowed the FDA to participate. The implementation of a Family Smoking Prevention and Tobacco Control Act is critically important, and I think members of this committee would have benefitted from hearing the FDA's perspective.

That being said, however, I do appreciate the willingness of GAO to come here today to testify about their oversight efforts on the law.

My district includes parts of the Bronx, where over 100,000 people have asthma. I live in that borough. This borough has some of the highest rates of asthma-related emergency room visits in all of New York. This reality is due in no small part to the prevalence of smoking and secondhand smoke exposure. Just Friday, a report by New York State Comptroller, Thomas DiNapoli, found that asthma-related medical expenses and lost productivity are costing my State an estimated $1.3 billion a year. Eliminating the use of tobacco products amongst children and youth can play an important role in reducing these asthma-related costs.

So I am pleased that we are holding hearings on this today, and I look forward to the testimony.

And I yield back.

Mr. PITTS. The Chair thanks the gentleman.

Now recognizes the chairman of the full committee, Mr. Upton, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman.

You know, it has been 5 years since the Family Smoking Prevention Tobacco Control Act was signed into law. We have a collective responsibility as the FDA's authorizing committee to ensure the Agency is implementing the law, and all laws, in a fair, consistent and transparent manner. FDA's decision should always be based on sound scientific evidence, with the health of our Nation's citizens in mind.

The GAO has done a thorough job overseeing the implementation efforts conducted by the Center for Tobacco Products to date, and their work continues.

I want to thank Dr. Marcia Crosse from the outset for her hard work on this front, and for her responsiveness to the committee staff.

GAO has raised a number of concerning issues about the efficiency and consistency of CTP's regulatory activities to date. For instance, they issued a report in September of last year noting that the center had yet to set any performance measures or reviewed timelines to ensure accountability and gauge progress. I am a firm believer that transparency does breed accountability. Congressman

Guthrie, as he noted, did introduce The Transparency in Tobacco User Fees Act, H.R. 389, which is a commonsense piece of legislation that would require the FDA to submit annual reports to Congress on how those user fees have been spent. FDA has such a statutory requirement for user fee programs, such as PDUFA, and the insight gained from such reports has led to improvements across the board.

And again, I welcome our witnesses.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

It has been almost 5 years since the Family Smoking Prevention and Tobacco Control Act was signed into law. We have a collective responsibility as the FDA's authorizing committee to ensure the agency is implementing this law- and all laws- in a fair, consistent and transparent manner. FDA's decisions should always be based on sound, scientific evidence with the health of our Nation's citizens in mind.

The Government Accountability Office has done a thorough job overseeing the implementation efforts conducted by the Center for Tobacco Products (CTP) to date, and their work continues. I would like to thank Dr. Marcia Crosse from the outset for her hard work on this front and for her responsiveness to committee staff.

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I am a firm believer that transparency breeds accountability. Congressman Guthrie has introduced the Transparency in Tobacco User Fees Act, H.R. 389, which is a commonsense piece of legislation that would require FDA to submit annual reports to Congress on how the user fees have been spent. FDA has such a statutory requirement for user fee programs such as PDUFA, and the insight gained from such reports has led to improvements across the board.

I welcome the opportunity to examine these issues in greater detail with today's hearing.

Mr. UPTON. I yield the balance of my time to the vice chair of the Health Subcommittee, Dr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for yielding.

The Chairman is correct; this subcommittee has an obligation as the principle authorizing committee that allowed the Center for Tobacco Products to be created in the first place, we have a responsibility for its oversight. The fact of the matter is, they have been up and running for 5 years, and this is the first hearing and they are not here.

We need to know how the Agency is implementing the law. We need to know what taxes are collecting and how they are allocating the resources. We have asked these questions over and over again for 5 years.

And here is the bottom line. Somebody already said it: tobacco—when used as directed, tobacco products cause 580,000 deaths every year.

The Food and Drug Administration is charged with seeing that medicines and devices are safe and effective. 480,000 deaths every year. You can't call that safe, but it darned sure is effective.

The fact of the matter is, this Agency never belonged within the Food and Drug Administration in the first place. I argued against that when the bill passed 5 years ago. I will continue to argue

against it today, but the fact of the matter is, they are in the same building, and as long as they are housed in the same building, it is this committee's obligation to require an accounting of how are the user fees collected, how are they spent. My understanding is there is over $1 billion in user fees that have been collected in the 5 years since this agency was created, and almost half of that remains unspent.

To put that number in perspective, it is 5 times the amount of user fees collected from medical device manufacturers, and we don't have an accurate accounting as to how the money has been spent and how it will be spent. We know there were challenges about the graphic labels, and that is tied up in the courts.

Stakeholders complain of the lack of any regulatory guidance, despite the fact they were given statutory direction by this committee.

Here is the bottom line. Since we approved this agency within an agency, has it improved the health of Americans? Every statistic tells us it is going in the wrong direction.

So this morning, where is the FDA? They could not find the time to come here and testify. In fact, this is the third time this year that they have been asked to come and testify before this committee. This committee, both sides of the dais, Republican and Democrat, should be seriously concerned about the fact that the FDA, the head of the Center for Tobacco Products, will not come to this committee and testify. They are always traveling, they are always out of town. Make your other directors available to us within that same agency. We don't mind hearing from them. We don't always have to hear from the same person, but at least make an effort to accommodate the committee staff when they ask you to be here when we have these hearings.

Mr. WAXMAN. The gentleman yield?

Mr. BURGESS. I hope the GAO can shine light on these actions.

Mr. WAXMAN. I would like the clarification about FDA not being here, because as I understand it, they were notified last week, a week. They said they needed more time, so it sounds like we haven't accommodated them to be here, not that they haven't accommodated us.

Mr. BURGESS. Yes, but this—just reclaim my time, this is the third time that we have asked Mr. Zeller to come here and testify, and the third time that he has been traveling for a speech or participating in another event. So after the FDA staff informed the committee staff that Mr. Zeller could not testify on April 7, committee staff informed the FDA that any or all of the various office heads within the Center for Tobacco Products could speak and testify to their regulatory activities. Food and Drug Administration informed the committee staff that there wasn't enough time to draft and clear formal testimony by April 7. In response, the committee staff told FDA that we would not require formal testimony be submitted, an arrangement that we have previously agreed to in special circumstances. The Food and Drug Administration decided they did not want to participate without submitting formal testimony, but they were open to testifying at some point in the future. And I think this subcommittee should do everything it can to ensure that that condition is met.

I yield back.

Mr. PITTS. The Chair now recognizes the ranking member of the full committee, Mr. Waxman, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman.

I think we are making a big to-do about nothing. The FDA has been offered a number of dates. We wouldn't accept their request. I don't think we have accommodated them, and I think this is a little silly. If we are going to have a hearing, FDA ought to be here.

But let us look at the big picture. Twenty years ago, this subcommittee held a famous hearing. Seven tobacco CEO executives, seven tobacco CEOs testified at that hearing and denied that cigarettes are harmful, that nicotine is addictive, that they didn't manipulate nicotine, that they certainly wouldn't go after kids, and their denials that day galvanized the antismoking movement.

A lot has happened in the last 20 years. Smoking rates have dropped, smoke-free laws have become widespread. In 2009, Congress passed the Family Smoking Prevention Tobacco Control Act on a bipartisan basis. The tobacco companies are trying to circumvent this law. The law banned the sale of candy-flavored cigarettes. So what did the tobacco companies do? They started selling candy-flavored little cigars. The law restricted marketing of cigarettes and smokeless tobacco to kids, but companies are using the same tactics to promote e-cigarettes to kids.

We have asked repeatedly for hearings in this committee to examine these outrageous practices, but the committee has refused to hold any hearings.

Today we are finally holding a hearing on that law that was passed in 2009, which I authored, but we are focusing on a very narrow issue. The timelines for reviewing applications submitted by the tobacco companies, not the public health issues that American families care about, and FDA is not able to testify because the committee would not accommodate the Agency's reasonable request for adequate time to prepare. This is a missed opportunity.

In the 50 years since the first Surgeon General report on smoking, we have made tremendous progress in reducing tobacco use. We have cut adult and youth smoking rates in half or more, we have prevented millions of premature smoking-related deaths. Since the enactment of the Tobacco Control Act, FDA has restricted the sale and marketing of cigarettes and smokeless tobacco to youths. FDA has set standards for companies that assert their products reduce harms, and the Agency has undertaken reviews of new tobacco product applications using a new public health standard, marking the first time this industry has been regulated. But our work is far from done. These are the things we ought to be looking at. More than 480,000 Americans die each year from smoking. Each day, thousands of children try their first cigarette. Cigarette use has declined, but we have seen an alarming increase in the use of candy-flavored little cigars and e-cigarettes by our kids. That should concern us, but not at today's hearing.

There is a long list of things we need to do. First, FDA must continue implementation of the Tobacco Control Act, and take full advantage of its authorities. That is why I and other members have repeatedly called on FDA to issue deeming regulations that will stop companies from marketing e-cigarettes to kids, and using candy-like flavors to entice our kids to smoke.

Secondly, we must take coverage—we must make coverage of tobacco cessation more accessible to current smokers through the Affordable Care Act.

Third, we must raise the taxes on all tobacco products, and close the loopholes that let companies avoid Federal taxes, like the lower tax rates for pipe tobacco.

Fourth, we must support effective public health campaigns and tobacco control programs that discourage smoking.

And fifth, we must encourage other nations to adopt strong tobacco control measures, and stop the tobacco companies using trade agreements to challenge these policies.

We are unlikely to tackle these issues during today's hearing, so I hope this will be the first of a series of hearings into the tobacco industry's practices, and our progress on tobacco control.

I appreciate GAO for testifying, and the work they have done, but it just reminds me that after the series of hearings that we had in 1994 which changed the tobacco issue forever, we hadn't had a hearing in this committee for many, many years after the Republicans took control, until one day we had a hearing, not on all these health issues, but why we shouldn't encourage people to use smokeless tobacco as a way to wean off smoking. Trade one addiction for another. Of course, we never invited anybody else to come in and testify about the other public health measures that were in place to encourage people and help people give up smoking.

So you sometimes wonder, is this committee concerned about public health or are they concerned about special interests. And I put that question out there for people to think about.

Yield back my time.

Mr. PITTS. The Chair thanks the gentleman.

That concludes the opening statements. As always, the written opening statements of all members will be made part of the record.

We have one panel today, one witness. I will invite our witness to please come to the witness table and introduce her at this time, Dr. Marcia Crosse, Director, Health Care, U.S. Government Accountability Office. Your written testimony will be made a part of the record, and you will be given 5 minutes to summarize your testimony.

So at this time, Chair recognizes Dr. Crosse, 5 minutes for an opening statement.

STATEMENT OF MARCIA CROSSE, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

Ms. CROSSE. Thank you. Chairman Pitts, Ranking Member Pallone, and members of the subcommittee, I am pleased to be here today as you examine implementation of the Family Smoking Prevention and Tobacco Control Act, enacted almost 5 years ago in June 2009.

The act represents the first time that FDA has had the authority to regulate tobacco products. It requires that tobacco manufacturers submit information to be reviewed by FDA in order to market certain new tobacco products. FDA reviews the products using a public health standard, taking into account the risks and benefits of tobacco products on the population as a whole, including users and non-users. The act also established the Center for Tobacco Products, CTP, within FDA. CTP implements the act by reviewing submissions for marketing new tobacco products, enforcing prohibitions on the sale of certain tobacco products, developing and issuing regulations and guidance, and engaging in public education about the risks associated with tobacco product use. The act also authorizes FDA to assess and collect user fees from each tobacco manufacturer and importer. All of CTP's activities are funded exclusively through user fees, and unspent user fees may be carried over from year to year.

My statement today will discuss the extent to which FDA has spent its tobacco user fees, and the status of CTP's reviews of new tobacco product submissions.

At the end of fiscal year 2012, just over 3 years after the Tobacco Control Act was passed, CTP had spent less than half of the user fees it had collected to that point. The time it took to award contacts contributed to the center spending less than it had planned.

In fiscal year 2013, CTP was able to award contracts for a number of activities, including media campaigns to educate youth on the dangers of tobacco use. By the end of last year, CTP had spent over 80 percent of the approximately $1.75 billion in user fees collected by that time.

Turning to product reviews. It has taken FDA a number of years to begin making decisions on submissions for new tobacco products. Nearly all of the almost 4,500 submissions received by CTP were made under the substantial equivalence, or SE, pathway. Under the SE pathway, CTP determines whether the product has the same characteristics as a predicate tobacco product, or has different characteristics that do not raise different questions of public health. About 80 percent of the SE submissions FDA received were provisional SE submissions. This means they were received by FDA prior to a statutory deadline in March 2011, allowing the product to be marketed unless CTP finds that they are not substantially equivalent. SE submissions received after that deadline are called regular SE submissions, and these products cannot be marketed until CTP determines that they are substantially equivalent to predicate products.

CTP made its first decisions on SE submissions in June 2013, and, as of December 31, 2013, CTP has made a final decision on a total of 30 of the 4,490 SE submissions it had received. All 30 final decisions, that is, substantially equivalent or not substantially equivalent, were for regular SE submissions.

In February 2014, CTP made its first decisions on provisional SE submissions, finding products in 4 submissions to be not substantially equivalent to predicate products, and issued orders to stop the further sale and distribution of these 4 products. CTP officials and manufacturers told us that several factors increased the time it took CTP to review SE submissions, such as CTP requests for

additional information from manufacturers, and having to hire and train staff. However, we found that CTP has not had performance measures that include time frames for making final decisions on SE submissions. We reported last year that the lack of such performance measures limits CTP's ability to reasonably assure efficient operations and effective results. We recommended that FDA establish such performance measures, and the Agency agreed with our recommendation.

As of last week, FDA officials said that they expect to identify performance measures that include time frames for some types of submissions in spring 2014, and to implement the measures by October 2014. However, the Agency has not determined when it will establish performance measures for the largest part of its backlog of submissions, the provisional SE submissions for products that are currently on the market.

In addition, although FDA has increased its staff and training for staff, tobacco industry stakeholders express concerns about whether CTP will have a sufficient number of qualified staff to review the current backlog, and also review new submissions that may be made in the future, particularly if FDA asserts jurisdiction over new types of tobacco products.

In summary, in the past year, FDA has taken a number of steps, such as media campaigns and conducting product reviews, that have begun to result in actions and final decisions. However, there are many remaining challenges for the Agency, particularly if it expands the scope of its authority to include additional types of tobacco products.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions that you or members of the subcommittee may have.

[The prepared statement of Ms. Crosse follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 10:15 a.m. EDT
Tuesday, April 8, 2014

TOBACCO PRODUCTS

FDA Spending and New Product Review Time Frames

Statement of Marcia Crosse
Director, Health Care

GAO Highlights

Highlights of GAO-14-508T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

April 8, 2014

TOBACCO PRODUCTS

FDA Spending and New Product Review Time Frames

Why GAO Did This Study

In 2009, the Tobacco Control Act granted FDA authority to regulate tobacco products such as cigarettes. The act authorizes FDA to assess and collect user fees from each tobacco manufacturer and importer for FDA activities related to tobacco product regulation. The act also requires that manufacturers submit information—for example, a statement of the tobacco product's ingredients—to be reviewed by FDA in order to market new tobacco products. FDA reviews the products using a public health standard, taking into account the risks and benefits of tobacco products on the population as a whole, including users and nonusers. The act represents the first time that FDA has had the authority to regulate tobacco products.

This testimony highlights and provides selected updates to key findings from our September 2013 report, entitled, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process* (GAO-13-723). This report examined (1) the extent to which FDA spent its tobacco user fee funds, and (2) the status of CTP's reviews of new tobacco product submissions. GAO reviewed FDA data on tobacco user fees collected by FDA and spent by all of CTP's offices. GAO also analyzed CTP data on product submissions, including whether specific steps in the review process had been completed.

What GAO Recommends

In its September 2013 report, GAO recommended FDA establish time frames for making decisions on submissions. FDA plans to identify time frames in spring 2014 and implement them by October 2014.

View GAO-14-508T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

The Food and Drug Administration (FDA) spent (obligated) less than half of the $1.1 billion in tobacco user fees it collected from manufacturers and others from fiscal year 2009 through the end of fiscal year 2012; however, FDA's spending increased substantially in fiscal year 2013. Through December 31, 2013, FDA spent nearly 81 percent of the approximately $1.75 billion in fees collected by that time. According to officials in FDA's Center for Tobacco Products (CTP), the center established by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to implement the act's provisions, the time it took to award contracts contributed to the center spending less than it had planned to spend. In fiscal year 2013, FDA was able to carry out a number of activities that were originally planned for fiscal years 2011 and 2012, such as efforts to educate youth on the dangers of tobacco use. About 79 percent ($1.12 billion) of user fees spent as of December 31, 2013, was spent by three CTP offices: Office of Health Communication and Education, Office of Science, and Office of Compliance and Enforcement.

As of January 7, 2013, CTP had finished initial, but not final, review steps for most of about 3,800 submissions it had received for new tobacco products (those not on the market on February 15, 2007). Ninety-nine percent of the submissions received were made under the substantial equivalence (SE) pathway, through which CTP determines whether the product has the same characteristics as a predicate tobacco product (a product commercially marketed in the United States on February 15, 2007, or previously found to be substantially equivalent) or has different characteristics that do not raise different questions of public health. For most SE submissions received by January 7, 2013, CTP took more than a year and a half from the date a submission was received to the date CTP's initial review steps were completed; initial review steps precede a scientific review step during which CTP determines whether the product is substantially equivalent to a predicate product. CTP made its first decisions on SE submissions in late June 2013—about 3 years after FDA's receipt of the first SE submission—and as of December 31, 2013, had made final decisions for 30 of the 4,490 SE submissions the agency had received. CTP officials stated that CTP requests for additional information from manufacturers for submissions and having to hire and train new staff impacted the time it took to review submissions. GAO also found that CTP has not had performance measures that include time frames for making final decisions on SE submissions by which to assess its progress. Time frames would allow CTP to evaluate its efficiency and effectiveness and help it make appropriate adjustments.

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee,

I am pleased to be here today to discuss the Food and Drug Administration's (FDA) implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Tobacco use is the leading cause of preventable death, disease, and disability, and it is a significant contributor to health care costs in the United States. In June 2009, the Tobacco Control Act granted the FDA, an agency within the Department of Health and Human Services (HHS), authority to regulate tobacco products such as cigarettes.[1] The act requires that tobacco manufacturers submit information—for example, a statement of the product's ingredients and a description of the methods used for manufacturing the product—to be reviewed by FDA in order to market new tobacco products. FDA reviews the products using a public health standard, taking into account the risks and benefits of tobacco products on the population as a whole, including users and nonusers. The act represents the first time that FDA has had the authority to regulate tobacco products.

The Tobacco Control Act also established the Center for Tobacco Products (CTP) within FDA to be responsible for implementing the act.[2] CTP was formed in 2009—the first new center within FDA in 21 years—and it implements the act by reviewing submissions for marketing new tobacco products, enforcing prohibitions on the sale of certain tobacco products, developing and issuing regulations and guidance, engaging in public education about the risks associated with tobacco product use, and performing other activities.[3] The act also authorizes FDA to assess and

[1]Pub. L. No. 111-3, div. A, 123 Stat. 1776 (2009). Tobacco products that FDA currently regulates include cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. The Tobacco Control Act enables FDA to assert jurisdiction over other tobacco products—for example, cigars, pipe tobacco, hookah, and e-cigarettes that do not make drug claims—through rulemaking. In October 2013, FDA submitted to the White House Office of Management and Budget (OMB) a proposed rule to regulate other tobacco products that are not currently regulated. As of April 2, 2014, the proposed rule was still under review by the OMB and had not been issued by FDA.

[2]Tobacco Control Act, § 101(b), 123 Stat. at 1787 (codified at 21 U.S.C. § 387a(e)).

[3]In addition to the term submission, CTP uses the terms report, request, and application (depending on the new tobacco product) to refer to the package of information that manufacturers provide to FDA for review in order to legally market a new tobacco product.

collect user fees from each tobacco manufacturer and importer and specifies that the tobacco user fees may only be applied towards FDA activities that relate to the regulation of tobacco products.[4] All of CTP's activities are funded exclusively through tobacco user fees.

My statement will highlight key findings from our September 2013 report on FDA's review process for new tobacco products, and includes selected updates to the report.[5] Among other things, our report examined (1) the extent to which FDA spent its tobacco user fee funds, and (2) the status of CTP's reviews of new tobacco product submissions.

To examine the extent to which FDA has spent its tobacco user fee funds, we reviewed FDA's data, including information from CTP on tobacco user fees from the fourth quarter of fiscal year 2009 through the fourth quarter of fiscal year 2012, such as the amounts collected by FDA, and the amount spent by all of CTP's offices.[6] We also reviewed FDA and CTP documents, such as FDA budget justification documents. In addition, we obtained and reviewed updated information from CTP on tobacco user fees collected and spent, including spending by each CTP office, through December 31, 2013.

To examine the status of CTP's reviews of new tobacco product submissions, we analyzed data maintained by CTP's Office of Science (OS)—the CTP office primarily responsible for conducting reviews of new tobacco product submissions—regarding all submissions received by FDA as of January 7, 2013. This included data on whether specific steps of the review process were completed for each submission, and key

[4]User fees are a fee assessed to users for goods or services provided by the federal government. The Tobacco Control Act specified the total amount of user fees authorized to be collected for each fiscal year beginning with fiscal year 2009, and authorized user fees to remain available until expended (which means that FDA may carry over user fees to subsequent fiscal years if they are not obligated by the end of the fiscal year in which they were collected). Fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriations acts. For fiscal year 2014, Congress appropriated $534 million in tobacco user fees for collection and obligation—the total amount authorized under the Tobacco Control Act.

[5]GAO, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process*, GAO-13-723 (Washington, D.C.: Sept. 6, 2013).

[6]For the purposes of this testimony, spending means obligations, including those for which expenditures have been made. The term obligation refers to a definite commitment by a federal agency that creates a legal liability to make payments immediately or in the future.

dates for each submission. We also reviewed relevant laws, regulations, and agency documents (such as guidance documents and draft standard operating procedures); we interviewed OS officials to learn about the process for tracking and reviewing submissions, and to identify factors that contributed to the time CTP took to review new tobacco product submissions. We compared CTP's review processes against internal control standards, which specify that performance measures such as time frames and the monitoring of actual performance against measures are an integral part of operating efficiently, achieving effective results, and planning appropriately.[7] We also interviewed industry representatives from manufacturers and tobacco trade associations to learn about factors that may have contributed to the time taken by CTP to review submissions. In addition, we obtained and examined updated data on the number of new tobacco product submissions received by FDA as of December 31, 2013. We also discussed factors affecting timeframes with CTP officials.

We assessed the reliability of FDA data we received by reviewing related documentation, performing data reliability checks (such as examining the data for missing values), and interviewing CTP officials. After taking these steps, we determined that the data we used were sufficiently reliable for our purposes.

We conducted the work for the report on which this statement is based from November 2012 to September 2013, and updated selected information in April 2014, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

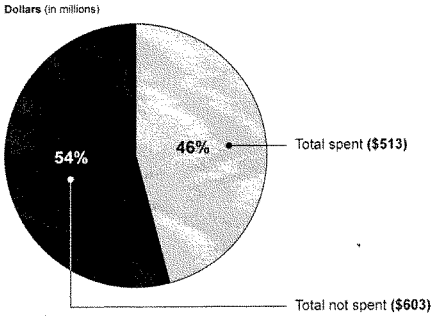
[7]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: Nov. 1999) and its supplemental guide, *Internal Control Management and Evaluation Tool*, GAO-01-1008G (Washington, D.C.: Aug. 2001).

FDA Spent Less Than Half of the User Fees Collected by the End of Fiscal Year 2012; Spending Increased Substantially in Fiscal Year 2013

FDA spent (obligated) less than half of the tobacco user fees it collected from manufacturers and others through the end of fiscal year 2012; however, FDA's spending increased substantially in fiscal year 2013. From fiscal year 2009 through the end of fiscal year 2012, FDA had collected about $1.1 billion in tobacco user fees; $603 million of these user fees remained unspent at the end of fiscal year 2012 and, thus, remained available to CTP (see fig. 1). The $513 million CTP did spend was substantially less than it had planned to spend. For example, in fiscal years 2011 and 2012, CTP spent about 45 percent of what it had planned to spend. CTP officials told us that the time it took to award contracts contributed to the center spending less than planned. For example, CTP planned to award a $145 million contract in fiscal year 2012 for a public health education campaign, but most of that amount was not awarded until the first quarter of fiscal year 2013. Spending for other contracts for both fiscal years 2011 and 2012 was lower than expected for a number of reasons, according to CTP officials: fewer contracts than expected were awarded, the scope of a contract changed, or CTP was short of staff to support the work of the contract.[8]

[8]CTP officials told us that fewer than expected contracts were awarded in those fiscal years because, for example, CTP and FDA spent significant amounts of time to determine the structure of public education campaign contracts.

Figure 1: Total Tobacco User Fees Spent and Not Spent by FDA through Fiscal Year 2012

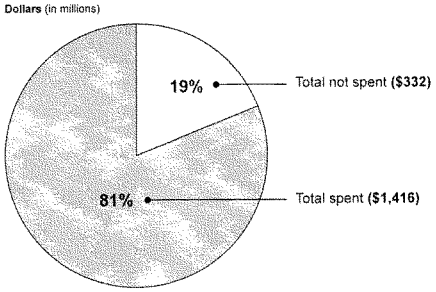


Source: GAO analysis of FDA data.

Note: This figure shows the tobacco user fees collected from fiscal year 2009 through fiscal year 2012 (which totaled about $1.1 billion), the percentage and amount of these fees spent during this period, and the percentage and amount of these fees remaining unspent at the end of this period. The total amount collected is the amount received through fiscal year 2012. The figure does not include about $62 million that was billed in fiscal year 2012 but collected in fiscal year 2013. Of the almost $513 million spent by FDA, the Center for Tobacco Products spent almost $468 million. The remaining funds were spent by other FDA entities (including the Office of Regulatory Affairs, Headquarters, and the Office of the Commissioner) and include funds spent on U.S. General Services Administration rent, other rent, and rent-related activities.

The proportion of collected tobacco user fees that FDA spent increased substantially in fiscal year 2013. Through December 31, 2013, FDA had collected nearly $1.75 billion in tobacco user fees and spent nearly $1.42 billion; $332 million of these fees remained unspent (see fig. 2).

Figure 2: Total Tobacco User Fees Spent and Not Spent by FDA as of December 31, 2013

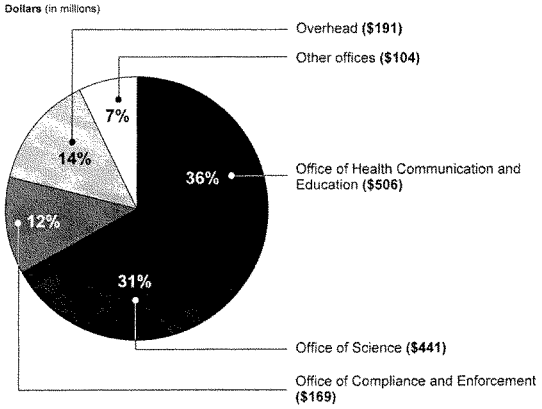


Source: GAO analysis of FDA data

Note: This figure shows the tobacco user fees collected from fiscal year 2009 through December 31, 2013 (which totaled about $1.75 billion), the percentage and amount of these fees spent during this period, and the percentage and amount of these fees remaining unspent at the end of this period. Of the $1.42 billion spent by FDA, the Center for Tobacco Products and FDA's Office of Regulatory Affairs spent about $1.36 billion. The remaining funds were spent by other FDA entities (including headquarters and the Office of the Commissioner) and spent on U.S. General Services Administration rent, other rent, and rent-related activities.

More than half of FDA's spending on tobacco-related activities through December 31, 2013, (61 percent) occurred in fiscal year 2013. FDA spent $868 million that fiscal year. As the contracting issues the agency encountered in the initial years of the center were addressed, FDA was able to carry out a number of activities in fiscal year 2013 that were originally planned for fiscal years 2011 and 2012 such as public health education campaigns. About 79 percent ($1.12 billion) of user fees spent as of December 31, 2013, was spent by three CTP offices: Office of Health Communication and Education, OS, and Office of Compliance and Enforcement (see fig. 3). In fiscal year 2013, CTP's Office of Health Communication and Education was responsible for the majority of the spending, which supported, in large part, its efforts to educate youth on the dangers of tobacco use.

Figure 3: FDA Spending by Center for Tobacco Products Office as of December 31, 2013



Source: GAO analysis of FDA data.

Note: This figure excludes FDA spending on tobacco-related activities in fiscal year 2009. Overhead includes U.S. General Services Administration rent and rent-related activities; Center for Tobacco Products and FDA overhead (information technology infrastructure and centralized funding for, among other things, furniture, office equipment, and center-wide training); and the tobacco-related spending of FDA headquarters and the Office of the Commissioner. Other offices include CTP's Office of the Center Director, Office of Management, Office of Policy, and Office of Regulation. Spending for the Office of Compliance and Enforcement includes spending for FDA's Office of Regulatory Affairs, which conducts inspections.

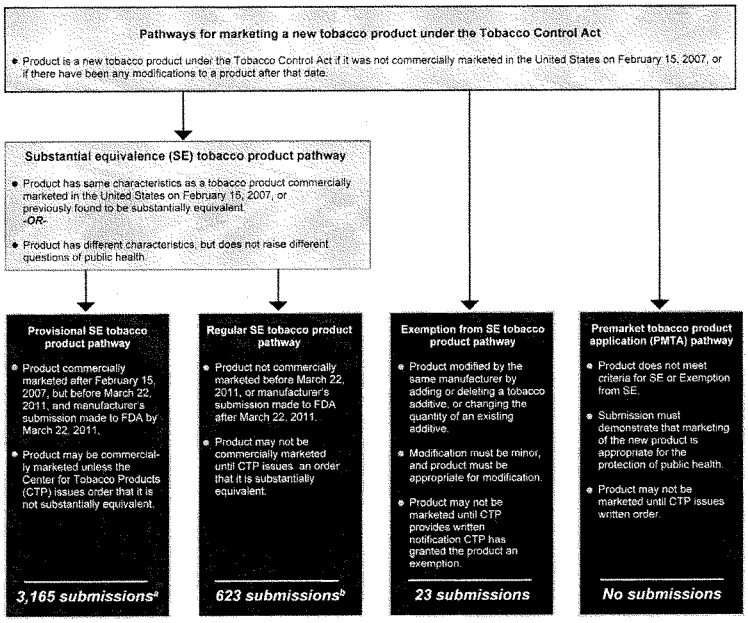
CTP Finished Initial, but Not Final, Review Steps for Most Submissions, and Lacks Time Frames for Its Review Processes

As of January 7, 2013, CTP had finished initial, but not final, review steps for most of about 3,800 submissions for new tobacco products (those not on the market on February 15, 2007). Ninety-nine percent of the submissions received by FDA were made under the substantial equivalence (SE) pathway. Under this pathway for new tobacco products, CTP determines whether the product in an SE submission has the same characteristics as a predicate tobacco product (a product commercially marketed in the United States on February 15, 2007, or previously found by FDA to be substantially equivalent) or has different characteristics that do not raise different questions of public health. About 84 percent (3,165) of the 3,788 SE submissions received as of January 7, 2013, were provisional SE submissions—that is, they were received by FDA prior to a statutory deadline allowing the product to be marketed unless CTP finds that they are not substantially equivalent.[9] SE submissions received after that statutory deadline—called regular SE submissions—cannot be marketed until CTP determines they are substantially equivalent. In addition to submissions under the SE pathway, FDA had received 23 submissions under the Exemption from SE pathway and had not received any submissions under the Premarket Tobacco Product Application (PMTA) pathway.[10] See figure 4 for information on each new tobacco product submission pathway and the number of submissions FDA received under each as of January 7, 2013.

[9]Almost all of the provisional SE submissions were received in the second quarter of fiscal year 2011—3,115 of the provisional SE submissions were received within the 3 weeks prior to the statutory deadline of March 22, 2011.

[10]Eligibility for the Exemption from SE pathway is limited to new tobacco products that are minor modifications of an existing tobacco product (adding, deleting, or changing the quantity of an additive) already marketed by the same manufacturer. New tobacco products that are not substantially equivalent or are not minor modifications of an existing tobacco product are subject to the PMTA pathway, which, among other things, requires submission of full reports of investigations of health risks. According to CTP officials and industry representatives, one reason for the lack of submissions under the PMTA pathway may be the challenge in demonstrating that a manufacturer has met the public health standard (appropriate for the protection of public health) for the PMTA pathway.

Figure 4: Number of Submissions Received by FDA for Each New Tobacco Product Pathway as of January 7, 2013



Source: GAO summary of FDA information.

[a]Of the 3,165 provisional SE submissions, 44 were withdrawn by the manufacturer as of January 7, 2013.

[b]Of the 623 regular SE submissions, 20 were withdrawn by the manufacturer as of January 7, 2013.

As of January 7, 2013, CTP finished initial, but not final, review steps for over two-thirds of the SE submissions the agency received since June 2010.[11] For most SE submissions, CTP took more than a year and a half from the date a submission was received to the date CTP's initial review steps were completed. Initial review steps include CTP's determination of whether the new product is a type regulated by FDA and whether the submission is missing information.[12] These initial review steps are followed by a scientific review, which involves an assessment of the new product by scientists in different disciplines (such as chemistry and toxicology) to determine whether it is substantially equivalent to a predicate tobacco product. As of January 7, 2013, CTP had not finished scientific review for any SE submissions—that is, had not made any decisions on SE submissions.

CTP made its first decisions on SE submissions in late June 2013—about 3 years after FDA's receipt of the first SE submission—and as of December 31, 2013, CTP had made a final decision on a total of 30 of the 4,490 SE submissions it had received. All 30 final decisions were for regular SE submissions—FDA found 17 submissions to be substantially equivalent and 13 submissions to be not substantially equivalent to a predicate tobacco product. In addition, CTP had refused to accept 22 of the 59 Exemption from SE submissions because the submissions did not meet statutory requirements, and had made no decisions for the 4 PMTA submissions. Of the 4,490 SE submissions FDA received as of December 31, 2013, 201 submissions had been withdrawn by manufacturers; of the 63 non-SE submissions FDA received, none were withdrawn. (See table 1.)

[11]FDA received the first SE submission on June 11, 2010.

[12]Our analysis of data provided by CTP found that the length of time to determine whether regular SE submissions were missing information improved over time.

Table 1: Number of New Tobacco Product Submissions and Status of FDA Review, as of December 31, 2013

Submission type		Submissions received	Initial review completed	Decisions: Closed review without decision (withdrawal)	Decisions: Product meets criteria for marketing	Decisions: Product does *not* meet criteria for marketing	Decisions: Refuse to accept or refuse to file
Substantial Equivalence (SE)[a]	Provisional[b]	3,557	3,230	117	0	0	0
	Regular[c]	933	862	84	17	13	0
	Total SE	4,490	4,092	201	17	13	0
Exemption from SE[d]		59	30	0	0	0	22
Premarket tobacco product application (PMTA)[e]		4	0	0	0	0	0

Source: GAO summary of FDA information.

Notes: The Tobacco Control Act requires that manufacturers of tobacco products submit information—for example, a statement of the product's ingredients—to be reviewed by FDA using the public health standard in order to legally market tobacco products in the United States.

[a]Manufacturers use the SE pathway if a new tobacco product has the same characteristics as a predicate tobacco product (a product commercially marketed in the United States on February 15, 2007, or previously found by FDA to be substantially equivalent); or has different characteristics, but does not raise different questions of public health.

[b]Provisional SE submissions are for new tobacco products commercially marketed after February 15, 2007, but before March 22, 2011. Provisional SE submissions were received by FDA by March 22, 2011. The tobacco products represented in these submissions may be commercially marketed unless the Center for Tobacco Products (CTP) issues an order that they are not substantially equivalent.

[c]Regular SE submissions are for new tobacco products not yet commercially marketed. Regular SE submissions were received by FDA after March 22, 2011. The tobacco products represented in these submissions may not be marketed until CTP issues an order that they are substantially equivalent.

[d]Manufacturers use the Exemption from SE pathway for new tobacco products with minor modifications (adding, deleting, or changing the quantity of an additive) of another product marketed by the same manufacturer.

[e]Manufacturers use the PMTA pathway for new tobacco products that do not meet the criteria for the other two pathways. Products included in PMTA submissions can only be legally marketed after FDA issues an order permitting their marketing.

In February 2014, CTP made its first decisions on provisional SE submissions, finding products in four provisional SE submissions to be not substantially equivalent to predicate products. The agency issued orders on February 21, 2014, to stop the further sale and distribution of four tobacco products currently on the market.[13] According to FDA, the

[13]FDA publishes its final decisions—including the four orders for its decisions to stop the further sale and distribution of tobacco products on the market that were issued on February 21, 2014—on its website: http://www.fda.gov/tobaccoproducts/labeling/marketingandadvertising/ucm339928.htm (accessed Apr. 3, 2014).

company making the SE submissions did not provide sufficient information to support a finding of substantial equivalence—for example, the company did not fully identify eligible predicate tobacco products as required for CTP to perform an SE review.

CTP officials and manufacturers told us that several factors (such as CTP requests for additional information from manufacturers for submissions and having to hire and train new staff) impacted the time it took CTP to review SE submissions. Another factor affecting review time frames was CTP's decision to place a higher priority on its review of regular SE submissions than on its review of provisional SE submissions, which contributed to longer review times for provisional SE submissions when compared to regular SE submissions. Specifically, according to OS officials, in the summer of 2011 CTP prioritized reviews for regular SE submissions over provisional SE submissions, so resources were shifted away from provisional SE submissions. CTP officials said that there were three reasons for placing a higher priority on its review of regular SE submissions over provisional SE submissions: (1) tobacco products in provisional SE submissions could remain on the market legally (unless and until CTP issued an order of not substantially equivalent), (2) FDA received a large number of provisional SE submissions on March 21, 2011 (the day before the statutory deadline for submitting provisional SE submissions), making it impractical to prioritize reviews by the date the submission was received, and (3) CTP required time to assess which approach to reviewing provisional submissions would be the most effective at addressing the public health burden of tobacco use.

While CTP has been working to address these factors by, for example, disseminating information to manufacturers to improve submission quality and developing training for staff, CTP has not had performance measures that include time frames for making final decisions on SE submissions by which to assess its progress.[14] Time frames would allow CTP to evaluate its efficiency and effectiveness and help it make appropriate adjustments. Under federal standards for internal control, control activities that establish performance measures, such as time frames, and the

[14]The Tobacco Control Act does not mandate a time frame for CTP's review of new tobacco product submissions with the exception of PMTA submissions. For PMTA submissions, the act requires CTP to issue an order stating whether the product may be marketed as promptly as possible, but not later than 180 days after FDA's receipt of a submission.

monitoring of actual performance against measures are an integral part of operating efficiently, achieving effective results, and planning appropriately.[15] We reported that the lack of performance measures like time frames for reviews of SE submissions will limit CTP's ability to evaluate policies, procedures, and staffing resources in relation to CTP's submission review process and, in turn, limit CTP's ability to reasonably assure efficient operations and effective results. We recommended that FDA establish performance measures that include time frames for making decisions on new tobacco product submissions and that the agency monitor performance relative to those time frames.[16] HHS agreed with our recommendation, and as of April 2, 2014, FDA officials said that they expect to identify performance measures that include time frames for the regular SE and Exemption from SE review processes in spring 2014, and to implement these performance measures by October 2014.[17]

In addition, although FDA has increased its staff and training for staff, tobacco industry stakeholders expressed concerns about whether CTP will have a sufficient number of qualified staff to review the backlog of the more than 4,000 new tobacco product submissions received as of December 31, 2013 and also review new submissions that may be made in the future, particularly if FDA asserts jurisdiction over new types of tobacco products that are not currently subject to FDA's regulatory authority. CTP officials reported that many additional staff have been and will continue to be hired and trained, and the center does not expect hiring qualified staff to be a continuing challenge for the purpose of conducting product reviews.

[15]While we focused on the timeliness of the reviews in our work, other dimensions of an organization's performance—such as the outcomes to be achieved, quality, and cost—are equally important for evaluating overall efficiency and effectiveness.

[16]GAO-13-723, 39.

[17]In response to our recommendation, FDA stated that the agency will take a phased approach to implementing these performance measures and time frames, starting with regular SE submissions and Exemption from SE submissions. FDA stated that as the agency gains more experience with reviewing provisional SE submissions, it will begin to implement performance measures and time frames with respect to those submissions.

Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this testimony are listed in appendix I.

Appendix I: GAO Contact and Staff Acknowledgments

GAO Contact	Marcia Crosse, (202) 512-7114 or crossem@gao.gov
Staff Acknowledgments	In addition to the contact named above, Kim Yamane, Assistant Director; Danielle Bernstein; Hernán Bozzolo; Britt Carlson; Sandra George; Cathleen Hamann; Erin Henderson; Mariel Lifshitz; Richard Lipinski; and Lisa Motley made key contributions to this statement.

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Mr. PITTS. The Chair thanks the gentlelady.

I will begin the questioning. Recognize myself 5 minutes for that purpose.

Dr. Crosse, GAO's September 2013 report recommended that FDA establish performance measures that include time frames for making decisions, and that the Agency monitor performance relative to these time frames. What actions, if any, has FDA taken in response to these recommendations?

Ms. CROSSE. They agreed with the recommendations, and they have told us that this spring, they will establish time frames for 2 types of submissions, for the regular SE submissions and for the exemption from SE submissions, but that is a subset of the larger pool. They have not yet determined when they are going to establish time frames for the larger portion of their backlog, and that is the earlier submissions that were made prior to the March 2011 deadline.

Mr. PITTS. These seem like general, good government practices that FDA should have already implemented, without GAO having to make such a recommendation. Are there not time frames for review in the Tobacco Control Act?

Ms. CROSSE. The Tobacco Control Act only established time frames for review for one type of application, and that type of application is one that requires more information to be provided. It is one where there is no predicate product on the market, and the act established a 180 day time frame for decisions on those applications. It did not establish time frames for the substantial equivalence submission, which have made up the vast majority of submissions that FDA has received.

Mr. PITTS. How does FDA prioritize reviews of the substantial equivalence submissions?

Ms. CROSSE. Right now, the officials have told us that they are prioritizing the regular SE submissions, and those are for products that are not yet on the market, for products that need approval by FDA before those products can be marketed. So they are prioritizing ones for products that are not on the market. Among the provisional SE submissions, they have divided those submissions into 4 groups, 4 tiers, that they have assigned risk levels to, and they are prioritizing those that they believe pose the highest risk.

Mr. PITTS. Now, is it true that some of these submissions are for products that actually have reduced levels of harmful ingredients, and if so, would there be a way for FDA to prioritize these types of submissions?

Ms. CROSSE. It is possible, but there is another pathway, the modified risk tobacco product submissions. FDA has received only 7 submissions of that type, and that is where the manufacturer is making a claim that it actually reduces the risk, and none of those have had sufficient information for FDA to proceed. So all of those submissions are at a halt at this point, and withdrawn by the manufacturer.

The products that have come in through the regular SE pathways are not making claims that they reduce the risk to public health, although it is possible that they could.

Mr. PITTS. We have heard that one factor affecting the long time frames for FDA review is the fact that it took them a while to get the Center for Tobacco Products up and running. They have had now 5 years. Have they gotten any faster over time?

Ms. CROSSE. They have gotten somewhat faster in the initial steps that they go through in determining their jurisdiction, and in determining the completeness of the application, particularly for the regular submissions, they now feel that they are at a point where they can establish some time frames for those reviews. They haven't made enough decisions on the provisional SE submissions for us to determine whether or not they are getting any faster. There have only been just 4 decisions, all for a single type of product, from a single manufacturer.

Mr. PITTS. All right, thank you.

The Chair recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

Dr. Crosse, in April 2011, FDA indicated that it would issue regulations asserting jurisdiction over additional tobacco products like e-cigarettes, little cigars and pipe tobacco, and as you testified in October, FDA submitted a proposed deeming rule to OMB, but the rule has not yet been issued by FDA.

Over the past few years, we have seen dramatic increases in the use of e-cigarettes and flavored little cigars among youth, and there is also evidence that manufacturer activity targeting youth has driven this growth in alternative tobacco products, and that FDA, in action, made it easier for manufacturers to do so.

So I would like to find out more about FDA's proposed regulations and the public health costs of delay. And my first question, I have a lot, is last week, the Centers for Disease Control and Prevention at CD—or Prevention—I am sorry. The Centers for Disease Control and Prevention, or the CDC, reported that the number of calls to poison centers involving e-cigarette liquids rose from 1 per month in September 2010, to 215 per month as of February of this year.

Did you see this CDC report, and if so, what were your impressions?

Ms. CROSSE. Yes, I did see the CDC report, and I think it is concerning because nicotine, in a liquid form like that, can be a potent poison. With the growth of e-cigarettes, there are more liquids being distributed, as I understand it, for refill purposes, both to businesses and in some quantities for purchase by individuals. And as with any poison, it is a concern if children can have access to that.

Mr. PALLONE. Well, in fact, members of this committee have repeatedly written to FDA raising the alarm about the various risks that e-cigarettes pose to children and adolescents. We pointed out that e-cigarette makers are producing products with kid-friendly flavors such as cookies and cream milkshake, and we have called on FDA to issue deeming regulations to bring an end to manufacturers targeting our youth through aggressive ad campaigns, as well as event sponsorships and other tactics once used by cigarette manufacturers.

So, Dr. Crosse, last September CDC reported that between 2011 and '12, the percentage of high school students who had used e-cigarettes more than doubled. Are you aware of these findings?

Ms. CROSSE. I have seen the CDC statistics, yes.

Mr. PALLONE. And are you also aware that CDC's Director, Dr. Tom Frieden, and other experts, have raised concerns that e-cigarettes could be a gateway product to conventional cigarette and other tobacco products use?

Ms. CROSSE. Yes, I have seen that statement.

Mr. PALLONE. The importance of FDA issuing deeming regulations extends beyond e-cigarettes. Flavored cigars, for example, are also currently unregulated. In October, CDC reported that sales of little cigars have skyrocketed over the past decade, and more than 40 percent of middle and high school students who smoke were reportedly using these flavored products.

Dr. Crosse, I would like to ask you a series of questions regarding FDA's ability to take specific actions if the Agency asserts jurisdiction over e-cigarettes and flavored little cigars.

First, could the Agency prohibit the sales of these products to minors, and require age verification prior to purchase?

Ms. CROSSE. It is my understanding that they have that authority.

Mr. PALLONE. Could the Agency prohibit brand name sponsorships of events that are widely attended by youth?

Ms. CROSSE. Yes, I believe that they could extend that current prohibition to new products that were deemed under their control.

Mr. PALLONE. Could FDA prohibit the use of characterizing flavors that are attractive to kids?

Ms. CROSSE. Yes, I believe that they have the authority.

Mr. PALLONE. And finally, could FDA take steps to inform the public about the harms of ingesting, inhaling or absorbing e-cigarette nicotine cartridges through the skin or eyes?

Ms. CROSSE. Yes, they have authority to conduct public education campaigns.

Mr. PALLONE. I just think it is crucial that FDA acts quickly to deem additional tobacco products. In the absence of regulation, manufacturers take advantage of regulatory loopholes to target impressionable children and teens. The recent Surgeon General's report reiterated what we have known for a long time, that exposure to nicotine in youth increases the risk of lifelong tobacco product use.

So do you have any insight into why release of the deeming rule has been delayed?

Ms. CROSSE. I don't have any information on that. FDA has announced that its deeming regulation will include a number of tobacco products that it does not currently regulate. I do not know what the delays are for this deeming rule.

Mr. PALLONE. I mean if, you know, obviously, Mr. Chairman, if at any point Dr. Crosse could get us more information about, you know, the delay or when this is going to come out, we would appreciate you providing the committee with that and, you know, and any written followup. If I could ask through the chairman.

Ms. CROSSE. Yes. I have no information beyond the Commissioner's statement last week at the Appropriations hearing that it would be very soon.

Mr. PALLONE. OK. So let me just say that evidence from GAO, CDC, this committee and others has demonstrated that the use of e-cigarettes, little cigars and other unregulated products has increased dramatically, and this is due on part to inaction on the deeming rule. So I just have to emphasize, Mr. Chairman, that FDA has to act quickly to assert jurisdiction over all these tobacco products.

Thank you.

Mr. PITTS. The Chair thanks the gentleman.

Now recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you, Mr. Chairman. And thank you for coming today. I appreciate that, Dr. Crosse.

Do you have any more data on what the backlog at CTP looks like, and can you let us know how many of the SE submissions within the backlog relate to different—product changes, label changes and name changes? It is not just product changes they can regulate, it is label and name as well.

Ms. CROSSE. I don't have information at the moment on that. We are conducting further work, and we expect to issue a report in late June, that was mandated by the Tobacco Control Act, that actually will have some additional information.

Mr. GUTHRIE. OK, thanks. And it is my understanding, and you said, that 99 percent of submissions to the FDA are SEs, substantial equivalence, which in theory these should be quicker to review than new products submission, and yet as you note, it is taking years for them to be reviewed. And FDA has similar pathways for other products in other FDA agencies. It takes roughly 5 months to review a 510(k) for medical devices, 6 to 10 for new pharmaceutical drugs coming to market, and the CTP is taking years for these steps, for these SEs.

Can you discuss the approval times at CTP compared to those of drug and device centers at FDA, and in your opinion, why does CTP have such a lag on decision-making when other centers are able to turnaround products in a better manner?

Ms. CROSSE. Well, CTP was starting from scratch, and they indicated that they had a number of delays because they needed to hire staff, they needed to develop a process, and they needed to develop the science around tobacco products because these products had not been previously regulated. They needed to gain an understanding of the risks posed by different types of tobacco products, the constituents within tobacco products, and what risks might be posed by changes to tobacco products.

Mr. GUTHRIE. Are they beyond those points now, or are they still——

Ms. CROSSE. They still have a significant amount of research underway, and, in fact, that has absorbed a lot of the budget of the Office of Science, which is the office that makes decisions about substantial equivalence. They say that they are much further along that process. They clearly are much slower than the Center for Drugs or the Center for Medical Devices, although I will note that

GAO reported in 1983, on the Center for Devices that had been established in 1976, and we commented at that time that they were being very slow to fulfill the requirements of their authority. So I think——

Mr. GUTHRIE. But——

Ms. CROSSE [continuing]. It is an issue when you are starting up a center from scratch.

Mr. GUTHRIE. But there were some subsequent reauthorizations the product manufacturers and FDA worked through to try to find a way to work. Do you think that—in your opinion, do you think that Congress should impose statutory timelines?

Ms. CROSSE. You know, I don't think I have enough information to speak to that point at this point in time, because I think they are still feeling their way through it, and I think we haven't had enough information to base that decision on. They have a concern—not my concern—their concern is that when a product is approved through the SE pathway, it then can become a predicate. And so they don't want to make mistakes because they want to have an understanding of what the likely public health impact would be of a new product, because it then becomes a predicate that a subsequent product can use.

Mr. GUTHRIE. OK, and then my final question, my legislation would require the CTP to provide annual reports to Congress, all it does is outlining how their user fees are being spent, the number of submissions received, the number of applications approved or denied, and the number still pending and the number of modified risk products. That is what this application does—that is what this legislation I proposed does.

In your opinion, is this information that the CTP has readily available? I mean if we pass this bill today, would that information be available for the CTP to provide, or do you think it would be a burden on the CTP to provide that information?

Ms. CROSSE. No, I believe this is information that they have readily available. And, in fact, my understanding is that the appropriators have put report language in to require something similar.

Mr. GUTHRIE. Do you think that is helpful information for Congress to have?

Ms. CROSSE. I think it is appropriate for Congress to have information on the operations of the center. There is already a required report, but it does not require that those specifics be included.

Mr. GUTHRIE. Well, and I thank you for coming. I think you—all—every time you testify, you always do a good job, and you do your job well and testify well. I appreciate it very much.

Ms. CROSSE. Thank you.

Mr. GUTHRIE. Thank you, and I yield back.

Mr. PITTS. The Chair thanks the gentleman.

Now recognize the gentlelady, Dr. Christensen, 5 minutes for questions.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. Good morning, Dr. Crosse.

Ms. CROSSE. Good morning.

Mrs. CHRISTENSEN. Thank you for your testimony. I remember when the law was being drafted, and one of the key issues for the Congressional Black Caucus for many organizations and for all of

the living past HHS Secretaries was a menthol issue, and I know that FDA was granted broad authority to address menthol as an additive in cigarettes, ranging from doing nothing, to reducing the concentration, to removing menthol altogether. And I appreciate the approach the FDA has taking around the issue of other flavorings and the sensitivity.

My question to you would be, are you able to provide an update about where FDA is on the menthol issue, in particular, what types of studies have been conducted, whether menthol—have they been able to determine whether menthol exacerbates directly or indirectly the incidence of lung cancer, et cetera, and if there are any preliminary results?

Ms. CROSSE. I am afraid I don't have that information. That is specific to menthol.

Mrs. CHRISTENSEN. OK. Well, my other question goes back to the fees. Again, we thank you for your testimony on the fees. My colleagues have commented on user fee carryover, and how the user fees are being spent, and I want to make sure the record is clear on a few points.

What portion of FDA's tobacco user fees have been spent as of December 31, 2013?

Ms. CROSSE. They have spent 81 percent of the user fees they have received through that time.

Mrs. CHRISTENSEN. Thank you. You mentioned that most of the user fees were spent by 3 offices at FDA, one of which is the Office of Health, Communication and Education, and as you stated today, FDA devoted a portion of its fiscal year 2013 user fees on a public health education campaign. From your review of FDA's user fee spending, can you tell the subcommittee whether the Agency's user fee spending is consistent with the purposes and authorities of the Tobacco Control Act?

Ms. CROSSE. Yes. We did not identify any spending that was not consistent with their authorities, and the different provisions of the Tobacco Control Act.

Mrs. CHRISTENSEN. Thank you. Since the investment in the Real Cost Campaign has come up this morning, I wanted to take a moment to comment on the importance of this campaign.

It is an evidenced-based campaign that launched in February, and will target millions of youth between the ages of 12 and 17 who are already experimenting with cigarettes, that are open to smoking. So, Mr. Chairman, we know that the vast majority of current smokers started when they were kids. Every day in the U.S., more than 3,200 kids smoke their first cigarettes, and more than 700 youth aged under 18 become daily smokers. So these statistics underscore the need for targeted youth tobacco prevention efforts, particularly when you put this investment in context. The amount FDA spent on the Real Cost Campaign for the entire year was less than the amount the tobacco industry spends on marketing and promotional efforts for a single week.

Well, I have some more time. Yes. So the GAO makes clear that FDA review of new products must become more efficient and effective. I am concerned that they are not placing enough priority on requiring changes to products that are already on the market to make them less harmful or addictive. The most recent Surgeon

General's report found that cigarettes are more dangerous today than they were when the first Surgeon General's report on smoking was issued 50 years ago. Remarkably, cigarette smokers today have a higher risk for lung cancer than smokers in 1964, despite smoking fewer cigarettes. The Surgeon General report also found that some, if not all, of this increased risk is likely caused by changes in the composition and design of cigarettes. Fortunately, FDA now has the authority to set product standards that require changes to products to make them less harmful or addictive.

Do you know if FDA plans to respond to the alarming findings in the more recent Surgeon General's report, and if there are any plans underway for FDA to use its authority to set product standards?

Ms. CROSSE. I am not aware of specific regulatory actions that FDA may have underway, but they do have a number of different studies, scientific studies, to try to understand, I think, the impact and the risks posed by different constituents in tobacco products.

Mrs. CHRISTENSEN. Thank you.

And, Mr. Chairman, I yield back the balance of my time. Thank you.

Mr. PITTS. The Chair thanks the gentlelady.

Now recognizes the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. MURPHY. Hello, Doctor. Good to have you here today.

Ms. CROSSE. Thank you.

Mr. MURPHY. You say in your report CTP is limited in its ability to evaluate policies, procedures and staffing resources in relation to its substantial equivalence review process, and in turn is limited in its ability to reasonably assure efficiency and effectiveness.

So in your conversations with the Agency, did you get a feel for how the approval process would be affected if FDA proposes deeming regulations for other products that it doesn't currently regulate?

Ms. CROSSE. Well, certainly, industry expressed concerns to us that, if the number of products to be regulated is greatly expanded, that FDA will not have sufficient resources, will not have sufficient staff to be able to review those applications. FDA assured us that they believe that the challenges of initially staffing the office are behind them, and that they believe they could go through routine processes if they need to hire or train additional staff, and that additional products under their regulatory authority would not pose new challenges.

Mr. MURPHY. Will that fulfill all the things that they need to do prior to issuing deeming regulations to make sure the backlog isn't made worse?

Ms. CROSSE. I don't believe that it is required that they complete those steps prior to issuing deeming regulations. You know, we think that it is important that they get their processes under control with routine procedures and time frames established for staff so that they can better determine how many staff they need. We think that without having those kinds of benchmarks in place, it is difficult for them to determine for themselves whether they have the essential resources, and whether there are bottlenecks in certain parts of their process.

Mr. MURPHY. OK, thank you. Is it fair to say that reviewing new tobacco product submissions, and approving or denying them for entrance into the marketplace, is one of the core functions to the Center for Tobacco Products under the Tobacco Control Act?

Ms. CROSSE. Yes, it is one of the core functions.

Mr. MURPHY. And is it also fair to say that reviewing substantial equivalence applications is one of the three main determinations that CTP has in carrying out this core function of reviewing new tobacco products for marketplace suitability?

Ms. CROSSE. That is part of their authority, yes.

Mr. MURPHY. You state in your study CTP is "limited in its ability to evaluate policies, procedures and staffing resources in relation to its substantial equivalence review process, and in turn, is limited in its ability to reasonably assure efficiency and effectiveness."

So given your review that CTP is limited in its ability to reasonably assure efficiency and effectiveness, in this core function of reviewing SC or premarket applications, do you believe CTP is presently capable of handling even more responsibilities and a much greater volume of applications which would result from the new deeming rule CTP and FDA plan to propose to dramatically expand its scope of authorities under the Tobacco Control Act?

Ms. CROSSE. You know, I don't think I have sufficient insight into that, but even if FDA proposes this deeming, I believe it will be a number of years before such regulations would go into effect in the normal course of how long it takes to get a regulation in place, so there may be a number of years further before any new products would actually begin to be regulated by FDA. So I can't speak to what may happen in the future in terms of——

Mr. MURPHY. Sure.

Ms. CROSSE [continuing]. Them dealing with their backlog.

Mr. MURPHY. Well, we want to work you in this, but I am trying to find out if you have confidence that CTP can at this time, given its backlog it already has of SE applications, efficiently and effectively process a whole new onslaught of applications that would rise from a new deeming rule.

Ms. CROSSE. I think were they to arrive today, that would pose a problem. As I say, I can't predict how soon new product applications might arrive, and what the status would be of their backlog at that point in time.

Mr. MURPHY. Well, what do you infer from the fact that—I understand there is zero premarket tobacco product applications have been submitted. There is no statutory—do you have any thoughts on that?

Ms. CROSSE. Actually, there were—I believe that there were four that were submitted——

Mr. MURPHY. OK.

Ms. CROSSE [continuing]. But none were found to have all of the information that FDA required.

You know, it is a different standard. It is not unlike with medical devices where there are many more products that go through the 510(k) process, as opposed to the PMA process. Here, this is for products where there is no predicate product that they can point to, so there is not a similar prior product on the market before Feb-

ruary 15, 2007, that they can point to and say this product is like that, or like an approved product through the SE process to say that that is a predicate. So, you know, as more products get approved through the SE——

Mr. MURPHY. Um-hum.

Ms. CROSSE [continuing]. Process, there may be predicates available that could continue to allow products——

Mr. MURPHY. Well, is it——

Ms. CROSSE [continuing]. To go in that pathway. The PMTA process requires a lot of different information than manufacturers may have yet developed.

Mr. MURPHY. I hope one of the questions you can answer in writing later on is about a new product review being more complex than a substantial equivalence review, and help us with that information.

Thank you very much. I yield back.

Mr. PITTS. The Chair thanks the gentleman.

And now recognizes the vice chairman of the subcommittee, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman, and Dr. Crosse, welcome to our subcommittee again.

Ms. CROSSE. Thank you.

Mr. BURGESS. I am sorry I had to step out for a moment, but just tell me if you have already—and I apologize if you have already addressed this, but what is the average time that a substantial equivalence has been sitting at the Center for Tobacco Products?

Ms. CROSSE. The bulk of the applications have been sitting there since March of 2011. They received over 3,000 applications in the first 3 weeks of March 2011, just prior to the deadline for a provisional SE product, and so that those products can be marketed until FDA makes a decision. And so the bulk of the backlog has been sitting there for now more than 3 years.

Mr. BURGESS. So you evaluate other agencies that have a substantial equivalence pathway, do you not?

Ms. CROSSE. Yes, well, the medical devices at FDA.

Mr. BURGESS. So is this an unusual backlog, given your experience with other substantial equivalence pathways?

Ms. CROSSE. I do think it is an unusual backlog. I think it was a bit of an unusual circumstance because of the deadline that resulted in this bolus of applications all in a very short period of time, rather than a growing steady stream.

Mr. BURGESS. OK. Given that, the way the information was delivered, does it seem to be that they are accommodating at the Center for Tobacco Products now, accommodating this bolus that they received?

Ms. CROSSE. They have, as of yet, only made four decisions. So they still have that bolus sitting there. They have made some progress in sorting through it, but they have not yet reached decisions.

Mr. BURGESS. And the 4 decisions that they have reached, were those positive or negative decisions?

Ms. CROSSE. Those were negative decisions. They ordered four products off the market.

Mr. BURGESS. Can you give the committee—and maybe I should know this, but can you give the committee an idea of what were those products?

Ms. CROSSE. They were four products that are called bidis, I believe. They are an Indian type of cigarette, and FDA said that sufficient information on a predicate had not been supplied by the manufacturer in order to meet the standard for a determination of substantial equivalence.

Mr. BURGESS. So was that a product that was already on the shelves prior to the passage of the CTP?

Ms. CROSSE. No. If it required a provisional SE application, it would have been a product that came onto the market in the United States after February 15, 2007, but before March 22, 2011. So in that window of time, products that came onto the market were required to submit these provisional SE applications.

Mr. BURGESS. Well, what is your opinion on why the Center for Tobacco Products has this lag in their decision-making, when other centers are able to turn things around in a more timely fashion?

Ms. CROSSE. Well, they did have to staff up from scratch. They had to develop their procedures. They have taken a lot of time, they tell us, to try to understand the science of tobacco, which they did not have sufficient information on before, and they have now engaged both in contracts with CDC and with NIH, and with universities, to try to gain a better understanding of the risks posed by different types of tobacco products and constituents in tobacco products.

Mr. BURGESS. Dr. Crosse, I believe I could help them there. When used as directed, 480,000 deaths a year. What is there to the science that they don't understand? It is a dangerous product.

Ms. CROSSE. Well, the standard requires that they determine whether or not the new product is any more dangerous, poses different dangers to public health than the existing products, because the existing products are allowed to continue to be marketed.

Mr. BURGESS. So what if Congress were to establish a timeline of 90 days for substantial equivalence applications, and 180 days for new tobacco product applications, would that be helpful or hurtful?

Ms. CROSSE. I don't know whether or not they could meet that standard at the current time. There may come a point in time where they have regular procedures and where they do not have such a backlog, but I don't know if that would help them or not. I just don't have the information to say.

Mr. BURGESS. Well, it can't be a resource or a revenue issue, correct?

Ms. CROSSE. That is correct. They tell us that they now have over 500 staff, and they believe that that is a fairly steady state for them, and they have resources, they have not expended all their user fees.

Mr. BURGESS. 500 staff in an agency that didn't even exist 5 years ago, and a surplus of user fees. You know, I just have to say I am mystified as to why we are having to study this. It shouldn't even be a problem.

Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The Chair thanks the gentleman.

Now recognize the gentleman from Texas, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman, and the Ranking Member for having the hearing today, and, Dr. Crosse, for your testimony.

The 2009 Tobacco Control Act was historic in saving legislation representing the first time the FDA was granted the authority to regulate tobacco products, and I hope this is just the first series of hearings on implementation of the Tobacco Control Act. And I agree with my Texas colleague that this was the first new center in the FDA in 20 years. Is that correct?

Ms. CROSSE. Yes, actually, and that was when the Center for Drugs and Biologics was divided into two centers. So, even in that situation, it was not creating a center from scratch.

Mr. GREEN. OK. Well, and I guess I am concerned like he is, we have that number of staff members and yet we are not moving as quick as we could.

The law is necessary. The next step is addressing tobacco use, which is is initiated and sustained by the aggressive and sometimes dubious strategies of the tobacco industry. Its continued effective implication would allow the FDA to reduce tobacco product addictiveness and harm, and take other necessary actions. According to the GAO report, tobacco product, FDA needs to set time frames for review process. The FDA Center for Tobacco Products created by the Tobacco Control Act has gotten off to a slow start, and I want a better understanding what is the issue.

I understand it is conducting your reviews to the tobacco products submissions, and the Agency is using a new public health standard, one that is different than the safe and effective standard used for medical products. Can you describe that standard that the FDA must be using in reviewing these submissions?

Ms. CROSSE. Yes. They need to understand whether or not the product is going to pose any different risks to public health than currently legal tobacco products, and by that, that means to the public health in general, both to the users of those products, but also to non-users, to people who may be exposed in other ways, either to fumes or in some other way to the constituents of that product.

Mr. GREEN. The GAO report focused on the need for the FDA to establish time frames for making decisions on submissions as a performance measure to improve the CTP review process. I want to ask you more about GAO's recommendation. In making its recommendation, did GAO consider other performance measures besides established timelines that could be helpful in reviewing the SE submissions in a more timely manner?

Ms. CROSSE. Well, in part, we particularly focused on the time frames because it was clear that this was taking substantial amounts of time, and that they had not established any benchmarks either for individual staff performance or for the performance of the center as a whole.

We certainly think it is important that they understand what kinds of guidances are necessary, and what kind of communications with industry may be helpful, but also what kinds of information is most important to share with the public. And it is only in the last year that they have put out those major contracts for media

campaigns to try to address their responsibility for reducing the use of tobacco products by youth.

Mr. GREEN. OK. Mr. Chairman, I appreciate this hearing, and hopefully, we will have someone from the FDA because they have come to our hearings pretty often, and to come back and explain what they are doing 5 years later.

I also want to remind my colleagues that, according to the GAO, the vast majority of substantial equivalence backlog for products that can remain on the market while the FDA reviews their applications, the majority of the substantial equivalence applications submitted to FDA were incomplete, slowing down the review process as the Agency had to request additional information and await responses from tobacco companies.

Last week the FDA announced ¼ of the regular substantial equivalence applications had already been resolved, and FDA has stated the Agency is ready to initiate review of any newly submitted applications.

Even as the FDA becomes more efficient in its review process, it is important to make sure that the new products coming on the market through the substantial equivalence pathway are not causing greater harm to the public health. And I would hope our subcommittee would continue to monitor this to see just how the Tobacco Control Act is being enforced, because a lot have supported it and feel like the FDA needs to do their job.

So I yield back my time.

Mr. BURGESS [presiding]. Gentleman yields back.

The Chair recognizes the gentlelady from North Carolina, 5 minutes for questions, please.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you, Dr. Crosse, for being with us today on this issue.

I too was hopeful that a representative from the FDA would be with us. I know it is difficult for you to be able to answer some of the questions simply based on the study and report that was put forward, and I know that you can see, and I think you share with us the questions of why this hasn't moved quicker than it should. I think you have identified a few things. One, because they collect the user fees, there is plenty of revenue, they have got their staff in place. What is left? What is left to keep them from moving forward in a more timely fashion?

Ms. CROSSE. Well, one thing that they have told us that they continue to try to determine is exactly what information they may need in applications. Representative Green was correct in that a number of the initial applications did not contain information that FDA determined subsequently——

Mrs. ELLMERS. Um-hum.

Ms. CROSSE [continuing]. That they needed in order to reach decisions. Now, some of those deadlines required that applications come in——

Mrs. ELLMERS. Um-hum.

Ms. CROSSE [continuing]. Prior to FDA putting out guidance on what was needed. And so there has been a lot of back-and-forth. At this point in time though, certainly, you know, there has been sufficient time, I believe, for them to have——

Mrs. ELLMERS. That they should have——

Ms. CROSSE [continuing]. For them to have identified what kinds of information they need in an application.

Mrs. ELLMERS. So at what point did the FDA put out the guidance for those application requests?

Ms. CROSSE. I don't have a date in my head. I'm sorry. We can find out——

Mrs. ELLMERS. Well, if you can get that——

Ms. CROSSE. We can find out——

Mrs. ELLMERS [continuing]. I would like to know.

Ms. CROSSE. Yes.

Mrs. ELLMERS. I want to make sure that there are guidelines in place, first of all. But there again, I am kind of stumped, and I realize that much of what we do and the government can be very bureaucratic and not necessarily move as quickly as the private marketplace, but as you can see, this is affecting the private marketplace. I mean, obviously, there are products that can't move forward and get on the market as a result of this, and one of the things that I have been thinking about in relation to this is how does this particular situation with the Tobacco Control Act differ from other user-fee industry-related—what is missing? One of the things that I support my colleague Brett Guthrie for his legislation, and I also associate myself to Dr. Burgess' comments on setting a timeline in place as well, but one of the things that I realize is missing is this can just go on into perpetuity. There is no sundown, there is no re-evaluation or need for reauthorization of this particular act.

In your opinion, would this be helpful for us to be able to help enforce what the CTP is doing?

Ms. CROSSE. You know, I don't think I am in a position to weigh in on whether or not it would be helpful to have it sunset. The user fee structure is quite different. The responsibilities assigned to FDA——

Mrs. ELLMERS. Um-hum.

Ms. CROSSE [continuing]. Under this act are quite different.

Mrs. ELLMERS. Um-hum.

Ms. CROSSE. The user fees are intended to fund not only the reviews of the product applications as they are for devices or for drugs, for example, but also to fund the research, the media campaigns and the enforcement of——

Mrs. ELLMERS. Um-hum.

Ms. CROSSE [continuing]. The requirements of the Tobacco Control Act, and FDA has undertaken a lot of enforcement actions to try to ensure that teenagers are prevented from having access to purchase tobacco products.

Mrs. ELLMERS. But at the same time, I mean, there is obviously, as you can see, and I know you agree, there is just this incredible backlog.

So, I mean, are there other situations like this where we have user fees that are being shared, where there isn't a sundown provision, or there isn't reauthorization in place?

Ms. CROSSE. You know, I am not qualified to speak to user fees across the Federal Government. I don't believe there are similar circumstances at FDA, but there may be user fee programs in other government agencies that are similar, that I just am not aware of.

Mrs. ELLMERS. OK. Well, there again, I think this is just one of those issues that we are all kind of baffled by why this is, and it almost seems as if it is not an organized effort to keep products from moving forward. And I do think that this is something that I would like to continue to work on, and there again—I am out of time.

Thank you very much for coming today, and helping us to understand this issue.

And, Mr. Chairman, I yield back the remainder of my time.

Mr. BURGESS. Gentlelady yields back.

The Chair now recognizes the distinguished gentleman from Louisiana, the Honorable Bill Cassidy, 5 minutes for questions, please.

Mr. CASSIDY. Thank you.

The increase in sales of pipe tobacco. People aren't buying a lot more pipes, so I presume they are rolling this in some sort of paper and making their own cigarettes?

Ms. CROSSE. GAO put out a report last year, or 2012, rather, that pointed out a huge shift in the use of pipe tobacco for roll-your-own cigarettes, subsequent to the changes in taxation on different types of tobacco products in the Children's Health Insurance Program Reauthorization Act, CHIPRA, in 2009, when taxes were greatly increased on certain types of tobacco products. There was a tremendous shift so that consumers were no longer using roll-your-own tobacco, but rather using pipe tobacco for roll-your-own cigarettes. And we have substantial data pointing to a huge shift in that market, and a huge loss of revenue to the Federal Government because of that shift.

Mr. CASSIDY. Can you make a guestimate as to whether or not there has been any discouragement—let me start over. If we know that there is a certain amount of regular cigarettes which are purchased, and then there is the roll-your-own, we have raised taxes on the regular cigarettes, does it not look like it is the same amount of tobacco being consumed, or is there a decrease in the per capita use of tobacco?

Ms. CROSSE. The data in that report did not point to any decrease in the overall use of tobacco but rather to a shift in order to avoid taxes.

Mr. CASSIDY. So we shifted, if you will, from something which is at least filtered to something that is unfiltered, arguably which has more health implications by using it unfiltered.

Ms. CROSSE. You know, some roll-your-owns, I believe, actually can attach a filter from some machines, and I can't speak to what the proportion is of the different types of roll-your-own tobacco cigarettes that are made in these tobacco shops now using pipe tobacco instead of roll-your-own tobacco.

Mr. CASSIDY. Now, under the Family Smoking Prevention Tobacco Control Act, roll-your-own tobacco is any tobacco product which, I am reading here, because of its appearance, type, packaging, labeling, is suitable for use or likely to be offered to or purchased by consumers of tobacco for making cigarettes. Cigarette tobacco is defined as a product consisting of loose tobacco intended for use by consumers in a cigarette.

In your opinion, does the product labeled as pipe tobacco, about which you reported in April of '12, meet either or both of these definitions?

Ms. CROSSE. You know, the Treasury, which imposes the taxes, indicated that it was difficult for them to make that distinction between the roll-your-own tobacco and the pipe tobacco that's sold in tobacco shops.

Mr. CASSIDY. So related to that then, let me just ask specifically, are there any provisions in the Tobacco Control Act which permit a manufacturer product which meets either definition, to exempt themselves from the act simply by labeling their product something other than roll-your-own? Could it be the exact same tobacco, in this bag it is called roll-your-own, taxed, and here it is pipe tobacco, not taxed?

Ms. CROSSE. I can't speak to that. I know that the pipe tobacco is allowed to be flavored, so that if it is a flavored product, it could not currently be labeled as roll-your-own, because that is currently regulated by FDA and flavorings are prohibited. But in terms of the constituents or, you know, the extent to which the tobacco has been finely chopped or requires a certain blend, I don't know if that could be the same.

Mr. CASSIDY. OK, thank you.

I will yield the remainder of my time to Mr. Guthrie.

Mr. GUTHRIE. Thank you. One of my colleagues on the other side did mention that last week, right before this hearing, CTP put out that they are working to get rid of the backlog, and it is a massive move to get rid of the backlog. But as I understand it, there are two lines. There is one line you get into to say, if you get in this line, we are going to tell you to go to that line, and that line is the one that matters, and all they did was say we are not going to make you go through two lines now, you are going to have to go to the back of the other line.

So there was no—the announcement that they made, it is my understanding, did not improve the determinations whether it is safe or unsafe, or can be sold or not sold. All it did was say, we are just going to make one line longer by getting rid of the other line. Is that an accurate description?

Ms. CROSSE. You know, that is not my understanding of the announcement that they made. I believe that the announcement focused on the regular SE submissions, and the line for products that are not currently allowed to be on the market, you know, those provisional SEs—I would restate, the large bolus of applications that are sitting there waiting in the queue, those products are currently on the market. They do not have to await an FDA decision to enter the market, they are on the market. They are waiting for a decision about whether or not they can remain on the market or have to be removed.

So FDA is focusing on working at the backlog of applications for products that cannot enter the market until they have reached a decision. That is a smaller group. They received something over 900 applications for those products, and they have reached 30 decisions. So that is the backlog—my understanding of their announcement is that is the backlog that they are focusing on right now.

Mr. BURGESS. OK——

Mr. GUTHRIE. Thank you.

Mr. BURGESS [continuing]. Well, the gentleman's time has expired.

The Chair now recognizes the gentlelady from California, 5 minutes for questions, please.

Mrs. CAPPS. Thank you, Mr. Chairman. And, Dr. Crosse, thank you for your testimony.

As a public health nurse, the issue of tobacco use and our Nation's wellbeing and healthcare expenditures is one that we cannot ignore. Thanks to the Tobacco Control Act, tobacco companies can no longer mark "light" or "low-tar" cigarettes, misleading smokers who may otherwise have quit, but we do know there is much more we need to do to hold tobacco companies accountable for their marketing, and I urge the chairman to hold a hearing on the many issues that Ranking Member Waxman pointed out, but especially on e-cigarettes and the other products that continue to be targeted at our young people.

We should not lose sight of why the Tobacco Control Act requires tobacco companies to receive authorization to market their products in the first place, and I encourage the subcommittee to hold hearings on the continual efforts by tobacco companies to skirt the rules, as opposed to a hearing like this, based on the business concerns of these same companies.

Dr. Crosse, I understand that there were some initial roadblocks that slowed down the review process for substantial equivalence, or SE submissions, and are being addressed by FDA.

Ms. CROSSE. That is my understanding.

Mrs. CAPPS. OK. Could you please comment on the extent to which incomplete submissions from manufacturers has been a roadblock to the review process?

Ms. CROSSE. Yes. Both FDA and manufacturers told us that incomplete submissions did slow down the review, that manufacturers did not have a good understanding of what information was required, and FDA itself was still developing its understanding of what information it might need in order to reach a decision. And so virtually every application that has come in has required some communication with the manufacturer to try to either understand part of the application, or to obtain additional information to supplement the application.

Mrs. CAPPS. So this clearly needs to be addressed.

And could you elaborate on the steps FDA has taken to improve its review process?

Ms. CROSSE. Well, they have undertaken a lot of research to understand the science behind different tobacco products, they have organized their staff and their procedures in order to have a number of routine steps that an application goes through, so that there now is a jurisdictional review initially, and then a completeness review that takes place before a product enters actually the scientific review for the merits of the product.

And so they have organized a process, they have developed steps, they have identified staff who are responsible for the different steps of the process, but they have yet to complete the process for very many of the applications.

Mrs. CAPPS. In September of last year, the GAO recommended that FDA establish time frames for making decisions on new tobacco product submissions.

You indicated in your testimony today that FDA agreed with GAO's recommendations, and plans to identify time frames for decision-making on new tobacco products submission. And the agency, is it still on track to identify these time frames this spring?

Ms. CROSSE. Yes, it is on track to identify time frames for the regular SE submissions. They have not yet decided when they will have time frames in place for the provisional SE submissions because they tell us they do not yet have enough experience themselves with getting something through the complete process to know what time frames to establish.

Mrs. CAPPS. Well, it is helpful for the subcommittee to hear that FDA has already agreed to establish and implement performance measures, including decision-making time frames, for regular SE submissions. Excuse me.

Once these standards are in place, we can better monitor FDA's progress. As FDA has focused on regular SE submissions, and continues to undertake these reviews, have the review times improved?

Ms. CROSSE. The review times have improved, we understand, for the regular SE submissions. It is not clear that they have improved for the provisional SE submissions because they haven't made very many decisions yet, so we can't see any kind of trend.

Mrs. CAPPS. I see. For decades, tobacco companies deliberately misled the public about the risks of smoking, and there is evidence that today's products are perhaps even more harmful and addictive than those from past decades.

My colleagues on the other side of the aisle have talked about setting time frames for review of these SE submissions. Mr. Chairman, we need to hear from FDA about the wisdom of this approach. We should be incentivizing tobacco companies to manufacture products that reduce harmfulness, not delay that process further.

And I yield back the balance of my time.

Mr. BURGESS. Gentlelady yields back.

Now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes. Your questions, please.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. Thank you, Dr. Crosse, for being here today. Appreciate that.

I was a little concerned with some of the folks who said, on the other side of the aisle, that we needed to be more accommodating. I was pleased that the acting chairman went through the list of things that we did to accommodate the FDA. Not only did we say that other people could show up, as opposed to the head of this particular department, but that they didn't have to have a written statement that had to be approved in advance, we are just trying to get to the information.

And, you know, I had to make the comment to the acting chair that when I ran for election, I thought I was being elected to the United States Congress, not to a discussion committee to accommodate every whim of bureaucracy. And so I am a little disturbed that the FDA didn't bother to send somebody here to testify today, par-

ticularly in light of the fact of the accommodations that were made to say, OK, you don't have to have a written statement, you can send somebody who is, you know, a deputy. We understand they might say, "I don't know the answer to that question, that is a little bit outside of my realm, but I will get you an answer." Sometimes those things happen, but it is interesting that, you know, with all the busy schedules that so many of us are keeping, we were able to have this hearing, but nobody from the—how many employees did you say there were, over 500, with this particular division of the FDA?

Ms. CROSSE. Yes.

Mr. GRIFFITH. That none of those 500-and-some people could accommodate the United States Congress.

That being said, I will say that the Agency, you know, as it states, is responsible for advancing the public health by helping to speed innovations. Further, they state the Agency protects, promotes the health and safety of all Americans by promoting innovation that addresses public health needs.

Ms. Crosse, is it your opinion that the FDA is able to keep pace with the advances in science and product technology, not only for the Center for Tobacco Products, but for other industries it regulates? And before you answer, let me tell you one of the concerns I have is working on the mobile apps that are out there, and I have talked to the FDA about this, but you can do all kinds of things on your cell phone today that you didn't used to be able to do, and I related to them on one occasion that, in Africa, a team of doctors were able to put together a $8 hack that would send pictures back of parasites found in children's stool, and get it immediately analyzed by somebody in the United States. And I said can we use that in our country if somebody comes up with that, or does it have to first go through your regulatory process, and the answer was basically, well, if they are using it to diagnose what type of parasite it is, that makes it diagnostic, it would have to be regulated. Sometimes it seems they are just not, my opinion, they are just not able to keep up.

If you can answer that question, both in regard to the Center for Tobacco Products and in other areas from your observation, to the best of your ability.

Ms. CROSSE. Well, I can't speak directly to the mobile apps, but we have previously examined activities at FDA, and raised some concerns certainly in the Center for Devices about their ability to have staff with all of the technical expertise for the rapidly changing technologies, and for the software that is included in medical devices, for example. That has been a concern that we have identified in the past, and that FDA has acknowledged is a challenge for them.

Mr. GRIFFITH. I appreciate that.

I would say in regard to the tobacco products, and I don't know the answer, we all want to know what is in the products, what the health effects are of those products, and we certainly want them to get that done in a timely fashion. I will say that, you know, when I was in the fourth grade, growing up in Virginia, they used to teach us the history that one of the first times that somebody was smoking a cigar, walking down the streets of London, some-

body ran into a local store where they all kept water buckets in case a fire broke out, and threw water on the man because he was on fire, he had smoke coming out of his mouth.

So it would seem to me that if we could get to some more of these smokeless products, it would probably help folks. That is the gut reaction. I would like to see the science on it.

Do you think that they are going to be able to give us some of that, and reduce this backlog dramatically in the next couple of years?

Ms. CROSSE. Well, with regard to smokeless products, I think that that depends upon the applications that are submitted to them. That is dependent upon the industry. Some of those products are currently not deemed to be subject to FDA regulation, and so products of those types can enter the market right now. I think that there is not currently a sufficient understanding, though, of the risks posed by those products, and whether or not they simply allow someone who smokes to co-use those types of products, or use those products in situations where they can't use a cigarette because of restrictions on where they can smoke, or whether or not it allows them to cease use of tobacco products, which we do know is dangerous to their health.

Mr. GRIFFITH. Yes. And we certainly need to get the answers to these questions because, you know, even a number of healthcare individuals have indicated that there is a good possibility that things like the e-cigarette may be a step in between smoking the smoke tobacco and moving away from using the product at all.

Ms. CROSSE. Yes, of course, if they are making smoking cessation claims, then they would be subject to regulation as a drug, and subject to regulation in a different part of FDA. So, you know, I think the concern is whether or not they become a gateway product to allow young people to then begin smoking cigarettes, and I think the science is just not there yet to know.

Mr. GRIFFITH. Yes, ma'am. I appreciate that, and I hope that the center will get to work and get it done.

Thank you so much, and I yield back.

Mr. BURGESS. The gentleman's time has expired.

The Chair now recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for your questions, please.

Mr. SHIMKUS. Thank you, Mr. Chairman. If I can get the staffer to move. Mike Bilirakis. Thank you.

Mr. BILIRAKIS. Gus Bilirakis.

Mr. SHIMKUS. Yes, yes, yes. Well, anyway, your staffer, get him to move. Thanks. Mike's dad.

Mr. BILIRAKIS. Yes.

Mr. SHIMKUS. That is his dad, former committee member, it is an easy mistake.

So welcome. And actually, I am following a lot of Morgan's comments, and a lot of comments all other folks have made, but I want to start with—I was going to flip the questions around, but you ended up with this whole, if there is a statement of smoking cessation claimed, it goes into another part or another area of regulation, versus just tobacco use product, is that correct?

Ms. CROSSE. That is my understanding, yes.

Mr. SHIMKUS. And because another former colleague, not Mike Bilirakis, but Steve Buyer, when we passed this bill in 2009, kept trying to address these issues of nicotine gum, snuff, and now you could make some debate about e-cigarettes, that, yes, do provide nicotine to the individual consumer, but you could also argue, especially with e-cigarettes, that in the vaporized form versus a burning form, and all those issues, there may be some health benefits over a burned tobacco product is kind of the debate, and so, in this process, we need to get the FDA to move in the direction of evaluating this, right? Or shouldn't the FDA, in essence, be like the referee on the court in making judgments?

Ms. CROSSE. Well, I think that the statute gives them that authority and that responsibility, and that they have announced that they intend to deem additional tobacco products, and as I understand it, virtually all additional tobacco products, as subject to their regulation.

Mr. SHIMKUS. And so intent to deem, I guess that is part of the reason why we are here, right? How long does it take to have an intent to deem, and how long should it?

Ms. CROSSE. Well, rulemaking, as I am sure you are aware, is typically a years-long process. They first announced their intent to deem in 2010, but it was not clear whether they at that time intended to deem all products at once, or product after product individually. My understanding is that they now have made a determination to deem multiple products at one time, and so, therefore, needed to develop the information to support that rulemaking. We had other work that had examined rulemaking at FDA that had a range of 1 year to 14 years, so this is still in that range.

Mr. SHIMKUS. Yes, but the importance of the intent to deem is to provide information to the consuming public, the adult consuming public, correct?

Ms. CROSSE. Well, yes, and to make determinations about the safety and controls that might be required for different types of products.

Mr. SHIMKUS. Because they should be using science and evidence in this decisionmaking process, correct?

Ms. CROSSE. That is what they are saying that they are trying to develop, is a scientific base to understand the risks posed by different types of tobacco products.

Mr. SHIMKUS. And we would hope that they will do that sooner rather than later for all of us involved. I would think that would be the argument.

And then on the—my time is running short, but also following up on Morgan's comments is technology and moving rapidly, bureaucracy does not, we fight that issue across the board in the telecom world. And you talk about apps, but is the FDA's ability to keep up with the innovation and science and product technology for the Center for Tobacco Products, have you seen that that is lagging also?

Ms. CROSSE. Well, I think it is too soon to say whether it is lagging. I think they have just been mounting it in the last several years. And so——

Mr. SHIMKUS. You know, I think that is what frustrates a lot of us here, and I know people—there is a role for government, but in

the private sector, you can't mount something for years. You would never have a product, you would never have a return on investment, and your competitors would move right past you. So we would wish that they would move expeditiously.

And thank you, Mr. Chairman, I yield back.

Mr. BURGESS. Gentleman yields back.

That being all the members of the subcommittee, the Chair now recognizes Mr. Bilirakis, 5 minutes for questions, please.

VOICE. Is that Mike or Gus?

Mr. BILIRAKIS. Yes. Either one. I can get Mike——

Mr. BURGESS. Either one.

Mr. BILIRAKIS [continuing]. In short notice if you want him. Thank you, but I am a member of the subcommittee as well, but turning to—thank you very much for appearing today. I appreciate it very much, Doctor.

Turning to staffing levels at the Center for Tobacco Products, how many FTEs are currently in the various offices?

Ms. CROSSE. My understanding is that they currently have a total of about 511 staff, and the figures I have are that the Office of Science, which is the office that makes the decisions on product reviews, they have 194 staff, and that the Office of Health Communications has 44 staff, and the Office of Compliance and Enforcement has 116 staff.

Mr. BILIRAKIS. Thank you. Do most of these employees have previous experience regulating tobacco products in other government agencies?

Ms. CROSSE. No, because tobacco products weren't regulated previously, and so they may have experience in regulating products, but not necessarily tobacco products. They did bring in a number of scientists who had done research on tobacco products, but not for purposes of regulation.

Mr. BILIRAKIS. Thank you.

Next question. Has FDA implemented the small business provisions included in the statute, including the establishment of the office to assist small tobacco manufacturers for the provision of technical assistance, and has the Agency issued any small business guidance?

Ms. CROSSE. You know, I am not certain. We can get back to you on that. I know that they have had some implementation in that area, but we did hear concerns from manufacturers that that was an issue for them in terms of being able to get the information that they needed.

Mr. BILIRAKIS. You are not sure about the small business guidance?

Ms. CROSSE. I am just not sure. I don't think that we looked at it explicitly.

Mr. BILIRAKIS. OK, you will get back to me?

Ms. CROSSE. Yes, we will.

Mr. BILIRAKIS. All right, thank you very much.

Anybody like some time here?

Thank you. I yield back, Mr. Chairman.

Mr. BURGESS. The gentleman yields back.

That concludes the questions by the members of the subcommittee. I would remind all members they have 10 business days

to submit questions for the record, and ask the witness to respond to the questions promptly. Members should submit their questions by the close of business on Tuesday, April 22.

Without objection, the subcommittee is adjourned. Thank the witness.

[Whereupon, at 11:49 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Statement for the Record
U.S. Representative Kathy Castor
Energy & Commerce Committee Hearing on the Tobacco Control Act
April 8th, 2014

Thank you Mr. Chairman for holding this important hearing to examine the steps FDA is taking to implement the Tobacco Control Act.

The goal of the Tobacco Control Act is to ensure tobacco companies do not market tobacco products to children thereby preventing addiction to tobacco products. Nevertheless, as we have seen over the years, tobacco companies target children with flavored cigarettes and other tobacco products with flavors like vanilla, strawberry and chocolate. The Centers for Disease Control (CDC) issued a study last October stating that flavored tobacco use is rising – more than 40 percent of middle and high school students who smoke use flavored little cigars and flavored cigarettes.

We all know the dangers of cigarette use; however, there is a new device for those needing a nicotine fix. Electronic cigarettes, or e-cigarettes, allow users to "smoke" liquid nicotine. The e-cigarette industry is currently unregulated, but the FDA has indicated it will expand its jurisdiction over e-cigarettes thanks to the Tobacco Control Act.

While research is still ongoing on the health impacts of e-cigarettes, there is growing evidence in the rise of use of these products by youth. According to the same CDC study referenced above, e-cigarette use doubled among middle and high school student between 2011 and 2012. E-cigarette makers are targeting children with the same flavors they used in cigarettes. The nicotine infused fluid used in e-cigarettes come in fruit and candy flavors like gummy bears, vanilla cupcake and berry blast. There are no federal age restrictions for purchasing e-cigarettes, unlike traditional cigarettes, making it easier for minors to purchase these products at the corner store or over the internet.

Earlier this month, the CDC issued another troubling study regarding the rise in calls poison control centers are seeing about e-cigarettes and liquid nicotine poising. According to the study, e-cigarettes account for a growing percentage of monthly e-cigarette and cigarette exposure calls, from 0.3 percent in September 2010 to 41.7 percent in February 2014. More than half of the calls involve children 5 years old or younger. The argument could be made that due to the candy and fruit flavoring of the nicotine, we are seeing such a substantial number of calls involving children. Individuals were being poisoned by ingesting the liquid or by skin absorptions. This is a scary and preventable trend once we better educate the public of the harm these liquids can cause.

We still have considerable research to do to understand the long-term impact e-cigarettes have on the health of our children and adults. It is my hope that through regulation by the FDA and continued studying by the CDC and other stakeholder groups, we can discourage youth from using any form of nicotine and tobacco products.

I

113TH CONGRESS
1ST SESSION

H. R. 389

To require the submission to the Congress of annual reports on the tobacco user fees assessed and collected under section 919 of the Federal Food, Drug, and Cosmetic Act.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 23, 2013

Mr. GUTHRIE introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To require the submission to the Congress of annual reports on the tobacco user fees assessed and collected under section 919 of the Federal Food, Drug, and Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Transparency in Tobacco User Fees Act of 2013".

SEC. 2. REPORTING ON TOBACCO USER FEES.

Section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s) is amended by adding at the end the following:

"(f) REPORTING.—

"(1) IN GENERAL.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under this section, the Secretary shall, with respect to such fiscal year, prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning such fees.

"(2) CONTENTS.—Each report under paragraph (1) shall, with respect to the fiscal year involved, include at a minimum the following:

"(A) The total amount of fees assessed and collected under this section.

"(B) A description of how such fees have been, or are intended to be, used.

"(C) The total amount of fees assessed and collected under this section which have not been obligated.

"(D) The total amount of fees assessed and collected under this section which have been obligated, but have not been expended.

"(E) Of the fees assessed and collected under this section, the portion of such fees which have been, or are intended to be, provided to public or private entities outside of the Federal Government.

"(F) The total number of tobacco products for which an application is received, or an order is issued, under section 910.

"(G) Of the applications received under section 910—

"(i) the number of such applications disposed of; and

"(ii) the number of such applications which remain pending.

"(H) The total number of modified risk tobacco products (as defined in section 911(b)) for which an application is received, or an order is issued, under section 911.

"(I) Of the applications received under section 911—

"(i) the number of such applications disposed of; and

"(ii) the number of such applications which remain pending.".

○

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

April 24, 2014

Dr. Marcia G. Crosse
Director
Health Care
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Dr. Crosse:

Thank you for appearing before the Subcommittee on Health on Tuesday, April 8, 2014, to testify at the hearing entitled "Examining the Implementation of the Tobacco Control Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Thursday, May 8, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

May 6, 2014

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Subject: Responses to Questions Following GAO Testimony Entitled *TOBACCO PRODUCTS: FDA Spending and New Product Review Time Frames*

Dear Mr. Chairman,

On April 8, 2014, GAO testified at a hearing on examining the implementation of the Tobacco Control Act. The enclosed document is GAO's response to the Subcommittee's questions for the record. For questions regarding GAO's April 8 testimony and the following enclosure, please contact me at (202) 512-7114 or crossem@gao.gov.

Sincerely yours,

Marcia Crosse
Director, Health Care

Enclosure

cc: Sydne Harwick
John Stone
Carly McWilliams

Attachment I – Additional Questions for the Record

The Honorable John Barrow

1. How do you assess FDA's capacity to regulate e-cigarettes?

GAO has not conducted the work necessary to assess FDA's capacity to regulate e-cigarettes. In reporting on FDA's reviews of new tobacco product submissions, we noted that FDA has increased its staff and training for staff. However, tobacco industry stakeholders expressed concerns about whether FDA's Center for Tobacco Products (CTP) will have a sufficient number of qualified staff to review the backlog of the more than 4,000 new tobacco product submissions received as of December 31, 2013 in addition to the new submissions that may be made in the future, particularly if FDA asserts jurisdiction over new types of tobacco products that are not currently subject to FDA's regulatory authority.[1] CTP officials reported that many additional staff have been and will continue to be hired and trained, and the center does not expect hiring qualified staff to be a continuing challenge for the purpose of conducting product reviews.

In April 2014, FDA issued a proposed rule that, if finalized, would deem all products that meet the statutory definition of a tobacco product, including e-cigarettes, to be subject to FDA's regulatory authority.[2] It is not yet known whether the size of the backlog of new tobacco product submissions or FDA's resources to handle such a backlog will be different if FDA issues a final rule deeming e-cigarettes and other tobacco products not currently regulated by FDA to be subject to its authority.

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[1]GAO, *Tobacco Products: FDA Spending and New Product Review Time Frames.* GAO-14-508T (Washington, D.C.: Apr. 8, 2014), 13.

[2]79 Fed. Reg. 23142 (Apr. 25, 2014).

Attachment 2 – Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Gus Bilirakis

1. **Has FDA implemented the small business provisions included in the statute, including the establishment of the Office to Assist Small Tobacco Manufacturers for the provision of technical assistance? Has FDA issued any small business guidance?**

GAO has not conducted the work necessary to assess FDA's implementation of the small business provisions included in the statute. However, in conducting work on FDA's authority and resources to regulate the manufacture, marketing, and distribution of tobacco products, we have learned that FDA's Center for Tobacco Products (CTP) has conducted outreach and small business assistance activities, including establishing the Office of Small Business Assistance. Since fiscal year 2010, CTP and its Office of Small Business Assistance have responded to inquiries from small manufacturers and retailers, and provided information on relevant tobacco guidance and regulations, primarily through webinars. For example, in March 2012, FDA issued guidance to help small businesses understand and comply with FDA's tobacco product regulations, and, in August 2012, FDA held a webinar, Compliance Training for Small Businesses – *Common Issues Identified During FDA's Scientific Evaluation of Substantial Equivalence Reports.*[3] Officials from a trade organization representing small tobacco businesses reported that, in their view, provisions in the statute to protect small business have not been implemented by FDA as Congress intended. For example, although an Office of Small Business Assistance has been established by CTP, these officials said that small businesses still lack the technical, scientific, and other nonfinancial assistance they require. They told us that they had difficulty getting their questions answered by the Office of Small Business, often waiting months or even years for an answer.

The Honorable Renee Ellmers

1. **You stated that FDA continues to try to determine exactly what information they need in applications and the lack of that information prevents the Agency from moving forward in a timely fashion. A number of the initial applications did not contain information that FDA needed in order to reach decisions and some of those deadlines required that applications come in prior to FDA putting out guidance on what was needed. At what point did the FDA put out the guidance for those application requests?**

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[3]The Food and Drug Administration Center for Tobacco Products, Guidance for Industry: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products – Small Entity Compliance Guide, accessed April 28, 2014, http://www.fda.gov/downloads/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm297536.pdf. For additional information on FDA compliance webinars, see http://www.fda.gov/TobaccoProducts/ResourcesforYou/BreakTheChain/ucm220111.htm (accessed April 28, 2014).

CTP officials told us that insufficient information from manufacturers in Substantial Equivalence (SE) submissions for new tobacco products has had the most significant impact on review times for those submissions. According to CTP officials, the majority of SE submissions were incomplete and required follow-up with manufacturers to obtain additional information, such as a full description of both the new tobacco product and the predicate tobacco product. CTP officials reported that they spent significant time sending out letters requesting missing information from manufacturers and awaiting the manufacturers' responses.

Industry representatives agreed that the lack of completeness of submissions had an impact on reviews, but they told us that guidance provided by CTP was neither timely nor adequate for manufacturers to provide what CTP would consider SE submissions with sufficient information. Manufacturers we interviewed said they were not able to include all information indicated in CTP guidance that was issued on January 5, 2011, for provisional SE submissions, which needed to be submitted by March 22, 2011, in order for those products to remain on the market provisionally. In addition, they reported that the January 2011 guidance did not direct manufacturers to include some information by the March 22, 2011, submission deadline that CTP later requested in its September 2011 draft guidance or Advice and Information letters, such as an environmental assessment (which is information used by CTP to determine the environmental impact of granting an SE submission).