Report to the House and Senate Committees on Appropriations

Tobacco Product User Fees

Report in Response to the
Consolidated Appropriations Act, 2021

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Date

Executive Summary

On December 27, 2020, the Consolidated Appropriations Act, 2021 (P.L. 116-260) was enacted into law, which provided appropriations under Division A, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2021 for the fiscal year ending September 30, 2021. The accompanying Joint Explanatory Statement directed the Food and Drug Administration (FDA or the Agency) to submit a financial report on tobacco product user fees and their use to fund programs and activities related to regulating tobacco products.

This report responds to this directive by providing fiscal year (FY) 2020 actual obligations and FY 2021 planned expenditures, including a description of program areas. This report also responds to other areas of congressional interest.

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Introduction

On December 27, 2020, the Consolidated Appropriations Act, 2021 (P.L. 116-260) was enacted into law, which provided appropriations under Division A, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2021 for the fiscal year ending September 30, 2021. The accompanying Joint Explanatory Statement directed the Food and Drug Administration (FDA or the Agency) to submit the following:

> *"The agreement directs FDA to submit a financial report to the Committees within 120 days of enactment of this Act, to be made publicly available online, with respect to tobacco product user fees and their use to fund programs and activities related to regulating tobacco products within FDA."*

In response to this directive, FDA prepared the following report. In addition, FDA is aware of ongoing congressional interest in a variety of user fee-funded programs and activities and therefore is attaching to this report the June 2020 report to Congress entitled *Progress and Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act*.

FY 2020 Obligations and FY 2021 Planned Expenditures

The Center for Tobacco Products' (CTP's) fiscal year (FY) 2020 obligations and FY 2021 planned expenditures listed by program area are included in Table 1 on the next page.

Table 1. CTP's FY 2020 Obligations and FY 2021 Planned Expenditures.

	FY 2020 Actual Obligations (dollars in millions)		FY 2021 Planned Expenditures (dollars in millions)	
Program Area	**Acquisitions**	**Personnel/ Operating**	**Acquisitions**	**Personnel/ Operating**
Scientific Research and Research Infrastructure	$ 222.9	$ 61.9	$ 273.2	$ 74.1
Compliance and Enforcement	$ 57.5	$ 62.7	$ 65.9	$ 72.5
Public Education Campaigns	$ 145.8	$ 6.4	$ 159.2	$ 6.9
Communications	$ 15.6	$ 6.4	$ 8.2	$ 6.9
Leadership, Management Oversight, and Administrative	$ 11.6	$ 27.5	$ 9.9	$ 28.2
Overhead	$ 131.6	$ 29.3	$ 73.0	$ 28.6
Total	**$ 585.0**	**$ 194.2**	**$ 589.4**	**$ 217.2**
	Total Actual Obligations: $779.2		**Total Planned Expenditures: $806.6**	

Carryover Balance from FY 2020 (dollars in millions): $253.5[1]

CTP is fully funded by tobacco user fees, and such fees are authorized to remain available until expended.

[1] Carryover can vary from year to year based on when user fee payments are received from industry. Contract obligations are sometimes delayed until the next fiscal year due to protests or difficulty awarding. This delay would be reflected in the carryover. Carryover exists due to tobacco industry user fees being collected at the end of each quarter, so most of the fourth quarter collections are not available for obligation until the first quarter of the following fiscal year. Therefore, there will always be a carryover balance equal to at least the fourth quarter projected collections, which is currently $178 million. CTP's budget became flat at $712 million per year beginning in FY 2019. With required increases for payroll and overhead in the future, carryover is expected to decrease substantially in the next several years.

The two program areas that account for the largest personnel/operating costs in CTP are (1) Scientific Research and Research Infrastructure and (2) Compliance and Enforcement. These two program areas are managed by CTP's two largest offices, the Office of Science, which currently has 538 staff, and the Office of Compliance and Enforcement, which currently has 290 staff and also utilizes a dedicated cadre of staff from FDA's Office of Regulatory Affairs to perform inspections and other regulatory work.

The budget for Scientific Research and Research Infrastructure fluctuates as a result of collecting data for the Population Assessment of Tobacco and Health (PATH) Study, which is discussed in greater detail in the Investment in Scientific Research section below. Similarly, the Public Education Campaigns budget also fluctuates due to differences in contract structure and campaign strategies. Beginning in FY 2021, a process change was implemented to align information technology (IT) applications and systems to the program area they support rather than including them in the Overhead program area with the general IT infrastructure costs.

Description of Program Areas

Scientific Research and Research Infrastructure: Informs FDA's efforts to achieve our goals of tobacco prevention and cessation, and reducing tobacco harms. This includes premarket review of new tobacco products and review of claims of modified risk tobacco products.

Compliance and Enforcement: Enforcement of the Federal Food, Drug, and Cosmetic Act as amended by the Tobacco Control Act and implementing regulations, including Regulations for Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents. Includes tobacco operations (e.g., inspections) by the FDA Office of Regulatory Affairs (ORA).

Public Education Campaigns: Public education campaigns in concert with regulatory action to reduce tobacco use and improve public health.

Communications: Campaign-specific websites where target audiences can seek additional information about the harms of tobacco product use and connections to resources for quitting.

Leadership, Management Oversight, and Administrative Services: Leadership and management oversight of all tobacco program operations and activities to support the programmatic mission of the Center, including the development of regulatory and policy documents.

Overhead: Includes general IT infrastructure, centralized expenses, General Services Administration rent, other rent and rent-related services, and FDA Headquarters.

Status of Tobacco Product Applications

The review of product applications is a critical component of FDA's comprehensive tobacco product regulation. In reviewing tobacco product applications, FDA evaluates new products, including new products resulting from product changes, and modified risk tobacco products and determines whether such products can be marketed. This is one of FDA's most important consumer protection responsibilities.

The Agency has taken many steps to set clear expectations for industry and to improve timeframes for product review, including increasing scientific staffing, establishing performance measures that set timeframes for reviewing substantial equivalence (SE) reports, providing feedback to industry, holding meetings with industry, developing resources to help companies provide complete submissions, and sending letters and other communications to clarify expectations for industry. The Agency has also issued multiple guidance documents related to premarket review and hosted training webinars.

Per a court order, premarket applications for many new tobacco products—including e-cigarettes, certain cigars, and certain hookah products—that were on the market as of August 8, 2016, were due to the Agency by September 9, 2020.[2]

Table 2 summarizes the status of tobacco product applications received, including Exemption Requests (EX REQ), Regular SE Reports, Premarket Tobacco Product Applications (PMTAs), and Modified Risk Tobacco Product (MRTP) Applications, through August 12, 2021. The numbers for PMTAs are expected to change as FDA continues to process applications submitted after September 9, 2020. FDA has processed submissions that cover over 8 million products under the PMTA pathway. This figure includes 1.3 million products that were the subject of applications submitted after September 9, 2020.

FDA understands the great interest from the public about what product applications were submitted and the progress the Agency has made in reviewing the thousands of tobacco product submissions received on or before the September 9, 2020, deadline.

[2] See https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline?utm_campaign=ctp-sept9&utm_content=landingpage&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms.

As part of our broader commitment to transparency, FDA is also posting expanded data on our new Tobacco Product Application Metrics & Reporting webpage which can be found here: *https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting*. For the first time, we are posting all metrics both by pathway (SE, EX REQ, and PMTA) and by product category type (e.g., cigarette, electronic nicotine delivery system (ENDS), cigars, smokeless). This webpage will be updated regularly and will provide more detailed updates of the Agency's progress on premarket application review than previously available. The new website includes:

- List of deemed new tobacco products that are or were the subject of applications submitted to FDA by September 9, 2020 https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-list
- List of negative actions and other actions that impact marketing (includes refuse-to-accept, refuse-to-file, marketing denial order, not substantially equivalent, not exempt, withdrawals by applicant, and administrative closures)
- List of positive marketing orders (includes marketing granted order, SE orders, and exempt orders)

Table 2. Tobacco Product Applications Received, Open, Pending, and Closed by Product Class.

Application Status	Product Class[3]	Cumulative through 8/12/2021				
		Exemption Requests	Regular SE Reports	Provisional SE Reports	PMTAs[4]	Modified Risk Tobacco Applications
Received	Cigarettes	964	1,513	2,392	18	18

[3] In this column, "Other" includes tobacco products that are not defined (e.g., nicotine gel, dissolvable products from extracts) and products not under CTP's jurisdiction.

[4] The number of ENDS PMTAs received is an underestimate. Because FDA has received millions of PMTAs over the past year, the Agency has not completed processing all received PMTA submissions to have an accurate estimate. This number is likely to increase as FDA continues to process all of the received PMTA submissions.

	Roll Your Own	27	1,178	646	4	0
	Smokeless	58	508	589	14	19
	ENDs	0	2	18	8,038,294	14
	Cigars	338	3,250	0	15	0
	Pipe Tobacco Products	0	1,815	0	12	0
	Waterpipe Tobacco Products	1,439	2,710	0	75	0
	Other	0	3	0	679	0
	Total	2,826	10,979	3,645	8,039,111	51
Open	Cigarettes	147	149	394	5	6
	Roll Your Own	2	130	13	0	0
	Smokeless	3	93	76	0	7
	ENDs	0	0	0	1,775,033	0
	Cigar	156	2,895	0	10	0
	Pipe Tobacco Products	0	1,463	0	12	0

	Waterpipe Tobacco Products	883	769	0	11	0
	Other	0	1	0	218	0
	Total	1,191	5,500	483	1,775,289	13
Closed[5]	Cigarettes	817	1,364	1,998	13	12
	Roll Your Own	25	1,048	633	4	0
	Smokeless	55	415	513	14	12
	ENDs	0	2	18	6,263,261	14
	Cigar	182	355	0	5	0
	Pipe Tobacco Products	0	352	0	0	0
	Waterpipe Tobacco Products	556	1,941	0	64	0
	Other	0	2	0	461	0
	Total	1,635	5,479	3,162	6,263,822	38

[5] "Closed" includes refuse-to-accept, refuse-to-file, remove from review, issuance of an order, environmental information request, withdrawn, or closure due to administrative issues.

Update on Enforcement and Compliance Actions

FDA has a comprehensive compliance and enforcement program to monitor industry's compliance with regulatory requirements and to restrict access and marketing of tobacco products, including e-cigarettes, to youth. Since October 1, 2019, as part of the Youth Tobacco Prevention Plan and consistent with FDA's policy to prioritize the enforcement of certain e-cigarettes and other deemed products on the market, the Agency has taken the following actions to stop youth use of, and access to, ENDS products:

- Prior to the partial stop work order issued in March 2020 due to the COVID-19 pandemic, conducted over 65,000 retail inspections to crack down on the sale of tobacco products, including ENDS products, to minors at both brick-and-mortar and online retailers.

- Issued more than 7,000 warning letters and civil money penalties to retailers for illegally selling tobacco products, including ENDS products to minors.

- Issued over 200 warning letters to online and brick-and-mortar establishments, including 7-Eleven and Shell, for selling unauthorized flavored, cartridge-based e-cigarette products.

- Prior to temporarily halting inspection activities due to COVID-19, conducted inspections of over 140 tobacco manufacturing establishments and over 400 vape shops, and conducted investigations involving thousands of websites.

- Issued over 130 warning letters to companies that had not submitted premarket applications to FDA and were continuing to sell or distribute unauthorized ENDS after September 9, 2020. Collectively, the companies that received those warning letters have over 1.4 million products listed with FDA.

- Issued a warning letter to XL Vape LLC (doing business as Stig Inc.), a popular disposable e-cigarette brand among youth, for the unauthorized sale of their ENDS products.

- Issued warning letters to two companies for illegally marketing unauthorized menthol-flavored e-liquids that featured cartoon images of, e.g., vampires and kings.

- Issued warning letters to ten companies, including Puff Bar, for the unauthorized sale of flavored disposable e-cigarettes and e-liquids that imitated packaging for products such as Cinnamon Toast Crunch cereal, Twinkies, and Cherry Coke.

- Issued warning letters to companies for marketing unauthorized products, such as a backpack and sweatshirt with hidden pockets to conceal an e-cigarette.

- Issued warning letters to companies for marketing unauthorized products that resembled smartwatches and children's toys, such as a video game system and a fidget spinner.

- Issued warning letters to companies marketing e-liquids that imitated packaging for food products that appeal to youth, such as candy, or featured cartoon characters like SpongeBob SquarePants.

- Issued a warning letter to e-liquid manufacturer StemStix Inc. for marketing new tobacco products without authorization, marketing tobacco products with false and misleading advertising, and marketing unauthorized modified risk tobacco products.

- Refused admission into the United States of at least 380 lines of ENDS products, including disposables, for violations of the FD&C Act.

- In collaboration with U.S. Customs and Border Protection, seized more than 33,000 units of counterfeit, unauthorized e-cigarettes coming from China.

- Sent official requests to four e-cigarette companies—each active with large followings on social media and not using age restriction tools on those platforms—to submit information about their marketing practices to FDA.

Retailer Compliance Check Program

As of December 31, 2020, FDA had contracts for tobacco retailer compliance check inspections in approximately 50 states and territories, and one tribal jurisdiction. However, FDA issued a stop work order on March 19, 2020, as a safety measure in response to the COVID-19 pandemic. In FY 2021, retailer inspections resumed on a limited basis in certain areas where the spread of COVID-19 was less prevalent. Compliance check inspections pertain to tobacco marketing, sales, and distribution of tobacco products at retail locations and include ensuring compliance with age and ID verification requirements. In general, inspections are conducted by FDA commissioned inspectors in the jurisdiction under contract. FDA commissions and trains these officials to conduct inspections on the Agency's behalf. FDA currently utilizes more than 700 commissioned inspectors.

Although most tobacco retailers comply with FDA's tobacco laws and regulations, FDA conducts compliance check inspections and issues advisory and enforcement actions such as warning letters, civil money penalties, and no-tobacco-sale orders when violations are found. Table 3 lists the different enforcement actions that have resulted from these inspections.

Table 3. Enforcement Actions from CTP's Tobacco Retailer Inspection Program.*

Enforcement Action	FY 2020 Actuals	FY 2021 (as of 5/31/2021)	Total Since the Program's Inception (as of 5/31/2021)
Retailer Inspections	65,717	8,933	1,210,714
Total Warning Letters	4,906	95	98,138
Warning Letters Resulting from the Sale of ENDS Products to Minors	1,166	26	11,588
Total Civil Money Penalties	2,327	8	25,828
Civil Money Penalties Resulting from the Sale of ENDS Products to Minors	480	2	2,057
No-Tobacco-Sale-Orders	38	1	220

* In March 2020, FDA issued stop work orders to the contractors engaged in tobacco retail compliance check inspections and vape retail inspections due to COVID-19. The Agency subsequently extended the stop work orders through the end of FY 2020. As a result, FDA conducted about half the number of inspections it had expected to conduct in FY 2020.

Tobacco 21

On December 20, 2019, legislation to amend the FD&C Act and to raise the federal minimum age of sale of tobacco products from 18 to 21 years was enacted. It is now illegal for a retailer to sell tobacco products—including cigarettes, cigars and e-cigarettes—to anyone under 21. The legislation also required FDA to publish a final rule making conforming amendments to our regulations to reflect this statutory change. The law also provides that such final rule must increase the federal minimum for verification of tobacco product purchaser age by retailers, from under 27 years of age to under 30 years of age. FDA is currently working to issue this final rule. Until the regulation is changed, the current requirement of verifying identification by means of photo identification for those under 27 years of age remains in effect.

FDA's enforcement of the new federal minimum age law is generally carried out using the same process that was used to enforce the previous minimum age of sale. The Agency continues to conduct compliance check inspections of tobacco product retailers to determine a retailer's compliance with federal laws and regulations. During Undercover Buy inspections, underage tobacco product purchasers (who are under the supervision of FDA-commissioned inspectors) attempt to purchase tobacco products. If, during these inspections, a tobacco product is sold to an underage purchaser, FDA sends the retailer a Compliance Check Inspection Notice which informs the retailer that a potentially violative inspection occurred at the establishment.

Initially, FDA recognized that both the Agency and some retailers would need to update current practices to implement the new law and stated that FDA would use only minors under the age of 18 years in the compliance check program during the ramp up period. During this period of transition, FDA expected retailers to follow the law and take measures to ensure an individual who purchases tobacco products is 21 years of age or older, including checking IDs.

Now that a reasonable transition period has concluded, FDA is using people under the age of 21 years in its nationwide compliance check inspection program to determine retailer compliance. FDA expects that retailers will continue to verify the age of anyone under the age of 27.

FDA has also taken numerous steps to help tobacco retailers adhere to the new law. For example, in spring 2019, as part of FDA's "This Is Our Watch" national retailer education program, the Agency mailed digital programmable calendars to tobacco retailers nationwide. The calendar enables retailers to set the age on the digital calendar to the federal minimum age of sale of tobacco products to 21. The Agency also created the "FDA's Age Calculator" mobile application (app) to help retailers, through the use of their personal smartphone, determine if the purchaser is of legal sales age. This app can be updated by users to reflect the new federal minimum age of sale. In addition, in February 2020, FDA published a webinar to help tobacco retailers understand how the new federal minimum age of sale impacts their establishments. Information on all these materials—as well as additional resources such as a fact sheet on the new law and answers to commonly asked questions—can be found on the "Tobacco 21" landing page.[6] This webpage was launched in March 2020 to serve the public with a single location on FDA's website for the latest information and resources related to the new law.

[6] See https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21.

Manufacturers' Compliance and Enforcement Activities

FDA regularly inspects registered establishments that manufacture or process tobacco products to determine their compliance with existing laws and regulations. CTP's coordination with ORA has increased considerably as the scope of these activities continues to expand to include manufacturers and importers of deemed tobacco products and additional provisions in the final rule regarding deeming tobacco products to be subject to the FD&C Act.[7] Since the inception of the Tobacco Program's manufacturer inspection activities through June 2021, CTP has overseen the completion of more than 2,600 inspections of vape shops to verify whether they were engaged in manufacturing activities, and ORA has completed over 900 routine biennial inspections of tobacco manufacturers. As mentioned above, in March 2020, FDA temporarily postponed manufacturing inspections, including tobacco, due to the COVID-19 pandemic and the related stop work order for inspection contracts impacts work related to FDA's vape shop inspections. In FY 2021, manufacturer inspections resumed on a limited basis where the spread of COVID-19 is less prevalent. FDA is also utilizing remote regulatory assessments.

Investment in Scientific Research

FDA invests in research to inform its regulatory actions by addressing scientific knowledge gaps and adding to the evidence-based knowledge. This regulatory research informs FDA's tobacco regulatory activities and helps the Agency better understand tobacco use and the risks associated with it, which support FDA's mandate to reduce the public health burden of tobacco product use in the United States. In FY 2020, FDA invested more than $220 million in scientific research with a focus on reducing youth initiation of tobacco use, reducing tobacco product harms, and encouraging those who already use tobacco products to quit. FDA's research priorities address the following Scientific Domains:

- Chemistry and Engineering: understanding the chemical constituents in tobacco products and the methods for measuring them across products with diverse characteristics
- Toxicity: understanding how tobacco products and changes to tobacco product characteristics affect their potential to cause morbidity and mortality

[7] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, Final Rule, 81 FR 28974 (May 10, 2016).

- Addiction: understanding the effect of tobacco product characteristics on addiction and abuse liability across populations

- Health Effects: understanding the short- and long-term health effects of tobacco products across populations of special relevance, as appropriate

- Behavior: understanding the knowledge, attitudes, and behaviors related to tobacco product use and changes in tobacco product characteristics across populations, as appropriate

- Communications: understanding how to effectively communicate to the public regarding the health effects of tobacco products and nicotine (including addiction), through media campaigns, and digital media

- Marketing Influences: understanding the impact of marketing on susceptibility to using tobacco products (both classes of products and products within classes) and transitions between experimentation, initiation to regular use, and dual use among different populations

- Impact Analysis: understanding the impact of potential FDA regulatory actions.

FDA has encouraged research studies to include, when appropriate, populations of special relevance, including youth, socioeconomically disadvantaged populations, racial/ethnic minorities, underserved rural populations, people with co-morbid mental health conditions and/or substance use disorders, military/veteran populations, pregnant women or women of reproductive age, and sexual and gender minorities.

FDA funds the Tobacco Regulatory Science grant program, a key component of which is the establishment of the Tobacco Centers of Regulatory Science (TCORS). TCORS are made up of scientists at research institutions across the country with a broad range of expertise (e.g., in epidemiology, economics, toxicology, addiction, and marketing). TCORS have the ability and capacity to respond to FDA's research priorities as issues involving tobacco products and public health arise. Currently, there are nine research centers funded for FY 2018 to FY 2022 as part of the TCORS 2.0 program.

Another key component of FDA's tobacco regulatory science research program is the PATH Study. FDA funds the PATH Study via a contract with the National Institutes of Health's (NIH's) National Institute on Drug Abuse, with both agencies collaborating on the scientific aspects of the study, such as the appropriate inclusion of biomarkers to assess tobacco exposure and potential harm. The PATH Study is an ongoing, nationally representative, longitudinal cohort study of approximately 46,000 users of tobacco products and non-users at risk for tobacco use, age 12 and older. Research topics include evaluating patterns of tobacco use over time, such

as switching products and using multiple products, as well as seeking to understand perceptions, knowledge, and attitudes. Since data collection started in FY 2013, five data collection waves and a special collection have been made available to the public. Two additional special collections were conducted during the COVID-19 pandemic and data are forthcoming. In 2020, the PATH Study adapted the Wave 5.5 special data collection with youth and young adults 13-19 years of age for the COVID-19 pandemic by modifying the data collection protocol. A special data collection, the PATH Adult Telephone Survey, was launched in September 2020 to address adult tobacco use during the pandemic. Similarly, the Wave 6 data collection with youth, young adults, and adults was launched in March 2021, with a protocol to address tobacco use during the pandemic. PATH Study data have resulted in more than 300 peer-reviewed publications by FDA, NIH, and other scientists. Studies have examined youth use of cigarettes, e-cigarettes, and other tobacco products; tobacco use initiation, cessation, and relapse; tobacco product attributes such as flavors and device types; perceptions of the harmfulness of tobacco products; and health disparities in tobacco use.

Investment in Public Education Campaigns

Beginning in 2014, FDA began implementing multiple public education campaigns designed to reduce cigarette initiation among populations who continued to have high prevalence of use and remained susceptible to cigarette use. With the changing tobacco landscape and the increased youth initiation and use of e-cigarettes, FDA began prioritizing prevention efforts to address youth use of vaping products in 2017 and has steadily increased budget allocation to reverse escalating youth use. In addition, FDA has been continuously monitoring the national usage rates of all tobacco products to determine the most pressing needs and then aligning the best approaches for campaign messaging and development. In 2020, several public education campaigns and their related outcome evaluation research were completed.

Going forward, FDA will continue comprehensive youth prevention efforts based on prevalence of use. A concerted focus will remain on driving down e-cigarette use, the most used tobacco product among all youth. While cigarette use has declined to the lowest recorded rates, cigarettes remain the most harmful combustible tobacco product and therefore an area of concern. Research is in progress to explore the need for additional new programs to educate youth about the harms of cigarette and other tobacco use.

Table 4 lists the launch dates and descriptions of FDA's past and present tobacco public education campaigns. Details of these campaigns are provided below the table.

Table 4. The Launch Dates and Descriptions of FDA's Tobacco Public Education Campaigns.

Campaigns	Launch date	Description
"The Real Cost" Cigarette Campaign	February 2014	Educates at-risk youth ages 12 to 17 about the harmful effects of cigarette use.
"The Real Cost" Smokeless Campaign	April 2016	Educates at-risk male youth ages 12 to 17 about the harmful effects of smokeless tobacco use.
"The Real Cost" E-Cigarette (ENDS) Campaign	September 2018	Educates at-risk youth ages 12 to 17 about the harmful effects of e-cigarette use.
"Fresh Empire" Campaign	May 2015	Prevents and reduces cigarette use among high at-risk African American, Hispanic, and Asian American/ Pacific Islander youth ages 12 to 17.
"This Free Life" Campaign	May 2016	Prevents and reduces tobacco use among Lesbian, Gay, Bisexual, and Transgender (LGBT) young adults ages 18 to 24.
"Every Try Counts" Campaign	January 2018	Encourages cigarette smokers to quit through messages of support that underscore the health benefits of quitting. Targets smokers ages 25 to 54 who have attempted to quit smoking in the last year but were unsuccessful.

"The Real Cost" - Cigarette Prevention

In February 2014, FDA launched its first ever national youth tobacco prevention campaign, "The Real Cost," which was designed to prevent youth who were open to using tobacco from doing so and to reduce the number of youths who moved from experimenting with tobacco to regular use.

Overall, nationally representative data suggests that the percentage of youth who currently use cigarettes has declined from 3.8 percent in 2018 to 3.2 percent in 2020. Although the decline at the national level is evident, state-level prevalence of current cigarette smoking has remained

higher than the national average in certain states. In 2021, to address the remaining high usage rates of cigarettes in key locations across America, "The Real Cost" Cigarette Campaign will continue to provide national paid media messages, while focusing on states that have the highest youth cigarette usage rates, which include Alabama, Arkansas, Kentucky, Louisiana, North Carolina, North Dakota, Oklahoma, South Dakota, Tennessee, West Virginia, Iowa, Mississippi, Montana, New Mexico, Alaska, Pennsylvania, South Carolina, Virginia, and Wyoming. Additionally, the campaign is exploring opportunities to deliver critical cigarette prevention messaging to specific audiences that are at higher risk of smoking. FDA launched new advertising for the campaign in December 2020.

"The Real Cost" - ENDS Prevention

In September 2018, FDA launched "The Real Cost" E-Cigarette Campaign to prevent youth e-cigarette use. The campaign targets nearly 10.7 million youth, ages 12 to 17, who have ever used e-cigarettes or are open to trying them and highlights information about the potential risks of e-cigarette use. The campaign launched with national digital advertising and posters placed in all public and private school bathrooms. In 2019, this campaign's advertising expanded to television and remains FDA's highest public education priority. FDA will be expanding e-cigarette prevention messaging to American Indian/Alaska Native (AI/AN) youth audiences, a population that has historically had higher tobacco usage rates. FDA has conducted research with AI/AN youth to understand tobacco beliefs and perceptions and is determining the best messaging approaches to reach this at-risk audience.

Since the launch, the campaign has shown positive results for effective reach and engagement. This campaign has reached up to 85 percent of all teenagers nationwide and has generated over 5 billion views from teen exposure and high online engagement. Across social media platforms, FDA has engaged teen audiences with more than 3.5 million likes, over 350,000 shares, and over 88,000 comments. Additionally, on the campaign's social media channels, approximately 10 percent of the total comments from teens are asking for help and resources to quit vaping.

In an ongoing collaboration with NIH's National Cancer Institute (NCI), FDA and NCI have developed vaping cessation content for teens to be added to the Teen.SmokeFree.gov website. Since the web content launched in July 2019, there have been over 2 million page views with visitors spending an average of 4 minutes per page to learn how to quit vaping, manage nicotine withdrawal, and acquire tips for managing stress and anxiety.

“The Real Cost” - Smokeless Tobacco Prevention

To educate youth about the dangers of smokeless tobacco use, FDA expanded “The Real Cost” campaign in April 2016 to include new advertising targeting hard-to-reach rural male youth ages 12 to 17 at-risk of smokeless tobacco use. The campaign advertisements, built on extensive qualitative research and theories of health behavior change, aimed to deliver facts in relevant and attention-grabbing ways about the dangers of smokeless tobacco use. The overall strategic platform for this messaging area was “smokeless doesn’t mean harmless.” The campaign advertisements were in market at high reach and frequency levels using a variety of tactics—including through local television, radio, and outdoor signs—and precise targeting on digital and social media platforms based on teens’ passion points. The advertisements initially educated nearly 600,000 rural male youth in 35 rural media markets where smokeless tobacco use was relatively high. In January 2019, the campaign expanded to 20 states after the end of the evaluation period, reaching nearly 3 million male youth by using a digital-only media strategy.

During the 3 years the campaign was in market, “The Real Cost” Smokeless Campaign achieved significant reach to the rural male youth audience. The messaging resonated with the audience, and the campaign achieved high levels of receptivity among the audience. Overall, the campaign was able to reach more than 90 percent of the target audience, and there were over 14 million social media engagements with the campaign’s social media channels.

As a result of prioritizing e-cigarettes and combustible tobacco products, the smokeless public education campaign ended in December 2020. However, FDA will continue to provide youth messaging and resources for stakeholders on smokeless tobacco prevention.

“Fresh Empire”

The "Fresh Empire" Campaign was implemented from October 2015 through June 2020 and educated the nearly five million at-risk African American, Hispanic, and Asian American/Pacific Islander youth who were open to smoking, or experimenting with cigarettes, about the harms of tobacco use. The campaign used broadcast TV, radio, digital advertising, and social media to reach the target audience with messaging on addiction caused by cigarette smoking.

During the 4 years the campaign was in market, “Fresh Empire” was able to achieve significant reach to the at-risk youth audience through engaging, cutting-edge marketing approaches. Innovative tactics—such as using influencers and brand ambassadors; casting authentic and aspirational talent related to teens’ interests of music, dance, and fashion; and aligning digital and social advertising with key cultural moments—worked in tandem to increase the saliency of the tobacco messaging and to build a significant brand following. Campaign messaging focused

on being a positive influence for younger siblings and the cosmetic and health consequences of smoking cigarettes. These messages resonated with the audience, and the campaign achieved high levels of receptivity. Overall, the campaign was able to reach 95 percent of the audience, and there were over 424 million social media engagements with the campaign's social media channels. Although paid media efforts for "Fresh Empire" have ended, insights from the campaign's implementation are being used to inform current youth prevention campaigns and have provided FDA valuable learnings in how best to use media to reach subpopulations for future prevention efforts.

"This Free Life"

FDA ran the "This Free Life" Campaign from May 2016 through February 2020. LGBT young adults are nearly twice as likely to use tobacco as other young adults, ultimately resulting in the loss of tens of thousands of LGBT lives to tobacco use each year. The "This Free Life" campaign was designed to reach occasional or "social" smokers through print and digital advertising, as well as through social media, to help prevent tobacco-related death and disease in the LGBT community.

During the campaign's 3-year implementation, "This Free Life" was able to reach 95 percent of the target audience primarily through digital-only tactics. "This Free Life" was also able to reach LGBT subpopulations by using innovative approaches with influencers and tailored messaging. The campaign's messaging resonated with the target audience and received over 172 million likes, comments, and shares on the campaign's social channels. Insights from the "This Free Life" campaign's implementation are being used to inform future youth prevention and adult cessation messaging and have provided FDA valuable learnings in how best to use media to reach LGBT audiences who remain at higher risk for tobacco usage.

"Every Try Counts"

FDA's first adult cessation campaign, "Every Try Counts," encouraged cigarette smokers to quit smoking through messages of support that underscored the health benefits of quitting. The campaign leveraged a novel strategic approach that utilized positive, non-graphic messaging and reframed past quit attempts not as failures, but as important steps towards future success. The paid media portion of the campaign was in market from January 2018 through April 2020. The campaign was initially implemented in point-of-sale (POS) retail locations where cigarettes were sold. As the first multi-city POS tobacco cessation campaign, "Every Try Counts" delivered messages where smokers often encounter tobacco advertising and triggers for smoking relapse. Additionally, each ad included a call to action to drive smokers to the campaign website, which features quitting tips, "practice the quit" text message programs, and online cessation counseling.

In February 2020, "Every Try Counts" expanded to a national digital campaign to reach a broader audience and messaging reached over 45 million adult smokers. Overall, "Every Try Counts" served over 769 million digital impressions and drove more than 1.6 million unique visitors to EveryTryCounts.gov prompting over 15,000 sign ups for text message programs designed to help smokers quit.

Although there are no continued paid media efforts for "Every Try Counts" in 2021, FDA plans to continue to develop a range of educational materials for adults that address the benefits of cessation and nicotine misperceptions. Assets will be disseminated to public health partners and stakeholders. Knowledge from "Every Try Counts" and ongoing research among adult smokers have provided FDA with valuable learnings about how to best reach smoking adults and will inform future educational efforts.

Select print advertisements are available for use via both CTP's content-sharing platform (called the Exchange Lab) and the Centers for Disease Control and Prevention's Media Campaign Resource Center (MCRC). The Exchange Lab and MCRC provide access to cessation materials for use by states and/or other public health organizations and agencies.

"American Indian/Alaska Native" Campaign

FDA will be expanding its e-cigarette prevention messaging to American Indian/Alaska Native (AI/AN) youth audiences, a population that has historically had higher tobacco usage rates. FDA has conducted research with AI/AN youth to understand tobacco beliefs and perceptions and is determining the best messaging approaches to reach this at-risk audience.

Scholastic

Since the fall of 2018, FDA has collaborated with Scholastic, the global children's publishing, education, and media company, to develop youth e-cigarette prevention resources for middle and high school educators. Resources are available in English and Spanish and include lesson plans, activity sheets, and videos to help teachers start educational conversations with their students about the harms of youth e-cigarette use. These free educational materials, as well as a teacher resource guide and youth addiction and cessation materials, have been distributed to more than 1.3 million educators and have reached an estimated 2.7 million students. In January 2021, FDA and Scholastic developed new content for the 2020-2021 school year, including a student magazine, an e-cigarette prevention poster contest, and a content refresh of previous materials.

Outcome Evaluations

A critical factor in reducing youth tobacco use is to produce and maintain effective levels of campaign awareness within the target population. Studies have specifically confirmed the effectiveness of media campaigns in reducing youth tobacco use. NIH's NCI and the Community Preventive Services Task Force have conducted comprehensive scientific reviews of studies on the effectiveness of media campaigns to reduce tobacco use. The reviews concluded that media campaigns to prevent and control tobacco use have been and are effective.

FDA is implementing multi-year outcome evaluation studies for the Agency's public education campaigns. For example, the study design for the original cohort, and now Cohort 2, of "The Real Cost" E-Cigarette Campaign, is "longitudinal," meaning the study will attempt to follow the same individuals over time to track changes in targeted tobacco-related knowledge, attitudes, and beliefs. An evaluation found that in the first 2 years of the "The Real Cost" smoking prevention effort, more than 587,000 youth, ages 11 to 19, were prevented from initiating cigarette smoking—half of whom might have gone on to become established smokers—saving more than $53 billion by reducing smoking-related costs like early loss of life, costly medical care, lost wages, lower productivity, and increased disability. Due to collective public health efforts, beliefs and risk perceptions about vaping are rapidly evolving among teens. Twenty-nine of 34 items assessing youth beliefs about vaping in the "The Real Cost" E-Cigarette Campaign evaluation changed in the direction of increased perceptions of risk and improved knowledge of harm. In addition, recent outcome evaluation data showed that approximately 79 percent of youth were aware of at least one campaign ad from "The Real Cost" E-Cigarette Campaign, and 75 percent of teens were aware of "The Real Cost" brand.

These results not only reinforce the importance of these public education efforts in reducing the public health and financial burden of tobacco use but also highlight the importance of investing in tobacco-related education campaigns that can garner huge returns. During the first 2 years of "The Real Cost" smoking prevention campaign, for example, FDA realized a cost savings of $180 for every dollar of the nearly $250 million invested.