DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

Docket No. FDA-2019-N-3065

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

This proposed rule would require that one of up to 13 new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, appear on cigarette packages and in cigarette advertisements. The proposed rule would further require that, for cigarette packages, the required cigarette health warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly and equally distributed throughout the United States in accordance with a plan approved by the Food and Drug Administration (FDA). The proposed rule would also require that, for cigarette advertisements, the required cigarette health warnings must be rotated quarterly in alternating sequences in advertisements for each brand of cigarettes in accordance with a plan approved by FDA. The proposed new cigarette health warnings would promote greater public understanding of the negative health consequences of cigarette smoking by presenting information about the health risks of smoking to smokers and nonsmokers in a format that helps people better understand these consequences. Despite the informational effects of this proposed rule, there is a high level of uncertainty around quantitative economic benefits at this time, so we describe them qualitatively. The cost of this proposed rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of required cigarette health warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. We estimate that, at the mean, the present value of the costs of this proposed rule is about $1.6 billion using a three percent discount rate and roughly $1.2 billion using a seven percent discount rate (2018$). If the information provided by the cigarette health warning on each cigarette package was valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.

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Introduction and Summary

Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We estimate that for a small manufacturer or importer[1] who would be affected by this proposed rule, initial costs could represent between 2.5 and 35.6 percent of their annual receipts and recurring costs could represent from 0.4 to 4.4 percent of their annual receipts. Hence, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

[1] Note that for the purposes of the proposed rule, importers are considered manufacturers.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

Summary and Accounting Statement

This proposed rule would require that one of up to 13 new cigarette health warnings,[2] each comprising a textual warning statement paired with an accompanying color graphic image, appear on cigarette packages and in cigarette advertisements. The proposed rule would further require that, for cigarette packages, the required cigarette health warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed throughout the United States in accordance with a plan approved by the Food and Drug Administration (FDA). The proposed rule would also require that, for cigarette advertisements, the required cigarette health warnings must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA.

[2] To the extent the number of warnings included in a final rule is less than 13, the costs of the rule would accordingly be less. For purposes of this analysis, we base our estimates on the assumption that 13 warnings would be required.

Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking, and benefit diverse populations that have disparities in knowledge about the negative health consequences of smoking.

The direct economic benefits of providing information on cigarette health warnings are difficult to quantify, and we do not predict the size of these benefits at this time. We discuss the informational effects qualitatively.

The cost of this proposed rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of required cigarette health warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. Using a 20-year time horizon, we estimate that the present value of the costs of this proposed rule ranges from $1.3 billion to $1.9 billion, with a mean estimate of $1.6 billion, using a three percent discount rate, and ranges from $1.0 billion to $1.5 billion, with a mean estimate of $1.2 billion, using a seven percent discount rate (2018$). Annualized costs, which are presented below in Table 1, range from $88.6 million per year to $129.7 million per year, with a mean estimate of $107.5 million per year, using a three percent discount rate, and range from $94.6 million per year to $139.8 million per year, with a mean estimate of $115.3 million per year, using a seven percent discount rate (2018$).

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a break-even approach. If the information provided by the cigarette health warning on each cigarette package was valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.

Table 1. Summary of the Informational Effects and Costs of the Proposed Rule (in millions of 2018$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Informational Effects		Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking and help reduce disparities in knowledge about the negative health consequences of smoking across diverse populations. If the information provided by the cigarette health warning on each cigarette package was valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.						
Costs	Annualized Monetized $millions/year	$115.3	$94.6	$139.8	2018	7%	20 Years	Effective date of 15 months from date of publication of final rule.
		$107.5	$88.6	$129.7	2018	3%	20 Years	

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these costs, this proposed rule would be considered a regulatory action under EO 13771.

Table 2. EO 13771 Summary Table (in Millions of 2016$, Over an Infinite Time Horizon)

Item	Primary Estimate (7%)
Present Value of Costs	$985.8
Present Value of Cost Savings	$0
Present Value of Net Costs	$985.8
Annualized Costs	$69.0
Annualized Cost Savings	$0
Annualized Net Costs	$69.0

Notes: All amounts have been discounted relative to year 2016 from year 2021, the latter of which is the estimated year in which the proposed rule would become effective once finalized. Because of this additional discounting step, the present value estimate presented here is lower than the comparable present value estimate associated with a 20-year time horizon. Effective date is 15 months from date of publication of final rule.

Preliminary Regulatory Impact Analysis

Background

To help inform consumers of the potential hazards of cigarette smoking, Congress passed the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 that required a printed text-only warning to appear on cigarette packages (Public Law 89-92). The 1965 warning requirement was modified by later amendments to FCLAA, including the Comprehensive Smoking Education Act of 1984 (Public Law No. 98-474), which extended the warning requirement to cigarette advertising and updated the warning to four warnings, frequently referred to as the Surgeon General's warnings.

In 2009, in enacting the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31), Congress further amended FCLAA and directed FDA to promulgate new cigarette health warnings that would include a graphic component depicting the negative health consequences of smoking to accompany the textual warning statements (section 201 of the Tobacco Control Act). Section 202 of the Tobacco Control Act also allows FDA to adjust the statutory textual warning statements if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In the *Federal Register* of June 22, 2011, FDA issued a final rule requiring color graphics depicting the negative health consequences of smoking to accompany the nine new textual warning statements. However, the final rule was challenged in court by several tobacco companies, and on Aug. 24, 2012, the United States Court of Appeals for the District of Columbia vacated the rule and remanded the matter to the Agency. R.J. Reynolds Tobacco Co., v. Food & Drug Administration, 696 F.3d 1205 (D.C. Cir. 2012),

overruled on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18, 22-23 (D.C. Cir. 2014) (en banc). On Dec. 5, 2012, the Court denied the government's petition for panel rehearing and rehearing en banc, and the government decided not to seek further review of the Court's ruling. In a letter to Congress on March 15, 2013, the Attorney General reported FDA's intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act.

Market Failure Requiring Federal Regulatory Action

Cigarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined. In developing this proposed rule, FDA determined that the public holds misperceptions about the health risks associated with smoking. Market failure arising from inadequate information can provide an economic rationale for the mandatory disclosure of the negative health consequences associated with cigarette smoking. This proposed rule can address information asymmetries regarding these negative health consequences at the point of purchase. While many consumers are aware of some of the risks associated with smoking, those risks are not fully known and calibrated by every consumer.

In addition to problems of information, the addictiveness of cigarettes is likely to generate inefficiencies in the market for these products. In their model of addictive behavior, Gruber and Koszegi identify intrapersonal market failures, or internalities, stemming from time inconsistent preferences [Ref. 1]. An internality is defined as a "within-person externality…which occurs when a person underweighs or ignores a

consequence of his or her behavior for him- or herself" [Ref. 2]. Internalities lead to suboptimal choices in the sense that individuals consume too little of goods with beneficial intrapersonal effects and too much of goods with harmful intrapersonal effects. The psychology and economics literature suggest several sources of internality-related market failures. Although individuals may recognize some of the risks inherent in these behaviors, they continue to make suboptimal choices that cause a divergence between the utility-maximizing consumption level and the consumption level they select.

Time inconsistency may also generate inefficiencies in the market for cigarettes. Time inconsistency exists when consumers use lower rates of discount for consequences far in the future than for consequences close to the present. Time-inconsistent consumers make current decisions that they would not make from the perspective of their future selves. For some consumers, the problem is noticeability. Even if some relevant information regarding possible harms is on the cigarette package in the form of the Surgeon General's warnings, it might not be sufficiently prominent at the time of purchase and use to overcome the tendency to discount future harms.

Addiction and time inconsistency may be complementary or may describe different types of smokers. Alternating or conflicting preferences of the different selves violate the assumption of stable preferences, i.e. making choices consistent with your preferences, and can provide a rationale for policy interventions. Both addiction and time inconsistency imply that smokers do not fully incorporate their health cost into the price of smoking. Policy interventions that reduce these inefficiencies by providing consumers prominent information on the negative health consequences of smoking at the point of purchase could enhance social welfare.

For cigarette health warning labels to effectively promote greater public understanding of the negative health consequences of cigarette smoking, they must attract and maintain attention [Ref. 3, 4]. However, recent surveys on tobacco use show that a minority of smokers see or notice the current Surgeon General's warnings [Ref. 5, 6, 7, 8]. A major study on tobacco policy in the United States by the Institute of Medicine in 2007 concluded that U.S. cigarette package warnings are both "unnoticed and stale" [Ref. 9].

Pictorial cigarette health warnings have been shown to be effective in promoting understanding of the negative health consequences of smoking by increasing the noticeability of warning messages and by increasing knowledge of and learning of the negative health consequences of smoking [Ref. 5, 10, 11]. Larger cigarette health warnings increase important outcomes related to understanding the health risks of cigarette use [Ref. 5, 8, 12, 13, 14, 15, 16, 17, 18, 19, 20]. This proposed rule would present information about the health risks of smoking to smokers and nonsmokers through new cigarette health warnings on cigarette packages and in cigarette advertisements.

Section 201 of The Tobacco Control Act directs FDA to promulgate new cigarette health warnings that would include both a larger textual warning statement and an accompanying color graphic depicting the negative health consequences of smoking. Without Federal regulatory action, there is considerable evidence that the current Surgeon General's warnings are largely unnoticed and unconsidered by both smokers and nonsmokers. Therefore, mitigating the information asymmetries and internalities of not

understanding the negative health consequences of cigarette smoking requires Federal regulatory action.

Purpose of the Proposed Rule

This proposed rule would establish new required cigarette health warnings to appear on cigarette packages and in cigarette advertisements. These new cigarette health warnings would consist of textual warning statements accompanied by color graphics depicting the negative health consequences of cigarette smoking. The proposed statements are:[3]

- WARNING: Tobacco smoke can harm your children.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Smoking causes head and neck cancer.
- WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- WARNING: Smoking during pregnancy stunts fetal growth.
- WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- WARNING: Smoking causes COPD, a lung disease that can be fatal. [paired with an image of diseased lungs]
- WARNING: Smoking causes COPD, a lung disease that can be fatal. [paired with an image of man with an oxygen tank]
- WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
- WARNING: Smoking causes cataracts, which can lead to blindness.

[3] The proposed text warning "WARNING: Smoking causes COPD, a lung disease that can be fatal" appears twice because it is accompanied by two different color graphic images.

FDA has determined that the proposed new cigarette health warnings would advance the government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. Each proposed cigarette health warning statement was developed to address gaps in public understanding of the health risks of smoking. In FDA's consumer research studies, each proposed cigarette health warning statement demonstrated statistically significant improvements, as compared to the Surgeon General's warnings, on both the two outcomes of "new information" and "self-reported learning" (i.e., knowledge gain) [Ref. 21].

The proposed rule would further require that, for cigarette packages, the required cigarette health warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product, and be randomly distributed throughout the United States in accordance with a plan approved by the FDA. The proposed rule would also require that, for cigarette advertisements, the required cigarette health warnings be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA. As required by section 201 of the Tobacco Control Act, the new cigarette health warnings would appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of advertisements. The required cigarette health warnings for packages and advertisements would become effective fifteen months after the date the final rule publishes in the *Federal Register*, and plans would be required to be submitted no later than five months after the final rule publishes in the *Federal Register*.

Baseline Conditions

The Comprehensive Smoking Education Act of 1984 (Public Law No. 98-474) requires the presence of one of four text-only health warnings on cigarette packages and in cigarette advertisements.[4] In addition, the law established the location and format for these warning statements and mandated that the warnings be rotated quarterly. As implemented, for example, this means the Surgeon General's warnings currently appear on a side panel of cigarette packages. The four rotational health warnings, referred to as Surgeon General's warnings, currently used are:

- "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy."
- "SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health."
- "SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth and Low Birth Weight."
- "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide."

As described in the proposed rule Section V.A. "The Current Surgeon General's Warnings Are Inadequate," a substantial body of research shows that the Surgeon General's warnings do not effectively communicate information about the adverse health effects of smoking to the American public because they do not attract attention [Ref. 5, 6, 22], are not remembered [Ref. 23, 24], and do not prompt thoughts about the risks of smoking [Ref. 5, 8, 25].

The current Surgeon General's warnings do not effectively communicate information about the adverse health effects of smoking to the American public. While

[4] Slightly different health warnings were required on outdoor billboard advertisements.

most smokers consider themselves informed about the health risks of smoking, surveys of smokers indicate that a substantial percentage of smokers are misinformed or do not know about the negative health consequences of smoking [Ref. 17, 26, 27]. Results from the International Tobacco Four Country Survey find that most respondents from the U.S. agree that lung cancer and heart disease are caused by smoking, but only 68 percent agreed that smoking causes lung cancer in nonsmokers and only 34 percent agreed that smoking causes impotence [Ref. 17]. Studies have also documented that people are largely unaware of the health risks of smoking specific to women, including infertility, osteoporosis, early menopause, spontaneous abortion, ectopic pregnancy, and cervical cancer [Ref. 28].

In developing this proposed rule, FDA carefully examined the scientific literature, including the recent 2014 Surgeon General's Report, titled "The Health Consequences of Smoking: 50 Years of Progress," which identified health conditions that were recently established to be causally linked to cigarette smoking. Those health conditions examined in the 2014 Surgeon General's Report are in addition to the more than forty unique health consequences already known to be caused by smoking and exposure to secondhand smoke.

Results from the 2017 National Health Interview Survey (NHIS) indicate that approximately 34.3 million U.S. adults (or 14 percent of the U.S. adult population) are current cigarette smokers. Among adolescents, data from the 2018 National Youth Tobacco Survey (NYTS), a nationally representative survey of U.S. students attending public and private schools in grades 6 through 12, showed that past 30-day smoking prevalence among high school students was 8.1 percent, representing 1.2 million young

people, and past 30-day prevalence among middle school students was 1.8 percent, representing 200,000 youth.[5] Using Nielsen Retail Measurement Services (RMS) data, we estimate that in 2018, 9.7 billion packs of cigarettes were sold.[6] Daily smokers, who in 2016 averaged 14.1 cigarettes per day, are potentially exposed to the warnings on packages over 5,100 times per year. Cigarette smoking prevalence has generally declined over the past several decades. Using 2014 – 2018 Nielsen RMS data, we find that the number of cigarette UPCs has decreased by an average of about 2.7 percent each year.[7]

The proposed cigarette health warnings would also appear prominently on cigarette advertisements, occupying at least 20 percent of the area at the top of advertisements. We do not have data on the current number of cigarette advertisements. To provide some context for the prevalence of advertisements, we note that the Federal Trade Commission Cigarette Report for 2017 (FTC Cigarette Report) estimates that cigarette manufacturers spent approximately $1.3 billion on cigarette advertising and promotion (not including the price discounts paid to cigarette retailers and wholesalers to

[5] See NYTS "Estimates of Current Tobacco Use Among Youth" at https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm and NHIS Table A-12 at https://ftp.cdc.gov/pub/Health_Statistics/NCHS/NHIS/SHS/2017_SHS_Table_A-12.pdf.

[6] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information.

[7] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 258-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information.

help lower the price of cigarettes to consumers) in 2017.[8] According to the FTC Cigarette Report, cigarette manufacturers spent $48.5 million on point-of-sale advertisements, $34.6 million for direct mail advertising, $25.1 million for company websites, $14.9 million on magazine advertising, and $1.8 million on outdoor advertising. In addition, cigarette manufacturers spent $263.3 million on other advertising and promotional activities, $301.9 million on coupons, and $563.0 million on promotional allowances to cigarette retailers and wholesalers, including "payments for stocking, shelving, displaying, and merchandising brands, volume rebates, and incentive payments."

Informational Effects

The proposed new cigarette health warnings would advance the government's interest of promoting greater public understanding of the negative health consequences of cigarette smoking by presenting information about the health risks of smoking to smokers and nonsmokers in ways that are superior to the current Surgeon General warnings. Section V.B. of the proposed rule, "Cigarette Health Warnings that Are Noticeable, Lead to Learning, and Increase Knowledge Will Promote Public Understanding about the Negative Health Consequences of Smoking" describes in detail studies that demonstrate how pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they (1) increase the noticeability of warnings messages; (2) increase knowledge of and learning of negative consequences of

[8] See Table 2G of the 2017 FTC Cigarette Report at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2017-federal-trade-commission-smokeless-tobacco-report/ftc_cigarette_report_2017.pdf

smoking; and (3) reduce disparities in knowledge about the negative health consequences of smoking across diverse populations.[9]

To understand a message, individuals must first notice the message and then process that information. Large pictorial cigarette health warnings result in higher noticeability of and attention to the warning message compared to text-only cigarette warnings [Ref. 5, 10, 12, 13, 16, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41]. The increased attention to pictorial cigarette health warning promotes understanding of the negative health consequences of smoking. One study found that smokers who reported noticing the cigarette health warnings were more likely to report health beliefs about the specific health consequences contained in the warnings, compared to those who did not notice the warnings [Ref. 10]. Furthermore, cross-country comparisons demonstrate that compared to smokers in countries without pictorial cigarette health warnings, and after controlling for other potential explanatory variables, smokers in countries with pictorial cigarette health warnings are more knowledgeable of the health risks caused by smoking [Ref. 29, 40]. Pictorial cigarette health warnings have been shown to convey the risk of specific health effects from smoking, particularly for health effects that are less well known, such as gangrene, blindness, and bladder cancer [Ref. 42].

Pictorial cigarette health warnings have been shown to be more noticeable than text-only warnings across socioeconomic categories including race/ethnicity, income, and education [Ref. 43]. This may be due in part to the poor readability of the current Surgeon General's warnings. A study evaluating the readability of the current Surgeon

[9] To view the complete section, see the proposed rule at 84 FR 42754, https://www.federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements.

General's warnings found that “each of the four cigarette warnings require a reading level typical of college students or college graduates” [Ref. 44]. Cigarette health warnings with accompanying images that support the text, such as the ones proposed in this rule, would help adults and adolescents with lower literacy and health literacy understand the negative health consequences of smoking.

Additional research has shown that being a member of a group with lower socioeconomic status is associated with having lower knowledge of the negative health consequences of smoking [Ref. 45, 46]. To the extent that the proposed cigarette health warnings can reduce the disparities found in consumer understanding about the harms of smoking, this rule would increase understanding among these diverse populations of the negative health consequences of smoking.

The specific warnings included in this proposed regulation have demonstrated statistically significant improvements, as compared to the control condition (i.e., the Surgeon General's warnings), on two outcomes—"New information" and "Self-reported learning" (i.e., knowledge gain)—in the final consumer research study conducted by FDA, consistent with the government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking [Ref. 21, 47].

Costs of the Proposed Rule

The cost of this proposed rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of required cigarette health warnings for cigarette packages and quarterly

rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule.

1. Number of Affected Entities

Labeling and advertising requirements will affect domestic cigarette manufacturers and importers of foreign-made cigarettes. Data from the U.S. Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) indicate that there were 32 cigarette manufacturing firms and 27 cigarette importers in the United States in 2017, the most recent year for which these data are available.

2. Cost of Changing Cigarette Labels

This proposed rule would require the redesign of the front and back of cigarette packages to incorporate new cigarette health warnings that would occupy the top 50 percent of the front and rear panels of the package. Current Surgeon General's warnings would need to be removed. While manufacturers would likely only redesign their labels once to accommodate the space necessary for the proposed new cigarette health warnings, separate printing cylinders would be required to include the new warnings provided by FDA on each product package. To estimate the cost associated with changing cigarette labels, we use the FDA Labeling Cost Model [Ref. 48].

The FDA Labeling Cost Model, which was built based on discussions with trade associations and product manufacturers and completed in August 2015, estimates the costs of making labeling changes for a range of products, including cosmetics, dietary supplements, foods, over-the-counter medications, pet foods, retail medical devices, and tobacco products and accessories. Labeling changes are categorized in the model as either minor, major, or extensive. A minor label change is defined as a one-color/printing

plate change that does not require a label redesign. Examples include one or more of the following: minimal changes to an ingredient list; the addition of a toll-free number; and minimal changes to a claim, caution statement, or disclaimer on the back or side of a package. A major label change is defined as a multiple-color/printing plate change that requires a label redesign. Examples include changes to the name of the product; substantial changes to an ingredient list; substantial changes to or elimination of a claim; the addition of or substantial changes to a caution statement; and the addition of or substantial changes to a disclaimer. An extensive labeling change is defined as a major format change that requires a change to the product packaging to accommodate labeling information. Examples include the addition of a peel-back label and increases in the package surface area for labeling information.

Labeling costs are calculated in the model as low (5^{th} percentile), mean, and high (95^{th} percentile) cost estimates and include labor, materials, and recordkeeping costs, which are measured on a per-UPC basis, and inventory costs, which are measured on a per-sales-unit basis. Labor costs comprise both administrative labor costs and non-administrative labor costs. Administrative labor costs include the cost of conducting administrative activities such as reviewing the regulation and determining a response; the cost of coordinating with various internal departments to determine and implement the response; and the cost of working with outside vendors to change graphics and/or produce new packaging. Non-administrative labor costs include the labor costs associated with graphic design and prepress activities (convert the graphic design into the film or files that are used to engrave the printing plates, color trap the design to prevent white or black spaces between the colors and prepare proofs for approval) incurred by

either the manufacturer's employees or outside vendors or consultants. Materials costs are associated with printing plates and other miscellaneous materials. Recordkeeping costs are associated with activities related to reviewing and updating records of labeling information. Finally, inventory costs comprise discarded inventory and disposal costs for labels or printed packages that become obsolete as a result of the labeling requirement (for effective dates of 24 months or longer from the date of publication of the final rule, the model estimates that there are no discarded inventory and disposal costs). To calculate inventory costs, the model estimates the cost per sales unit of each printed package or label and multiplies this value by the estimated remaining inventory, the latter which varies by distance of effective date from the date of publication of the final rule. To provide a range of costs estimates for the requirements of this proposed rule, and as stated above, we present costs at the low, mean and high levels as estimated by the FDA Labeling Cost Model.

The model estimates that a labeling change requires a minimum of 15 months to fully implement, and that any labeling change that must be incorporated in 15 months or less always incurs overtime and rush charges (equal to 40 percent of labor, materials, and recordkeeping costs) for completing all of the label change activities on a faster than usual schedule and sometimes (for effective dates of nine months or less from the date of publication of the final rule) incurs costs associated with applying stickers to some sales units due to insufficient time to print new labels before the change must be implemented. The model further estimates that manufacturers who can coordinate a required labeling change (regulatory labeling change) with a planned voluntary labeling change (non-regulatory labeling change) would incur lower costs associated with the required labeling

change than they would otherwise. Farther out effective dates increase the proportion of required labeling changes that can be coordinated with planned voluntary labeling changes. However, note that even if manufacturers can coordinate a required labeling change, the model includes costs of administrative and recordkeeping activities associated with labeling changes. Such costs are estimated in the model at 50 percent of the non-overtime/non-rush administrative and recordkeeping costs associated with an uncoordinated label change.

Using 2018 Nielsen RMS data, we estimate that a total of 3,063 cigarette UPCs (3,007 branded and 56 private label) would be affected by this proposed rule.[10] With a proposed effective date of 15-months from the date of publication of the final rule, the FDA Labeling Cost Model estimates that eight percent of branded label changes and six percent of private-label changes can be coordinated with a previously scheduled, non-regulatory labeling change. Associated with this proposed rule, we estimate the number of UPCs that would have to undertake an uncoordinated labeling change to be 2,819 UPCs and we estimate the number of UPCs that could undertake a coordinated labeling change to be 244 UPCs. As stated earlier, under the proposed rule, the front and rear panel of every cigarette package would need to be redesigned to incorporate the proposed cigarette health warnings that would occupy the top 50 percent of the area of the front

[10] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information.

and rear panels of cigarette packages, and the current warning would need to be removed. Such a change is classified by the FDA Labeling Cost Model as a major change.

Table 3 summarizes the total cost of a major labeling change (one cigarette health warning per UPC). Total labeling costs are estimated to range from $34.3 million to $85.6 million, with a mean estimate of $54.7 million (2018$).

Table 3. Cost of a Major Label Change for Cigarettes (in 2018$)

	Low	Mean	High
Label Design Costs			
# Uncoordinated UPCs	2,819	2,819	2,819
Labor Costs ($/UPC)	$4,495	$9,603	$18,069
Material Costs ($/UPC)	$7,472	$9,451	$11,698
Recordkeeping Costs ($/UPC)	$49	$94	$163
Total Costs ($/UPC)	$12,016	$19,148	$29,930
Total Label Design Costs for Uncoordinated UPCs ($)	$33,873,104	$53,978,212	$84,372,670
# Coordinated UPCs	244	244	244
Labor Costs ($/UPC)	$395	$1,354	$3,059
Material Costs ($/UPC)	$0	$0	$0
Recordkeeping Costs ($/UPC)	$17	$34	$60
Total Costs ($/UPC)	$412	$1,388	$3,119
Total Label Design Costs for Coordinated UPCs ($)	$100,528	$338,672	$761,036
TOTAL LABEL DESIGN COSTS ($)	$33,973,632	$54,316,884	$85,133,706
Inventory Costs			
# Discarded Labels	11,611,468	11,611,468	11,611,468
Cost Per Discarded Label ($/Label)	$0.027	$0.032	$0.037
TOTAL INVENTORY COSTS ($)	$313,510	$371,567	$429,624
TOTAL COSTS	$34,287,142	$54,688,451	$85,563,330

Notes: FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information. Effective date is 15 months from date of publication of final rule. We used 2018 Nielsen RMS data to estimate the number of cigarette UPCs. The number of uncoordinated and coordinated UPCs depend on the number of cigarette UPCs as well as, respectively, the percentage of UPCs which cannot and can be coordinated, both of which are estimated using the FDA Labeling Cost Model. The number of discarded labels depends on the estimated number of sales units, the source of which is 2018 Nielsen RMS data, as well as an estimate of the percentage of those sales units which will be discarded, the latter which is estimated using the FDA Labeling Cost Model. Lastly, note that Nielsen only provides a point estimate of UPCs and sales units, not a range. Hence, the number of UPCs and the number of discarded labels is the same at low, mean, and high.

We estimate that materials costs for printing plates and prepress activities would be approximately 13 times as large as estimated in Table 3 for uncoordinated UPCs due to the proposed requirement for 13 separate cigarette health warnings (each UPC would require 13 printing plates, one for each warning label). For coordinated UPCs, we estimate that materials costs for printing plates and prepress activities would be roughly 12 times the uncoordinated materials costs illustrated in Table 3: each UPC would require 13 printing plates, one for each cigarette health warning label, but one of these label changes is a coordinated label change, for which materials costs do not get assigned.

Table 4 shows the total cost of a major cigarette labeling change that reflects that each cigarette UPC would require 13 printing plates, one for each cigarette health warning label (13 warnings per UPC). Total labeling costs associated with this proposed rule are estimated to range from $308.9 million to $515.5 million, with a mean estimate of $402.1 million (2018$). Note that, to the extent the final rule specifies fewer cigarette health warnings, total labeling costs would be lower.

Table 4. Cost of a Major Cigarette Label Change With 13 Warning Labels (in 2018$)

	Low	Mean	High
Label Design Costs			
# Uncoordinated UPCs	2,819	2,819	2,819
Labor Costs ($/UPC)	$4,495	$9,603	$18,069
Material Costs ($/UPC)	$97,136	$122,863	$152,074
Recordkeeping Costs ($/UPC)	$49	$94	$163
Total Costs ($/UPC)	$101,680	$132,560	$170,306
Total Label Design Costs for Uncoordinated UPCs ($)	$286,635,920	$373,686,640	$480,092,614
# Coordinated UPCs	244	244	244
Labor Costs ($/UPC)	$395	$1,354	$3,059
Material Costs ($/UPC)	$89,664	$113,412	$140,376
Recordkeeping Costs ($/UPC)	$17	$34	$60
Total Costs ($/UPC)	$90,076	$114,800	$143,495
Total Label Design Costs for Coordinated UPCs ($)	$21,978,544	$28,011,200	$35,012,780
TOTAL LABEL DESIGN COSTS ($)	$308,614,464	$401,697,840	$515,105,394
Inventory Costs			
# Discarded Labels	11,611,468	11,611,468	11,611,468
Cost Per Discarded Label ($/Label)	$0.027	$0.032	$0.037
TOTAL INVENTORY COSTS ($)	$313,510	$371,567	$429,624
TOTAL COSTS	$308,927,974	$402,069,407	$515,535,018

Notes: Effective date is 15 months from date of publication of final rule.

Manufacturers will also incur labeling costs related to planned future labeling changes. According to the FDA Labeling Cost Model, products are typically relabeled every three to four years [Ref. 48]. In addition, using 2014 – 2018 Nielsen RMS data, we find that the number of cigarette UPCs has decreased by an average of about 2.7 percent each year.[11] Thus, we reduce the number of cigarette UPCs by 2.7 percent each year and

[11] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 258-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information.

estimate labeling costs in years 4, 7, 10, 13, 16, and 19 of the proposed rule using the per-UPC cost of a coordinated labeling change whereby materials costs are calculated as 12 times the per-UPC non-rush materials costs associated with an uncoordinated label change.[12] The per-UPC cost of a coordinated label change with materials costs calculated in this way ranges from $64,455/UPC to $103,375/UPC with a mean estimate of $82,390/UPC (2018$). Total labeling costs in years 1 (reproduced from Table 4 above), 4, 7, 10, 13, 16, and 19 are illustrated below in Table 5. We request comment on our approach to estimating labeling costs related to planned future labeling changes. More specifically, we request comment and data regarding planned future labeling changes and how these might be coordinated with cigarette health warning label requirements, but that have not been captured by our analysis.

[12] We use a standard 20-year time horizon, where $t = 1$ represents the first year of the rule.

Table 5 - Cost of Planned Future Major Cigarette Label Changes With 13 Warning Labels (in 2018$)

		Labeling Costs		
t	**# UPCs**	**Low**	**Mean**	**High**
1	3,063	$308,927,974	$402,069,407	$515,535,018
2	2,980	-	-	-
3	2,900	-	-	-
4	2,822	$181,892,010	$232,504,580	$291,724,250
5	2,746	-	-	-
6	2,672	-	-	-
7	2,600	$167,583,000	$214,214,000	$268,775,000
8	2,530	-	-	-
9	2,462	-	-	-
10	2,396	$154,434,180	$197,406,440	$247,686,500
11	2,331	-	-	-
12	2,268	-	-	-
13	2,207	$142,252,185	$181,834,730	$228,148,625
14	2,147	-	-	-
15	2,089	-	-	-
16	2,033	$131,037,015	$167,498,870	$210,161,375
17	1,978	-	-	-
18	1,925	-	-	-
19	1,873	$120,724,215	$154,316,470	$193,621,375
20	1,822	-	-	-

Notes: Effective date is 15 months from date of publication of final rule.

3. Annual Design and Operation Costs of Random and Equal Display and Distribution and Quarterly Rotation Requirements

This proposed rule would require for each brand random and equal display and distribution of new cigarette health warnings on cigarette packages and quarterly rotation of new cigarette health warnings in cigarette advertisements. Related to this, manufacturers of cigarettes will be required to submit plans for cigarette packages and advertisements to FDA (manufacturers likely already have some experience incorporating these types of display, distributional, and rotational logistics due to the required rotation of the Surgeon General's warnings). In their plan, the manufacturer will need to demonstrate how they plan to achieve the random and equal display and

distribution of the required warning statements on packages and the quarterly rotation in advertisements. More specifically, for each brand of cigarettes, the plan for packaging should explain how: each of the warnings will be randomly displayed during each 12-month period on each brand, how each of the warnings will be displayed in as equal a number of times as possible on each brand of the product, and how packages will be randomly and equally distributed in all areas of the United States in which the product is marketed. The plan for each cigarette brand for advertising should explain how the required warning statements will be rotated quarterly in advertisements and how the quarterly rotations will occur in alternating sequence. The plan should specifically indicate the initial rotation timeframe on which quarterly rotation is based and, if the rotation timeframe varies for different types/forms of advertising, specify the different quarterly timeframes associated with the different types/forms of advertising, and describe the quarterly schedule for rotating each of the required warnings for each cigarette brand. Plans will be required to be submitted to FDA no later than five months after the date of publication of the final rule and before advertising or commercially marketing a product that is subject to the rule. FDA estimates it may take between four and six months, on average, to review and approve an initial plan. After FDA approves an initial plan, a supplement to the approved plan would need to be submitted to FDA and approved before making any changes to the random and equal display or distribution of required warning statements on packages or the quarterly rotation of required warning statements in advertisements contained in the original plan. Manufacturers will be required to maintain a copy of their FDA-approved plan (recordkeeping) and this copy must be available for inspection and copying by officers or employees of FDA.

Based on FDA's experience with information collections for other tobacco product plans (i.e., smokeless OMB control number 0910-0671 and cigars OMB control number 0910-0678), we estimate that manufacturers will spend an average of 150 hours per manufacturer to prepare and submit a plan for packaging and advertising and that about half of manufacturers will submit a supplement, which we estimate will take manufacturers an average of 75 hours each to prepare and submit.

Related to the recordkeeping requirement described above, we estimate that, annually, each manufacturer will keep an average of 1.5 records, which reflects the estimate above that all manufacturers will submit initial plans and about half will submit supplements, and that recordkeeping will take manufacturers an average of about three hours per record. According to Bureau of Labor Statistics Occupational Employment Statistics data, the wage for a Logistician, defined as someone who analyzes and coordinates the logistical functions of a firm or organization, ranges from $42.72 per hour to $115.33 per hour with a mean estimate of $75.69 per hour (2018$), including 100 percent overhead. Combining these hour and wage estimates, we estimate that the annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements range from $0.5 million to $1.3 million with a mean estimate of $0.9 million (2018$). Table 6 illustrates these costs.

Table 6. Estimated Annual Design and Operation Costs of Random and Equal Display and Distribution and Quarterly Rotation Requirements (in 2018$)

	Low	Mean	High
Initial Plan	$378,072	$669,857	$1,020,671
Supplements	$94,518	$167,464	$255,168
Recordkeeping	$11,342	$20,096	$30,620
Total	$483,932	$857,417	$1,306,459

4. Advertising Restrictions: Cost to Remove and Replace Noncompliant Advertising

We do not have data on the current number of cigarette advertisements. The FTC Cigarette Report estimates that cigarette manufacturers spent approximately $1.3 billion in 2017 on cigarette advertising and promotion, not including the price discounts paid to cigarette retailers and wholesalers to help lower the price of cigarettes to consumers.[13] According to the FTC Cigarette Report, cigarette manufacturers spent $48.5 million on point-of-sale advertisements, $34.6 million for direct mail advertising, $25.1 million for company websites, $14.9 million on magazine advertising, and $1.8 million on outdoor advertising. In addition, cigarette manufacturers spent $263.3 million on other advertising and promotional activities, $301.9 million on coupons, and $563.0 million on promotional allowances to cigarette retailers and wholesalers, including "payments for stocking, shelving, displaying, and merchandising brands, volume rebates, and incentive payments". Price promotions to retailers and wholesalers are a major marketing expense for cigarette manufacturers and according to industry documents and interviews with retailers, the leading cigarette manufacturers require retailers to enter into contracts if they want to participate in cigarette price promotion programs [Ref. 49, 50]. These tobacco company incentive programs require retailers to follow specific product placement and advertising placement for the manufacturer's specific brands. Specifically, retailers are provided with advertising and told where it should be placed, and typically it is the manufacturer's sales representatives who move or alter such advertising [Ref. 51].

[13] See Table 2G of the 2017 FTC Cigarette Report at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2017-federal-trade-commission-smokeless-tobacco-report/ftc_cigarette_report_2017.pdf

The sale of cigarettes is highly concentrated among three types of retailers: gas station "forecourts", convenience stores, and tobacco specialist shops. These retailers accounted for over 86 percent of cigarette sales by volume in 2017. In addition, based on proprietary data from Euromonitor, two manufacturers accounted for over 81 percent of cigarette sales by volume in 2017.

Given cigarette market concentration and sales programs, we understand that advertising is regularly replaced in the ordinary course of business. Based on this assumption, and because the statutory requirements would not take effect until 15 months after the date of publication of the final rule, FDA does not expect that the proposed rule would create any additional burden for manufacturers related to the removal and replacement of non-compliant advertising. We request comments on this assumption in general, and in particular on the total number of cigarette advertisements by type of advertisement (e.g., point-of-sale, direct mail, websites, magazines, outdoor advertising billboard), the average cost per advertisement by type of advertisement and by cost category (e.g., idea generation, printing costs, . . .), and how often advertisements are changed (i.e. how often new advertisements are rotated into the mix).

There is, however, a recurring opportunity cost associated with the proposed rule in that the rule will require manufacturers to devote 20 percent of their advertising space which would otherwise be used for promotional content to the display of warning labels. Hence, using advertising spending data obtained from the FTC Cigarette Report, we estimate that this recurring opportunity cost equals 20 percent of the sum of point-of-sale, direct mail, magazine, and outdoor advertising spending, or 0.2 x $102 million = $20.4 million per year (2018$). We request comment on this approach.

5. Government Administration and Enforcement Costs

To implement and enforce this proposed rule, FDA estimates that the equivalent of 15 full-time equivalent employees (FTEs) would be required annually. However, this work would be conducted by existing staff. Using an average fully-loaded annual cost of about $211,962 per FTE (2018$), our estimate of annual government administration and enforcement costs associated with this proposed rule is roughly $3,179,430 (2018$). These government costs represent an opportunity cost, but this rule would not result in changes to overall FDA accounting costs, the size of the federal budget, or the amount of tobacco industry user fees.

6. Summary of Costs

Table 7 illustrates our year-by-year estimates of the costs that are associated with this proposed rule. We use a standard 20-year time horizon, where $t = 1$ represents the first year of the rule. Included in $t = 1$ is the initial cost associated with changing cigarette labels. Included in $t = [4, 7, 10, 13, 16, 19]$ are costs associated with planned future cigarette labeling changes. Included in $t = 1$ through $t = 20$ are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements, advertising opportunity costs, and government administration and enforcement costs.

As presented in Table 7, the present value of the estimated total costs of the proposed rule ranges from $1.3 billion to $1.9 billion, with a mean estimate of $1.6 billion, using a three percent discount rate, and ranges from $1.0 billion to $1.5 billion, with a mean estimate of $1.2 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the proposed rule ranges from $88.6 million to $129.7

million, with a mean estimate of $107.5 million, using a three percent discount rate, and ranges from $94.6 million to $139.8 million, with a mean estimate of $115.3 million, using a seven percent discount rate (2018$).

Table 7. Estimated Total Cost of the Proposed Rule (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$333.0	$426.6	$540.4
2	$24.1	$24.5	$24.9
3	$24.1	$24.5	$24.9
4	$206.0	$257.0	$316.6
5	$24.1	$24.5	$24.9
6	$24.1	$24.5	$24.9
7	$191.7	$238.7	$293.7
8	$24.1	$24.5	$24.9
9	$24.1	$24.5	$24.9
10	$178.5	$221.9	$272.6
11	$24.1	$24.5	$24.9
12	$24.1	$24.5	$24.9
13	$166.4	$206.3	$253.0
14	$24.1	$24.5	$24.9
15	$24.1	$24.5	$24.9
16	$155.1	$192.0	$235.1
17	$24.1	$24.5	$24.9
18	$24.1	$24.5	$24.9
19	$144.8	$178.8	$218.5
20	$24.1	$24.5	$24.9
Present Value			
3%	$1,318.6	$1,598.7	$1,929.7
7%	$1,002.4	$1,221.3	$1,480.8
Annualized Amount			
3%	$88.6	$107.5	$129.7
7%	$94.6	$115.3	$139.8

Notes: Effective date is 15 months from date of publication of final rule. Included in *t = 1* is the initial cost associated with changing cigarette labels, illustrated in Table 4. Included in *t = [4, 7, 10, 13, 16, 19]* are costs associated with planned future cigarette labeling changes from Table 5. Included in *t = 1* through *t = 20* are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 6, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

Break-even Calculation

This proposed rule would promote greater public understanding about the negative health consequences of smoking through updated cigarette health warnings on cigarette packages and in cigarette advertisements. As described above, consumers would receive the information provided in the cigarette health warnings.

Instead of developing quantitative estimates of economic benefits at this time, which present unique challenges, we undertake a break-even calculation to describe the magnitude of non-quantified benefits required for the benefits to equal or exceed the costs of the regulation.

The mean estimate of the cost of this proposed rule, annualized over 20 years, is $107.5 million per year using a three percent discount rate and $115.3 million per year using a seven percent discount rate (2018$). The welfare gains of this proposed rule would come from the value consumers receive from the information provided in the cigarette health warnings on cigarette packages and advertisements. Both smokers and nonsmokers would be exposed to these cigarette health warnings because cigarette health warnings on advertisements would be seen in public spaces and cigarette packages are not always concealed and are often visible to those other than the person carrying the package [Ref. 11, 52]. However, we do not know what proportion of the public would be exposed to the cigarette health warnings. Thus, we estimate a break-even point on a per cigarette package basis.

Using Nielsen RMS data, we estimated that about 9.7 billion packs of cigarettes were sold in the United States in 2018.[14] If the information provided by the cigarette

[14] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS

health warning on each cigarette package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits generated by the proposed rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$). This per-pack estimate provides one way to estimate the value the public would need to receive from the information provided on the cigarette health warnings in order to break even with the costs of the rule and is equivalent to 0.16 percent of the average cost of a pack of cigarettes, based on a national average cost of $6.27 per pack.[15] Note that this break-even calculation does not include the value of information provided to the public through cigarette health warnings on advertisements because we do not know the current number of cigarette advertisements. The break-even point would be even smaller if we included the benefits generated by cigarette health warnings on advertisements.

service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information. Nielsen RMS data do not capture all cigarette sales. For example, the FTC reports that in "2017, the major cigarette manufacturers sold 229.1 billion cigarettes domestically," or 11.5 billion packs of 20 cigarettes (see page 2 of the FTC Cigarette Report). Note, however, that use of the FTC sales figure in place of the Nielsen sales figure does not change our annualized cost estimates of the proposed rule, and only very slightly changes our breakeven estimate, from about $0.012 annually to $0.010 annually.

[15] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 11-week period ending March 23, 2019 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information.

Distributional Effects

This proposed rule could lead to losses to some segments of U.S. society that would likely be offset by gains to other segments of society. The purpose of the rule is to promote greater public understanding of the negative health consequences of smoking. Although the rule is not premised on this assumption, it is possible that greater public understanding of these health risks will lead to a decline in cigarette smoking.[16] We consider that possibility not to justify the rule but for purposes of this economic analysis. In the event there is a decline in cigarette smoking, sectors affiliated with tobacco and tobacco products could lose sales revenues, and governments could lose tax revenues. Simultaneously, non-tobacco-related industries could gain sales revenues, because dollars not spent on tobacco products could be spent on other products, and individuals who have reduced their cigarette smoking could effectively gain governments' lost tax revenues.

International Effects

Data gathered by Euromonitor International in July 2018 reveals that about $96.4 billion worth of cigarettes were consumed in the United States in 2017 (2018$). Using 2017 trade data from the United Nations Commodity Trade Statistics Database,[17] we estimate that of this amount only approximately $436 million consists of imported

[16] We note that some studies, such as Huang et al. (2014) and Azagba and Sharaf (2013), have found large economic effects from the introduction of graphic cigarette health warnings, although those studies' analytic approaches, data sources, and methodologies have been critiqued in subsequent research such as Irvine and Nguyen (2019) and Beleche et al. (2018) [Refs. 53, 54, 55, 56]. The outcomes examined in these studies contribute to understanding potential willingness-to-pay estimates that could be calculated based on the proposed rule; for more information on the willingness-to-pay concept, see OMB Circular A-4, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

[17] See "Cigarettes containing tobacco" for the USA 2017 Imports at http://data.un.org/Data.aspx?d=ComTrade&f=_l1Code%3a25

cigarettes (2018$). Regardless of manufacturing location, cigarette products commercially distributed in the U.S. would be required to include the cigarette health warnings described in this proposed rule. However, this proposed rule would not apply to cigarettes domestically manufactured for export, whose value, according to trade data from the United Nations Commodity Trade Statistics Database, totaled roughly $1.8 billion in 2017 (2018$).

Uncertainty and Sensitivity Analysis

A potential source of uncertainty related to our estimate of the costs of this proposed rule that is not captured by our use of statistical ranges is the method by which we estimate the annual costs associated with the random and equal display and distribution and quarterly rotation requirements. As a sensitivity analysis, we use data from the FDA Labeling Cost Model and estimate these costs on a per-UPC basis. More specifically, we estimate that the annual administrative cost associated with the random and equal display and distribution and quarterly rotation requirements would be equal to two-fifths[18] of the administrative labor cost of a coordinated label change and the annual recordkeeping cost would be equal to the recordkeeping cost of a coordinated label change. Table 8 illustrates these costs and Table 9 presents estimates of the total cost of the proposed rule using this method to estimate the annual costs of the random and equal display and distribution and quarterly rotation requirements. Using this method, the

[18] Administrative labor costs in the Labeling Cost Model comprise (i) reviewing the regulation, (ii) determining a response to the regulation, coordinating with various internal departments to (iii) determine a response and (iv) implement a response, and (v) working with outside vendors to change graphics and/or produce new packaging. We estimate that two of these five categories, (iii) and (iv), most closely relate to the required administrative activities associated with the random and equal display and distribution and quarterly rotation requirements.

present value of the estimated total costs of the proposed rule ranges from $1.3billion to $1,97 billion, with a mean estimate of $1.6 billion, using a three percent discount rate, and ranges from $1.0 billion to $1.5 billion, with a mean estimate of $1.2 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the proposed rule now ranges from $88.6 million to $132.3 million, with a mean estimate of $108.4 million, using a three percent discount rate, and ranges from $94.6 million to $142.4 million, with a mean estimate of $116.2 million, using a seven percent discount rate (2018$).

Table 8. Estimated Annual Design and Operation Costs of Random and Equal Display and Distribution and Quarterly Rotation Requirements (in 2018$)

	Low	**Mean**	**High**
# UPCs	3,063	3,063	3,063
Administrative Costs/UPC	$157	$542	$1,223
Total Administrative Costs	$480,891	$1,660,146	$3,746,049
Recordkeeping Costs/UPC	$17	$34	$60
Total Recordkeeping Costs	$52,071	$104,142	$183,780
Total Costs	$532,962	$1,764,288	$3,929,829

Table 9. Estimated Total Cost of the Proposed Rule When Using a Different Method to Estimate the Annual Design and Operation Costs of the Random and Equal Display and Distribution and Quarterly Rotation Requirements (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$333.0	$427.5	$543.0
2	$24.1	$25.4	$27.5
3	$24.1	$25.4	$27.5
4	$206.0	$257.9	$319.2
5	$24.1	$25.4	$27.5
6	$24.1	$25.4	$27.5
7	$191.7	$239.6	$296.3
8	$24.1	$25.4	$27.5
9	$24.1	$25.4	$27.5
10	$178.5	$222.8	$275.2
11	$24.1	$25.4	$27.5
12	$24.1	$25.4	$27.5
13	$166.4	$207.2	$255.6
14	$24.1	$25.4	$27.5
15	$24.1	$25.4	$27.5
16	$155.1	$192.9	$237.7
17	$24.1	$25.4	$27.5
18	$24.1	$25.4	$27.5
19	$144.8	$179.7	$221.1
20	$24.1	$25.4	$27.5
Present Value			
3%	$1,318.6	$1,612.1	$1,968.4
7%	$1,002.4	$1,230.8	$1,508.3
Annualized Amount			
3%	$88.6	$108.4	$132.3
7%	$94.6	$116.2	$142.4

Notes: Effective date is 15 months from date of publication of final rule. Included in *t = 1* is the initial cost associated with changing cigarette labels, illustrated in Table 4. Included in *t = 4, 7, 10, 13, 16,* and *19* are costs associated with planned future cigarette labeling changes from Table 5. Included in *t = 1* through *t = 20* are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 8, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

The difference in the estimated total cost of the proposed rule between the sensitivity analysis and the primary analysis is small. For example, at the mean, our estimate of the present value of total costs in the sensitivity analysis is between $9.5 million and $13.4 million larger, depending on the discount rate used, than in the primary

analysis, and our estimate of the annualized value of total costs in the sensitivity analysis is $0.9 million larger than in the primary analysis, regardless of the discount rate used (2018$).

The break-even point in this sensitivity analysis is very similar to the estimate presented in the primary analysis above. If the information provided by the cigarette health warning on each package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits generated by the proposed rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

Analysis of Regulatory Alternatives to the Proposed Rule

We consider three regulatory alternatives to the proposed rule: an otherwise identical rule with a proposed effective date of 24 months from the date of publication of the final rule, an otherwise identical rule with a proposed effective date of 6 months from the date of publication of the final rule, and an otherwise identical rule requiring that one of up to nine new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, appear on cigarette packages and in cigarette advertisements. We estimate costs and do a break-even calculation for these alternatives below, although not all regulatory alternatives may be legally viable.

1. Effective Date of 24 Months from Date of Publication of Final Rule

An effective date of 24 months from the date of publication of the final rule would reduce the one-time costs of this rule through three avenues: the number of UPCs that can be coordinated with a previously scheduled label change is increased, rush charges for the label design are eliminated, and discarded inventory costs are eliminated. Table 10 shows the total cost of a major cigarette labeling change that reflects both an

effective date of 24 months from the date of publication of the final rule, as well as that each cigarette UPC would require 13 printing plates, one for each cigarette health warning label (13 warnings per UPC). Looking at Table 10, we estimate total labeling costs associated with the proposed rule under this regulatory option range from $217.0 million to $360.3 million, with a mean estimate of $281.8 million (2018$).

Table 10. Cost of a Major Cigarette Label Change With 13 Warning Labels (in 2018$)

	Low	Mean	High
Label Design Costs			
# Uncoordinated UPCs	2,392	2,392	2,392
Labor Costs ($/UPC)	$3,211	$6,860	$12,906
Material Costs ($/UPC)	$69,380	$87,752	$108,610
Recordkeeping Costs ($/UPC)	$35	$67	$116
Total Costs ($/UPC)	$72,626	$94,679	$121,632
Total Label Design Costs for Uncoordinated UPCs ($)	$173,721,392	$226,472,168	$290,943,744
# Coordinated UPCs	671	671	671
Labor Costs ($/UPC)	$395	$1,354	$3,059
Material Costs ($/UPC)	$64,043	$81,002	$100,256
Recordkeeping Costs ($/UPC)	$17	$34	$60
Total Costs ($/UPC)	$64,455	$82,390	$103,375
Total Label Design Costs for Coordinated UPCs ($)	$43,249,305	$55,283,690	$69,364,625
TOTAL LABEL DESIGN COSTS ($)	$216,970,697	$281,755,858	$360,308,369
Inventory Costs			
# Discarded Labels	0	0	0
Cost Per Discarded Label ($/Label)	$0.027	$0.032	$0.037
TOTAL INVENTORY COSTS ($)	$0	$0	$0
TOTAL COSTS	$216,970,697	$281,755,858	$360,308,369

Notes: FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information. Effective date is 24 months from date of publication of final rule. We used 2018 Nielsen RMS data to estimate the number of cigarette UPCs. The number of uncoordinated and coordinated UPCs depend on the number of cigarette UPCs as well as, respectively, the percentage of UPCs which cannot and can be coordinated, both of which are estimated using the FDA Labeling Cost Model. The number of discarded labels depends on the estimated number of sales units, the source of which is 2018 Nielsen RMS data, as well as an estimate of the percentage of those sales units which will be discarded, the latter which is estimated using the FDA Labeling Cost Model. Lastly, note that Nielsen only provides a point estimate of UPCs and sales units, not a range. Hence, the number of UPCs and the number of discarded labels is the same at low, mean, and high.

The total cost of the proposed rule if the effective date is 24 months from the date of publication of the final rule is presented in Table 11. The present value of the estimated total costs of the proposed rule ranges from $1.3 billion to $1.8 billion, with a mean estimate of $1.5 billion, using a three percent discount rate, and ranges from $916.6 million to $1.4 billion, with a mean estimate of $1.1 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the proposed rule ranges from $82.6 million to $119.6 million, with a mean estimate of $99.6 million, using a three percent discount rate, and ranges from $86.5 million to $126.1 million, with a mean estimate of $104.7 million, using a seven percent discount rate (2018$).

Table 11. Estimated Total Cost of the Proposed Rule if the Effective Date is 24 Months from the Date of Publication of the Final Rule (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$241.1	$306.3	$385.2
2	$24.1	$24.5	$24.9
3	$24.1	$24.5	$24.9
4	$206.0	$257.0	$316.6
5	$24.1	$24.5	$24.9
6	$24.1	$24.5	$24.9
7	$191.7	$238.7	$293.7
8	$24.1	$24.5	$24.9
9	$24.1	$24.5	$24.9
10	$178.5	$221.9	$272.6
11	$24.1	$24.5	$24.9
12	$24.1	$24.5	$24.9
13	$166.4	$206.3	$253.0
14	$24.1	$24.5	$24.9
15	$24.1	$24.5	$24.9
16	$155.1	$192.0	$235.1
17	$24.1	$24.5	$24.9
18	$24.1	$24.5	$24.9
19	$144.8	$178.8	$218.5
20	$24.1	$24.5	$24.9
Present Value			
3%	$1,229.4	$1,481.9	$1,779.0
7%	$916.6	$1,108.9	$1,335.8
Annualized Amount			
3%	$82.6	$99.6	$119.6
7%	$86.5	$104.7	$126.1

Notes: Effective date is 24 months from date of publication of final rule. Included in *t = 1* is the initial cost associated with changing cigarette labels, illustrated in Table 4. Included in *t = 4, 7, 10, 13, 16,* and *19* are costs associated with planned future cigarette labeling changes from Table 5. Included in *t = 1* through *t = 20* are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 6, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

If the information provided by the cigarette health warning on each package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits generated by the proposed rule with an effective date of 24 months from the date of

publication of the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

2. Effective Date of Six Months from Date of Publication of Final Rule

With an effective date of six months from the date of publication of the final rule, the FDA Labeling Cost Model estimates that there is not enough time for any of the labeling changes to be coordinated with previously scheduled changes and that manufacturers would incur costs associated with applying stickers to some sales units due to insufficient time to print new labels before the change must be implemented. Table 12 shows the total cost of a major cigarette labeling change that reflects both an effective date of six months from the date of publication of the final rule, as well as that each cigarette UPC would require 13 printing plates, one for each cigarette health warning label (13 warnings per UPC). We estimate total labeling costs associated with this proposed rule under this regulatory option range from $695.0 million to $3.2 billion, with a mean estimate of $1.4 billion (2018$).

Table 12. Cost of a Major Cigarette Label Change With 13 Warning Labels (in 2018$)

	Low	Mean	High
Label Design Costs			
# Uncoordinated UPCs	3,063	3,063	3,063
Labor Costs ($/UPC)	$4,495	$9,603	$18,069
Material Costs ($/UPC)	$97,138	$122,861	$152,068
Recordkeeping Costs ($/UPC)	$49	$94	$163
Total Costs ($/UPC)	$101,682	$132,558	$170,300
Total Label Design Costs for Uncoordinated UPCs ($)	$311,451,966	$406,025,154	$521,628,900
# Coordinated UPCs	0	0	0
Labor Costs ($/UPC)	$395	$1,354	$3,059
Material Costs ($/UPC)	$89,666	$113,410	$140,370
Recordkeeping Costs ($/UPC)	$17	$34	$60
Total Costs ($/UPC)	$90,078	$114,798	$143,489
Total Label Design Costs for Coordinated UPCs ($)	$0	$0	$0
TOTAL LABEL DESIGN COSTS ($)	$311,451,966	$406,025,154	$521,628,900
Inventory Costs			
# Discarded Labels	15,440,782	15,440,782	15,440,782
Cost Per Discarded Label ($/Label)	$0.027	$0.032	$0.037
Total Discarded Inventory Cost	$416,901	$494,105	$571,309
# Units to Which Stickers Would Be Applied	4,911,789,429	4,911,789,429	4,911,789,429
Sticker and Application Cost ($/Unit)	$0.078	$0.201	$0.551
Total Sticker Cost	$383,119,576	$987,269,675	$2,706,395,975
TOTAL INVENTORY COSTS ($)	$383,536,477	$987,763,780	$2,706,967,284
TOTAL COSTS	$694,988,443	$1,393,788,934	$3,228,596,184

Notes: FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information. Effective date is six months from the date of publication of the final rule. We used 2018 Nielsen RMS data to estimate the number of cigarette UPCs. The number of uncoordinated and coordinated UPCs depend on the number of cigarette UPCs as well as, respectively, the percentage of UPCs which cannot and can be coordinated, both of which are estimated using the FDA Labeling Cost Model. The number of discarded labels depends on the estimated number of sales units, the source of which is 2018 Nielsen RMS data, as well as an estimate of the percentage of those sales units which will be discarded, the latter which is estimated using the FDA Labeling Cost Model. The number of units to which stickers would be applied depends on the estimated number of sales units, the source of which is 2018 Nielsen RMS data, as well as an estimate of the percentage of those sales units which would be stickered, the latter which is estimated using the FDA Labeling Cost Model. Lastly, note that Nielsen only provides a point estimate of UPCs and sales units, not a range. Hence, the number of UPCs and the number of discarded labels is the same at low, mean, and high.

The total cost of the proposed rule if the effective date is six months from the date of publication of the final rule is presented in Table 13. Under such an effective date, the present value of the estimated total costs of the proposed rule ranges from $1.7 billion to $4.6 billion, with a mean estimate of $2.6 billion, using a three percent discount rate, and ranges from $1.4 billion to $4.0 billion, with a mean estimate of $2.1 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the proposed rule ranges from $113.8 million to $306.8 million, with a mean estimate of $172.2 million, using a three percent discount rate, and ranges from $128.7 million to $379.1 million, with a mean estimate of $202.8 million, using a seven percent discount rate (2018$).

Table 13. Estimated Total Cost of the Proposed Rule if the Effective Date is Six Months from the Date of Publication of the Final Rule (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$719.1	$1,418.3	$3,253.5
2	$24.1	$24.5	$24.9
3	$24.1	$24.5	$24.9
4	$206.0	$257.0	$316.6
5	$24.1	$24.5	$24.9
6	$24.1	$24.5	$24.9
7	$191.7	$238.7	$293.7
8	$24.1	$24.5	$24.9
9	$24.1	$24.5	$24.9
10	$178.5	$221.9	$272.6
11	$24.1	$24.5	$24.9
12	$24.1	$24.5	$24.9
13	$166.4	$206.3	$253.0
14	$24.1	$24.5	$24.9
15	$24.1	$24.5	$24.9
16	$155.1	$192.0	$235.1
17	$24.1	$24.5	$24.9
18	$24.1	$24.5	$24.9
19	$144.8	$178.8	$218.5
20	$24.1	$24.5	$24.9
Present Value			
3%	$1,693.5	$2,561.5	$4,563.8
7%	$1,363.3	$2,148.1	$4,016.4
Annualized Amount			
3%	$113.8	$172.2	$306.8
7%	$128.7	$202.8	$379.1

Notes: Effective date is six months from date of publication of final rule. Included in *t = 1* is the initial cost associated with changing cigarette labels, illustrated in Table 4. Included in *t = 4, 7, 10, 13, 16,* and *19* are costs associated with planned future cigarette labeling changes from Table 5. Included in *t = 1* through *t = 20* are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 6, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

If the information provided by the cigarette health warning on each package were valued at about $0.02 (for every pack sold annually nationwide), then the benefits generated by the proposed rule with an effective date of six months from the date of

publication of the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

3. Nine Cigarette Health Warnings

An otherwise identical rule requiring that one of up to nine new cigarette health warnings appear on cigarette packages and in cigarette advertisements would reduce both the initial and recurring labeling costs of this rule through a reduction in material costs. Table 14 shows the total cost of a major cigarette labeling change that reflects both an effective date of 15 months from the date of publication of the final rule, as well as that each cigarette UPC would require nine printing plates, one for each cigarette health warning label (nine warnings per UPC). We estimate total initial labeling costs associated with this proposed rule under this regulatory option range from $217.4 million to $372.2 million, with a mean estimate of $286.3 million (2018$).

Table 14. Cost of a Major Cigarette Label Change With 9 Warning Labels (in 2018$)

	Low	Mean	High
Label Design Costs			
# Uncoordinated UPCs	2,819	2,819	2,819
Labor Costs ($/UPC)	$4,495	$9,603	$18,069
Material Costs ($/UPC)	$67,248	$85,059	$105,282
Recordkeeping Costs ($/UPC)	$49	$94	$163
Total Costs ($/UPC)	$71,792	$94,756	$123,514
Total Label Design Costs for Uncoordinated UPCs ($)	$202,381,648	$267,117,164	$348,185,966
# Coordinated UPCs	244	244	244
Labor Costs ($/UPC)	$395	$1,354	$3,059
Material Costs ($/UPC)	$59,776	$75,608	$93,584
Recordkeeping Costs ($/UPC)	$17	$34	$60
Total Costs ($/UPC)	$60,188	$76,996	$96,703
Total Label Design Costs for Coordinated UPCs ($)	$14,685,872	$18,787,024	$23,595,532
TOTAL LABEL DESIGN COSTS ($)	$217,067,520	$285,904,188	$371,781,498
Inventory Costs			
# Discarded Labels	11,611,468	11,611,468	11,611,468
Cost Per Discarded Label ($/Label)	$0.027	$0.032	$0.037
TOTAL INVENTORY COSTS ($)	$313,510	$371,567	$429,624
TOTAL COSTS	$217,381,030	$286,275,755	$372,211,122

Notes: Effective date is 15 months from date of publication of final rule.

Regarding labeling costs related to planned future labeling changes, per-UPC recurring labeling costs range from $43,109/UPC to $69,965/UPC with a mean estimate of $55,394/UPC (2018$). Total labeling costs in years 1 (reproduced from above), 4, 7, 10, 13, 16, and 19 are illustrated below in Table 15.

Table 15 - Cost of Planned Future Major Cigarette Label Changes With 9 Warning Labels (in 2018$)

		Labeling Costs		
t	**# UPCs**	**Low**	**Mean**	**High**
1	3,063	$217,381,030	$286,275,755	$372,211,122
2	2,980	-	-	-
3	2,900	-	-	-
4	2,822	$121,653,598	$156,321,868	$197,441,230
5	2,746	-	-	-
6	2,672	-	-	-
7	2,600	$112,083,400	$144,024,400	$181,909,000
8	2,530	-	-	-
9	2,462	-	-	-
10	2,396	$103,289,164	$132,724,024	$167,636,140
11	2,331	-	-	-
12	2,268	-	-	-
13	2,207	$95,141,563	$122,254,558	$154,412,755
14	2,147	-	-	-
15	2,089	-	-	-
16	2,033	$87,640,597	$112,616,002	$142,238,845
17	1,978	-	-	-
18	1,925	-	-	-
19	1,873	$80,743,157	$103,752,962	$131,044,445
20	1,822	-	-	-

Notes: Effective date is 15 months from date of publication of final rule.

The total cost of the proposed rule if the effective date is 15 months from the date of publication of the final rule and the number of cigarette health warnings is nine is presented in Table 16. Under such a scenario, the present value of the estimated total costs of the proposed rule ranges from $1.0 billion to $1.4 billion, with a mean estimate of $1.2 billion, using a three percent discount rate, and ranges from $765.1 million to $1.1 billion, with a mean estimate of $921.1 million, using a seven percent discount rate (2018$). The estimated annualized cost of the proposed rule ranges from $68.0 million to $97.3 million, with a mean estimate of $81.3 million, using a three percent discount rate, and ranges from $72.2 million to $104.7 million, with a mean estimate of $86.9 million, using a seven percent discount rate (2018$).

Table 16. Estimated Total Cost of the Proposed Rule (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$241.5	$310.8	$397.1
2	$24.1	$24.5	$24.9
3	$24.1	$24.5	$24.9
4	$145.8	$180.8	$222.3
5	$24.1	$24.5	$24.9
6	$24.1	$24.5	$24.9
7	$136.2	$168.5	$206.8
8	$24.1	$24.5	$24.9
9	$24.1	$24.5	$24.9
10	$127.4	$157.2	$192.5
11	$24.1	$24.5	$24.9
12	$24.1	$24.5	$24.9
13	$119.2	$146.8	$179.3
14	$24.1	$24.5	$24.9
15	$24.1	$24.5	$24.9
16	$111.7	$137.1	$167.1
17	$24.1	$24.5	$24.9
18	$24.1	$24.5	$24.9
19	$104.8	$128.3	$155.9
20	$24.1	$24.5	$24.9
Present Value			
3%	$1,011.1	$1,209.8	$1,448.3
7%	$765.1	$921.1	$1,109.2
Annualized Amount			
3%	$68.0	$81.3	$97.3
7%	$72.2	$86.9	$104.7

Notes: Effective date is 15 months from date of publication of final rule. Included in $t = 1$ is the initial cost associated with changing cigarette labels, illustrated in Table 14. Included in $t = [4, 7, 10, 13, 16, 19]$ are costs associated with planned future cigarette labeling changes from Table 15. Included in $t = 1$ through $t = 20$ are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 6, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

If the information provided by the cigarette health warning on each package were valued at about $0.009 (for every pack sold annually nationwide), then the benefits generated by the proposed rule under this regulatory option would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We estimate that for a small manufacturer or importer who would be affected by this proposed rule, initial costs could represent between 2.5 and 35.6 percent of their annual receipts and recurring costs could represent from 0.4 to 4.4 percent of their annual receipts. Hence, we find that the proposed rule will have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

Description and Number of Affected Small Entities

This proposed rule would affect small cigarette manufacturing entities. It may also impact importers, to the extent that they repackage or relabel and advertise imported cigarettes or face relabeling and advertising costs passed on by foreign manufacturers.

As stated previously in this document, based on data obtained from the TTB, there were 32 active cigarette manufacturers and 27 active cigarette importers in 2017.[19] U.S. Census data offer the best available evidence of the proportion of cigarette manufacturers and importers that are small. Manufacturers of tobacco products covered by this proposed rule would be designated under the North American Industry Classification System (NAICS) as tobacco manufacturers (NAICS 312230). Most importers covered by this proposed rule would be classified as tobacco and tobacco

[19] We note that there may be some overlap between the count of cigarette manufacturers and cigarette importers from TTB data. This overlap would create an overestimate of the number of affected small entities.

product merchant wholesalers (NAICS 424940). The Small Business Administration (SBA) size standard for tobacco manufacturers is 1,500 employees and for tobacco and tobacco product merchant wholesalers is 250 employees.[20] Table 17 shows the SBA size thresholds for small businesses in each of these categories, as well as the most comparable size categories available from the U.S. Census, as well as the number and percentage of firms below each Census size category.[21] The proportion of businesses estimated to be small may be understated because the Census size categories are lower than the SBA threshold. Using these data, we estimate that about 30 (= 0.93 x 32) small cigarette manufacturers and roughly 25 (= 0.93 x 27) small cigarette importers could be affected by this proposed rule.

Table 17. SBA Size Standards and Census Size Categories for Tobacco Manufacturers and Importers

NAICS	Description of NAICS Category	SBA Size Standard (employees)	Information from 2016 Statistics of U.S. Businesses (U.S. Census)			
			Census Size Category (employees)	Total Number of Firms	Number of Firms below Census Size Category	Percentage below Comparable Census Size Category
312230	Tobacco Manufacturing	1,500	500	121	112	93%
424940	Tobacco and Tobacco Product Merchant Wholesalers	250	100	1,217	1,135	93%

[20] See pages 8 and 24 at https://www.sba.gov/sites/default/files/2018-07/NAICS%202017%20Table%20of%20Size%20Standards.pdf.

[21] See "U.S., 6-digit NAICS" at https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html.

Description of the Potential Impacts of the Rule on Small Entities

1. Effects on Small Manufacturers and Importers

To estimate how much of the initial label change cost and how much of the recurring label change costs and recurring design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements would be incurred by small domestic cigarette manufacturers and importers as a result of the proposed rule, we subtract from the total of these costs those costs estimated to be incurred by large domestic manufacturers and importers. Using 2018 Nielsen RMS data, we estimate that roughly 72 percent of cigarette UPCs belong to a brand marketed by the four largest cigarette manufacturers or importers by sales.[22] Assuming that these costs are roughly proportional to the number of UPCs, we attribute 72 percent of these costs to these four manufacturers or importers, leaving 28 percent of these costs, or between $86.5 million and $144.3 million in initial costs and between $12.7 million and $20.5 million in recurring costs, to be incurred by small manufacturers and importers (2018$). If costs are distributed equally among the 55 small cigarette manufacturers and importers, then this implies initial costs of roughly $1.6 million to $2.6 million per small cigarette manufacturer or importer and recurring costs of about $0.2 million to $0.4 million per small cigarette manufacturer or importer (2018$). Based on 2012 U.S. Census Bureau Statistics of U.S. Businesses data, the most recent year for which receipts data are

[22] FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See http://www.nielsen.com/us/en.html for more information.

available, annual receipts per tobacco manufacturer employing less than 500 employees range from about $4.5 million per firm (those with less than 20 employees) to roughly $102 million per firm (those with 100 to 499 employees) (2018$),[23] and annual receipts per tobacco wholesaler employing less than 100 employees range from about $7.9 million per firm (those with less than 20 employees) to roughly $65.2 million per firm (those with 20 to 99 employees) (2018$).[24] Thus, we estimate that initial costs for a small cigarette manufacturer or importer would represent between 2.5 percent (= $2.6 million / $102 million) and 35.6 percent (= $1.6 million / $4.5 million) of their annual receipts, and recurring costs would represent between 0.4 percent (= $0.4 million / $102 million) and 4.4 percent (= $0.2 million / $4.5 million) of their annual receipts.

2. Alternatives to Minimize the Burden on Small Entities

The biggest source of the burden of this rule on small entities is the initial cost associated with changing cigarette labels. One way in which this burden could be eased is to extend the effective date for small manufacturers and importers. For example, if the effective date was increased to 24 months from the date of publication of the final rule for small manufacturers and importers, then for a small manufacturer or importer affected by the proposed rule, we estimate that initial labeling costs would represent between 1.8 percent and 24.4 percent of their annual receipts, compared to between 2.5 percent and 35.6 percent of annual receipts if the effective date was 15 months from the date of

[23] See "Data by Enterprise Employment Size, U.S. and States, U.S., 6-digit NAICS" at https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html. The most granular that we could get using these data is NAICS 312230, "Tobacco Manufacturing", versus our desired granularity of NAICS 312221, "Cigarette Manufacturing".

[24] See "Data by Enterprise Employment Size, U.S. and States, U.S., 6-digit NAICS" at https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html. We used NAICS 424940.

publication of the final rule (note that the recurring costs do not vary by effective date and so would not change). An even further out effective date would reduce initial labeling costs even more. One possible downside to extending the effective date for small manufacturers and importers, however, is that doing so could result in different cigarette products bearing different warnings, thus potentially creating consumer confusion about the relative risk of those different cigarette products.

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