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

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

This final rule requires that 11 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 final rule further requires that, for cigarette packages, these required 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 final rule also requires that, for cigarette advertisements, the required warnings be rotated quarterly in alternating sequences in advertisements for each brand of cigarettes in accordance with a plan approved by FDA. The final new cigarette health warnings will 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. We describe economic benefits qualitatively. The cost of this final 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 the required 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 final 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 were valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.

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Introduction and Summary

Introduction

We have examined the impacts of the final 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 final 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 who would be affected by this final rule, initial costs could represent between 2.3 and 42 percent of their annual receipts and recurring costs could represent from 0.1 to 2.7 percent of their annual receipts. Hence, we find that the final rule will have a significant economic impact on a substantial number of small entities.

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 final rule would result in an expenditure in any year that meets or exceeds this amount.

Summary and Accounting Statement

This final rule requires that 11 new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, in the form of a photorealistic image, appear on cigarette packages and in cigarette advertisements.[1] The final rule further requires that, for cigarette packages, the required 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 final rule also requires that, for cigarette advertisements, the required warnings must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA.

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. We do not predict the size of these benefits at this time. We discuss the informational effects qualitatively.

The costs of this final rule consist 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 the required 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 final rule ranges from $1.5 billion to $1.7 billion, with a mean estimate of $1.6 billion, using a three percent discount rate, and ranges from $1.1 billion to $1.3 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 $100 million per year to $114 million per year, with a mean estimate of $107 million per year, using a three percent discount rate, and range

[1] For the purposes of discussion throughout this document, FDA uses the term "cigarette health warnings" to refer to the required warnings.

from $107 million per year to $122 million per year, with a mean estimate of $114 million per year, using a seven percent discount rate (2018$).

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 were valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.

Table 1. Summary of the Informational Effects and Costs of the Final 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 were valued at about $0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the final rule would equal or exceed the estimated annual costs.						
Costs	Annualized Monetized $millions/year	$114.4	$106.6	$122.2	2018	7%	20 Years	Effective date of 15 months from date of publication of final rule.
		$106.7	$100.0	$113.5	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. With a seven percent discount rate, discounted relative to year 2016, the estimated annualized net costs equal $73 million in 2016 dollars over an infinite horizon. Based on these costs, this final rule is 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	$1,046.0
Present Value of Cost Savings	$0.0
Present Value of Net Costs	$1,046.0
Annualized Costs	$73.2
Annualized Cost Savings	$0.0
Annualized Net Costs	$73.2

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

Comments on the Preliminary Economic Analysis of Impacts and Our Responses

On August 16, 2019, FDA issued a proposed rule to establish new cigarette health warnings for cigarette packages and advertisements (84 Federal Register 42754). We prepared a preliminary regulatory impact analysis (PRIA) for the proposed rule. In the paragraphs below, we describe and respond to the comments received on the PRIA. Many comments were outside the scope of this rule. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

1. General Comments about the PRIA

(Comment 1) Some comments criticize FDA's reliance on cost-benefit analysis as inadequate or irrational. One comment also stated that the PRIA was irrelevant because the rulemaking was mandated by Congress.

(Response 1) FDA disagrees that the cost-benefit analysis prepared in connection with this rule is inadequate, irrational, or irrelevant. The PRIA is an analysis intended to provide information to decision makers and the public about the expected benefits and costs of a proposed rule. As described in the PRIA,[2] the cigarette health warnings being finalized in this rule will 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. We describe benefits qualitatively and use a break-even approach to describe the magnitude of benefits required for the benefits to

2 See https://www.fda.gov/media/130053/download.

equal or exceed the costs of the regulation. We also describe the costs associated with changing cigarette labels to accommodate the new cigarette health warnings, costs associated with the requirements for random and equal display and distribution of the required warnings on cigarette packaging and quarterly rotation of the required warnings in alternating sequence in cigarette advertising, and costs associated with government administration and enforcement of the rule.

2. Comments on Informational Effects

(Comment 2) Many comments expressed concern that the PRIA does not discuss behavioral change. The commenters point out that the PRIA discusses information in and of itself, but not how information may or may not lead to behavior change. Other comments suggest citing literature that evaluates both sides of the issue.

(Response 2) By providing additional warning information on product packaging and advertising, the rule increases the amount of information about products' health risks that is available to consumers and helps consumers understand the negative health consequences of cigarette smoking. Although it is possible that greater public understanding of these health risks could result in potential behavior change, such as a decline in cigarette smoking, seeking additional medical screenings, or otherwise adjusting health care coverage, the rule is not premised on this assumption.

(Comment 3) Multiple comments suggest providing additional analyses showing the benefit of the proposed rule based upon behavioral outcomes.

(Response 3) For several reasons, this analysis does not attempt to quantify potential behavioral changes resulting from the new required warnings. The purpose of the rule is informational. As discussed throughout the final rule, the Government's interest in this final rule is to promote greater public understanding of the negative health consequences of cigarette smoking. Including this information on product packaging and advertising increases the amount of information about products' health risks that is available to consumers and helps consumers understand the negative health consequences of cigarette smoking.

(Comment 4) One comment suggested estimating the value of information through time spent seeking information on the negative health consequences of smoking on FDA's website.

(Response 4) FDA provides public information on the negative health effects of tobacco use through the "Tobacco Products: Health Information" website.[3] However, at this time we do not have information on the number of website views or the total amount of time spent on these webpages. If we did have the information, it would still be difficult to translate this into an estimated value of information of the negative health consequences of smoking cigarettes for a couple reasons. First, the information provided on those pages is not limited to cigarette use; thus, it is not clear what proportion of time spent seeking information is relevant to cigarette health warnings. Second, without knowing more about the consumer (e.g., age, wage, smoking status), it would be difficult to translate this into an estimated value of information. We decline to make any changes in response to this comment.

(Comment 5) Some comments encouraged FDA to estimate consumers' willingness to pay for the information.

(Response 5) The purpose of the rule is to promote greater public understanding of the negative health consequences of smoking. Although it is possible that greater public understanding of these health risks could lead to a decline in cigarette smoking or adjusting health behaviors in other ways to mitigate the impact of the negative health consequences of smoking, such as seeking additional medical screenings, adjusting health insurance coverage, adjusting 401k contributions or otherwise adjusting health care coverage, the rule is not premised on this assumption. 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 pictorial 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) [Ref. 1, 2, 3, 4]. The outcomes examined in these studies contribute to understanding potential willingness-to-pay (WTP) estimates that could be calculated somewhat indirectly (that is, if their smoking dissuasion estimates were multiplied together with potential estimates of health and longevity effects per dissuasion and a value of a statistical life or value of a statistical life-year). The more direct WTP method(s) suggested by the commenters, and exemplified by Rousu et al. (2014) and Pacek et al. (2019), may provide a basis for quantifying potential benefits to smokers (and to other individuals, to the extent that their short- or long-term preferences or well-being are

[3] See https://www.fda.gov/tobacco-products/public-health-education/health-information

internalized by smokers when they purchase cigarettes) of this final rule [Ref. 5, 6]. Rousu et al. combine experimental auction results regarding how much current smokers are willing to pay for a pack of cigarettes with a pictorial warning on the front of the pack, compared to a pack of cigarettes with a smaller text-only warning on the side of the pack (treatment sample size = 47). The authors combine these results, which include positive WTP for some smokers, with real market demand data to isolate a smoker's estimated "value of information" (VOI). They conclude that pictorial warnings have "a higher value than a label that only contains text, insofar as changing purchase behavior" (Rousu et al. 2014). Pacek et al. (2019) use another WTP method to evaluate the effect of pictorial warnings on the "purchasing behavior among HIV-positive smokers," a vulnerable subpopulation (sample size = 222). The authors use Amazon Mechanical Turk (MTurk)[4] to collect data on "attitudes, perceptions, and behaviors related to tobacco use" (Pacek et al. 2019). Study participants were shown a pack of cigarettes with a text-only warning and another pack of cigarettes with a pictorial warning. In each scenario, participants were provided a hypothetical price for each pack and asked to select one of the two packs. The authors conclude that while price is the driving force for most participants (i.e., most participants choose the lowest-priced pack of cigarettes, regardless of label), data suggest some participants changed their purchasing decisions in order to avoid the pictorial warnings. While we acknowledge that studies such as these use WTP methodologies and OMB Circular A-4 notes WTP as a foundational concept in regulatory impact analysis, we do not estimate potential behavior change in our analysis, because the purpose of the rule is informational and is not premised on consumer behavior change. Even if we were to consider consumer behavior change, Pacek et al. focus on a very specific, potentially non-representative subpopulation, and although Rousu et al. may capture a somewhat broader population, other uncertainties attend their results (e.g., the assumptions implicit in their derivation of VOI from WTP are not fully stated, but appear not to be fully consistent with more common hedonic estimation approaches, which if followed would reduce slightly the magnitude of the VOI result and reverse it to the opposite sign; the confidence interval around Rousu et al.'s VOI is large; and hypothetically applying the (short-term) WTP estimates may not capture long-term trends such as potential wear out over time). Moreover, these WTP studies do not, for the most part, capture the interests of important

[4] See https://www.mturk.com/ for more information about this research tool.

populations: middle school and high school students who are not yet smokers or are not yet addicted to nicotine. Populations for whom consumption is illicit are often not included in revealed-preference studies, and the comments have identified no available data providing a WTP analysis for these populations. As before, FDA applies a break-even approach 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.

(Comment 6) One comment suggested estimating the health benefits from reduced healthcare costs from smoking or indirectly from secondhand smoke. Another comment notes that states and localities will benefit from the proposed warnings through reduced medical costs.

(Response 6) This analysis does not attempt to quantify potential behavioral changes resulting from the new required warnings. The purpose of the rule is informational. As discussed throughout the final rule, the Government's interest in this final rule is to promote greater public understanding of the negative health consequences of cigarette smoking. While we do not estimate the reduced healthcare costs from smoking or indirectly from secondhand smoke, we acknowledge that the rule may have impacts along these dimensions.

3. Comments on Costs

(Comment 7) One comment suggested that the cigarette companies' reduced ability to communicate branding and other messages through their packs may result in lost communication potential.

(Response 7) As noted in the final rule, and in accordance with the Sixth Circuit decision in *Discount Tobacco,* 674 F.3d at 530-31, 567, FDA believes that the statutorily-required placement of warnings at the top 50 percent of front and rear panels of cigarette packages, and the top 20 percent of advertisements, leaves sufficient room for manufacturer speech, including branding and other messages. There is ample room for manufacturers to distinguish their products from other products using the lower half of a cigarette package and the remaining 80 percent of advertisements for brand names, logos, or other information. There is also additional space on the side panels of cigarette packages with the removal of the Surgeon General's warnings. In addition, the economic analysis discusses the opportunity costs related to reduced advertising space. As stated in the analysis, there is a recurring opportunity cost associated with the final rule in that the rule will require manufacturers to devote 20 percent of their advertising space which could otherwise be used for promotional content to the display of warning labels. We believe this

captures cost due to lost potential to communicate branding. While we acknowledge that there is some analogous cost to manufacturers as regards packages, we lack data with which to quantify it, and we reiterate that manufacturers retain ample space in the remaining 50 percent of the front and back of the cigarette package and 80 percent of advertising space in which to undertake their preferred speech.

(Comment 8) One comment stated that there may be potential confusion and search costs that may arise as packages become more similar as cigarette health warnings take up the majority of the package's surface area.

(Response 8) Self-service displays of cigarettes are generally prohibited under the Tobacco Control Act. Instead, a customer must ask a retail employee for the desired brand of cigarettes. Manufacturers will still have the majority of the package's surface area for their messaging (e.g., brand names, logos, other information), including the additional space on the side panels of cigarette packages with the removal of the Surgeon General's warnings. We also expect that manufacturers will place product names prominently on the package so that there will be no difficulty in locating the desired product. In addition, the location of each type of cigarette is determined through contracts between retailers and manufacturers [Ref. 7]. If retailers continue to stock product in the same location, there will be no additional search costs for retail establishment employees and thus no additional time needed for either party to complete the transaction. We expect no effect on search costs to retail employees due to this final rule.

(Comment 9) A few comments suggested that there may be psychological costs from having "gratuitous" pictures "forced upon" consumers.

(Response 9) FDA disagrees with those comments that suggest the required warnings' images are gruesome and designed to disgust or to evoke an emotional response. In developing the proposed images, FDA used a science-based, iterative research process to develop, test, and refine images that are factually accurate; that depict common visual presentations of the health conditions and/or showed disease states and symptoms as they are typically experienced; that present the health conditions in a realistic and objective format devoid of non-essential elements; and that are concordant with the statements on the same health conditions. On the issue of impact quantification, see *Response 5* (above) discussing Rousu et al. and Pacek et al. and their limitations.

(Comment 10) One commenter stated that FDA failed to take into account the cost of changing cylinders during the printing cycle, the labor costs for designing and engraving new cylinders, and the cost of redesigning labels. The commenter argued that FDA illustrated a fundamental misunderstanding of the printing process for the vast majority of cigarette packaging, which the comment states is a gravure process using engraved cylinders.

(Response 10) The PRIA used the FDA Labeling Cost Model to estimate the costs of incorporating the proposed cigarette health warnings on cigarette packs. The Labeling Cost Model indicates that most tobacco manufacturers use rotogravure printing and includes costs associated with using this type of printing process. The Labeling Cost Model assumes that part of the labeling change process includes engraving new plates or cylinders. Therefore, the engraving and material costs estimated by the model already include the costs associated with multiple (six to ten) cylinders. Additionally, the model shows that cigarettes are assumed to use "paperboard – cigarette carton" as their primary package-label type, and 95 percent of UPCs with the package-label type "paperboard – cigarette carton" are assumed to use gravure as the printing method. Therefore, the model assumes that the large majority of cigarette packages would be labeled using gravure printing. In the PRIA, cigarette package printing materials are labeled "printing plates" instead of "printing cylinders," which may have led to some of the confusion about assumed printing types. We have corrected this terminology in this final regulatory impact analysis (FRIA). In addition, we recognize that the required labels are complex, potentially requiring more labor hours and materials than other labels. Conversely, we received a comment from industry stating that they could fit nine required warnings on one set of gravure printing metal cylinders and thus the costs are overestimated (see *Comment 12* below for more discussion). We have adjusted the cost estimates toward the high end of the range produced by the Labeling Cost Model in order to better capture the potential for higher than average printing costs, including labor costs of changing cylinders and designing and engraving new cylinders. As noted in *Comment 12* and elsewhere, this may result in overestimated labeling costs.

(Comment 11) Two comments raise concerns related to satisfying the "random and equal" requirement of proposed § 1141.10(g) for 13 different warnings without significant changes to packaging production. These comments note that because 13 is both a prime and odd number, printing 13 different warnings equally is incompatible with industry-wide printing practices. One comment suggests that FDA either require a random and equal distribution of 12 or 9 warnings

or random but unequal display of 13 warnings. The other comment proposes that FDA require 9 different warnings and provide greater flexibility for the random and equal requirement because of printing method variation across the industry.

(Response 11) While we agree that printing 9 warnings would use fewer materials and thus be less costly than printing the 11 required warnings (as shown in Table 14), the commenters did not provide data showing the disproportionate costs of finalizing a set of 11 warnings compared to 9 due to the incompatibility with industry-wide printing practices. FDA is requiring 11 warnings, as compared to the 13 proposed in the proposed rule and discussed in comments. However, because both 11 and 13 are prime numbers, the concerns raised by the comments may still apply. We are addressing those concerns in the final rule by offering manufacturers more flexibility in how they comply with the "random and equal" requirement. Specifically, we are permitting the front and rear panels of cigarette packages to carry different warnings. In addition, the cost of final rule assumes that each warning will require its own set of cylinders, but it is possible that one set of cylinders could be used to print more than one label, thus lowering costs. This issue is also discussed in *Comment 12*.

(Comment 12) One comment received from industry said that they could fit nine required warnings on one set of gravure printing metal cylinders. The Labeling Cost Model assumes that each required warning would need its own set of cylinders, which includes six to ten individual cylinders.

(Response 12) We agree that manufacturers may be able to fit more than one required warning on a set of gravure cylinders. However, it is not clear from this comment that all manufacturers can economize printing cylinders in the same way. Thus, we continue to assume that each of the 11 required warnings must have its own set of gravure printing cylinders, which may lead to overestimating the labeling costs.

(Comment 13) A tribal government stated its opposition to the proposed rule, requested full further disclosure and review of the data, methodologies, summaries, and conclusions associated with the rulemaking prior to final promulgation, and requested meaningful tribal consultation prior to finalization to fully address the impact on and costs incurred by tribal governments. The commenter expressed concern about the proposed rule's effect on funding, stating that most reservation land is held in federal trust so that real property tax revenue is unavailable, and tribes may rely on tobacco revenues to fund basic governmental services. The commenter added that

tribes, unlike states, do not receive payments for smoking cessation programs from the Master Settlement Agreement.

(Response 13) We disagree that the tribal consultation for the proposed rule was inadequate. There were several opportunities for tribes to engage with FDA about the proposed rule, including the impact and costs of the proposed rule on tribal manufacturers. Tribal manufacturers are implicitly included in any analysis of domestic manufacturers. We did not receive comments providing us with new information regarding increased costs that we could incorporate into the analysis.

4. Comments on Break-even Approach

(Comment 14) One comment requested that FDA should "reach an explicit conclusion as to whether the proposed rule's informational benefits are likely to outweigh costs." Other comments suggested comparing the magnitude of the break-even analysis with estimates, such as value of a statistical life, number of people impacted by the rule, and WTP for pictorial health warnings estimated in the literature.

(Response 14) As described in the text below, despite the informational effects of the rule, there is a high level of uncertainty around quantified economic benefits at this time and we therefore apply a break-even analysis. We believe that comparing the break-even calculation with the suggested study results may be misleading.

(Comment 15) Multiple comments suggested conducting break-even analysis per smoker, not per pack.

(Response 15) FDA disagrees with these comments. A focus on smokers alone would be unduly narrow, as it would exclude any benefits to nonsmokers, who will also be exposed to the required warnings on cigarette packages and in cigarette advertisements.

(Comment 16) Multiple comments suggested alternative break-even calculations that would estimate the number of statistical lives that would need to be "saved" through reduced smoking-related deaths to break even.

(Response 16) FDA disagrees with these comments. In addition to being the leading cause of preventable death in the United States, smoking "leads to disease and disability and harms nearly

every organ of the body."[5] Thus, smoking causes morbidity and lost productivity that is not reflected in looking merely to reduced mortality rates. FDA believes that a per-package break-even analysis provides a helpful 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.

(Comment 17) Multiple comments suggested estimating the number of people that would need to be persuaded to quit smoking to break even.

(Response 17) FDA disagrees with these comments. Section V.B of the proposed rule described the scientific evidence demonstrating that pictorial cigarette warnings are effective in helping the public better understand the negative health effects of smoking.[6] As discussed in the response above, FDA believes that a per-package break-even estimate is a more helpful approach.

(Comment 18) Some commenters suggested alternative ways of describing the benefits relative to the costs. For instance, an individual commenter stated that the proposed rule would only cost $0.01 per individual package, compared to the billions of dollars in health care costs spent on those afflicted with health conditions as a result of smoking. One individual commenter said that the proposed cost of the rule is far less than the estimated cost of smoking in the United States, which is over $300 billion per year. Another individual commenter stated that the implementation cost of the proposed rule pales in comparison to the $9.5 billion spent by cigarette and tobacco companies on advertising in 2016. Lastly, an individual stated that pictorial cigarette warnings are a low-cost way to effectively control tobacco use.

(Response 18) We agree with the comment that, as described in the break-even analysis, if the information provided by the cigarette health warning on each cigarette package were valued at about $0.01 per pack sold annually, or 0.2 percent of the average cost of a pack of cigarettes, then the benefits generated by the final rule would equal or exceed the estimated annualized costs. While the estimated cost of smoking in the United States may be over $300 billion per year, it is difficult to estimate total healthcare spending in the absence of smoking. Although we agree that smoking leads to disease and disability, FDA believes that a per-package break-even

[5] See the Center for Disease Control and Prevention's (CDC) "Fast Facts" at https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm.

[6] See 84 FR 42754, https://www.federalregister.gov/documents/2019/08/16/2019-17481/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements

estimate is a more helpful way for decision-makers to understand the magnitude of non-quantified benefits required for the benefits to equal or exceed the costs of the regulation.

5. Comments on Distributional Effects

(Comment 19) One comment notes that while states and localities may lose tax revenues from cigarette sales, this will be offset through reduction in medical costs paid for in part by states.
(Response 19) Although the final rule is not premised on behavior change but rather on promoting greater public understanding of the negative consequences of smoking, FDA agrees that if the rule leads to a decrease in cigarette sales, reduced tax revenues may be offset by reductions in medical costs, many of which are borne by government bodies [Ref. 8]. However, FDA has not quantified behavior change (such as reduced cigarette sales) due to the final rule and thus, FDA does not develop quantitative estimates of such distributional effects.
(Comment 20) Many comments suggest that the proposed cigarette health warnings will mitigate tobacco-related health disparities among groups with (a) low English proficiency, (b) low income, and (c) low education.
(Response 20) FDA agrees that cigarette smoking disparities exist among specific subpopulations in the United States. As described in section IV.A of the proposed rule, smoking prevalence is higher in some subpopulations (e.g., those with lower socioeconomic status) than the general U.S. population [Ref. 9, 10, 11]. Because some subpopulations experience disparities in knowledge of the health harms of smoking due to lower health information access and lower health literacy, the required warnings may reduce disparities found in consumer understanding about the harms of smoking. The PRIA describes these effects within the informational effects section; in this FRIA, we have also added them to the distributional effects section.

6. Comments on Alternatives

(Comment 21) One comment was concerned that the alternatives presented in the PRIA largely duplicate the proposed rule with some timing changes but do not show that we have adequately investigated alternative mechanisms for achieving the goal of the rule. The comment suggested that FDA consider an additional alternative such as changing the existing Surgeon General's text-only warnings on cigarette packages and advertisements and keeping the same size and placement of the required warnings.

(Response 21) FDA respectfully declines to analyze an alternative that would diverge from requirement to combine text and color graphics that Congress set out in the Tobacco Control Act, which amends section 4 of the FCLAA. In line with this approach, we removed the regulatory alternative of a shorter, 6-month effective date for the rule because the statute specifies a 15-month effective date. Moreover, as described in the "Summary of Changes" in the FRIA, we have included two additional regulatory alternatives: the proposed rule (with 13 warnings) and a rule with a 33-month compliance period after the 15-month effective date of the final rule.

7. Comments on Small Entities

(Comment 22) FDA received two comments addressing the PRIA's treatment of small retailers and tobacco product resellers. One comment suggested that small retailers may be unduly burdened if FDA were to require them to submit cigarette plans for the display and rotation of the required warnings. The other comment asserted that the rule "could have a devastating impact on our small businesses" but did not provide a basis to identify or quantify this burden.
(Response 22) FDA disagrees that small retailers will be unduly burdened by the requirement to submit cigarette plans for the display and rotation of the required warnings. As described in the PRIA, "the leading cigarette manufacturers require retailers to enter into contracts if they want to participate in cigarette price promotion programs [Ref. 12, 13]. 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. 7]."

Moreover, the comment overlooked numerous provisions in the proposed rule, now finalized in the final rule, that restrict the circumstances in which retailers will be liable. Under § 1141.1(c), retailers will not be in violation for cigarette packaging that: (1) contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or part 1141. However, this subsection does require retailers to ensure that all cigarette packages they display or sell contain a warning that is unobscured by stickers, sleeves, or other materials on the packages, for example. Further, under § 1141.1(d), the advertisement requirements in § 1141.10 will apply to a retailer only if the retailer is responsible for or directs the warnings for advertising. Retailers would be liable if they display, in a location open to the public, an

advertisement that does not contain a warning (§ 1141.1(d)). (To be sure, retailers will be in violation of the FCLAA and the final rule if they alter cigarette advertising in a way that is material to the requirements, for example, by obscuring or covering up the warning (e.g., blocking with a sticker or marker), shrinking the warning, or using a sleeve to cover the warning.) Thus, we expect the majority of the burden will be placed on the cigarette manufacturers to submit cigarette plans for the display and rotation of the required warnings on cigarette advertisements, and we do not expect retailers or small retailers to be unduly burdened by this requirement.

Summary of Changes

We have made edits to the analysis based on changes applied to the final rulemaking. Specifically, the number of required warnings has been reduced from 13 to 11 and estimates in the economic analysis have been changed accordingly. There are no other substantial changes between the analysis of the proposed rule and the final rule. We have also updated the FRIA based on the comments received, outlined above. Namely, we have adjusted the cost estimates toward the high end of the range produced by the Labeling Cost Model, extended the distributional effects section to discuss disparities across subpopulations and edited the cost analysis to remove the incorrect usage of the term "printing plates." In addition, we have included two additional regulatory alternatives: the proposed rule (with 13 warnings) and an alternative with a 33-month compliance period after the 15-month effective date of the final rule. We have removed the alternative that gives an effective date of six months from date of publication of final rule. Finally, we have corrected some minor calculation errors.

Final 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, which 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 the FCLAA, including the Comprehensive Smoking Education Act of 1984 (Public Law No. 98-474), which extended the requirement to cigarette advertising and updated it to include 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 the FCLAA and directed FDA to promulgate new cigarette health warnings that would include a color graphic component depicting the negative health consequences of smoking to accompany new 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 finds 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 in part 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.

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 final 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 final rule addresses information asymmetries regarding these negative health consequences at the point of purchase and through advertising. 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. 14]. 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. 15]. 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 warnings to effectively promote greater public understanding of the negative health consequences of cigarette smoking, they must attract and maintain attention [Ref. 16, 17]. However, recent surveys on tobacco use show that only a minority of smokers see or notice the current 1984 Surgeon General's warnings [Ref. 18, 19, 20, 21]. 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. 22].

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. 18, 23, 24]. Larger cigarette health warnings increase important outcomes related to understanding the health risks of cigarette use [Ref. 18, 21, 25, 26, 27, 28, 29, 30, 31, 32, 33]. This final rule presents 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. There is considerable evidence that the current 1984 Surgeon General's warnings are largely unnoticed and unconsidered by both smokers and nonsmokers, and that without Federal regulatory action, that will continue to be the case. Therefore, mitigating the information asymmetries and internalities of not understanding the negative health consequences of cigarette smoking requires Federal regulatory action.

Purpose of the Final Rule

This final rule establishes new required cigarette health warnings to appear on cigarette packages and in cigarette advertisements. These new cigarette health warnings consist of textual warning statements accompanied by color graphics, in the form of photorealistic images, depicting the negative health consequences of cigarette smoking. The final textual warning statements are:

- 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.
- 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 cataracts, which can lead to blindness.

FDA has determined that the final new cigarette health warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. In FDA's final consumer research study (OMB control number 0910-0866, "Experimental Study of Cigarette Warnings"), each final cigarette health warning demonstrated statistically significant improvements, as compared to the 1984 Surgeon General's warnings (i.e., the control condition), across almost all outcomes measured, including the outcomes of new information, self-reported learning, thinking about the risks, perceived informativeness, perceived understandability, perceived helpfulness understanding health effects, attention, and recall [Ref. 34].

The final rule further requires that, for cigarette packages, the required 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 FDA. The final rule also requires that, for cigarette

advertisements, the required 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 must 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 will become effective 15 months after the date the final rule publishes in the *Federal Register*; therefore, FDA strongly encourages entities to submit cigarette plans as soon as possible after publication of this final rule, preferably within five months after the publication of this final rule.

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.[7] 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, 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 section V.A of the proposed rule ("The Current Surgeon General's Warnings Are Inadequate"), a substantial body of research shows that the current 1984 Surgeon General's warnings do not convey relevant information about the adverse health effects of cigarette smoking in an effective way because they do not attract attention [Ref. 18, 19, 35], are not

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

remembered [Ref. 36, 37], and do not prompt thoughts about the risks of smoking [Ref. 18, 21, 38].

The current Surgeon General's warnings do not convey relevant information about the adverse health effects of cigarette smoking to the American public in an effective way. As discussed in section V.A.3 of the proposed rule, surveys of smokers and nonsmokers indicate that a substantial percentage of the public is misinformed or do not know about the negative health consequences of smoking.

In developing this final rule, FDA carefully examined the scientific literature, including the 2014 Surgeon General's Report, titled "The Health Consequences of Smoking: 50 Years of Progress," which identified additional 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 40 unique health consequences already known to be caused by smoking and exposure to secondhand smoke.

Results from the 2018 National Health Interview Survey (NHIS) indicate that approximately 34.2 million U.S. adults (or 13.7 percent of the U.S. adult population) are current cigarette smokers.[8] Among adolescents, data from the 2019 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 5.8 percent, and past 30-day prevalence among middle school students was 2.3 percent.[9] Using Nielsen Retail Measurement Services (RMS) data, we estimate that in 2018, 9.7 billion packs of cigarettes were sold.[10] 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

[8] See NHIS summary from "Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018" at https://www.cdc.gov/mmwr/volumes/68/wr/mm6845a2.htm

[9] See NYTS summary "Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019" at https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm

[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.

data, we find that the number of cigarette UPCs has decreased by an average of about 2.7 percent each year.[11]

The final required warnings must 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 help lower the price of cigarettes to consumers) in 2017.[12] 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 final required warnings will 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's warnings. Section V.B of the proposed rule, "Cigarette Health Warnings that Are Noticeable, Lead to Learning, and Increase Knowledge Will Promote

[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.

[12] 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

Public Understanding about the Negative Health Consequences of Smoking" describes in detail studies that demonstrate how pictorial cigarette 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 smoking; and (3) reduce disparities in knowledge about the negative health consequences of smoking across diverse populations.[13]

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 smaller text-only cigarette warnings [Ref. 18, 23, 25, 26, 29, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51]. 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 cigarette health warnings were more likely to report beliefs about the specific health consequences contained in the warnings, compared to those who did not notice the warnings [Ref. 23]. 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. 39, 50]. 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. 52].

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. 53]. Cigarette health warnings with accompanying images that support the text, such as the ones required in the final rule, 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. 10, 11]. This rule will increase understanding among these diverse populations of

[13] 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.

the negative health consequences of smoking and thereby reduce the disparities found in consumer understanding about the harms of smoking.

In FDA's final consumer research study, each of the final required warnings outperformed the Surgeon General's warnings (i.e., the control condition in the study) on the two outcomes FDA specified (as described in section VI.E of the proposed rule) as being predictive for promoting understanding of the risks associated with cigarette smoking, "new information" and "self-reported learning," consistent with the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking [Ref. 34, 54]. In addition, the final required warnings also demonstrated statistically significant greater scores in other measures of understanding when compared to the control warnings (see section VII.B of the final rule for a discussion of the study results for each required warning).

Costs of the Final Rule

The costs of this final rule consist 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 final rule requires 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 final new cigarette health warnings, separate printing cylinder sets 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. 55].

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: minimal changes to an ingredient list 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 (e.g., converting the graphic design into the film or files that are used to engrave the printing cylinders, and color trapping 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 gravure printing cylinder sets (one set is

estimated to include between six and ten cylinders) 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 compliance dates of 24 months or longer from the date of publication of the final rule, the Labeling Cost 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 of which varies by distance of effective date from the date of publication of the final rule. To provide a range of cost estimates for the requirements of this final 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 compliance dates of nine months or less from the date of publication of the relevant 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 compliance 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 final rule.[14] With a final effective date of

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

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 final 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 final rule, the front and rear panel of every cigarette package will need to be redesigned to incorporate the final cigarette health warnings that will occupy the top 50 percent of the area of the front and rear panels of cigarette packages, and the current 1984 Surgeon General's warnings will need to be removed. Such a change is classified by the FDA Labeling Cost Model as a major change.

Table 3 summarizes the FDA Labeling Cost Model's estimates for 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 Cigarette Label Change (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

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.

	Low	Mean	High
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 cylinder sets and prepress activities would be approximately 11 times as large as estimated in Table 3 for uncoordinated UPCs due to the final requirement for 11 separate cigarette health warnings. The Labeling Cost Model assumes that each UPC would require 11 sets of gravure printing cylinders, one for each warning label. Each set is estimated to contain six to ten cylinders; each cylinder is used with a different color or finish. However, based on industry comment, it may be possible to fit multiple warnings on each cylinder. Thus, material costs may be overestimated. Further, the final rule allows manufacturers to display different required warnings on the front and back panels of cigarette packages. This practice may also reduce the number of cylinders required to meet the standard. However, the Labeling Cost Model is not refined enough to capture any reduction in costs due to this.

Conversely, as discussed in *Comment 10*, the complexity of printing the required warnings may result in labels with higher than average labor and material costs. Thus, we adjust the cost estimates toward the high end of the range produced by the Labeling Cost Model, i.e., the "mean" estimated costs shown in Table 3 become the "low" costs in subsequent calculations, which shifts the possible distribution of costs upward.

For coordinated UPCs, we estimate that materials costs for gravure printing cylinder sets and prepress activities would be roughly 10 times the uncoordinated materials costs illustrated in Table 3: each UPC would require 11 gravure printing cylinder sets, one for each required

warning, 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 and assumes that each cigarette UPC would require 11 gravure printing cylinder sets, one for each required warning (11 warnings per UPC). Total labeling costs associated with this final rule are estimated to range from $344 million to $444 million, with a mean estimate of $394 million (2018$).

Table 4. Cost of a Major Cigarette Label Change With 11 Warning Labels (in 2018$)

	Low	**Mean**	**High**
Label Design Costs			
# Uncoordinated UPCs	2,819	2,819	2,819
Labor Costs ($/UPC)	$9,603	$13,836	$18,069
Material Costs ($/UPC)	$103,961	$116,320	$128,678
Recordkeeping Costs ($/UPC)	$94	$129	$163
Total Costs ($/UPC)	$113,658	$130,284	$146,910
Total Label Design Costs for Uncoordinated UPCs ($)	$320,401,902	$367,270,596	$414,139,290
# Coordinated UPCs	244	244	244
Labor Costs ($/UPC)	$1,354	$2,207	$3,059
Material Costs ($/UPC)	$94,510	$105,745	$116,980
Recordkeeping Costs ($/UPC)	$34	$47	$60
Total Costs ($/UPC)	$95,898	$107,999	$120,099
Total Label Design Costs for Coordinated UPCs ($)	$23,399,112	$26,351,634	$29,304,156
TOTAL LABEL DESIGN COSTS ($)	$343,801,014	$393,622,230	$443,443,446
Inventory Costs			
# Discarded Labels	11,611,468	11,611,468	11,611,468
Cost Per Discarded Label ($/Label)	$0.032	$0.035	$0.037
TOTAL INVENTORY COSTS ($)	$371,567	$400,596	$429,624
TOTAL COSTS	*$344,172,581*	*$394,022,826*	*$443,873,070*

Notes: Effective date is 15 months from date of publication of final rule. Mean cost estimates are an average of the low and high estimates.

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. 55]. 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.[15] Thus, we reduce

[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 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

the number of cigarette UPCs by 2.7 percent each year and estimate labeling costs in years 4, 7, 10, 13, 16, and 19 of the final rule using the per-UPC cost of a coordinated labeling change whereby materials costs are calculated as 10 times the per-UPC non-rush materials costs associated with an uncoordinated label change.[16] The per-UPC cost of a coordinated label change with materials costs calculated in this way ranges from $77,777/UPC to $86,665/UPC with a mean estimate of $82,221/UPC (2018$). Total labeling costs in years 1 (reproduced from Table 4 above), 4, 7, 10, 13, 16, and 19 are illustrated below in Table 5.

Table 5 - Cost of Planned Future Major Cigarette Label Changes With 11 Warning Labels (in millions 2018$)

		Labeling Costs		
t	**# UPCs**	**Low**	**Mean**	**High**
1	3,063	$344.2	$394.0	$443.9
2	2,980	$0.0	$0.0	$0.0
3	2,900	$0.0	$0.0	$0.0
4	2,822	$219.5	$232.0	$244.5
5	2,745	$0.0	$0.0	$0.0
6	2,671	$0.0	$0.0	$0.0
7	2,599	$202.2	$213.7	$225.3
8	2,529	$0.0	$0.0	$0.0
9	2,461	$0.0	$0.0	$0.0
10	2,394	$186.2	$196.9	$207.5
11	2,330	$0.0	$0.0	$0.0
12	2,267	$0.0	$0.0	$0.0
13	2,205	$171.5	$181.3	$191.1
14	2,146	$0.0	$0.0	$0.0
15	2,088	$0.0	$0.0	$0.0
16	2,032	$158.0	$167.0	$176.1
17	1,977	$0.0	$0.0	$0.0
18	1,923	$0.0	$0.0	$0.0
19	1,871	$145.6	$153.9	$162.2
20	1,821	$0.0	$0.0	$0.0

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

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.

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

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

This final rule requires for each brand random and equal display and distribution of the required warnings on cigarette packages and quarterly rotation of the required warnings in cigarette advertisements. Manufacturers likely already have some experience incorporating these types of display, distributional, and rotational logistics due to the required rotation of the current Surgeon General's warnings. In their plan, the manufacturer will need to demonstrate how it plans to achieve the random and equal display and distribution of required warnings on packages and the quarterly rotation of required warnings 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, each of the warnings will be displayed in as equal a number of times as possible on each brand of the product; and 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 warnings 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. FDA strongly encourages entities to submit cigarette plans as soon as possible after publication of this final rule, and in any event within five months after the publication of this final rule. FDA estimates it may take up to six months, on average, for the Agency 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 warnings on packages or the quarterly rotation of required warnings in advertisements. However, in lieu of a supplement to an FDA-approved plan for a new brand, manufacturers may reference in their initial plan "all brands" in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. Manufacturers will be required to maintain a copy (record) of their FDA-approved plan, and this copy must be

available for inspection and copying by officers or employees of FDA. The record(s) must be retained while in effect and for a period of not less than four years from the date of FDA's approval of the plan.

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. To the extent that manufacturers can create and maintain a plan in less time than estimated here, these costs are overestimated.

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. Cost to Remove and Replace Noncompliant Advertising

Although we do not have data on the current raw 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.[17] 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. 12, 13]. 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. 7].

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 requirements of this final rule will not take effect until 15 months after the date of publication

[17] 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

of the final rule, FDA does not expect that the final rule will create any additional burden for manufacturers related to the removal and replacement of non-compliant advertising.

There is, however, a recurring opportunity cost associated with the final 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.[18] 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 = $20.4 million per year (2018$).

5. Government Administration and Enforcement Costs

To implement and enforce this final rule, FDA estimates that the equivalent of 15 full-time equivalent employees (FTEs) will be required annually. However, this work could 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 final rule is roughly $3.2 million (2018$). These government costs represent an opportunity cost, but this rule will 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 final 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 final rule ranges from $1.5 billion to $1.7 billion, with a mean estimate of $1.6 billion, using a three percent discount rate, and ranges from $1.1 billion to $1.3 billion, with a mean estimate of $1.2

[18] Note that the current 1984 Surgeon General's warning requirements occupy about four percent of available space. Thus, the difference in space devoted to the warning label is 16, not 20 percent of the total advertisement and therefore our calculation may be an overestimated.

billion, using a seven percent discount rate (2018$). The estimated annualized cost of the final rule ranges from $100 million to $114 million, with a mean estimate of $107 million, using a three percent discount rate, and ranges from $107 million to $122 million, with a mean estimate of $114 million, using a seven percent discount rate (2018$).

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

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$368.2	$418.5	$468.8
2	$24.1	$24.4	$24.9
3	$24.1	$24.4	$24.9
4	$243.5	$256.4	$269.4
5	$24.1	$24.4	$24.9
6	$24.1	$24.4	$24.9
7	$226.2	$238.1	$250.1
8	$24.1	$24.4	$24.9
9	$24.1	$24.4	$24.9
10	$210.3	$221.3	$232.4
11	$24.1	$24.4	$24.9
12	$24.1	$24.4	$24.9
13	$195.6	$205.8	$216.0
14	$24.1	$24.4	$24.9
15	$24.1	$24.4	$24.9
16	$182.1	$191.5	$201.0
17	$24.1	$24.4	$24.9
18	$24.1	$24.4	$24.9
19	$169.6	$178.3	$187.1
20	$24.1	$24.4	$24.9
Present Value			
3%	$1,488.3	$1,587.8	$1,688.4
7%	$1,129.5	$1,211.6	$1,294.6
Annualized Amount			
3%	$100.0	$106.7	$113.5
7%	$106.6	$114.4	$122.2

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 final rule will 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 will receive new information provided in the cigarette health warnings that are designed to promote greater understanding of the negative health consequences of smoking.

Instead of developing quantitative estimates of economic benefits at this time, 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 final rule, annualized over 20 years, is $107 million per year using a three percent discount rate and $114 million per year using a seven percent discount rate (2018$). The welfare gains of this final rule will come from the value consumers receive from the information provided in the cigarette health warnings on cigarette packages and advertisements. Both smokers and nonsmokers will be exposed to these cigarette health warnings because cigarette health warnings on advertisements will be seen in public spaces, and because cigarette packages are often visible to those other than the person carrying the package [Ref. 24, 56]. However, we do not know what proportion of the public will be exposed to the cigarette health warnings. Thus, we estimate a break-even point on a per cigarette pack basis.

Using Nielsen RMS data, we estimated that about 9.7 billion packs of cigarettes were sold in the United States in 2018.[19] If the information provided by the cigarette health warning on each cigarette package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits generated by the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$). 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 0.2 percent of the average cost of a pack of cigarettes, based on a national average cost of $6.27 per

[19] 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. 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 final rule, and only very slightly changes our break-even estimate, from about $0.010 annually to $0.009 annually.

pack.[20] 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.

Distributional Effects

Pictorial cigarette warnings have been shown to be more noticeable than text-only warnings across socioeconomic categories including race/ethnicity, income, and education [Ref. 53]. A study evaluating the readability of the current warnings found that "each of the four cigarette warnings require[s] a reading level typical of college students or college graduates" [Ref. 57]. Less educated adults and adolescents may find that health warnings with concordant pictures, such as the ones in the final required warnings, help in understanding 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. 10, 11]. This rule will increase understanding among these diverse populations of the negative health consequences of smoking and thereby reduce the disparities found in consumer understanding about the harms of smoking.

This final 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 could lead to a decline in cigarette smoking.[21] We consider that possibility not to justify the rule but for

[20] 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.

[21] 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. 1, 2, 3,4]. The outcomes examined in these studies contribute to understanding potential willingness-to-pay estimates that could be calculated based on the final rule; for more information on the

purposes of the distributional 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,[22] we estimate that of this amount only approximately $436 million consists of imported cigarettes, or less than one percent of the total cigarettes consumed (2018$). Regardless of manufacturing location, cigarette products commercially distributed in the U.S. will be required to include the cigarette health warnings required by this final rule. However, this final rule will 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 final 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[23] of the administrative labor cost of a

willingness-to-pay concept, see OMB Circular A-4, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.

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

[23] 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)

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.

Table 8. Sensitivity Analysis: Using a Different Method to 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	$158	$542	$1,224
Total Administrative Costs	$483,954	$1,658,921	$3,747,887
Recordkeeping Costs/UPC	$17	$34	$60
Total Recordkeeping Costs	$52,071	$104,142	$183,780
Total Costs	$536,025	$1,763,063	$3,931,667

Table 9 presents estimates of the total cost of the final 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 present value of the estimated total costs of the final rule ranges from $1.5 billion to $1.7 billion, with a mean estimate of $1.6 billion, using a three percent discount rate, and ranges from $1.1 billion to $1.3 billion, with a mean estimate of $1.2 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the final rule now ranges from $100 million to $116 million, with a mean estimate of $108 million, using a three percent discount rate, and ranges from $107 million to $125 million, with a mean estimate of $115 million, using a seven percent discount rate (2018$).

The difference in the estimated total cost of the final 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 $9.6 million and $13.5 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 $0.9 million larger than in the primary analysis, regardless of the discount rate used (2018$).

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.

Table 9. Sensitivity Analysis: Estimated Total Cost of the Final 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	$368.3	$419.4	$471.4
2	$24.1	$25.3	$27.5
3	$24.1	$25.3	$27.5
4	$243.6	$257.3	$272.0
5	$24.1	$25.3	$27.5
6	$24.1	$25.3	$27.5
7	$226.3	$239.0	$252.8
8	$24.1	$25.3	$27.5
9	$24.1	$25.3	$27.5
10	$210.3	$222.2	$235.0
11	$24.1	$25.3	$27.5
12	$24.1	$25.3	$27.5
13	$195.7	$206.7	$218.6
14	$24.1	$25.3	$27.5
15	$24.1	$25.3	$27.5
16	$182.1	$192.4	$203.6
17	$24.1	$25.3	$27.5
18	$24.1	$25.3	$27.5
19	$169.7	$179.2	$189.7
20	$24.1	$25.3	$27.5
Present Value			
3%	$1,489.1	$1,601.3	$1,727.4
7%	$1,130.1	$1,221.2	$1,322.4
Annualized Amount			
3%	$100.09	$107.63	$116.11
7%	$106.67	$115.28	$124.82

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 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 $0.01 (for every pack sold annually nationwide), then the benefits generated by the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

Analysis of Regulatory Alternatives to the Final Rule

We consider four regulatory alternatives to the final rule. First, we present an otherwise identical rule with extended compliance periods of nine months and 33 months from the effective date of the final rule. Second, we present an otherwise identical rule requiring one of up to nine new cigarette health warnings, and, lastly, an otherwise identical rule requiring that one of up to 13 new cigarette health warnings appear on cigarette packages and in cigarette advertisements. We include the final regulatory option to compare the estimated costs and break-even calculation of this FRIA with the costs and break-even calculation estimated in the proposed RIA, published August 2019. We estimate costs and do a break-even calculation for these alternatives below.

1. Compliance Period of Nine Months from Effective Date of Final Rule

A compliance period of nine months from the effective date 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. All other assumptions remain unchanged from the primary analysis. Table 10 shows the total cost of a major cigarette labeling change that reflects both a nine-month compliance period and the assumption that each cigarette UPC would require 11 gravure printing cylinder sets, one set for each cigarette health warning label (11 warnings per UPC). We estimate total labeling costs associated with the final rule under this regulatory option range from $240 million to $309 million, with a mean estimate of $275 million (2018$).

Table 10. Cost of a Major Cigarette Label Change if the Compliance Date is 9 Months from the Effective Date of the Final Rule (in 2018$)

	Low	**Mean**	**High**
Label Design Costs			
# Uncoordinated UPCs	2,392	2,392	2,392
Labor Costs ($/UPC)	$6,860	$9,883	$12,906
Material Costs ($/UPC)	$74,252	$83,076	$91,901
Recordkeeping Costs ($/UPC)	$67	$92	$116
Total Costs ($/UPC)	$81,179	$93,051	$104,923
Total Label Design Costs for Uncoordinated UPCs ($)	$194,179,432	$222,577,348	$250,975,264
# Coordinated UPCs	$671	$671	$671
Labor Costs ($/UPC)	$1,354	$2,207	$3,059
Material Costs ($/UPC)	$67,502	$75,524	$83,546

	Low	Mean	High
Recordkeeping Costs ($/UPC)	$34	$47	$60
Total Costs ($/UPC)	$68,890	$77,777	$86,665
Total Label Design Costs for Coordinated UPCs ($)	$46,224,880	$52,188,599	$58,152,318
TOTAL LABEL DESIGN COSTS ($)	$240,404,312	$274,765,947	$309,127,582
Inventory Costs			
# Discarded Labels	0	0	0
Cost Per Discarded Label ($/Label)	$0.032	$0.035	$0.037
TOTAL INVENTORY COSTS ($)	$0	$0	$0
TOTAL COSTS	$240,404,312	$274,765,947	$309,127,582

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. Compliance date is nine months from the effective date 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. 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 final rule if the compliance date is nine months from the effective date of the final rule is presented in Table 11. The present value of the estimated total costs of the final rule ranges from $1.4 billion to $1.6 billion, with a mean estimate of $1.5 billion, using a three percent discount rate, and ranges from $1 billion to $1.2 billion, with a mean estimate of $1.1 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the final rule ranges from $93 million to $105 million, with a mean estimate of $99 million, using a three percent discount rate, and ranges from $98 million to $110 million, with a mean estimate of $104 million, using a seven percent discount rate (2018$). If the compliance period were extended beyond nine months, the estimated total cost of the final rule would decrease further because more label changes would be able to be coordinated with previously scheduled label changes.

Table 11. Estimated Total Cost of the Final Rule if the Compliance Date is 9 Months from the Effective Date of the Final Rule (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$264.5	$299.2	$334.0
2	$24.1	$24.4	$24.9
3	$24.1	$24.4	$24.9
4	$243.5	$256.4	$269.4
5	$24.1	$24.4	$24.9
6	$24.1	$24.4	$24.9
7	$226.2	$238.1	$250.1
8	$24.1	$24.4	$24.9
9	$24.1	$24.4	$24.9
10	$210.3	$221.3	$232.4
11	$24.1	$24.4	$24.9
12	$24.1	$24.4	$24.9
13	$195.6	$205.8	$216.0
14	$24.1	$24.4	$24.9
15	$24.1	$24.4	$24.9
16	$182.1	$191.5	$201.0
17	$24.1	$24.4	$24.9
18	$24.1	$24.4	$24.9
19	$169.6	$178.3	$187.1
20	$24.1	$24.4	$24.9
Present Value			
3%	$1,387.6	$1,472.0	$1,557.5
7%	$1,032.5	$1,100.2	$1,168.7
Annualized Amount			
3%	$93.3	$98.9	$104.7
7%	$97.5	$103.9	$110.3

Notes: Compliance date is nine months after the effective date 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 $0.01 (for every pack sold annually nationwide), then the benefits generated by the final rule with a compliance date of nine months from the effective date of the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

2. Compliance Period of 33 Months from Effective Date of Final Rule

A compliance period of 33 months from the effective date of the final rule (e.g., providing affected manufacturers a total of four years to comply with the requirements in the

final rule) would reduce the one-time costs even further because the number of UPCs that can be coordinated with a previously scheduled label change increases over time. The FDA's Labeling Cost model assumes that with a total of four years to comply, 100 percent of branded tobacco and 51 percent of private label products can coordinate label changes with previously scheduled label changes. Identical to the alternative described above, rush charges for the label design are eliminated and discarded inventory costs are eliminated. All other assumptions remain unchanged from the primary analysis. Table 12 shows the total cost of a major cigarette labeling change that reflects both a 33-month compliance period and the assumption that each cigarette UPC would require 11 gravure printing cylinder sets, one set for each cigarette health warning label (11 warnings per UPC). We estimate total labeling costs associated with the final rule under this regulatory option range from $211 million to $266 million, with a mean estimate of $239 million (2018$).

Table 12. Cost of a Major Cigarette Label Change if the Compliance Date is 33 Months from the Effective Date of the Final Rule (in 2018$)

	Low	Mean	High
Label Design Costs			
# Uncoordinated UPCs	27	27	27
Labor Costs ($/UPC)	$6,860	$9,883	$12,906
Material Costs ($/UPC)	$74,252	$83,076	$91,901
Recordkeeping Costs ($/UPC)	$67	$92	$116
Total Costs ($/UPC)	$81,179	$93,051	$104,923
Total Label Design Costs for Uncoordinated UPCs ($)	$2,227,543	$2,553,312	$2,879,081
# Coordinated UPCs	3,036	3,036	3,036
Labor Costs ($/UPC)	$1,354	$2,207	$3,059
Material Costs ($/UPC)	$67,502	$75,524	$83,546
Recordkeeping Costs ($/UPC)	$34	$47	$60
Total Costs ($/UPC)	$68,890	$77,777	$86,665
Total Label Design Costs for Coordinated UPCs ($)	$209,118,327	$236,097,801	$263,077,274
TOTAL LABEL DESIGN COSTS ($)	$211,345,871	$238,651,113	$265,956,355
Inventory Costs			
# Discarded Labels	0	0	0
Cost Per Discarded Label ($/Label)	$0.03	$0.03	$0.04
TOTAL INVENTORY COSTS ($)	$0	$0	$0
TOTAL COSTS	$211,345,871	$238,651,113	$265,956,355

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.

	Low	Mean	High

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. Compliance date is 33 months from the effective date 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. 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 final rule if the compliance date is 33 months from the effective date of the final rule is presented in Table 13. The present value of the estimated total costs of the final rule ranges from $1.3 billion to $1.5 billion, with a mean estimate of $1.4 billion, using a three percent discount rate, and ranges from $942 million to $1.1 billion, with a mean estimate of $1 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the final rule ranges from $85 million to $102 million, with a mean estimate of $94 million, using a three percent discount rate, and ranges from $89 million to $107 million, with a mean estimate of $98 million, using a seven percent discount rate (2018$).

Table 13. Estimated Total Cost of the Final Rule if the Compliance Date is 33 Months from the Effective Date of the Final Rule (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$235.41	$263.09	$290.84
2	$24.06	$24.44	$24.89
3	$24.06	$24.44	$24.89
4	$218.44	$243.89	$269.41
5	$24.06	$24.44	$24.89
6	$24.06	$24.44	$24.89
7	$203.11	$226.59	$250.14
8	$24.06	$24.44	$24.89
9	$24.06	$24.44	$24.89
10	$189.00	$210.65	$232.38
11	$24.06	$24.44	$24.89
12	$24.06	$24.44	$24.89
13	$176.00	$195.97	$216.02
14	$24.06	$24.44	$24.89
15	$24.06	$24.44	$24.89
16	$164.02	$182.45	$200.96
17	$24.06	$24.44	$24.89
18	$24.06	$24.44	$24.89
19	$152.99	$169.99	$187.08

	Non-Discounted		
t	**Low**	**Mean**	**High**
20	$24.06	$24.44	$24.89
Present Value			
3%	$1,268.40	$1,391.45	$1,515.63
7%	$942.19	$1,034.85	$1,128.31
Annualized Amount			
3%	$85.26	$93.53	$101.87
7%	$88.94	$97.68	$106.50

Notes: Compliance date is nine months after the effective date 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 $0.01 (for every pack sold annually nationwide), then the benefits generated by the final rule with a compliance date of 33 months from the effective date of the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

The FDA Labeling Cost Model assumes that with a compliance period of 45 months (or more) from the effective date of the final rule, all labels could be coordinated with previously scheduled label changes. Therefore, if the compliance period were extended beyond 33 months, the estimated total cost of the final rule would decrease further because more label changes would be able to be coordinated with previously scheduled label changes.

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. In addition, we received public comments from industry stating that total costs may be even lower due to components of the printing process that cannot be adjusted in the model. 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 gravure printing cylinder sets, one set for each cigarette health warning label (nine warnings per UPC). We estimate total initial labeling costs associated with this final rule under this

regulatory option range from $286 million to $372 million, with a mean estimate of $329 million (2018$).

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)	$9,603	$13,836	$18,069
Material Costs ($/UPC)	$85,059	$95,171	$105,282
Recordkeeping Costs ($/UPC)	$94	$129	$163
Total Costs ($/UPC)	$94,756	$109,135	$123,514
Total Label Design Costs for Uncoordinated UPCs ($)	$267,117,164	$307,651,565	$348,185,966
# Coordinated UPCs	244	244	244
Labor Costs ($/UPC)	$1,354	$2,207	$3,059
Material Costs ($/UPC)	$75,608	$84,596	$93,584
Recordkeeping Costs ($/UPC)	$34	$47	$60
Total Costs ($/UPC)	$76,996	$86,850	$96,703
Total Label Design Costs for Coordinated UPCs ($)	$18,787,024	$21,191,278	$23,595,532
TOTAL LABEL DESIGN COSTS ($)	$285,904,188	$328,842,843	$371,781,498
Inventory Costs			
# Discarded Labels	11,611,468	11,611,468	11,611,468
Cost Per Discarded Label ($/Label)	$0.03	$0.03	$0.04
TOTAL INVENTORY COSTS ($)	$371,567	$400,596	$429,624
TOTAL COSTS	$286,275,755	$329,243,439	$372,211,122

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.

Regarding labeling costs related to planned future labeling changes, per-UPC recurring labeling costs range from $55,389/UPC to $69,965/UPC with a mean estimate of $62,673/UPC (2018$). The total cost of the final 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 15. Under such a scenario, the present value of the estimated total costs of the final rule ranges from $1.2 billion to $1.5 billion, with a mean estimate of $1.3 billion, using a three percent discount rate, and ranges from $916 million to $1.1 billion, with a mean estimate of $1 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the final rule ranges from $81 million to $97 million, with a mean estimate of $89 million, using a three percent discount rate, and ranges from $87 million to $105 million, with a mean estimate of $96 million, using a seven percent discount rate (2018$).

Table 15. Estimated Total Cost of the Final Rule with 9 Warning Labels (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$310.3	$353.7	$397.1
2	$24.1	$24.4	$24.9
3	$24.1	$24.4	$24.9
4	$180.3	$201.3	$222.3
5	$24.1	$24.4	$24.9
6	$24.1	$24.4	$24.9
7	$168.0	$187.3	$206.7
8	$24.1	$24.4	$24.9
9	$24.1	$24.4	$24.9
10	$156.7	$174.5	$192.4
11	$24.1	$24.4	$24.9
12	$24.1	$24.4	$24.9
13	$146.2	$162.7	$179.2
14	$24.1	$24.4	$24.9
15	$24.1	$24.4	$24.9
16	$136.6	$151.8	$167.0
17	$24.1	$24.4	$24.9
18	$24.1	$24.4	$24.9
19	$127.7	$141.7	$155.8
20	$24.1	$24.4	$24.9
Present Value			
3%	$1,203.0	$1,324.8	$1,447.7
7%	$916.2	$1,012.1	$1,108.8
Annualized Amount			
3%	$80.9	$89.0	$97.3
7%	$86.5	$95.5	$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.

	Non-Discounted		
t	**Low**	**Mean**	**High**

If the information provided by the cigarette health warning on each package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits generated by the final rule under this regulatory option would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

4. Thirteen Cigarette Health Warnings

The final regulatory alternative is an otherwise identical rule requiring that one of up to 13 new cigarette health warnings appear on cigarette packages and in cigarette advertisements. We include the final regulatory option to compare the estimated costs and break-even calculation of this FRIA with the costs and break-even calculation estimated in the proposed RIA, published August 2019. This alternative would increase both the initial and recurring labeling costs of this rule through increased material costs. Table 16 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 13 gravure printing cylinder sets, one set for each cigarette health warning label (13 warnings per UPC). We estimate total initial labeling costs associated with this final rule under this regulatory option range from $402 million to $516 million, with a mean estimate of $459 million (2018$).

Table 16. 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)	$9,603	$13,836	$18,069
Material Costs ($/UPC)	$122,863	$137,469	$152,074
Recordkeeping Costs ($/UPC)	$94	$129	$163
Total Costs ($/UPC)	$132,560	$151,433	$170,306
Total Label Design Costs for Uncoordinated UPCs ($)	$373,686,640	$426,889,627	$480,092,614
# Coordinated UPCs	244	244	244
Labor Costs ($/UPC)	$1,354	$2,207	$3,059
Material Costs ($/UPC)	$113,412	$126,894	$140,376
Recordkeeping Costs ($/UPC)	$34	$47	$60
Total Costs ($/UPC)	$114,800	$129,148	$143,495
Total Label Design Costs for Coordinated UPCs ($)	$28,011,200	$31,511,990	$35,012,780
TOTAL LABEL DESIGN COSTS ($)	$401,697,840	$458,401,617	$515,105,394
Inventory Costs			

	Low	Mean	High
# Discarded Labels	11,611,468	11,611,468	11,611,468
Cost Per Discarded Label ($/Label)	$0.03	$0.03	$0.04
TOTAL INVENTORY COSTS ($)	$371,567	$400,596	$429,624
TOTAL COSTS	$402,069,407	$458,802,213	$515,535,018

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.

Regarding labeling costs related to planned future labeling changes, per-UPC recurring labeling costs range from $82,390/UPC to $103,374/UPC with a mean estimate of $92,882/UPC (2018$). The total cost of the final 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 13 is presented in Table 17. Under such a scenario, the present value of the estimated total costs of the final rule ranges from $1.6 billion to $1.9 billion, with a mean estimate of $1.8 billion, using a three percent discount rate, and ranges from $1.2 billion to $1.5 billion, with a mean estimate of $1.3 billion, using a seven percent discount rate (2018$). The estimated annualized cost of the final rule ranges from $107 million to $130 million, with a mean estimate of $118 million, using a three percent discount rate, and ranges from $115 million to $140 million, with a mean estimate of $127 million, using a seven percent discount rate (2018$).

Table 17. Estimated Total Cost of the Final Rule with 13 Warning Labels (in millions of 2018$)

	Non-Discounted		
t	**Low**	**Mean**	**High**
1	$426.1	$483.2	$540.4
2	$24.1	$24.4	$24.9
3	$24.1	$24.4	$24.9
4	$256.5	$286.5	$316.6
5	$24.1	$24.4	$24.9
6	$24.1	$24.4	$24.9

	Non-Discounted		
t	**Low**	**Mean**	**High**
7	$238.2	$265.8	$293.6
8	$24.1	$24.4	$24.9
9	$24.1	$24.4	$24.9
10	$221.3	$246.8	$272.4
11	$24.1	$24.4	$24.9
12	$24.1	$24.4	$24.9
13	$205.8	$229.3	$252.9
14	$24.1	$24.4	$24.9
15	$24.1	$24.4	$24.9
16	$191.4	$213.1	$234.9
17	$24.1	$24.4	$24.9
18	$24.1	$24.4	$24.9
19	$178.3	$198.3	$218.3
20	$24.1	$24.4	$24.9
Present Value			
3%	$1,591.8	$1,759.8	$1,929.0
7%	$1,216.4	$1,348.0	$1,480.3
Annualized Amount			
3%	$107.0	$118.3	$129.7
7%	$114.8	$127.2	$139.7

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 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.

If the information provided by the cigarette health warning on each package were valued at about $0.01 (for every pack sold annually nationwide), then the benefits generated by the final rule under this regulatory option would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018$).

Final 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 final rule, initial costs could represent between 2.3 and 32.6 percent of their annual receipts and recurring costs could represent from 0.1 to 2.7 percent of their annual receipts. Hence, we find that the final 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 Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

Description and Number of Affected Small Entities

This final rule affects 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.[24] 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 final rule are designated under the North American Industry Classification System (NAICS) as tobacco manufacturers (NAICS 312230). Most importers covered by this final rule are classified as tobacco and tobacco 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.[25] Using these classifications, 93 percent of tobacco manufacturers and tobacco and tobacco product merchant wholesalers are considered small businesses. Table 18 shows the SBA size thresholds for small businesses in each of these categories and the most comparable size categories available from the U.S. Census.[26] The

[24] 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.

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

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

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 final rule.

Table 18. 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%

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 will be incurred by small domestic cigarette manufacturers and importers as a result of the final 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.[27] Assuming

[27] 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.

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 $103 million and $131 million in initial costs and between $6.7 million and $7.0 million in recurring costs, to be incurred by small manufacturers and importers (2018$). If costs are distributed equally among the 55 small cigarette manufacturers and importers, then this implies initial costs of roughly $1.9 million to $2.4 million per small cigarette manufacturer or importer and recurring costs of about 0.12 million to $0.13 million per small cigarette manufacturer or importer (2018$). Based on 2012 U.S. Census Bureau Statistics of U.S. Businesses data, the most recent year for which receipts data are 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 $102 million per firm (those with 100 to 499 employees) (2018$),[28] 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 $65.2 million per firm (those with 20 to 99 employees) (2018$).[29] Thus, we estimate that initial costs for a small cigarette manufacturer or importer will represent between 2.3 percent (= $2.4 million / $102 million) and 42 percent (= $1.9 million / $4.5 million) of their annual receipts, and recurring costs will represent between 0.1 percent (= $127,000 / $102 million) and 2.7 percent (= $123,000 / $4.5 million) of their annual receipts.

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 adopt a compliance period for small manufacturers and importers. For example, if a compliance period were set for small manufacturers and importers at nine months after the effective date of the final rule, then for a small manufacturer or importer affected by the final rule, we estimate that initial labeling costs would represent between 1.7 percent and 30 percent of their annual receipts,

[28] 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".

[29] 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.

compared to 2.3 to 42 percent of annual receipts absent a compliance period (note that the recurring costs do not vary by compliance date and so would not change). An even further out compliance date reduces the initial labeling costs even more because more label changes can be coordinated with scheduled label changes. For instance, if a compliance period were set for small manufacturers and importers at 33 months after the effective date of the final rule, we estimate that initial labeling costs for a small manufacturer or importer would represent between 1.5 percent and 27 percent of their annual receipts.

One possible downside to adopting a compliance date for the small entities that comprise 93 percent of affected wholesales and importers, however, is that doing so could result in some cigarette products bearing updated warnings finalized in this rule and other cigarette products bearing the current 1984 Surgeon General's warnings for the length of the compliance period. As described throughout the final rule, the current 1984 Surgeon General's warnings on cigarette packages and in cigarette advertisements are inadequate and ineffective in communicating the health harms of smoking, and the larger pictorial warnings required by this rule are intended to be more effective in promoting greater public understanding of the negative health consequences of smoking. Adopting a compliance date for small entities that differs from the one for larger cigarette manufacturers, importers, distributors, and retailers would result in some cigarette packages and advertisements bearing the required warnings at different points in time, which could potentially create consumer confusion about the relative risk of those different cigarette products.

Another way to reduce the burden of the initial cost associated with changing cigarette labels would be to reduce the number of required warnings from 11 to nine. Reducing the number of warnings to nine decreases the average annualized value of costs discounted at 3 percent by $13 million per year (see Table 7 and Table 15). However, one downside to that approach is that the health information in two of the warnings would not be conveyed to the public. FDA undertook a rigorous science-based, iterative research process to develop and test new cigarette health warnings depicting the negative health consequences of smoking. As discussed in the preamble to the final rule, based on the results of FDA's consumer research studies, and the existing scientific literature on cigarette health warnings, FDA has concluded that the 11 final required warnings will advance the Government's interest of promoting greater public understanding of the negative health consequences of smoking.

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