DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products

Docket No. FDA-2024-N-5471

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

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this proposed rule is a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because businesses, including small businesses, would incur costs to comply with the proposed product standard, we find that the proposed 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 2023 threshold after adjustment for inflation is $183 million, using the 2023 Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in at least one year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

The summary of costs, benefits, and transfers is presented in Table 1. Benefits occur because the proposed rule would discourage people who do not use tobacco products from initiating combusted tobacco products and progressing to regular use and increase cessation or switching to potentially lower risk tobacco products among people who currently use covered combusted tobacco products and wish to quit. Lower prevalence of combusted tobacco product use would lead to reduced health consequences for people who formerly used combusted tobacco

products and those who were previously exposed to secondhand smoke. The main quantified benefits come from averted mortality and morbidity as a result of reduced prevalence for people who currently use combusted tobacco products, and reduced mortality from reduced exposure to secondhand smoke among people.[1, 2] We use the PHM output to estimate averted mortality and apply the value of a statistical life according to HHS guidance, while also requesting comment about our estimates (1). The morbidity estimates come from PHM output that evaluates the health difference for being in the state of smoking verse not smoking. Unquantified benefits include medical cost savings, productivity loss savings, reduced exposure to thirdhand smoke, and environmental impacts. We estimate that the present value of the quantified benefits over a 40-year time horizon ranges between $7.6 trillion and $33.2 trillion with a primary estimate of $30.6 trillion at a 2 percent discount rate. The primary annualized quantifiable benefits equal $1.1 trillion at a 2 percent discount rate.

As most of the benefits from avoided initiation among youth and young adults due to this proposed product standard are expected to fall outside of the 40-year time horizon of the main analysis, we present an extended analysis over a period beyond the 40-year time horizon to capture the impact on youth and young adults. The present value of quantified benefits, mostly attributable to youth and young adults, over this extended period range between $8.4 trillion and $19.7 trillion with a primary estimate of $19.1 trillion at a 2 percent discount rate. Additionally, we present the incidence of benefits for specific populations in the Distributional Effects section.

We expect this proposed rule, if finalized, to impose costs on industry to follow the product standard, on the broader economy to repurpose land, labor, and capital, on consumers impacted by the product standard, and on FDA to enforce this product standard. The tobacco market faces a one-time primary cost with a present value of $374 million at a 2 percent discount rate (low impact scenario estimate of $112 million to a high impact scenario estimate of $700 million) to read and understand the rule.[3] We use the PHM output on prevalence to estimate the baseline and policy market size. These estimates feed into cost estimates, such as lost producer surplus. Producers of combusted tobacco products incur a primary annualized producer surplus loss of $1.7 billion (low impact scenario of $0.2 billion and a high impact scenario of $2 billion) at a 2 percent discount rate. We expect that some manufacturers would reformulate their products to comply with this standard. We estimate a one-time reformulation cost with a present value of $0.6 billion (low impact scenario estimate of $8.8 billion to a high impact scenario

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[2] Please see our sensitivity analyses in Section II.M.5 and Section II.M.6 for a discussion of several additional sources of uncertainty that could result in the VSL approach underestimating or overestimating the benefits of the proposed rule.

[3] For the purposes of this PRIA, we use the population health model (PHM) to estimate impacts for a range of averted mortality and tobacco prevalence. The "high impact scenario", generally referred to as the upper bound, corresponds to the scenario where the policy has 95th percentile averted mortality projected by the PHM, which also corresponds with the lowest (5th percentile) post-policy combusted tobacco prevalence. For some costs (product reformulation, premarket submission, and review, and testing costs), the "upper bound" corresponds to the scenario with the fewest products and, thus, would reflect the lowest estimate of costs.

estimate of $0.04 billion). Manufacturers that reformulate would collectively incur a one-time cost to submit their new tobacco product for FDA review, estimated at a present value of $1 million at a 2 percent discount rate (low impact scenario estimate of $15 million to a high impact scenario estimate of $0.1 million). In addition, these manufacturers would also incur recurring costs to test the nicotine level of their products with a primary annualized estimate of $0.3 million (low impact scenario estimate of $1.9 million to a high impact scenario estimate of $0.1 million) at a 2 percent discount rate. We estimate a one-time cost for FDA to review submissions for new tobacco products at a present value of $1.0 million at a 2 percent discount rate (low impact scenario estimate of $15.3 million to a high impact scenario estimate of $0.1 million). The economy faces a one-time economic transition cost with a present value of $7.2 billion at a 2 percent discount rate (low impact scenario estimate of $4.3 billion to a high impact scenario estimate of $9.1 billion) to reallocate productive resources (such as labor and capital) currently devoted to the manufacture of normal nicotine content (NNC) covered combusted tobacco products to other tobacco products or to non-tobacco products. We estimate transition cost based on average industry capital expenditures and literature on the cost of labor transition. Consumers of NNC covered combusted tobacco products would face a one-time search cost with a present value of $1.4 billion at a 2 percent discount rate (low impact scenario estimate of $0.46 billion to a high impact scenario estimate of $2.8 billion) to find other tobacco products or nicotine replacement therapy as a replacement for the prohibited NNC products. We estimate one-time withdrawal costs for consumers who quit tobacco products, with a primary estimate present value of $1.4 billion at a 2 percent discount rate (low impact scenario estimate of $0.02 billion to a high impact scenario estimate of $8.9 billion). We estimate additional costs associated with FDA enforcement of the product standard to range from an annualized value of $3.3 million to $7 million at a 2 percent discount rate. Unquantified costs may include changes in consumer surplus for some people who smoke NNC products, including potential utility changes for consumers who switch from NNC to very low nicotine content (VLNC) combusted tobacco products. The present value of the costs over a 40-year time horizon has a primary estimate of $58 billion (low impact scenario estimate of $19.3 billion to a high impact scenario of $76.2 billion) at a 2 percent discount rate. The primary estimates for the annualized costs are $2.1 billion at a 2 percent discount rate.

In addition to benefits and costs, this rule would cause transfers from the Federal Government, state governments, and from firms to consumers, who in turn would spend this money in other sectors of the economy (including savings), in the form of reduced revenue and tax revenue. We also estimate transfers between or within firms to cover shifts in user fee obligation. The primary estimate for the annualized transfers from the Federal Government to consumers, in the form of reduced excise tax, ranges from $1.4 billion to $4.3 billion, with a primary estimate of $4.1 billion at a 2 percent discount rate. The primary estimate for the annualized transfers from state governments to consumers, in the form of reduced excise tax, ranges from $2.8 billion to $8.9 billion, with a primary estimate of $8.4 billion at a 2 percent discount rate. The primary estimate for the annualized transfers from the firms to consumers, in

the form of reduced revenue, is $20.0 billion at a 2 percent discount rate (low impact scenario of $6.2 billion; high impact scenario of $17.6 billion). The primary estimate for the annualized user fee obligation shifted from combusted tobacco products to noncombusted tobacco products has a range from $26.3 million to $461.1 million with a primary estimate of $332.6 million at a 2 percent discount rate. Transfers are summarized in Table 1.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (Millions of 2023 Dollars over a 40-Year Time Horizon)

Category	*Primary Estimate*	*Low Estimate*	*High Estimate*	*Dollar Year*	*Discount Rate*	*Time Horizon*	*Notes*
BENEFITS							
Annualized monetized benefits	$1,097,053	$273,521	$1,190,582	2023	2%	2025 – 2064 (40 years)	See footnote [4]
Unquantified benefits	Medical cost savings, productivity loss savings, reductions in smoking-related fires (excluding mortality), reduced litter, and other associated harms to the environment						
COSTS							
Annualized monetized costs	$2,077	$690	$2,729	2023	2%	2025 – 2064 (40 years)	
Unquantified costs	Changes in consumer surplus for some people who smoke normal nicotine content combusted tobacco products, including potential utility changes for consumers who switch from NNC to VLNC combusted tobacco products.						
TRANSFERS							
Annualized monetized Federal	$4,092	$1,386	$4,313	2023	2%	2025 – 2064 (40 years)	

[4] FDA notes that these results hinge on an expert elicitation in which the experts were provided peer reviewed literature on VLNC and NNC cigarette use in experiments. The literature and the expert elicitation specifically referenced the nicotine level of 0.4mg/g. However, due to the nature of variation in agricultural products, in 22nd Century Group, Inc.'s modified risk tobacco product applications, the company reported that after 9 years of sampling by the company, the average nicotine content of its genetically engineered VLNC tobacco is 0.6 mg nicotine per gram of total tobacco, with a range of 0.4 to 0.7 mg nicotine per gram of total tobacco. It is likely that the Quest and SPECTRUM Nicotine Research Cigarettes, used throughout the scientific literature that referred to the 0.4 mg nicotine per gram, also contained between 0.4 to 0.7 mg nicotine per gram of total tobacco (262). This suggests the literature the experts reviewed studied cigarettes in the range of 0.4-0.7mg/g as opposed to only 0.4mg/g. Therefore, the results of the expert elicitation are still applicable to a nicotine level of 0.7mg/g. Given our undated understanding of the true nicotine level in the available VLNC cigarettes, the forthcoming updated expert elicitation will ask about 0.7 mg/g. For reference, Nicotine content in the top 100 cigarette brands (2017) is 17.2 mg/g (261).

budgetary transfers							
Bearers of transfer gain and loss?	Transfers of Excise Tax Revenues from Federal Governments to Consumers						
Annualized monetized State budgetary transfers	$8,414	$2,848	$8,877	2023	2%	2025 – 2064 (40 years)	
Bearers of transfer gain and loss?	Transfers of Excise Tax Revenues from State Governments to Consumers						
Other annualized monetized transfers	$19,964	$6,235	$17,603	2023	2%	2025 – 2064 (40 years)	
Bearers of transfer gain and loss?	Transfers of Revenues from Tobacco Firms to Consumers						
Other annualized monetized transfers	$333	$26	$461	2023	2%	2025 – 2064 (40 years)	
Bearers of transfer gain and loss?	Transfers from User Fees Owed by Combusted Tobacco Firms to User Fees Owed by Noncombusted Tobacco Firms						
NET BENEFITS							
Annualized monetized net benefits	$1,094,976	$272,831	$1,187,853	2023	2%	2025 – 2064 (40 years)	

Category	*Effects*	*Notes*
Effects on State, local, or Tribal governments	Significant transfer of tax revenues for state governments. Potential transfer of tax revenue for local and tribal governments.	
Effects on small businesses	Significant revenue reductions and compliance costs for small, combusted tobacco product manufacturers. We expect most small, combusted manufactures would shut down or switch industries.	
Effects on wages	No significant wage impacts.	

Effects on growth	Anticipated growth in the noncombusted tobacco sector.	

We request comment on our estimates of benefits, costs, and transfers of this proposed rule.

C. Terminology

In Table 2, we discuss several terms used in this preliminary regulatory impact analysis and in Table 3 we define abbreviations used through this document.

Table 2. Terms Used in the Preliminary Regulatory Impact Analysis

Term	Description
We, our, us	We use these terms to refer to the United States Food and Drug Administration.
ENDS	Electronic Nicotine Delivery Systems (ENDS) that deliver aerosolized e-liquid when inhaled. Generally, ENDS include e-cigarettes and vape pens.
Cigarette	As defined in Section 900(3) of the Federal Food, Drug, & Cosmetic Act (FD&C Act) (21 U.S.C. 387(3)) and in this rule, the term "cigarette" (1) Means a product that: (i) is a tobacco product and (ii) meets the definition of the term "cigarette" in Section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)); and (2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco. However, for purposes of this document, FDA uses the term "cigarettes" when referring to combusted cigarettes, unless specifically stated otherwise. In general, the term is not meant to include any noncombusted tobacco products that meet the definition of cigarette in Section 900(3).
Cigarette Tobacco	As defined in Section 900(4) of the FD&C Act (21 U.S.C. 387(4)) and in this rule, the term "cigarette tobacco" means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under chapter IX of the FD&C Act also apply to cigarette tobacco.
Component or Part	FDA defined "component or part" in the Final Deeming Rule, which amended 21 CFR 1140.3. We have reiterated that definition in this rule as it applies to tobacco products within the scope of the proposed rule.

	"Component or part" in the context of part 1160 means any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product.
Roll-Your-Own (RYO) Tobacco	As defined in Section 900(15) of the FD&C Act (21 U.S.C. 387(15)) and in this rule, the term "roll-your-own tobacco" means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.
Tobacco Product	FDA generally defines tobacco products as defined in Section 201(rr) of the FD&C Act, and in this rule, the term "tobacco product" means any product that is made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that is: a drug under Section 201(g)(1) of the FD&C Act; a device under Section 201(h) of the FD&C Act; a combination product described in Section 503(g) of the FD&C Act (21 U.S.C. 353(g)); or a food under Section 201(f) of the FD&C Act if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.
Modeled Tobacco Products	The two types of tobacco products simulated directly by the Population Health Model (PHM) – (1) Cigarettes (including cigarette and RYO tobacco), and (2) noncombusted tobacco products (i.e., smokeless tobacco, ENDS, and HTPs).
Heated Tobacco Products that are Cigarettes	Heated tobacco products that meet the definition of a cigarette in the FD&C Act.
Covered tobacco product	The tobacco product categories covered by this proposed rule are cigarettes (other than HTPs and other noncombusted tobacco products that meet the definition of a cigarette), cigarette tobacco, roll-your-own (RYO) tobacco, cigars (including little cigars, cigarillos, and large cigars, but excluding premium cigars), and pipe tobacco (other than waterpipe tobacco).
Impacted tobacco products	Covered tobacco products and products that are expected to have increased consumption post policy (smokeless and ENDS).

Cigars	Within this document, "cigar" means covered or non-premium cigars.
Combusted tobacco products	Within this document, the term "combusted tobacco products" includes cigarettes (other than HTPs that meet the definition of a cigarette), cigarette tobacco, roll-your-own (RYO) tobacco, cigars (including little cigars, cigarillos, and large cigars, but excluding premium cigars), and pipe tobacco (other than waterpipe tobacco).
Combusted tobacco market	Within this document, the combusted tobacco market is the total market for all combusted tobacco products as defined above (e.g., excluding premium cigars).
Total tobacco market	The total tobacco market is defined as the market for all tobacco products excluding premium cigars.
Noncombusted tobacco products	Tobacco products that are not combusted tobacco products, such as smokeless tobacco (snus, snuff, and chewing tobacco), ENDS, and HTPs.
Premium cigars	A type of cigar that: • is wrapped in whole tobacco leaf; • contains a 100 percent leaf tobacco binder; • contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); • is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); • has no filter, nontobacco tip, or nontobacco mouthpiece; • does not have a characterizing flavor other than tobacco; • contains only tobacco, water and vegetable gum with no other ingredients or additives; and weighs more than 6 pounds per 1,000 units.
Population Health Model	FDA has developed a population health model that projects the impact of changes in tobacco product initiation, cessation, switching, and dual use on tobacco use prevalence, morbidity, and mortality in the United States, considering two types of tobacco products. See Center for Tobacco Products (2) for additional information.

Table 3. Abbreviations and Acronyms Used in the Preliminary Regulatory Impact Analysis

Abbreviation/Acronym	What It Means
AI/AN	American Indian/Alaska Native
ACES	U.S. Census Bureau, Annual Capital Expenditure Survey
BLS	Bureau of Labor Statistics

Abbreviation/Acronym	What It Means
CBO	Congressional Budget Office
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CPSC	U.S. Consumer Product Safety Commission
CTP	U.S. FDA, Center for Tobacco Products
EMI	Euromonitor International
ENDS	Electronic Nicotine Delivery Systems
E.O.	Executive Order
E.U.	European Union
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FR	The U.S. Federal Register
FTE	Full-time Equivalent (Employee)
GAO	U.S. Government Accountability Office
HHS	U.S. Department of Health and Human Services
HTP	Heated Tobacco Product
IRS	Internal Revenue Service
LGBTQI+	Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, and Other Sexual and Gender Minority Populations[5]
NAICS	North American Industry Classification System
NCHS	U.S. CDC, National Center for Health Statistics
NHANES	U.S. CDC, National Health and Nutrition Examination Survey
NHIS	U.S. CDC, National Health Interview Survey
NIDA	U.S. NIH, National Institute on Drug Abuse
NIH	National Institutes of Health
NNC	Normal Nicotine Content
NPRM	Notice of Proposed Rulemaking also referred to as 'the preamble'
NRT	Nicotine Replacement Therapy
NSDUH	U.S. Substance Abuse and Mental Health Services
NYTS	U.S. National Youth Tobacco Survey
PATH	U.S. Population Assessment of Tobacco and Health
PHM	Population Health Model
PRAMS	U.S. CDC, Pregnancy Risk Assessment Monitoring System
PRIA	Preliminary Regulatory Impact Analysis (This document)
RYO	Roll-Your-Own Tobacco
QALYs	Quality-Adjusted Life Years
QALDs	Quality-Adjusted Life Days
SBA	U.S. Small Business Administration

[5] Throughout this document, FDA uses the term "LGBTQI+" broadly when referring to lesbian, gay, bisexual, transgender, and queer (and other) communities. When we describe findings from the published literature, we refer specifically to the groups that are studied. For example, some authors examine tobacco-related outcomes for members who identify as lesbian, gay, bisexual, or transgender (LGBT) only; as such, the data are limited to those who identify as LGBT, and authors interpret the findings for those specific groups.

Abbreviation/Acronym	What It Means
SE	Substantial Equivalence
SGR	Surgeon General's Report
SIDS	Sudden Infant Death Syndrome
SLT	Smokeless Tobacco Product
TCA	The Family Smoking Prevention and Tobacco Control Act. (Pub.
TPMP	Tobacco Product Manufacturing Practice
TRLM NG	The Tobacco Registration and Listings Module Next Generation
TTB	Alcohol and Tobacco Tax and Trade Bureau
TUS-CPS	Tobacco Use Supplement to the Current Population Survey
UPC	Universal Product Code
U.S.	United States
VLNC	Very Low Nicotine Content
VSL	Value of a Statistical Life

II. Preliminary Economic Analysis of Impacts

A. Background

Cigarettes are responsible for the greatest amount of tobacco-related death and disease in the United States. Each year, 480,000 people die prematurely from a smoking-attributable disease (3). Cigarette smoking is causally linked with increased risk of at least 12 cancers (e.g., oral, esophageal, lung), heart disease, and many other negative health outcomes (3). The mortality rate among people who currently smoke cigarettes is 2 to 3 times as high as that among individuals who never smoked (4). It is estimated that individuals are living with a combined 14 million major smoking-related conditions in the United States (5), and the U.S. Surgeon General has reported that about 30 individuals will suffer from at least one smoking-related disease for every person that dies from smoking each year (6). Nicotine is the primary addictive constituent in tobacco products and can be delivered through a variety of products along a continuum of risk, with combusted cigarettes at the most harmful end of this continuum.

Nicotine is the primary addictive chemical in tobacco (3), and numerous Surgeon General's Reports (SGRs) from 1988 through 2020 have documented the many ways in which nicotine affects the brain and nicotine addiction drives smoking behavior. The 1988 SGR established: "1) Cigarettes and other forms of tobacco are addicting; 2) Nicotine is the drug in tobacco that causes addiction; and 3) The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine" (7). More recently, the 2020 SGR reported that "[n]icotine addiction is now increasingly emphasized as a main driver of both the initiation and continuation of smoking" (6). The role of nicotine addiction in driving cigarette use and cigarette sales is unambiguous.

Cigarette companies have engaged in extensive research to understand how nicotine operates within the human body and then designed their cigarettes to precisely control nicotine delivery and provide nicotine doses to create and sustain addiction.[6] These companies sought to identify the "optimum" dose needed to "satisfy" people who smoke cigarettes and, thereby, assure their continued smoking.[7] This proposed product standard would seek to set a maximum nicotine level requirement such that tobacco products covered by the proposed rule—cigarettes (other than heated tobacco products (HTPs) and other noncombusted tobacco products that meet the definition of a cigarette), cigarette tobacco, roll-your-own (RYO) tobacco, cigars (other than premium cigars), and pipe tobacco (other than waterpipe tobacco)—would no longer be able to create and sustain this addiction among people who smoke cigarettes and use certain other combusted tobacco products.

The proposed product standard would limit the addictiveness of the most toxic and widely used tobacco products, which would have significant public health benefits for all age groups. Researchers estimate that each year, only between 5.4 and 5.6 percent of people who smoked cigarettes successfully quit for good (8). Lowering nicotine of cigarettes and certain other combusted tobacco products to minimally addictive or nonaddictive levels would improve the ability of people who use combusted products to successfully quit using these products. It also would prevent experimenters (mainly youth) from moving beyond experimentation and progressing to regular use. Furthermore, it is well-established that secondhand tobacco smoke causes premature death and disease in children and in adults who do not smoke (9). Rendering cigarettes and certain other combusted tobacco products minimally addictive or nonaddictive would address the principal reason that people who smoke cigarettes have difficulty quitting smoking. If this proposed product standard is finalized, people who use cigarettes and certain other combusted tobacco products covered by this rule would be unable to obtain enough nicotine from those tobacco products to sustain addiction no matter how they smoked the products (10; 11; 12), making it easier for people who currently smoke cigarettes to make more successful quit attempts.

As stated throughout the notice of proposed rulemaking (NPRM), in the event that a nicotine product standard includes solely cigarettes within its scope, FDA expects that, to maintain their nicotine dependence, some number of people who are addicted to cigarettes would likely migrate to other similar combusted tobacco products (or engage in dual use with such products) after the product standard goes into effect, reducing the benefits of the standard. Therefore, to maximize the public health benefits, we are proposing to cover the following products under this proposed product standard: Cigarettes (other than HTPs that meet the definition of a cigarette and other noncombusted tobacco products that meet the definition of a cigarette), cigarette tobacco, RYO tobacco, cigars (including little cigars, cigarillos, and large

[6] *United States* v. *Philip Morris USA, Inc. et al.*, 449 F.2d 1, 307-309 (D.D.C. 2006).
[7] 449 F.Supp.2d at 309-11

cigars, but excluding premium cigars), and pipe tobacco (other than waterpipe tobacco). FDA requests comments, data, and research regarding this proposed scope.

B. Need for Federal Regulatory Action

1. Discussion of Tobacco Market Failure

This proposed rule addresses an inefficiency in the market caused by information asymmetry, by externalities, and by a behavioral bias, specifically an internality decision-making bias. An internality is defined as a "within-person externality…which occurs when a person underweighs or ignores a consequence of [their] own behavior for [themselves]" (13). This internality occurs insofar as the market price does not reflect the full health cost of using tobacco products because the addictiveness of tobacco products and the fact that most people who use tobacco products become addicted as youth or young adults causes consumers to underestimate the cost of negative health effects that may be known in an abstract sense but lack the immediate salience of the money and time associated with current consumption. Additionally, one of the major conclusions of the 2014 SGR was that the tobacco epidemic "was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes" (3 p. 7). The true or full price of smoking would include the value a fully informed and nonaddicted rational consumer would place on the negative health effects of consumption. However, consumers make purchasing decisions based on market prices for tobacco products that do not fully reflect the full social costs of consumption, including impacts to people who do not use tobacco products. This results in consumer choices that produce market failures and social welfare losses. Therefore, policy interventions, such as this proposed rule, reduce the gap between the market cost and the full social cost and enhance social welfare.

The psychology and economics literatures suggest several sources of internality-related market failures. As discussed in Gruber's 2002 paper on smoking internalities, internalities refer to a cost that consumers impose on themselves by taking actions that are not in their own best interest and can lead to feelings of regret (14). Many people who smoke cigarettes have varying preferences, either over time or at the same time, making it difficult to determine the true preferences underlying their consumption choices. For example, Schelling (15) notes that one "self" wants to stop smoking for health reasons, while the other "self" wants to continue smoking to avoid withdrawal symptoms, thus leading to inconsistent preferences at the same time. Nicotine dependence and initiation in adolescence complicates the notion of consumer preference in this context. Myopia and time inconsistency may be sources of internalities. Myopia, or a strong present bias, can explain the use of a product that yields utility in the present but whose continued use leads to health problems later. For instance, decisions made by people who smoke cigarettes at early stages of use may impose significant costs on their future selves. Time inconsistency exists when consumers use lower rates of discounting 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. Time inconsistency is particularly relevant in the case of tobacco products, for which the overwhelming majority of people who initiate tobacco product use in adolescence, when their still-developing brains tend to assess risks and rewards differently. Additional literature further explores internalities and other sources of market failure associated with consumption of addictive products (16; 17; 18).

Nicotine is the primary addictive chemical in tobacco (3), and numerous SGRs since 1988 have documented the many ways in which nicotine affects the brain and nicotine addiction drives smoking behavior. The 1988 SGR established: "1) Cigarettes and other forms of tobacco are addicting; 2) Nicotine is the drug in tobacco that causes addiction; and 3) The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine" (7). The 2020 SGR explains that "[n]icotine addiction is now increasingly emphasized as a main driver of both the initiation and continuation of smoking" (6). A Federal court ruled that the major U.S. cigarette companies "have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction" (Tobacco Control Act 2009, §2(49) (reciting findings of fact in U.S. v. Philip Morris USA, 449 F. Supp. 2d 1 (D.D.C. 2006), aff'd in relevant part, 566 F.3d 1095 (D.C. Cir. 2009)). Addiction increases the difficulty of incorporating the full costs of future negative health effects into the present decision to initiate or continue smoking and makes it more difficult to quit tobacco use. Therefore, this proposed product standard, which would reduce nicotine to minimally addictive or nonaddictive levels in cigarettes and certain other combusted tobacco products, would remove one of the key causes of the internality problem allowing consumers to make consumption choices that narrow the gap between current market consumption and the consumption expected when accounting for the full social cost of combusted tobacco.

Almost all people who use tobacco products started in adolescence when the brain's critical areas for decision-making are not fully developed, creating an environment for impulsive behavior and time inconsistency. Based on over 50 years of published and peer-reviewed scientific evidence and data, the 2014 SGR concluded that 87 percent of adults who currently smoke cigarettes, initiated use of tobacco products before the age of 18 (3). The 1994 and 2012 SGRs on smoking and health note that almost 90 percent of current adults who regularly smoke cigarettes initiated smoking before age 18, and 99 percent initiated smoking by age 26, which is notable given that 25 is the approximate age at which the brain has completed development (19; 20). Given that the brain continues development into an individual's mid-twenties, people who use tobacco products at these ages are more vulnerable to nicotine addiction (21). Exposure to nicotine during adolescence can have long-term consequences for executive cognitive function and for the risk of developing substance use disorders and various mental health problems as an adult (22; 23). Adolescent tobacco users who initiated tobacco use at earlier ages were more likely than those initiating at older ages to report symptoms of tobacco dependence, putting them

at greater risk for maintaining tobacco product use into adulthood (24). Youth may have problems with accurately processing and acting on information about risky activities by overestimating short-run benefits of engaging in the activity while underestimating potential adverse effects of the activity on health, safety, or well-being. For addictive goods such as NNC tobacco products, this misprocessing of information puts youth who experiment with them at risk of becoming dependent before they fully understand the consequences of their actions (25; 26; 20).

Combusted tobacco use is also associated with negative externalities that are typically not paid by the consumer. Between 2017 and 2018, approximately 25 percent of non-smokers were exposed to secondhand smoke, including 38 percent of 3- to 11-year-olds and 33 percent of 12- to 19-year-olds (27). Even though all states have instituted laws requiring fire-safety-compliant paper (beginning in 2003 with all states adopting these laws by 2012), between 2012 and 2016 there were an average of 18,100 home structure fires per year started by smoking materials, accounting for 1 in 20 of all home fires (28). The fatality rate for smoking-related residential building fires is seven times greater than for nonsmoking-related fires (29). Finally, litter is an additional externality of combusted tobacco products.

2. How This Proposed Rule Addresses the Market Failure

This proposed product standard would address the market failure discussed above by setting a maximum level of nicotine in finished cigarettes and certain other combusted tobacco products to minimally addictive or nonaddictive levels, allowing consumers to align their smoking behavior more closely with an understanding of the full cost of tobacco consumption. This proposal would help prevent experimenters (mainly youth) from initiating use and progressing to regular use of combusted tobacco products. Further, it would also have benefits for adults who currently use combusted tobacco products, most of whom want to quit but few who are successful because of the highly addictive nature of these products. This would lead to a significant reduction in combusted tobacco use, thereby reducing negative internalities and externalities associated with smoking as discussed in the previous section. This proposed product standard would narrow the gap between the market cost and the full social cost, causing significant gains in social welfare, including reductions in mortality and morbidity (illness) associated with combusted tobacco use. Additionally, reductions in combusted tobacco use would lessen the extent of the tobacco-related externalities discussed above.

C. Purpose of the Proposed Rule

This proposed product standard would limit nicotine yield by setting a maximum nicotine content level in covered products of 0.7 milligrams (mg) of nicotine per gram of total tobacco. As discussed in the Preamble of this Proposed Rule, we categorize current NNC cigarettes as

those with greater than or equal to 11.4 mg of nicotine per gram of total tobacco. Therefore, for cigarettes, the maximum nicotine level set by this standard is at least a 94 percent reduction in nicotine. However, FDA is not seeking to require the reduction of nicotine yields in any tobacco product to zero, which would violate section 907(d)(3) of the FD&C Act. The proposed nicotine product standard would apply to all manufacturers of covered tobacco products—cigarettes (other than HTPs and other noncombusted tobacco products that meet the definition of a cigarette), cigarette tobacco, RYO tobacco, cigars (including little cigars, cigarillos, and large cigars, but excluding premium cigars[8]), and pipe tobacco (other than waterpipe tobacco).

The proposed product standard would limit the addictiveness of the most toxic and widely used tobacco products, which would have significant public health benefits for all age groups. The proposed rule would have benefits for adults who use tobacco products, most of whom want to quit but are unsuccessful because of the highly addictive nature of these products. It also would help prevent experimenters (mainly youth) from moving beyond experimentation, developing an addiction to nicotine, and progressing to regular use of combusted tobacco products as a result of that addiction. Reducing the number of experimenters who become regular users of combusted tobacco products would help prevent the severe adverse health consequences of long-term smoking at the individual level and result in public health benefits at the population level.

D. Nicotine Population Health Model Discussion

To assess the potential public health impacts of a nicotine product standard, FDA developed a peer-reviewed population health projection model (hereafter referred to as "the population health model" or "PHM") using inputs derived from available empirical evidence and expert opinion to estimate the impact of changes in tobacco product initiation, cessation, switching, and dual use on tobacco use prevalence, morbidity, and mortality in the United States.

[8] On August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA's rule deeming tobacco products to be subject to FDA's tobacco product authorities "insofar as it applies to premium cigars." Cigar Ass'n of Am. v. FDA, No. 16-cv-01460, 2023 WL 5094869 (D.D.C. Aug. 9, 2023) appeal docketed, No. 23-5220 (D.C. Cir. argued Sept. 13, 2024). For purposes of its ruling, the district court specified that a premium cigar is a cigar that: (1) Is wrapped in whole tobacco leaf; (2) Contains a 100 percent leaf tobacco binder; (3) Contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); (4) Is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) Has no filter, nontobacco tip, or nontobacco mouthpiece; (6) Does not have a characterizing flavor other than tobacco; (7) Contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) Weighs more than 6 pounds per 1,000 units. The government has appealed the District Court's decision. When the deemed status of premium cigars is resolved, FDA will consider any impacts with respect to the proposed rule and take additional steps as warranted, including for example, by reopening the comment period and/or issuing a supplemental notice of proposed rulemaking. References to premium cigars in the preamble serve merely to clarify the current proposed scope of products covered, evaluate the scientific evidence related to non-premium cigars, and describe FDA's approach to modeling the projected public health impacts of this proposed standard.

Model code and inputs/outputs are available in the rulemaking docket [Docket No. FDA-2024-N-5471]. Specifically, the PHM projects use and harm from the following two types of tobacco products: (1) cigarettes and (2) noncombusted tobacco products (i.e., smokeless tobacco, electronic nicotine delivery systems (ENDS), and HTPs). Details of this peer-reviewed modeling approach have also been previously published in two peer-reviewed publications and are being concurrently posted to the docket for this proposed rule in FDA's scientific modeling document (30; 31; 2). These papers provide detail on the overall model in terms of the inputs, transition behaviors, and outputs, along with results from a simulation involving use of cigarettes, very low nicotine content (VLNC) cigarettes, and noncombusted products in the U.S. population over time. For a more detailed discussion of the PHM, please see the Preamble Section VIII.A or FDA's scientific modeling document (2). We request comment on the methodology and analysis (including the overall model in terms of the inputs, transition behaviors, and outputs as noted above) presented in the PHM report (2).

The PHM derives the input values and ranges for the potential impact of a nicotine product standard on changes in use of cigarettes and noncombusted tobacco products based on results from a formal expert elicitation conducted in 2018 through a contract with the FDA. The estimates from the 2018 expert elicitation supersede those collected in an initial expert elicitation conducted in 2015 (30) . The 2018 elicitation generally reconvened the same expert panel as 2015 and allowed them to update their estimates considering several studies that were not available at the time of the 2015 elicitation (e.g., Donny et al. 2015 (32); Hatsukami et al. 2017 (33)) on the effects of VLNC cigarettes, as well as changes in use of the two tobacco products including Electronic Nicotine Delivery Systems (ENDS) (e.g., Jamal et al. 2017 (34)). Specifically, the 2018 elicitation expert panelists were instructed to assume that the potential standard would limit the nicotine content of certain combusted tobacco products to no more than 0.4 milligrams of nicotine per gram of tobacco, based on available literature, and that once the standard was in effect[9], non-compliant cigarettes would be entirely unavailable, including from illegal or illicit sources. The 2015 elicitation methodology used to identify experts, develop the protocols, conduct the elicitations, and summarize the findings has been described in Apelberg et al. (2018). Additional details regarding the 2018 elicitation are provided in FDA's scientific modeling document (2). FDA is conducting another expert elicitation process and intends to publish the results of this update for public review and additional comment on this proposed standard in light of that update. In this new elicitation, experts have been instructed to consider a

[9] Due to the nature of variation in agricultural products, in 22nd Century Group, Inc.'s modified risk tobacco product applications, the company reported that after 9 years of sampling by the company, the average nicotine content of its genetically engineered VLNC tobacco is 0.6 mg nicotine per gram of total tobacco, with a range of 0.4 to 0.7 mg nicotine per gram of total tobacco. It is likely that the Quest and SPECTRUM Nicotine Research Cigarettes, used throughout the scientific literature that referred to the 0.4 mg nicotine per gram, also contained between 0.4 to 0.7 mg nicotine per gram of total tobacco (262). This suggests the literature the experts reviewed studied cigarettes in the range of 0.4-0.7mg/g as opposed to only 0.4mg/g. Therefore, the results of the expert elicitation are still applicable to a nicotine level of 0.7mg/g. As a reference point, normal nicotine content in the top 100 cigarette brands (2017) is 17.2 mg/g (261).

product standard that would limit the content of certain finished combusted tobacco products manufactured, distributed, or sold in the US to no more than 0.7 milligrams of nicotine per gram of tobacco in alignment with what is being proposed to ensure feasibility given the natural variation of an agricultural product.

The PHM incorporates the following tobacco-use transitions from the expert elicitation to estimate the impact of the policy relative to baseline: (1) cigarette smoking cessation; (2) people who smoke cigarettes switching to noncombusted tobacco products (e.g., smokeless tobacco and/or ENDS) rather than quitting tobacco use entirely; (3) people who continue to smoke cigarettes beginning dual use of cigarettes and noncombusted tobacco products; (4) people who do not smoke cigarettes initiating regular cigarette smoking; and (5) people who do not smoke who have been dissuaded from smoking cigarettes and certain other combusted tobacco products, who may instead initiate use of a noncombusted tobacco product. The model, based on input parameters derived from empirical evidence and expert estimates, projects the population size for nine tobacco product use states by age and sex in each time step (tobacco product use states are combinations of current, former, and never use for cigarettes and noncombusted tobacco products).[10]

Projected mortality probabilities for each of the nine tobacco use states (by age and sex) are then multiplied by the population size in each tobacco use state to project the numbers of individuals surviving and dying during the time step. Using these calculations, the model projects the impact of a potential nicotine product standard in terms of four main outcomes: (1) prevalence of cigarette smoking and noncombusted tobacco use; (2) mortality attributable to the two types of tobacco products (i.e., cigarettes and noncombusted tobacco products) the PHM considers; (3) life years lost due to tobacco use from the two types of tobacco product the PHM considers; and (4) quality-adjusted life years (QALYs) lost due to cigarette smoking-attributable morbidity in the U.S. population over time. Additional averted premature mortality from reductions in secondhand smoke, sudden infant death syndrome (SIDS) related to perinatal smoking, and smoking-related fires due to reductions in cigarette smoking, along with averted premature mortality from reductions in cigar and pipe tobacco use are calculated in a post-processing procedure based on the PHM output. We note that, based on the structure of the PHM, there is an implicit assumption that the average intensity of consumption (e.g., cigarettes per day) does not change as a result of this policy.[11] Therefore, it is assumed there would be no

[10] The nine tobacco product use states projected by the model include populations that: (1) have never used cigarettes or noncombusted tobacco products; (2) have never used cigarettes and currently use noncombusted tobacco products; (3) currently use cigarettes and have never used noncombusted tobacco products; (4) currently use cigarettes and formerly used noncombusted tobacco products; (5) have never used cigarettes and formerly used noncombusted tobacco products; (6) formerly used cigarettes and have never used noncombusted tobacco products; (7) formerly used cigarettes and currently use noncombusted tobacco products; (8) currently use cigarettes and noncombusted tobacco products; and (9) formerly used cigarettes and formerly used noncombusted tobacco products.

[11] Studies of VLNC cigarettes in smokers have shown that their use results in reductions in cigarettes smoked per day and exposure to toxic constituents among individuals who continue to smoke, which may reduce smoking-

compensatory smoking as the nicotine levels are reduced under the proposed approach (immediate nicotine reduction). For consistency, this assumption is maintained throughout the economic analysis.

Use of cigarettes made from RYO tobacco and subsequent health effects are included as part of the PHM estimates for cigarettes generally. The PHM inputs do not distinguish between manufactured and RYO cigarettes. Some data sources such as the National Youth Tobacco Survey (NYTS) and the Population Assessment of Tobacco and Health (PATH) Study ask specific questions about RYO cigarette smoking, whereas others such as the National Health Interview Survey (NHIS) do not. The PHM inputs (such as cigarette smoking initiation and prevalence) are for cigarette smoking overall. An analysis of International Tobacco Control Four Country Survey data collected in 2008 found that 10.9 percent of U.S. adults who smoke cigarettes reported smoking RYO cigarettes as at least part of their cigarette consumption and 5.7 percent reported smoking mainly or only RYO cigarettes as opposed to manufactured or factory-made cigarettes (35).

For the purposes of this analysis, the PHM is adjusted under the baseline and policy scenarios to model a scenario incorporating the proposed product standards to prohibit menthol as a characterizing flavor in cigarettes (87 FR 26454, May 4, 2022) (Menthol Product Standard) and to prohibit all characterizing flavors (other than tobacco) in cigars (87 FR 26396, May 4, 2022) (Cigar Flavors Product Standard). We assess an alternative baseline without these product standards in Section II.M.0. If finalized, these rules are anticipated to reduce overall youth initiation and increase cessation among individuals who smoke cigarettes and cigars. To incorporate the potential impacts of these proposed product standards, if finalized, the PHM estimates a scenario in which these product standards would become effective in 2025. In this scenario, the PHM utilizes estimates of the likely population health impact of those rules, quantified in peer-reviewed publications and discussed in the proposed rules (87 FR 26454, May 4, 2022; 87 FR 26396, May 4, 2022), to adjust the baseline inputs for initiation of cigarettes and noncombusted products as well as cessation of cigarettes and likelihood of switching to noncombusted products to incorporate the impact of those rules.

The PHM quantified the potential impact of a menthol cigarette product standard on the U.S. population for a scenario in which the implementation of a rule prohibiting menthol affects baseline model input parameters associated with cigarette smoking initiation, cigarette smoking cessation, noncombusted initiation, and switching from cigarettes to noncombusted products. Changes in use behaviors for users of the two tobacco product types that the PHM considers due to the implementation of a menthol cigarette product standard (primarily for people who would-initiate future menthol cigarette use and people who currently smoke menthol cigarettes) were derived from an expert elicitation by Levy et al. (36) that was developed to assess the impact on cigarette smoking initiation and cessation and noncombusted tobacco product use of a

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related disease risks. Consequently, additional public health benefits may be observed among those who continue to smoke cigarettes (but smoke fewer cigarettes per day) after a nicotine product standard is in place. Please refer section VII.F.6 of the NPRM for additional discussion.

hypothetical ban on menthol in cigarettes in the United States. The PHM used the results of the Levy et al., (36) expert elicitation to compute factors that can be used to scale cigarette smoking initiation and cessation rates, as well as switching and noncombusted product initiation, accounting for a potential reduction/increase in rates. As the authors of Levy et al. (2023) did in modeling the impacts of a hypothetical U.S. ban on menthol in cigarettes, the PHM assumes that people who currently smoke non-menthol cigarettes are unaffected by a menthol cigarette product standard and uses the average impact scenario from Levy et al. 2023. The PHM makes an additional adjustment to the cigar post-processing procedure to incorporate the impacts of a cigar flavor product standard, adjusting the nicotine standard policy impact to account for a reduction in baseline cigar use.[12] Please see Center for Tobacco Products (2) for a full description of how these adjustments were made.

We acknowledge that these adjustments incorporate the effects of published regulatory proposals that have not yet become effective. We consider the potential impacts of this proposed product standard without these adjustments in Section II.M.1.

The PHM also incorporates sensitivity analyses of various scenarios of illicit trade. See Section 2.4.2 of FDA's scientific modeling document for a complete discussion (2). There are three scenarios of illicit trade that are analyzed by the model categorized by the percent of smokers that may divert to use of NNC cigarettes under a proposed nicotine product standard: a low estimate of 3.8 percent, a primary estimate of 5.9 percent, and a high estimate of 21 percent of people who smoke cigarettes who may divert to use of NNC cigarettes under a proposed nicotine product standard. [13] The PHM also incorporates changes in smoking initiation assuming

[12] The proposed Tobacco Product Standard for Characterizing Flavors in Cigars (87 FR 26396, May 4, 2022) would, if finalized, prohibit characterizing flavors (other than tobacco) in cigars and their components or parts. On August 9, 2023, the court in Cigar Association of America v. Food and Drug Administration set aside FDA's deeming rule as it applied to premium cigars, making products that meet the definition of "premium cigar" in the court's order not subject to FDA's regulatory authority. However, the court's definition of "premium cigars" applies to certain cigars that do not have a characterizing flavor other than tobacco and contain only tobacco, water, and vegetable gum with no other ingredients or additives. Under the proposed Tobacco Product Standard for Characterizing Flavors in Cigars, cigar products that have a characterizing flavor other than tobacco will be prohibited. Thus, the proposed Tobacco Product Standard for Characterizing Flavors in Cigars, if finalized, would not affect products that meet the definition of "premium cigar" in the court's order. The district court's order is on appeal (see footnote 7, supra).

[13] We use 3.8 percent as a low-end estimate based on 2017 estimates of illicit trade volume in cigarettes from Euromonitor International (44). This estimate excludes interstate smuggling for purposes of tax avoidance. Using findings from the International Tobacco Control United States Survey (226), we estimate that 5.9 percent of U.S. smokers last purchased cigarettes from low-tax locations. We use these figures as proxies for the proportions of cigarette smokers who may actively seek out illicit NNC cigarettes under a nicotine product standard, although we note that the product standard would be implemented nationwide, avoiding disparate pricing/availability between states. We use 21 percent as a high-end estimate based on the difference in non-compliance rates between reduced nicotine intervention groups (78 percent) and control groups assigned to NNC cigarettes (57 percent) in clinical trial data from Donny et al. (32) and Nardone et al. (236). This estimate of 21 percent also represents the high-end of the range estimated in National Research Council (237), which reflected the methodology of the pack return survey by Fix et al. (258). This estimate of 21 percent also represents the high-end of the range estimated in National Research Council (237), which reflected the methodology of the pack return survey by Fix et al. (258).

that youth and young adults who would have initiated NNC cigarettes (in the absence of a rule) would seek to smoke NNC cigarettes via illicit trade. The model uses findings from an expert elicitation developed to gauge the impact of a menthol cigarette product standard in the United States (37), which indicate that among people ages 12-24 who would have otherwise initiated menthol cigarette use, 2.6 percent would initiate illicit menthol cigarette use (primary estimate). Experts' estimates ranged from 0 percent (low estimate) to 10 percent (high estimate). For our main analysis, we calculate the expected benefits of the product standard using PHM outputs that incorporate the primary illicit trade estimates (assuming 5.9 percent of people who smoke divert to use of NNC cigarettes and 2.6 percent of youth and young adults may newly seek to smoke NNC cigarettes via illicit trade under a proposed nicotine product standard). In Section II.M.2, we present sensitivity analyses calculating expected benefits under the other two illicit trade scenarios.

E. Baseline Conditions

As our primary baseline, we consider a state of the world in the absence of the proposed rule, but with FDA's proposed product standards to prohibit menthol as a characterizing flavor in cigarettes (87 FR 26454, May 4, 2022) and to prohibit all characterizing flavors (other than tobacco) in cigars (87 FR 26396, May 4, 2022). We consider a baseline absent these rules in Section II.M.1. For this analysis we use a 40-year time horizon from 2025-2064. We request comment on this time horizon.[14]

1. Prevalence Trends

The PHM estimates the prevalence of cigarette and noncombusted tobacco product use, in the first year of the time horizon, using prevalence estimates for the general population from 2020 NHIS data (38) and 2020 NYTS data (39), and population estimates from the 2020 U.S. Census data (40)[15]. For cigarettes and noncombusted tobacco products, the PHM begins with an initial population, divided into subgroups defined by age, sex, and tobacco product use status, accounting for all combinations of current, former, and never use for cigarettes and noncombusted tobacco products, that is representative of the U.S. population in a particular year. Then, using methodologies described in the modeling report (2), the PHM projects the

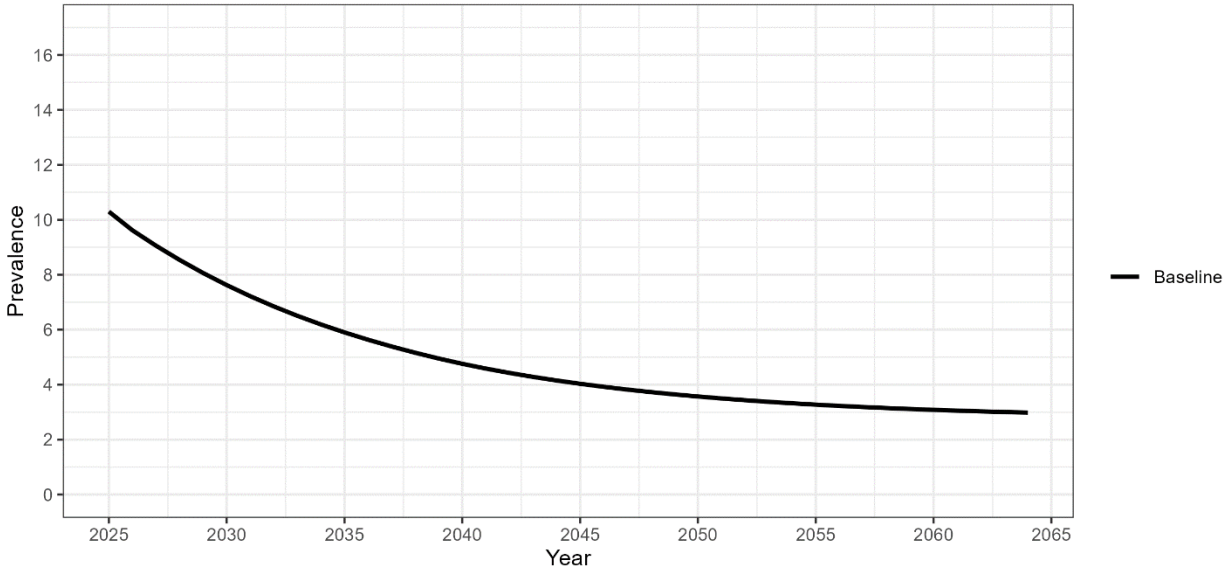
[14] We note that in a shorter time horizon of 20 years, annualized costs would be approximately $2 billion and annualized benefits would be approximately $805 billion using a 2% discount rate. This corresponds with an approximate 25% reduction in costs and benefits compared to the main analysis with a time horizon of 40 years. Annualized and net present value of benefits and costs for various time horizons can be constructed using the undiscounted results presented in Appendix D.

[15] In the PHM, the simulation model period starts at year 2021. To populate data on tobacco use prevalence, data from 2020 NYTS and NHIS were used instead of the 2021 data surveys due to challenges with data collection during the pandemic.

population changes for subsequent years in one-year time increments according to product use states and transitions (e.g., cessation, initiation, switching), while accounting for births, net migration, and deaths. Once the PHM has estimated the number of people using either cigarettes (which include RYO) and/or noncombusted products for each year over the time horizon in the absence of the rule, it then estimates the prevalence of use by dividing the population estimated to use these products by the projected U.S. population for each respective year.

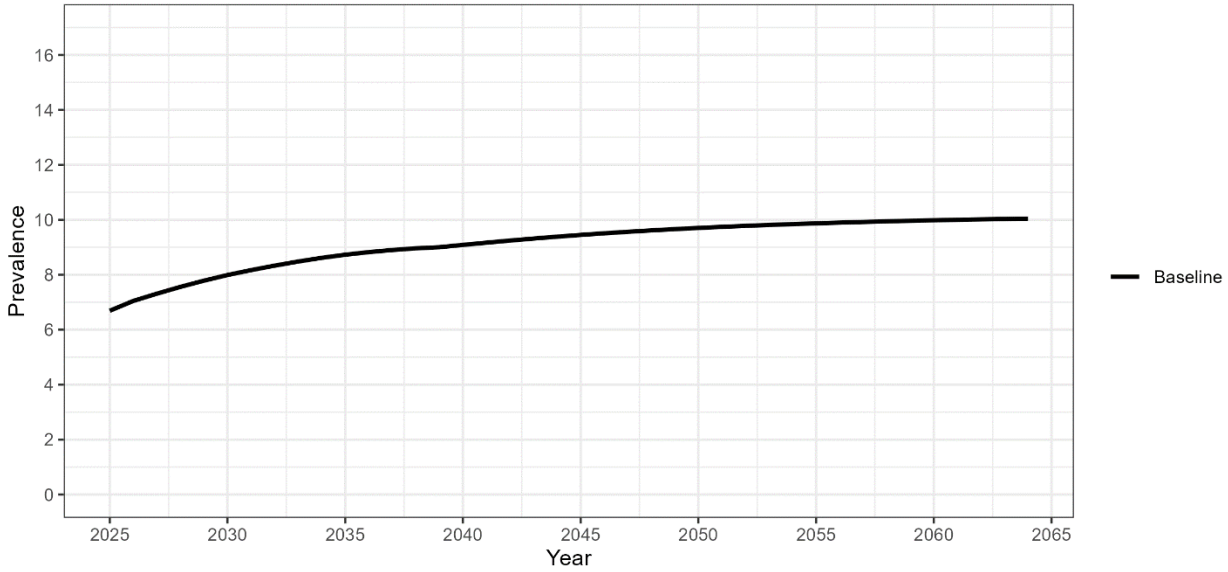
In the absence of the proposed rule, the PHM estimates that the adult prevalence of cigarette smoking declines over the time horizon. The model assumes that pipe tobacco and RYO follow the same declining prevalence trend as cigarettes. The PHM estimates that in the absence of the proposed nicotine product standard, cigarette smoking prevalence in the U.S. adult population would be approximately 10 percent in 2025 and would fall to approximately 3 percent by the end of the time horizon (2064). See Figure 1.

Figure 1. Baseline Prevalence of Cigarette Use, Incorporating the Impacts of the Menthol Product Standard



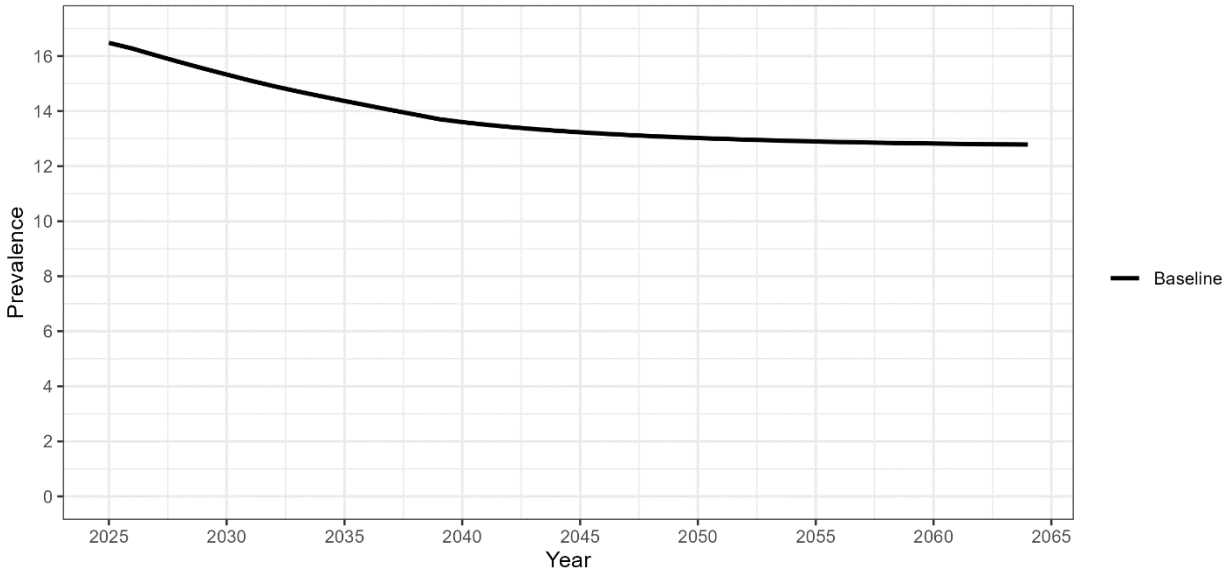
The PHM estimates that adult noncombusted tobacco use would increase over time. The PHM estimates that in the absence of the proposed nicotine product standard, adult noncombusted tobacco use prevalence in the U.S. adult population would be approximately 7 percent in 2025 and increase to approximately 10 percent by the end of the time horizon. See Figure 2.

Figure 2. Baseline Prevalence of Noncombusted Tobacco Product Use, Incorporating the Impacts of the Menthol Product Standard



Taken together, however, the model projects overall use of tobacco products (cigarettes or noncombusted tobacco products) to decrease over time, largely driven by the trends in cigarette prevalence combined with the overall size of the cigarette smoking population. The PHM estimates overall use of tobacco products would decrease from approximately 17 percent in 2025 to less than 13 percent by the end of the time horizon. See Figure 3.

Figure 3. Baseline Prevalence of Both Modeled Tobacco Product Use, Incorporating the Impacts of the Menthol Product Standard



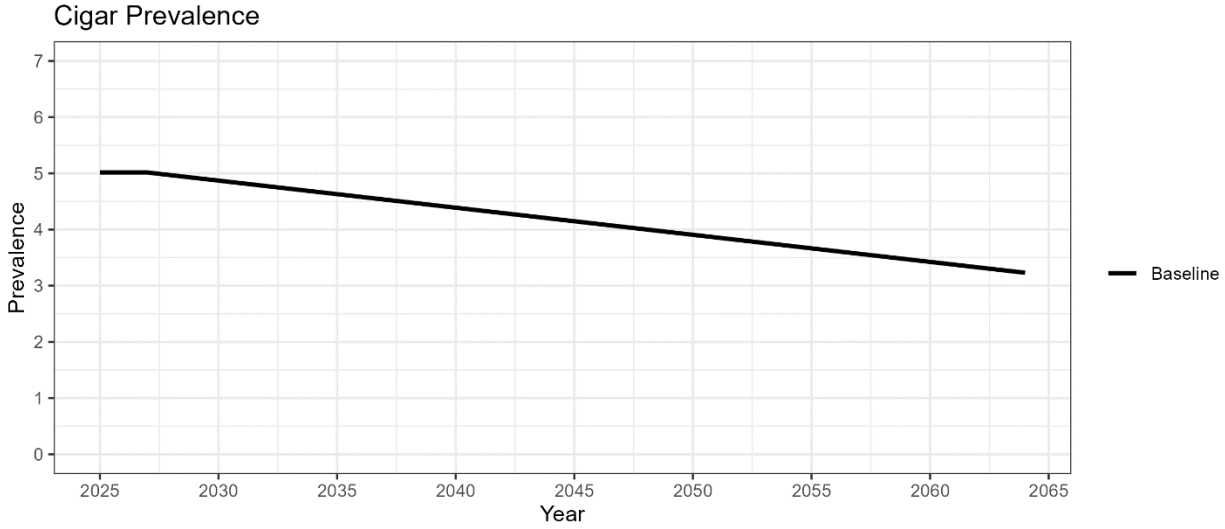
We estimate cigar smoking prevalence in the U.S. adult population by using a different methodology. Specifically, we assume a baseline prevalence of approximately 5.9 percent for 2025 using historical data from the PATH Study.[16] We note that adult cigar prevalence has been relatively stable over time, but we have seen reductions in youth and young adult cigar prevalence that would begin to impact overall adult cigar prevalence over the time horizon of this analysis. We estimate an average reduction in cigar prevalence of 37.5 percent based on two estimates of reduced young adult use: 29.9 percent[17] and 45 percent.[18] Therefore, we assume prevalence would decrease linearly throughout the time horizon, resulting in a 37.5 percent reduction from 2025 to 2064 in the absence of the proposed cigar flavors product standard. To incorporate the potential impacts of a cigar flavors standard at baseline, we assume a scenario in which a cigar flavors product standard were to become effective in 2025 and results in an additional 15 percent reduction in prevalence from cessation of exclusive cigar smokers (41). Accounting for the proposed cigar flavor standard, we estimate that cigar prevalence, in the absence of this proposed nicotine product standard, would be approximately 5.0 percent in 2025 and would decrease to approximately 3.1 percent by the end of the time horizon. Our estimates of cigar prevalence encompass both premium and non-premium cigars. We use our estimate for overall cigar prevalence, as discussed above, as a proxy for non-premium cigar prevalence. See Figure 4. We expect youth use of premium cigars to be relatively infrequent, given that analysis of NSDUH data from 2010 to 2019 found that the prevalence of past 30-day use of premium cigars among youth aged 12 to 17 years was 0.1 percent (42).

[16] PATH Study data from Wave 5: https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/OlderAdult-30Day-AnyCigar.pdf

[17] 29.9 percent is the reduction in cigar use among young adults (ages 18-24) between PATH Study Waves 1 and 5 (1 – (11/15.7)) https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/YoungAdult-30Day-AnyCigar.pdf

[18] Rostron et al. (256) reported that in 2015-2016 approximately 302,000 18-year-olds were people who smoke cigars on some or every day. Based on 2019 Census data and the PATH Study Wave 5 (2018-2019) data, the population of 18-year-old people who smoke cigars on some or everyday decreased to approximately 166,000 18-year-olds by 2019. This amounts to a 45 percent decrease in cigar smoking ((302,000 – 166,000)/302,000) over 3 years.

Figure 4. Baseline Prevalence of Cigar Use, Incorporating the Impacts of the Cigar Flavors Product Standard



2. Premature Deaths Attributable to Various Types of Tobacco Products

After estimating the prevalence of tobacco products in the general population, the PHM estimates the number of deaths attributable to tobacco products in the absence of the rule using the 2019 NHIS-Linked Mortality Files (NHIS-LMF) data (43). As described in FDA's scientific modeling document (2), the number of tobacco attributable deaths during each time step is determined by multiplying the probability of dying under each tobacco use state (based on relative mortality risk) by the estimated population in each tobacco use state. The PHM adjusts the baseline estimates for the Proposed Menthol Product Standard and the Proposed Cigar Flavors Product Standard.

At baseline, annual deaths attributable to exclusive cigarette use are estimated to decrease from approximately 280,000 at the beginning of the time horizon to approximately 60,000 by the end of the time horizon. That decrease represents an average reduction in annual deaths of approximately 4 percent each year. See Table 4. Annual deaths attributable to exclusive use of noncombusted products are estimated to increase from approximately 2,000 at the beginning of the time horizon to approximately 3,000 at the end of the time horizon, which represents an average increase in annual deaths of approximately 1 percent each year. Annual deaths attributable to the dual use of cigarettes and noncombusted tobacco products are estimated to decrease from approximately 130,000 at the beginning of the time horizon to approximately 65,000 at the end of the time horizon, an average of 2 percent each year. Taken together, the model predicts that overall annual tobacco attributable deaths for cigarettes and noncombusted tobacco products are estimated to decrease from approximately 410,000 at the beginning of the

time horizon to approximately 126,000 at the end of the time horizon, which is an average of 3 percent reduction each year at baseline.

FDA also estimates the number of attributable deaths from use of other combusted tobacco products (i.e., cigars and pipe tobacco), exposure to secondhand smoke, SIDS, and smoking-related fires at baseline. Analyses of these additional tobacco-attributable deaths use model projections and scales the estimate of deaths annually attributable to direct cigarette smoking from 2005 to 2009 (3), according to the number of premature deaths attributed to each of these causes. Specifically, there were 437,400 premature deaths annually attributable to cigarettes from 2005 to 2009, and an additional 41,280 deaths annually attributable to secondhand smoke exposure from all combusted products, primarily from cigarettes. Thus, after using the PHM to estimate the baseline number of deaths attributable to cigarettes, we multiply those baseline deaths by 0.094 (= 41,280/437,400) to arrive at the estimated number of secondhand smoke attributable deaths. This approach assumes that mortality from secondhand smoke from all combusted products follow the trend of cigarettes. We request comment on this assumption. Similarly, SIDS (0.001 = 400/437,400), fire-related (0.001 = 590/437,400), and pipe tobacco (0.003 = 1,095/437,400) attributable deaths are estimated using the same scalar approach. See Figure 5.[19] Cigarette, dual-use, and noncombusted attributable deaths are estimated using the PHM. Since secondhand smoke, fire, SIDS, and pipe tobacco attributable deaths are calculated using a scalar adjustment, the trends for these mortality sources are identical to the trend for cigarette deaths.

We estimate cigar-attributable deaths in two steps: 1) assuming a constant number of deaths (7,397)[20] for the entire time horizon, then 2) phasing in the estimated number of avoided deaths from the Cigar Flavors Product Standard as estimated in the PRIA for that rule (41)). As discussed in section VIII.D of the Preamble, by considering a relatively stable trend in adult cigar use[21] and assuming that adult cigar use is the main driver of cigar-attributable deaths in the close future, we assumed that non-premium cigar-attributable mortality would remain constant at 7,397 cigar-attributable deaths through 2064 (or roughly the time at which people aged 26 and older in 2021 who use cigars would all have reached age 70 and older).

For the purposes of this analysis, estimates are then adjusted for the mortality effects of a product standard prohibiting characterizing flavors other than tobacco in cigars. Specifically, we

[19] Note that the Figure is split into three panels based on the scale of anticipated deaths at baseline.

[20] 7,397 is the estimate of the number of annual cigar-attributable deaths due to non-premium cigars. We estimate that premature deaths from all cigar types is 9,246 annually (255). We estimate that among current (every day or some day) established (having ever used fairly regularly) people who smoke cigars, 80 percent reported smoking non-premium cigars and 20 percent reported smoking premium cigars using a classification methodology described previously in Corey et al., 2014 (214) and subsequently updated in National Academies of Science, Engineering, and Medicine, 2022 (42). On that basis, 7,397 deaths annually (= 0.8 x 9,246) are attributed to using non-premium cigars.

[21] Adult cigar smoking has historically remained stable. Data from the NHIS over 2000-2015 has shown that prevalence of current cigar smoking has remained generally stable at around 2.3 percent among U.S. adults aged 18 years and older (256). Adult (aged 26 years or older) cigar use also remained relatively stable in NSDUH data for 2011 and 2019 and did not significantly change (4.2 percent in 2011 to 4.0 percent in 2019 for cigars) (133).

use a scenario where the avoided cigar-attributable deaths from the flavored cigar rule begin to occur 2 years after the rule's potential effective date (2027) and would increase in a phased-in manner over a 30-year period. We then estimate a full annual mortality benefit of 780 avoided deaths would continue after 30 years (from 2026 to 2055), with a constant benefit of 780 deaths avoided until year 2064. Details regarding the calculation of avoided cigar-attributable deaths due to the flavored cigar proposed rule can be found in Appendix L of FDA's modeling document (2). The estimated deaths averted by a flavored cigar product standard were subtracted from baseline non-premium cigar-attributable deaths in the U.S. each year to produce yearly estimates for non-premium cigar deaths with a flavored cigar standard. This results in non-premium cigar-attributable deaths declining to approximately 6,600 per year by 2055 when adjusting for a flavored cigar standard. Thus, while cigar-attributable deaths appear to decrease with the phase-in of the Cigar Flavors Product Standard, the trend in cigar-attributable premature deaths flattens by the end of the period because of the underlying assumption of a constant number of annual cigar-attributable premature deaths. We note that this assumption reflects historical trends in cigar use rather than allowing cigar-attributable premature deaths to monotonically decrease at the same rate as cigarette-attributable premature deaths.

See Table 4 for a summary of the average baseline trends in deaths in the absence of the proposed nicotine product standard from the PHM output. Overall, tobacco-attributable premature deaths (which include premature deaths attributable to cigarettes, noncombusted products, and the dual use of both product types) are estimated to decrease approximately 3 percent each year. Cigarette-attributable deaths are estimated to decrease approximately 4 percent each year, while noncombusted-attributable deaths are estimated to increase by 1 percent per year, on average. Premature deaths attributable to smoking-related fires, SIDS, pipe tobacco use, and secondhand smoke exposure, are estimated to decrease approximately 3 percent each year. The number of cigar-attributable deaths in the absence of the rule is estimated to be relatively flat over the 40-year time horizon. Given the magnitude of the estimates of tobacco-attributable deaths from each source, we sort these estimates by their relative size: Impacts greater than approximately 10,000 annual tobacco attributable premature deaths, impacts between approximately 1,000 and 10,000 annual tobacco attributable premature deaths, and fewer than approximately 1,000 annual tobacco attributable premature deaths.

Figure 5. Baseline Smoking-Attributable Deaths from Various Sources in Absence of the Rule

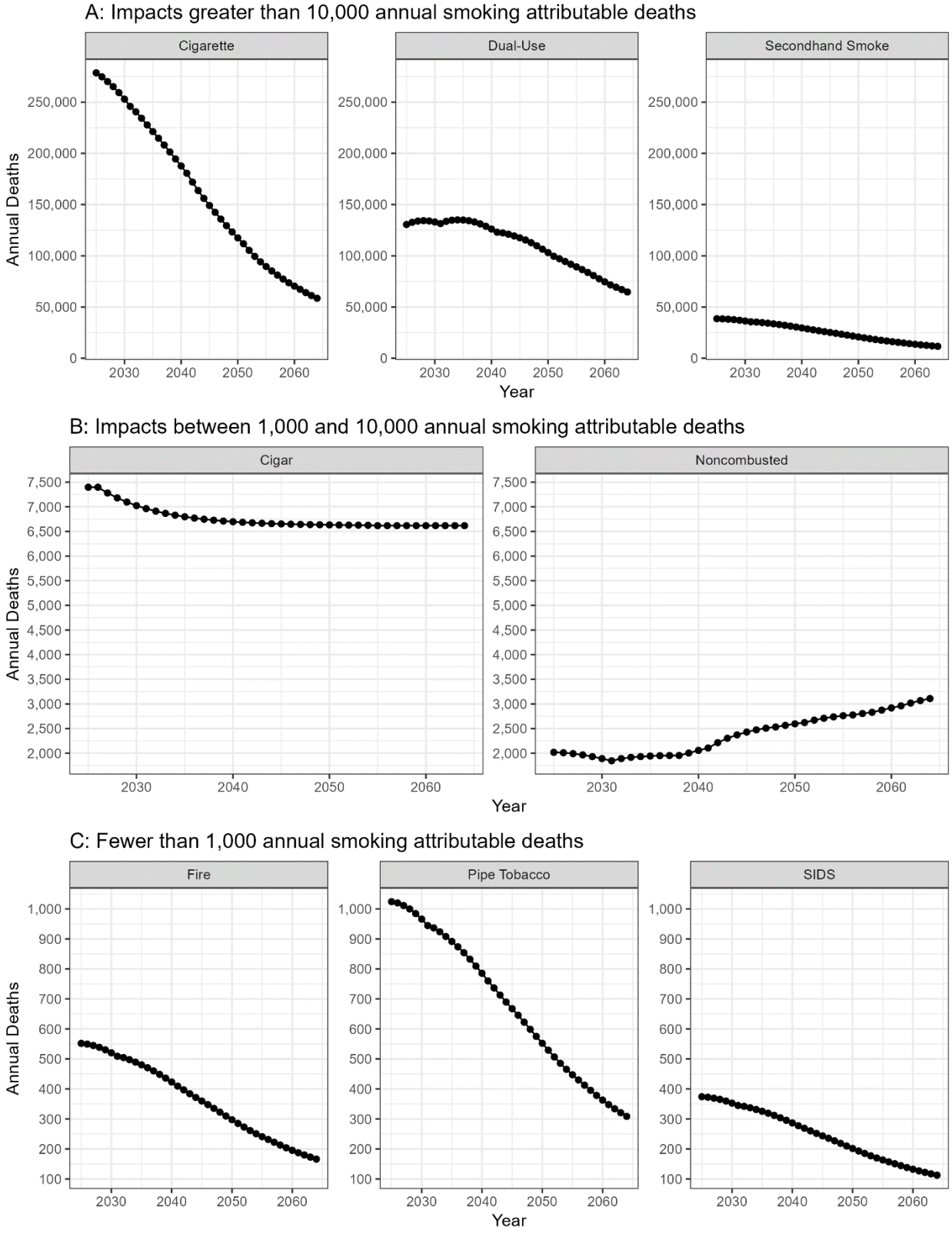


Table 4. Average Annual Trends for Deaths Attributable to Various Tobacco Products

Source of Estimate	Mortality Cause	Average Annual Change in Baseline Deaths[1]
FDA Population Health Model	*Overall Modeled Tobacco Product Use*	-3.2%
	Cigarette[2] Use	-4.2%
	Tobacco Product Dual-Use[2]	-1.9%
	Noncombusted[2] Tobacco Product Use	1.4%
Additional Analyses	Cigar[3] Use	-0.2%
	Smoking-Related Fire[4]	-3.2%
	SIDS[4] Resulting from Exposure to Tobacco Products	-3.2%
	Pipe Tobacco[4] Use	-3.2%
	Exposure to Secondhand Smoke[4]	-3.2%

Notes:
[1]Average annual change is the average (across the time horizon) percentage change from year to year in baseline deaths.
[2]Directly estimated from the population health model.
[3]Adjusted from population health model, accounting for the Cigar Flavors Product Standard
[4]Scalar adjustment to population health model

3. Sales Revenue and Market Trends

We use 2021 Euromonitor International (EMI) Passport data pulled in 2024 to benchmark revenue and quantity for the combusted and noncombusted tobacco product markets in the U.S., excluding cigars (44). We estimate revenue and quantity for cigar products using a dataset prepared by EMI in 2021 that categorizes the cigar market by premium, non-premium, and flavored subcategories in 2020 (45) (44). We report 2020 revenues and units for non-premium, tobacco flavored cigar products, adjusting revenue into 2023 dollars using the GDP deflator.[22]

[22] 2020 Prices are adjusted using the GDP Price Deflator with base year 2017, accessed at https://apps.bea.gov/iTable/?reqid=19&step=3&isuri=1&1921=survey&1903=13. The calculation is as follows: '2020 revenue in 2023 dollars' = '2020 revenue' x (122.27 / 105.38), where 122.27 and 105.38 are the GDP price deflators in 2023 and 2020, respectively.

These are the most recent data for which we have separate data for premium and non-premium cigars. Table 5 shows the data from these Euromonitor reports.

Table 5. Unadjusted Euromonitor Revenue and Quantity Data for 2021 ($ Millions, 2023)

Combusted Tobacco Products			
Category	**Revenue**	**Quantity**	**Quantity Units**
Cigarettes	$110,836	213,751	million sticks
Non-premium cigars (total)	$9,125	13,274	million units
Flavored non-premium cigars	$3,702	5,868	million units
Premium cigars	$10,213	714	million units
Pipe Tobacco	$1,560	11,837	metric tons (2205 lbs.)
RYO Tobacco	$359	1,726	million stick equivalent
Noncombusted Tobacco Products			
Category	**Revenue**	**Quantity**	**Quantity Units**
ENDS	$7,679	N/A	N/A
Smokeless tobacco	$11,095	58,107	metric tons (2205 lbs.)

Notes: 1.) All products above, besides cigars, are 2021 revenue and quantity values from the 2024 Euromonitor Passport data release. Cigar products are 2020 revenue and quantity values from a 2021 special report prepared by EMI. As FDA's product standards for menthol in cigarettes and flavors (other than tobacco) in cigars were not proposed until after 2021, these estimates do not include adjustments for these rules. Adjustments are reflected in Table 6. 2.) ENDS product units are the sum of 1) 'Closed Vaping Systems', 2) 'Open Vaping Systems Charging and Vaporizing Devices' and 3) 'E-liquids'. We omit the unit measure because we may not be able to make a meaningful comparison between units of the different categories.

We then make several adjustments to the data in Table 5 to serve as the basis of our baseline projections. The PHM estimate of cigarette prevalence accounts for the Menthol Product Standard in 2025 and therefore we do not make any further adjustments to the cigarette market. However, the post-processing procedure for cigars differs from the way the PHM treats cigarettes. As noted in section II.E.1, baseline cigar smoking prevalence in the U.S. adult population is projected using historical data from the PATH Study and a prevalence reduction is applied to account for the impacts of the Cigar Flavors Product Standard proposed rule, if the rule is implemented in 2025 (41). We similarly adjust the Euromonitor report data for non-premium cigar products to reflect reductions in the market revenue and quantity resulting from the Cigar Flavors Product Standard.[23] First, we sum the total units across all cigar categories (13,987 million) and reduce this by 30 percent to estimate 9,791 million sticks purchased following the Cigar Flavors Product Standard (CF) Proposed Rule. To adjust this estimate for the scope of this proposed standard which excludes premium cigars, we take the total quantity of

[23] Please see the Cigar Flavors PRIA for a detailed explanation on the scientific foundation and the methods that go into this adjustment (41), and section VIII.E of the Nicotine NPRM for additional discussion of how a cigar baseline was created in post-processing.

cigars estimated following the CF proposed rule and subtract the estimated quantity of premium cigars (714 million) to estimate 9,078 million units of tobacco flavored non-premium cigars. The reduction of non-premium cigars is smaller than the pre-policy quantity of non-premium flavored cigars because we assume some people who use flavored cigars switch to tobacco-flavored non-premium cigars after implementation of the policy. We calculate revenue by assuming people who smoke flavored cigars switch, on average, to similarly priced tobacco flavored non-premium cigars after the policy and therefore multiply post-policy quantity by pre-policy price (pre-CF policy revenue of $9,125 million divided by pre-CF policy quantity 13,274 million units, or an average unit price of $0.687) for an estimated revenue of $6,240 million ($0.687 per tobacco flavored non-premium cigar x 9,078 million units of tobacco flavored non-premium cigars). We recognize that the CF Rule, if finalized, may not be effective until 2025. The application of this adjustment is only for the purpose of constructing the baseline for cigars for the 2025 to 2064 time horizon. For all other non-cigar product categories, the revenue and quantity used in our analysis to construct the baseline and policy scenario revenue and quantity is identical to what is displayed in Table 5. Table 6 displays adjusted and final revenue and quantity used in this economic analysis.

Table 6 shows adjusted Euromonitor revenue and quantity of each tobacco product, by category. In 2021, cigarettes held the largest market share of revenues in both the combusted tobacco market and the total market for tobacco products, accounting for about 80 percent of the total tobacco market. The second largest combusted product category by market share is non-premium cigar products, which accounts for 4.5 percent of the total tobacco market revenue, followed by pipe tobacco and RYO, accounting for 1.1 and 0.3 percent of the total tobacco market revenue. In the noncombusted tobacco market, smokeless tobacco products (SLT) and ENDS products accounted for about 8.1 percent and 5.6 percent of the total tobacco market revenue as estimated by Euromonitor.[24, 25,26] In 2021, combusted tobacco products accounted for about 86 percent of the total market revenue and noncombusted products accounted for the remaining 14 percent.

Table 6. Adjusted Euromonitor Revenue and Quantity Data for 2021 ($ Millions, 2023)

Combusted Tobacco Products

Category	Revenue	Percent of Total Revenue[1]	Quantity	Quantity Units
Cigarettes	$110,836	80.4%	213,751	million sticks

[24] The smokeless tobacco product category consists of snuff, snus, and chewing tobacco.

[25] Euromonitor data also includes 'Tobacco Free Oral Nicotine' in the form of 'Nicotine Pouches' as a noncombusted product, which we do not include in this analysis.

[26] Euromonitor estimates sales through retail and online sales channels and does not separately estimate the size of the illicit market for ENDS products. However, we note that some unauthorized product sales may be included within estimates provided by Euromonitor.

Non-premium cigars	$6,240	4.5%	9,078	million units
Pipe Tobacco	$1,560	1.1%	11,837	metric tons (2205 lbs.)
Roll Your Own Tobacco	$359	0.3%	1,726	million stick equivalent

Non-Combusted Tobacco Products

Category	Revenue	Percent of Total Revenue	Quantity	Quantity Units
ENDS	$7,679	5.6%	N/A	N/A
Smokeless	$11,095	8.1%	58,107	metric tons (2205 lbs.)

Note: 1.) Pipe tobacco from Euromonitor Passport includes waterpipe tobacco. Therefore, these estimates represent an overestimate of revenues and quantity affected by the rule. 2). ENDS product units are the sum of 1) 'Closed Vaping Systems', 2) 'Open Vaping Systems Charging and Vaporizing Devices' and 3) 'E-liquids'. We omit the unit measure because we may not be able to make a meaningful comparison between units of the different categories (for example, mL per unit or tank volume).

[1] Not including premium cigars.

We calculate the quantity of the respective product category by starting with the initial value from the Euromonitor 2021 data, adjusted for the CF Proposed Rule and excluding premium cigars, as shown in Table 6. Assuming consumption and prevalence decrease at equal rates, we then adjust that quantity by the annual percentage change in prevalence using data from the PHM in each subsequent year, excluding cigars.[27] For example, Euromonitor reports that 213.75 billion cigarette sticks were sold in 2021. The PHM estimates that baseline adult cigarette smoking prevalence fell 5.35 percent between 2021 and 2022. Therefore, we estimate that 202.31 billion cigarette sticks were sold in 2022 (213.75 billion x (100-5.35 percent) = 202.31 billion). For cigar products, we use the annual percentage change in prevalence from the cigar specific trend, as previously discussed. We estimate the baseline price in each product category by dividing the Euromonitor revenues for that product category by its corresponding Euromonitor quantity, as shown in Table 6. We assume that baseline prices are held constant for each subsequent year, as presented in the CF and Menthol PRIAs (46; 41).[28]

We estimate the expected revenue from 2025 to 2064 by multiplying the constant 2021 price, in 2023 dollars, by the estimated quantity sold in each year, for each product category. For ENDS products, we assume the ratio of ENDS to SLT revenues remain constant and use this ratio as a scalar to estimate expected ENDS revenues from 2025 to 2064. For example, the ratio

[27] As mentioned earlier in the text, the PHM assesses prevalence, but not intensity, of tobacco product consumption. To derive the market impacts from the PHM, we assume that, on average, individuals continue to consume at the average pre-policy rate. If the proposed nicotine product standard policy causes reductions in intensity, then our estimates may overstate the market size since there would be both lower prevalence of combusted tobacco product users and lower consumption of combusted tobacco products for those who remain smokers.

[28] Historical Euromonitor Passport data on cigarette sales and revenue between 2010 to 2021 suggest that revenues and units change at differing rates (44). As a sensitivity analysis, we estimate producer surplus loss in the cigarette market under the assumption of an increasing baseline price. See Section II.M.8.

in 2021 is about 0.69. Thus, we estimate expected revenue for SLT in 2022 and multiply by 0.69 to estimate expected ENDS revenue in 2022. We request comments on this assumption.

The baseline estimated market revenues for combusted tobacco products in the 40-year period from 2025 to 2064 are shown below. Figure 6 displays baseline expected revenues for cigarettes and Figure 7 displays baseline expected revenue for cigars, pipe tobacco, and RYO Tobacco. While RYO and pipe tobacco share many similarities, there are a few critical regulatory differences. RYO tobacco is subject to Special Rule for Cigarettes (Section 907(a)(1)(A) of the FD&C Act), which prohibited cigarettes with flavors other than tobacco and menthol, and would be subject to the Menthol Proposed Rule, if finalized. Pipe tobacco that is not labeled or offered for sale as cigarette tobacco is not subject to either of these federal flavor restrictions. Given that pipe tobacco represents such a small part of the overall tobacco market, we make a simplifying assumption to analyze pipe tobacco trends as mirroring the trends for RYO tobacco and cigarettes. We estimate that in the absence of the proposed nicotine product standard, expected revenue for cigarettes is about $89 billion in 2025, $54.2 billion in 2034, $31.3 billion in 2044, $18.1 billion in 2054, and $10.4 billion in 2064. Expected revenue for non-premium cigars are about $5.3 billion in 2025, $5 billion in 2034, $4.4 billion in 2044, $3.9 billion in 2054, and $3.4 billion in 2064. Collectively, pipe and RYO tobacco accounts for 1.6 percent of the combusted tobacco product market revenue and 1.4 percent of the total tobacco product market revenue. Expected joint revenue for pipe and RYO is about $1.5 billion in 2025, $0.9 billion in 2034, $0.54 billion in 2044, $0.3 billion in 2054, and $0.18 billion in 2064.

Figure 6. Baseline Estimated Revenues of Cigarettes, Adjusted for Menthol Proposed Rule: 2025-2064 ($ Millions, 2023)

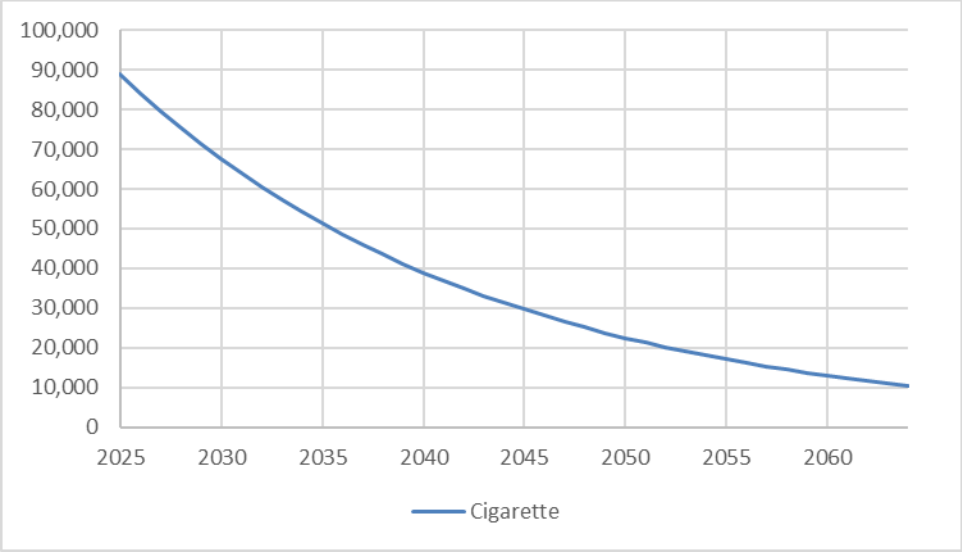
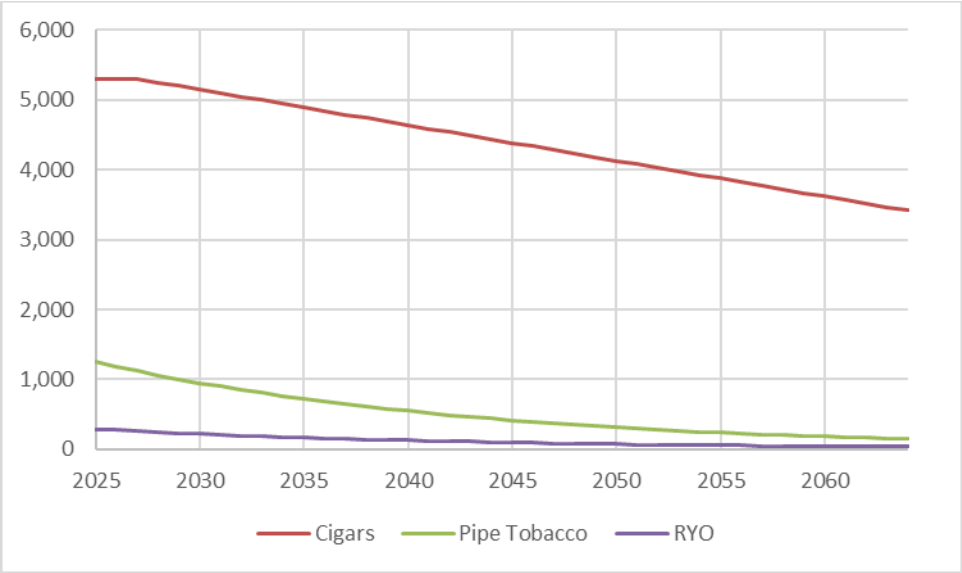
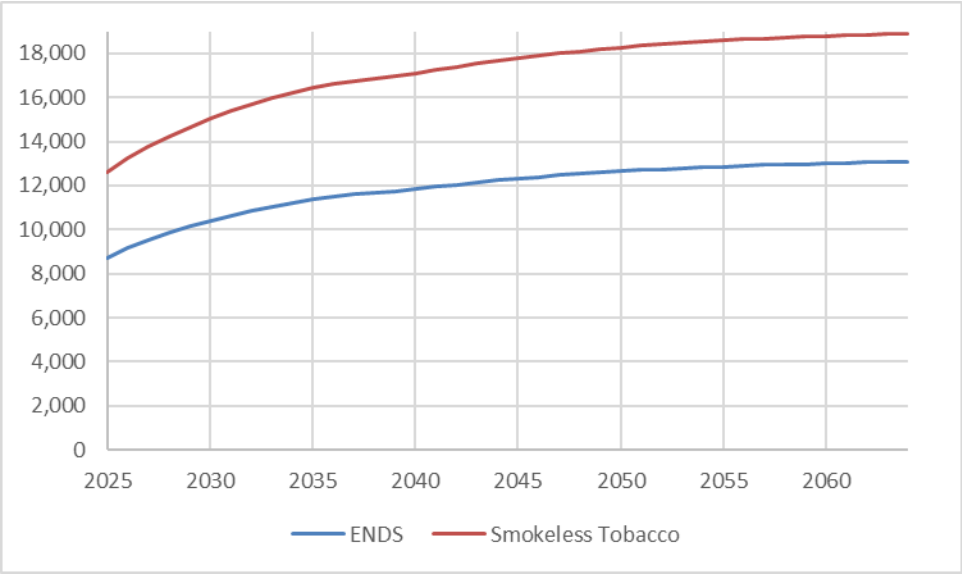


Figure 7. Baseline Estimated Revenues of Non-Premium Tobacco-Flavored Cigars, Pipe Tobacco, and RYO Tobacco, Adjusted for Menthol and Cigar Flavors Proposed Rules: 2025-2064 ($ Millions, 2023)



The baseline estimated market revenues for noncombusted tobacco products in the 40-year period from 2025 to 2064 are shown below in Figure 8. We estimate that in the absence of the proposed nicotine product standard, expected revenue for SLT is about $12.6 billion in 2025, $16.2 billion in 2034, $17.7 billion in 2044, $18.5 billion in 2054, and $18.9 billion in 2064. Expected revenue for ENDS is about $8.7 billion in 2025, $11.2 billion in 2034, $12.2 billion in 2044, $12.8 billion in 2054, and $13.1 billion in 2064.

Figure 8. Baseline Estimated Revenues of Noncombusted Products in Millions of 2023 Dollars: 2025-2064



4. Number of Affected Entities and Products

a. Current Manufacturers

FDA's internal database Tobacco Registration and Listing Module Next Generation (TRLM NG) captures and maintains self-reported establishment registration information and associated product listings, including labels, advertising, and consumer information. Using TRLM NG data as of September 2023, FDA has identified 1,585 domestic addresses for manufacturers and importers of impacted tobacco products, including 133 manufacturers and importers of cigarettes, cigars, pipe tobacco, and RYO tobacco, 1,427 manufacturers and importers of only ENDS products, 15 manufacturers or importers of only smokeless tobacco, and 10 dual operation facilities that manufacture both combusted and noncombusted products.[29] Of the 10 dual operation facilities, 7 manufacture SLT and combusted products, and 3 manufacture ENDS and combusted products.[30] TRLM NG registration by product type is shown below in Table 7.

Table 7. TRLM NG Data on Facility Registration by Product Type

	Combusted Only	ENDS Only	Smokeless Tobacco Only	Dual Operation	Total
Count	133	1,427	15	10	1,585
Percent	8.4%	90.0%	0.9%	0.6%	100.0%

Note: Percents do not sum to 100 due to rounding.

As this product standard applies to all combusted tobacco products available for sale in the United States besides premium cigars and waterpipe tobacco,[31] foreign manufacturers of these products intended for distribution in the U.S. market would also be affected. Currently,

[29] We note that there are several limitations with the TRLM NG data. These data are self-reported biannually by manufacturers to FDA. First, manufacturers that discontinue production of a product are expected to delist the product with FDA; however, this does not always happen. Second, there have also been cases where manufacturers were likely miscategorized by the type of product they produce. Third, the same product may also be listed multiple times due to slight misspellings or other factors, or the same product may be sold under multiple labels and therefore have multiple product listings. Additionally, the same product may be sold in multiple packaging configurations leading to multiple listings. Fourth, the currently available product listing data may also undercount the number of products manufactured by foreign firms because they are not yet required to list products. Fifth, technical difficulties and capacity restrictions with the TRLM NG system at the time of the initial registration compliance date for deemed products may also result in duplicative listings in the data. Some of the limitations of the current TRLM NG data may be resolved as companies provide updated product listing information on a biannual basis.

[30] Of the 158 firms that manufacture combusted and/or SLT products only 143 firms were available in the D&B data, Thus some of our analysis is limited to 143 firms.

[31] We note that in our data sources waterpipe and pipe tobacco are not separable, therefore our measures of pipe producers and market revenue include waterpipe tobacco. Waterpipe is a small segment of the pipe tobacco market, but this could create overestimates in our pipe tobacco assessment.

FDA does not require foreign manufacturers of tobacco products or domestic importers that do not manufacture, prepare, compound, or process tobacco products intended for distribution in the U.S. market to register and list. As a result, we use the number of domestic importers of cigarettes, cigars, pipe tobacco, and RYO tobacco from the Alcohol and Tobacco Tax and Trade Bureau (TTB) to estimate the number of establishments whose business of bringing combusted tobacco products into the U.S. market would be affected.[32] We estimate there to be no more than 150 importers of combusted tobacco products potentially affected by this rule. We note that we are unable to differentiate between manufacturers or importers of premium and non-premium cigar or pipe and waterpipe tobacco products, in our data source, so the number of affected entities in this section may be an overestimate. We request comment on additional data sources to identify the number of manufacturers and importers of affected products.

b. Other Affected Entities

In addition to manufacturers, entities that sell affected products, either as wholesalers or as retailers would also be impacted by this rule, if finalized. To estimate the number of these affected entities, we use the Statistics of U.S. Business (SUSB) data from 2021 (47). Although data for wholesalers of tobacco products are identified in a specific 2017 NAICS industry code[33] in the 2021 SUSB data (424940, Tobacco and Tobacco Product Merchant Wholesalers), data for retailers of tobacco products are not identified in a specific NAICS industry code in the SUSB data (i.e., SUSB groups all retailers, including those that sell tobacco products and those that do not sell tobacco products, together).

We incorporate product by industry data from the 2017 Economic Census to estimate the percent of establishments in each retail category that reported non-negligible retail sales of tobacco products (North American Product Classification System (NAPCS) code 5000325000, Retail sales of tobacco products and smoking accessories) (48). Multiplying these percentages by the count of establishments from the 2021 SUSB data, we estimate the number of tobacco-selling retail establishments in 2021. Assuming the distribution of tobacco-selling establishments approximates the distribution of tobacco-selling firms, we also multiply these percentages by the number of firms to estimate the number of tobacco-selling firms in 2021. If firms that have multiple establishments are more or less likely to sell tobacco products than firms with only one establishment this could introduce some uncertainty to our estimates.

[32] The TTB, a bureau under the U.S. Department of the Treasury, is responsible for collecting federal excise taxes on tobacco products and ensuring compliance with federal tobacco permitting requirements derived from Chapter 52 of the Internal Revenue Code. Entities that manufacture and/or import tobacco products—defined as "[c]igars, cigarettes, smokeless tobacco, pipe tobacco, and roll your own tobacco"—must apply for a TTB permit, and manufacturers/importers generally pay federal excise taxes after they remove tobacco products from their premises or withdraw products from customs custody for domestic consumption.

[33] The latest data available uses 2017 NAICS industry codes. Some of these classifications are different in the 2022 NAICS.

Table 8 presents the NAICS codes and descriptions for wholesalers and retailers potentially affected by the proposed product standard; estimates of firms and establishments from the 2021 SUSB data; data from the 2017 Economic Census on establishments that sell tobacco products within each retail category; and our estimates of 2021 firms and establishments that sell tobacco products.

Table 8. Affected Entities Other than Tobacco Manufacturers

2017 NAICS	2017 NAICS Description	Firms – 2021	Total Estab. - 2021	2017 Economic Census Data – Retail Sales of Tobacco Products			Applying the 2017% to:	
				Estab. Sell Tobacco – 2017	Total Estab - 2017*	% of Estab. With tobacco sales - 2017	2021 Firms Data	2021 Establishment Data
42494 [a]	Tobacco and Tobacco Product Merchant Wholesalers	1,343	1,546				1,343	1,546
44511	Supermarkets and Other Grocery (except Convenience) Stores	38,170	62,329	30,814	65,141	47.30%	18,054	29,482
44512	Convenience Stores	32,008	34,170	25,264	28,460	88.77%	28,414	30,333
44530	Beer, Wine, and Liquor Stores	31,497	35,533	18,700	34,440	54.30%	17,103	19,294
44611	Pharmacies and Drug Stores	19,261	43,879	19,247	45,358	42.43%	8,172	18,618
44711	Gasoline Stations with Convenience Stores	55,291	98,056	91,667	98,788	92.79%	51,305	90,986
44719	Other Gasoline Stations	9,062	12,869	3,725	16,581	22.47%	2,036	2,892

452311	Warehouse Clubs and Supercenters	37	8,070	6,735	8,202	82.11%	30	6,626
452319	All Other General Merchandise Stores	8,057	44,989	31,194	41,241	75.64%	6,094	34,030
453991	Tobacco Stores	12,492	14,512	10,415	10,415	100.00%	12,492	14,512
	Total	**207,218**	**355,953**	**237,761**	**348,626**		**145,044**	**248,318**

[a] By definition, all firms in NAICS 42494 sell tobacco products.

Given the complexities of growth and contraction in various industries, as well as the regularly changing landscape of state and local tobacco policies that may impact the types of establishments that sell tobacco products, we do not predict a trend in the number of tobacco-selling establishments beyond 2021. Furthermore, given that 2017 is the most recent year providing disaggregated data on retailers that sell tobacco, we assume the distribution of tobacco-selling retailers using 2017 tobacco establishment data approximates the distribution of tobacco-selling retailers in 2021. We request comment on these assumptions and more recent data to estimate the number of wholesalers and retailers that sell tobacco products by NAICS code.

c. Number of Affected Products

To understand the baseline state of the tobacco market, we first searched the active product listing information in TRLM NG as of February 2023 for all products under the category of "cigarettes," removing any products containing the words "vape" or "vapor" in their name, which netted a total of 1,712 unique cigarette products. Filtering these yielded 613 unique cigarette products with an identified flavor of "menthol" or with a product name that contained the word "menthol" if no flavor was listed. Following the same steps in TRLM NG for the category of RYO Tobacco, we found a total of 234 RYO tobacco products, 58 of which are menthol flavored. For this analysis, we consider a scenario in which a menthol product standard were to finalize before a nicotine standard, if finalized, would become effective, and therefore omit all menthol-flavored cigarette products. Thus, we estimate that in baseline, there are 1,099 affected cigarette products (1,099 = 1,712 – 613) and 176 RYO tobacco products (176 = 234 – 58). We also identify 8,961 pipe tobacco products and 515 smokeless tobacco products in the TRLM NG data that would be affected by the proposed rule.

We identify 31,737 tobacco-flavored cigars in the data. However, we are unable to differentiate premium from non-premium cigars in the TRLM NG data. Therefore, we make a simplifying assumption that the number of premium cigar products is proportional to the

percentage of premium cigar units sold relative to total cigar units sold, which is about 8 percent of total cigar units (8 percent = [714 million premium cigar units / 9,078 million total cigar units] x 100 percent). We request comment on this assumption. We estimate there to be 29,515 unique tobacco-flavored non-premium cigar products on the market affected by the rule (31,737 tobacco-flavored cigars x [100 percent – 8 percent]). We request comment on this estimation approach. Counts by product type are displayed below in Table 9.

Table 9. TRLM NG Data on Number of Affected Products by Tobacco Category

	Cigarettes	Cigar	RYO Tobacco	Pipe	Smokeless Tobacco	Total
Count	1,099	29,515	176	8,961	515	40,266
Percent	2.7%	73.3%	0.4%	22.3%	1.3%	100.0%

[1]We note that the count for pipe tobacco includes waterpipe tobacco. This may result in an overestimate. See discussion above.

5. Federal and State Excise Taxes

To understand the potential effects of the proposed rule on excise taxes, we estimate baseline excise tax revenues for the baseline volume sales of affected tobacco products in four categories: (1) cigarettes; (2) cigars; (3) smokeless tobacco products; and (4) pipe/RYO tobacco products. ENDS products are not taxed by the Federal Government. Since the state tax structure varies across the country and state-level ENDS tax revenues appear negligible relative to tax revenues from other tobacco products, we do not assess them in this analysis. We draw on data from several sources to estimate Federal and State excise tax rates and revenues, and we request comment on these data sources and estimates.

To estimate baseline excise tax revenues for affected cigarettes, we draw on data from the PHM and Euromonitor data (44) to estimate a 40-year stream of the number of people who smoke cigarettes and the number of sticks smoked. We convert the number of sticks to pack equivalents assuming that there are 20 cigarettes per pack, and we divide the estimated expenditures on cigarettes by the number of people who smoke cigarettes to yield a per person expenditure. We multiply the projected number of people who smoke cigarettes in each year of the 40-year horizon by the estimated expenditure per person to yield total consumer expenditures for tobacco products. We then assume that tax rates remain constant with respect to nominal prices over our 40-year time horizon. We multiply the 2021 estimated annual pack equivalents by the Federal ($1.01) and the 2021 adjusted average State per pack excise tax rate ($2.12 = $1.91 x 2023 GDP deflator) (49) to yield baseline Federal and State revenues. We acknowledge that there is variability in State cigarette tax rates but use the average in this analysis as an approximation of the total change in excise tax collections by States. We use the PHM to project the 40-year stream of people who smoke cigarettes that would continue to smoke under the baseline scenario.

We estimate that baseline excise tax revenues for cigarettes are approximately $526.8 billion (= $170.1 billion Federal revenues + $356.8 billion State revenues) over a 40-year time

horizon. Estimates of baseline sales volume, excise tax rates, and excise tax revenues for cigarettes are summarized in Table 10. We request comment on these data sources and our estimates.

Table 10. Estimated Baseline Sales Volume, Excise Tax Rates, and Revenues for Affected Cigarettes

Year Count	Year	Baseline Volume Sales for Cigarette Products			Excise Tax Rates (Per Pack)		Baseline Excise Tax Revenues		
		People who smoke cigarettes	Sticks (Millions)	Pack Equivalent (Millions)	Federal	State Average	Federal (Millions)	State (Millions)	Total (Millions)
0	2025	27,735,454	176,358	8,818	$1.01	$2.12	$8,906	$18,685	$27,591
1	2026	26,161,940	164,714	8,236	$1.01	$2.12	$8,318	$17,451	$25,769
2	2027	24,859,991	155,114	7,756	$1.01	$2.12	$7,833	$16,434	$24,268
3	2028	23,638,003	146,258	7,313	$1.01	$2.12	$7,386	$15,496	$22,882
4	2029	22,490,632	138,083	6,904	$1.01	$2.12	$6,973	$14,630	$21,603
5	2030	21,423,065	130,565	6,528	$1.01	$2.12	$6,243	$13,833	$20,427
…	…	…	…	…	…	…	…	…	…
39	2064	9,793,879	51,430	2,572	$1.01	$2.12	$2,597	$5,449	$8,046
40	2065	9,759,731	51,063	2,553	$1.01	$2.12	$2,579	$5,410	$7,989
Total		-	3,367,342	168,367	-	-	$170,051	$356,770	$526,821

One pack of cigarettes contains 20 cigarettes (sticks).

To estimate baseline excise tax revenue for affected cigars, we draw on data from the PHM as well as Euromonitor data to estimate a 40-year stream of people who smoke cigars and the number of cigars sold. To estimate an excise tax rate per cigar, we draw on IRS federal excise tax data (50), Census Bureau Annual Survey of State Government Tax Collections (STC) data (51), and TTB National Tobacco Statistics data (52). We total domestic and imported Federal excise tax revenues in 2022 from the IRS excise tax data, adjust these revenues to 2023 levels with the GDP deflator, and divide this total by the taxable quantity of cigars in 2022 reported in the TTB data to yield Federal excise tax revenue per cigar. To exclude premium cigars from this calculation, we draw on Euromonitor data to multiply the per cigar rate by the ratio of the percentage of dollars sales to percentage of units of cigars that are classified as non-premium. This yields an estimated Federal excise tax rate of $0.0996 per covered cigar.[34] To estimate average State excise tax rates for cigars, we draw on Census data and estimate the midpoint between low and high total State cigar taxes. We divide this estimate by the taxable quantity of cigars reported in TTB data to yield State excise tax revenue per cigar. To exclude premium cigars, we multiply this rate by the ratio of percentage dollar sales to percentage units

[34] TTB tax rates are $0.0505 per small cigar ($1.01 per pack of 20) and a maximum rate of $0.4026 per large cigar. In section II.E.3, we estimate an average per unit price of tobacco flavored pre-CF policy nonpremium cigars of approximately $0.663. Our estimated Federal excise tax rate is approximately 15 percent of the estimated price (= $0.663 / $0.0997).

of non-premium cigars. This yields an estimated average State excise tax rate for cigars of approximately $0.1863 per affected cigar.

We multiply the estimated number of cigars consumed in each year of the 40-year time horizon by the estimated per cigar Federal and average State excise tax rates to yield baseline excise tax revenues on affected cigars in each year of the 40-year horizon. We estimate that baseline excise tax revenues for cigars are approximately $73.3 billion (= $25.6 billion Federal revenues + $47.8 billion State revenues) over a 40-year time horizon. Estimates of baseline sales volume, excise tax rates, and excise tax revenues for cigars are summarized in Table 11. We request comment on these data sources and our estimates.

Table 11. Estimated Baseline Sales Volume, Excise Tax Rates, and Revenues for Affected Cigars

Year Count	Year	Baseline Volume Sales for Cigar Products (Millions of Units)	Excise Tax Rates (Per Unit)		Baseline Excise Tax Revenues		
			Federal	State Average	Federal (Millions)	State (Millions)	Total (Millions)
0	2025	7,716	$0.10	$0.11	$769	$1,437	$2,206
1	2026	7,716	$0.10	$0.11	$769	$1,437	$2,206
2	2027	7,716	$0.10	$0.11	$769	$1,437	$2,206
3	2028	7,642	$0.10	$0.11	$761	$1,423	$2,185
4	2029	7,568	$0.10	$0.11	$754	$1,410	$2,164
5	2030	7,493	$0.10	$0.11	$747	$1,396	$2,142
…	…		…	…			
39	2064	5,045	$0.10	$0.11	$503	$940	$1,442
40	2065	4,971	$0.10	$0.11	$495	$926	$1,421
Total		256,484	-	-	$25,556	$47.772	$73.328

To estimate baseline excise tax revenue for smokeless tobacco products, we draw on data from the PHM as well as Euromonitor data to estimate a 40-year stream of people who use smokeless tobacco products and the number of smokeless tobacco products sold. Euromonitor data reports the annual quantity of smokeless tobacco products by metric tonnes, which we convert to 1-ounce smokeless unit equivalents to estimate a per unit excise tax rate.

To estimate an excise tax rate per smokeless tobacco product, we draw on IRS federal excise tax data, Census STC data, and TTB data. We total domestic and imported Federal excise tax revenues in 2022 from IRS data and divide this total by the taxable quantity of smokeless tobacco products in 2022 (reported in metric tonnes and converted to 1-ounce unit equivalents) reported in TTB data, adjust these revenues to 2023 levels with the GDP deflator, to yield

Federal excise tax revenue per smokeless tobacco unit equivalent. This yields an estimated per smokeless unit equivalent Federal excise tax rate of approximately $0.0818 per unit.[35] To estimate average State excise tax rates for cigars, we draw on Census data and estimate the midpoint between low and high total State smokeless product taxes. We divide this estimate by the taxable quantity of smokeless products reported in TTB data to yield State excise tax revenue per smokeless unit equivalent. This yields an estimated average State excise tax rate for smokeless tobacco of approximately $0.1517 per product.

We multiply the estimated number of smokeless tobacco unit equivalents consumed in each year of the 40-year time horizon by the estimated per smokeless unit Federal and average State excise tax rates to yield baseline excise tax revenues on smokeless tobacco products in each year of the 40-year horizon. We estimate that baseline excise tax revenues for smokeless tobacco products are approximately $34.7 billion (= $12.2 billion Federal revenues + $22.6 billion State revenues) over a 40-year time horizon. Estimates of baseline sales volume, excise tax rates, and excise tax revenues for smokeless tobacco products are summarized in Table 12. We request comment on these data sources and our estimates.

Table 12. Estimated Baseline Sales Volume, Excise Tax Rates, and Revenues for Smokeless Tobacco Products

Year Count	Year	Baseline Volume Sales for Smokeless Tobacco Products		Excise Tax Rates (Per Unit)		Baseline Excise Tax Revenues		
		Number of People Who Use Smokeless Products	Units (Millions)	Federal	State Average	Federal (Millions)	State (Millions)	Total (Millions)
0	2025	18,016,415	2,421	$0.08	$0.15	$198	$367	$565
1	2026	19,166,657	2,576	$0.08	$0.15	$211	$391	$601
2	2027	20,064,364	2,696	$0.08	$0.15	$220	$409	$629
3	2028	20,918,703	2,811	$0.08	$0.15	$230	$426	$656
4	2029	21,712,824	2,918	$0.08	$0.15	$239	$443	$681
5	2030	22,450,411	3,017	$0.08	$0.15	$247	$458	$704
…	…	…	…	…	…	…	…	…
39	2064	32,710,114	4,396	$0.08	$0.15	$359	$667	$1,026
40	2065	32,874,670	4,418	$0.08	$0.15	$361	$670	$1,031
Total		-	148,848	-	-	$12,171	$22,575	$34,747

[35] In our analysis, the smokeless product category includes chewing tobacco and snuff. The TTB tax rate for a 1-ounce tin of snuff is $0.0944; the TTB tax rate for 1-ounce units of chewing tobacco is $0.0315. This smokeless product tax rate estimate combines both categories and yields a rate between the individual rates.

To estimate baseline excise tax revenue for affected pipe/RYO tobacco products, we draw on data from the PHM as well as Euromonitor data to estimate a 40-year stream of people who use pipe/RYO tobacco products and the number of pipe/RYO tobacco products sold. Euromonitor data reports the annual quantity of pipe/RYO tobacco products by metric tonnes, which we convert to 16-ounce smokeless unit equivalents to estimate a per unit excise tax rate. We multiply the estimated number of people who smoke cigarettes from the PHM by the ratio of pipe/RYO tobacco unit equivalents to cigarette pack equivalents to estimate the number of people who consume pipe/RYO over the 40-year time horizon.

To estimate an excise tax rate per pipe/RYO tobacco product, we draw on IRS federal excise tax data, Census STC data, and TTB. We total domestic and imported Federal excise tax revenues in 2022 from IRS data, adjust these revenues to 2023 levels with the GDP deflator, and divide this total by the taxable quantity of pipe/RYO tobacco products in 2022 (in pounds) reported in the TTB data to yield Federal excise tax revenue per pipe/RYO tobacco unit equivalent. This yields an estimated per unit equivalent Federal excise tax rate of approximately $5.3813 per affected unit. To estimate average State excise tax rates for pipe/RYO tobacco products, we draw on IRS federal excise tax data (50) and estimate the midpoint between low and high total State pipe/RYO product taxes. We divide this estimate by the taxable quantity of pipe/RYO products reported in TTB data to yield State excise tax revenue per unit equivalent. This yields an estimated average State excise tax rate for pipe/RYO tobacco of approximately $8.72 per affected product.

We multiply the estimated number of pipe/RYO unit equivalents consumed in each year of the 40-year time horizon by the estimated per unit Federal and average State excise tax rates to yield baseline excise tax revenues on affected pipe/RYO tobacco products in each year of the 40-year horizon. We estimate that baseline excise tax revenues for pipe/RYO tobacco products are approximately $16.5 billion (= $6.3 billion Federal revenues + $10.2 billion State revenues) over a 40-year time horizon. Estimates of baseline sales volume, excise tax rates, and excise tax revenues for pipe/RYO tobacco products are summarized in Table 13. We request comment on these data sources and our estimates.

Table 13. Estimated Baseline Sales Volume, Excise Tax Rates, and Revenues for Affected Pipe/RYO Tobacco Products

Year Count	Year		Baseline Volume Sales for Pipe/RYO Tobacco Products	Excise Tax Rates (Per Unit)		Baseline Excise Tax Revenues		
		Number of People Who Use	Units (Millions)	Federal	State Average	Federal (Millions)	State (Millions)	Total (Millions)

		Pipe/RYO Products						
0	2025	173,896	56	$5.38	$8.72	$300	$486	$786
1	2026	164,031	53	$5.38	$8.72	$283	$459	$742
2	2027	155,868	50	$5.38	$8.72	$269	$436	$705
3	2028	148,206	48	$5.38	$8.72	$256	$415	$670
4	2029	141,012	45	$5.38	$8.72	$243	$394	$638
5	2030	134,319	43	$5.38	$8.72	$232	$376	$607
…	…	…	…	…	…	…	…	…
39	2064	61,406	20	$5.38	$8.72	$106	$172	$278
40	2065	61,192	20	$5.38	$8.72	$106	$171	$277
Total		-	1,168	-	-	$6,286	$10,190	$16,476

We total the estimated excise tax revenues for cigarettes (Table 10), cigars (Table 11), smokeless tobacco products (Table 12), and pipe/RYO (Table 13). We estimate that baseline excise tax revenues for tobacco products are approximately $651.4 billion (= $214.1 billion Federal revenues + $437.3 billion State revenues) over a 40-year time horizon. These estimates are summarized in Table 14.

Table 14. Total Estimated Excise Tax Revenues for Affected Tobacco Products

		Total Baseline Excise Tax Revenues		
Year Count	Year	Federal (Millions)	State (Millions)	Total (Millions)
0	2025	$10,173	$29,976	$31,149
1	2026	$9,580	$19,738	$29,318
2	2027	$9,091	$18,716	$27,808
3	2028	$8,633	$17,760	$26,393
4	2029	$8,209	$16,876	$25,085
5	2030	$7,819	$16,062	$23,881
…	…	…	…	…
39	2064	$3,565	$7,227	$10,792
40	2065	$3,541	$7,177	$10,718
Total		$214,063	$437,308	$651,371

6. User Fees

FDA collects user fees every quarter from each domestic manufacturer and importer of six classes of tobacco products: cigarettes, cigars,[36] snuff, chewing tobacco, pipe tobacco, and RYO tobacco. While the statute sets snuff and chewing tobacco as separate tobacco product

[36] On August 9, 2023, the U.S. District Court for the District of Columbia issued an order in the case of *Cigar Association of America, et al. v. United States Food and Drug Administration et al.*, No. 16-cv-01460, 2023 WL 5094869 (D.D.C. Aug. 9, 2023), vacating "the FDA's decision to deem premium cigars". That decision is on appeal. *Cigar Ass'n of America v. U.S. Food & Drug Administration*, No. 23-5220 (D.C. Cir. argued Sept 13, 2024).

classes, both classes are within the larger smokeless category of tobacco products as defined in this document. The total amount of user fees is set by statute, and neither the amount of user fees collected, nor overall FDA accounting costs, would change because of this rule. The total amount of user fees collected in fiscal year 2019 and each fiscal year that has followed remains constant under the statute at $712 million. The amount of user fees paid by each tobacco product class is determined by the federal excise taxes associated with the class of tobacco product in domestic commerce, with the amount of user fees paid by each firm allocated according to the firm's market share within the tobacco product class. While ENDS products are subject to FDA authority and are indirectly impacted by the proposed product standard, FDA does not currently have the authority to assess user fees on manufacturers of ENDS products. For fiscal year 2023, approximately 83.6 percent ($595.5 million annually) of the tobacco user fees were allocated to the cigarette product class, 0.04 percent ($250,000 annually) to the RYO product class, 1.31 percent ($9.3 million) to the snuff category, 0.06 percent ($0.5 million) to the chewing tobacco category, 14.4 percent ($102.5 million annually) to the cigar product class (including premium and non-premium cigars), and 0.57 percent ($4 million annually) to the pipe tobacco product class (53).

While Congress set user fees at a constant $712 million per year this analysis is in constant 2023 dollars. We use the Federal Reserve Bank of Philadelphia's Survey of Professional Forecasters' 10-year-ahead inflation forecast as the average inflation over the time horizon to convert the nominal user fees into real 2023 dollars (54). Over the last 16 quarters the estimated 10-year-ahead inflation forecast averages 2.4%.

For our user fee analysis, we evaluate the tobacco market by product category. We follow the method as laid out in 21 C.F.R. § 1150.3. User fee obligations by class are determined based on the previous calendar year's federal tax revenue. To construct the baseline, we use the quantity estimates discussed in Section II.E.3 as our quantity times the federal maximum tax rate from TTB as discussed in 26 USC § 5701. See Figure 9 for a breakdown of the percent of user fees owed by tobacco product class and Table 15 presents the projected baseline dollar values owed by each product category.

Table 15. Total Projected Baseline User Fee Allocation by Product Category (2023, $)

	Total Allocation for				
Year	Cigarettes	RYO	Cigars	Pipe	Smokeless
2025	605,563,358	3,703,374	62,842,681	4,143,691	12,447,642
2030	581,219,683	3,554,498	67,036,058	3,977,115	19,639,266
2035	554,825,813	3,393,084	79,261,980	3,796,509	27,024,860
2040	532,414,904	3,256,029	90,219,428	3,643,158	33,888,539
2045	514,118,347	3,144,134	98,245,798	3,517,960	40,686,580
2050	500,988,341	3,063,837	102,766,241	3,428,115	46,476,792

2055	492,590,726	3,012,480	104,144,005	3,370,653	51,103,165
2060	488,133,102	2,985,219	102,930,656	3,340,151	54,681,206

In the existing federal tax structure, combusted tobacco products, especially cigarettes and cigars, are taxed at a relatively higher rate than noncombusted products. This means that as consumption shifts towards noncombusted products at baseline the ratio between user fee allocations and projected revenue for the combusted product categories will increase. We take the ratio of the projected user fee allocations by class to the projected post-tax revenues by class to assess the potential burden of user fees on tobacco product manufacturers. See Figure 10.

Figure 9. Percent of Total User fees by Category at Baseline Without the Proposed Rule

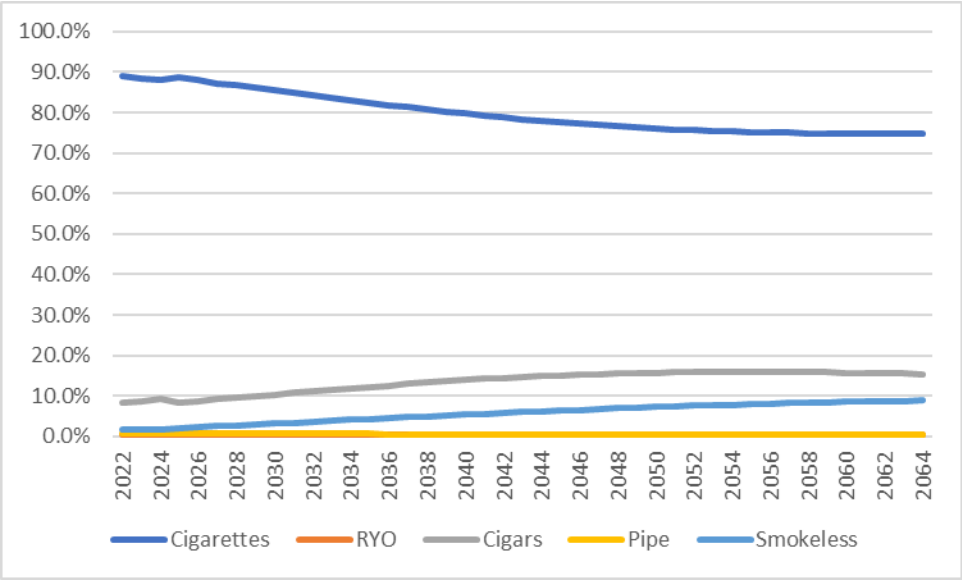
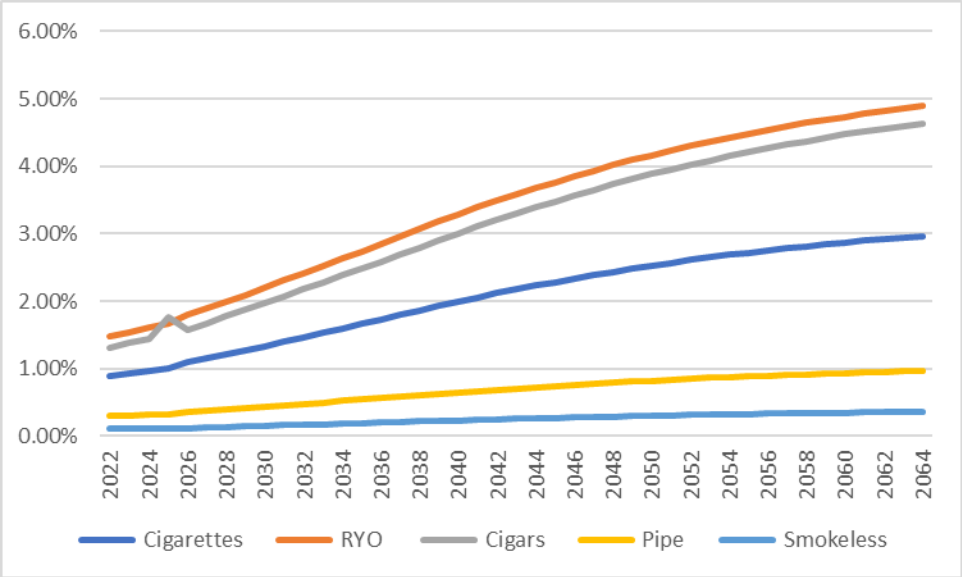


Figure 10. Baseline User Fee Obligation by Product Category as a Percent of Post-Tax Revenue



Because, at baseline, net tobacco unit sales are declining over time while the total user fee obligation is only declining at the rate of projected inflation for constant 2023 dollars and the revenues estimated above in Section II.E.3 assume that firms hold future prices constant at current rates (in 2023 dollars), user fees represent a continually increasing share of tobacco manufacturers' post-tax revenue for each respective tobacco product class. Our analysis estimates that in 2025 all manufacturers in a given category would collectively owe between 0.1 percent and 1.6 percent of the category's projected post-tax revenue from sales of that tobacco category. By 2064, they would collectively owe between 0.3 percent to 4.5 percent of the category's projected post-tax revenue in user fees at baseline. These assessments of revenue are specific to the revenue of each product category and do not consider firms' overall revenue or other lines of business. We note that a single manufacturer may produce tobacco products across a range of tobacco product classes that are subject to user fees, resulting in net transfers of user fees within firms. We request comment on these data sources, assumptions, and our estimates.

F. Estimated Impacts of the Nicotine Product Standard on Tobacco Use

In Section II.D, we describe the PHM used to estimate the changes in tobacco product initiation, cessation, switching, and dual use on tobacco use prevalence, morbidity, and mortality in the United States, for the modeled tobacco product types. This section describes the magnitude of estimated impacts under the proposed product standard.

For the purposes of this PRIA, we use the PHM to estimate impacts for a range of averted mortality and tobacco prevalence. The "high impact scenario," referred to as the upper bound in this analysis, corresponds to the scenario where the policy has the highest estimated averted

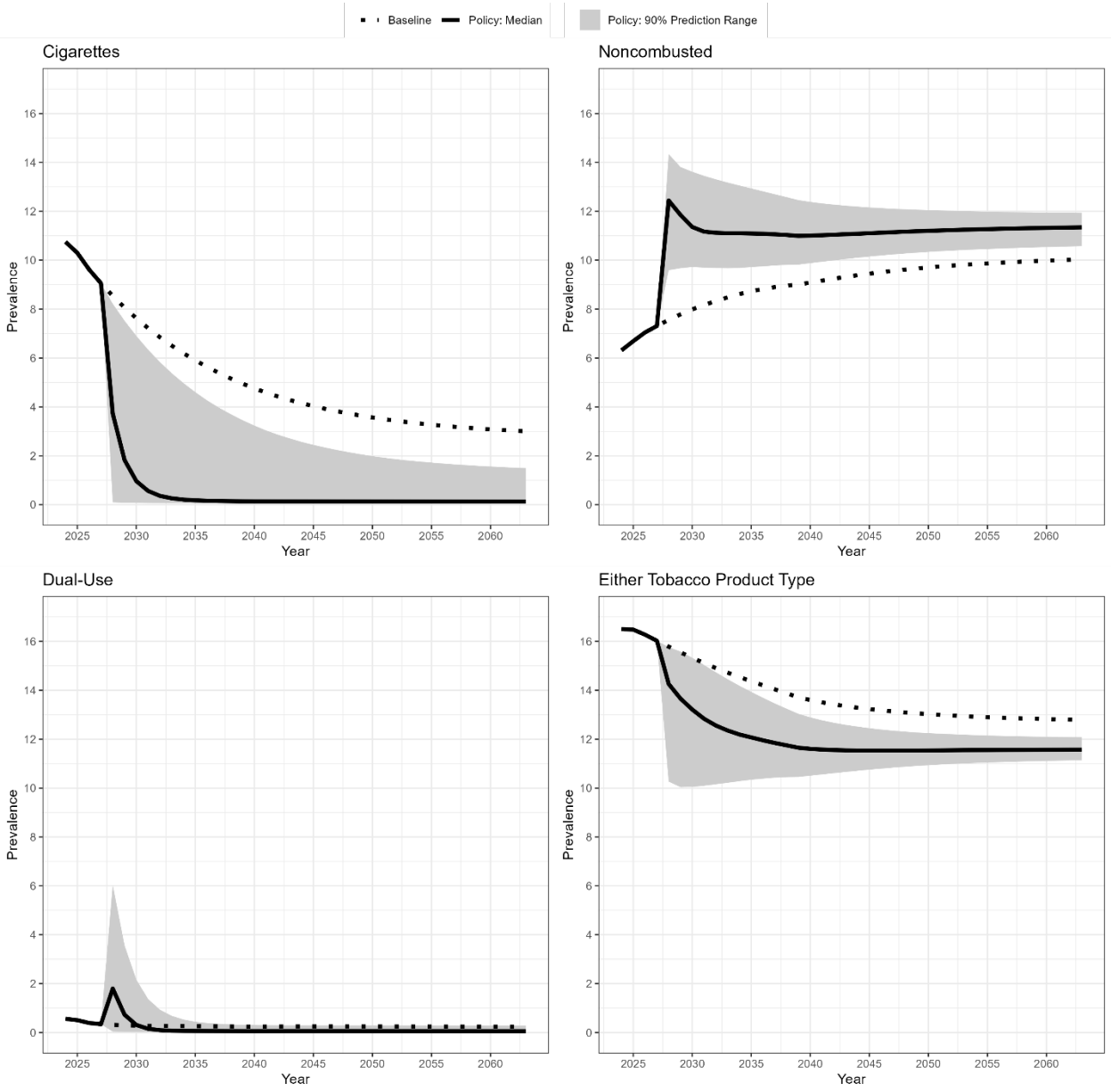
mortality (95th percentile results projected by the PHM) and the lowest (5th percentile) post-policy combusted tobacco prevalence. Conversely, the "low impact scenario," referred to as the lower bound in this analysis, is the scenario corresponding to the PHM results with the lowest averted mortality (5th percentile) and the highest (95th percentile) post-policy combusted tobacco prevalence from the PHM. The "primary impact scenario," referred to as the primary estimate in this analysis, corresponds to the PHM's averted mortality results at the 50th percentile and the 50th percentile post-policy combusted tobacco prevalence.

1. Prevalence of Tobacco Product Use

The PHM described above and in greater detail in Center for Tobacco Products (2), uses empirical data and an expert elicitation to construct a dynamic model that projects, among other things, the prevalence of two types of tobacco products: cigarettes and noncombusted products.

In Figure 11, we present the projected effects of the proposed nicotine product standard on the prevalence of cigarette, noncombusted tobacco, dual use, and overall tobacco product use. In this figure, baseline levels of prevalence are presented by a dashed line, the median policy effects are presented by at solid black line, and the 90 percent prediction range (5th to 95th percentile) is shaded in gray. As discussed in section II.D, the PHM model has been adjusted to account for the potential impacts of the Menthol and Cigar Flavors proposed product standards. With this proposed product standard, if finalized, we expect the prevalence of cigarette use to decrease from approximately 10 percent to less than 1 percent over the 40-year time horizon of the analysis. On the other hand, we expect the prevalence of noncombusted tobacco product use to increase from approximately 7 percent to approximately 11 percent over the time horizon of the analysis. More detailed information regarding these prevalence projections can be found in FDA's modeling document (2). We expect the prevalence of dual-use of both tobacco product types to initially increase as a result of the rule—driven primarily by the increase in the prevalence of noncombusted tobacco product use—before decreasing to nearly 0 percent over the time horizon of the analysis. Overall, the prevalence of use of either tobacco product type is expected to decrease from approximately 16 percent to approximately 12 percent over the time horizon.

Figure 11. Projected Prevalence of Tobacco Products Under the Policy Scenario, Adjusting for the Menthol and Cigar Flavors Proposed Rules



Note: 90% prediction range refers the 5th to 95th percentile of prevalence estimates from the PHM

2. Changes in Quantity Sold of Affected Tobacco Products

We estimate changes to quantity sold for tobacco products impacted by the policy under the low, primary, and high impact policy scenarios. The policy's reduction in smoking prevalence is expected to lead to an associated reduction in quantity sold for covered tobacco products. However, the policy is also expected to lead to an increase in noncombusted tobacco

use prevalence, which is associated with an increase in quantity sold for noncombusted tobacco products.

To calculate the quantity sold of tobacco products impacted by the policy, we assume consumption and prevalence change at equal rates, and then adjust the quantity of the product by the annual percentage change in prevalence using data from the PHM under the respective policy impact scenario. For example, the first year the policy is expected to impact prevalence and quantity is in 2028. In 2027, we estimate there to be 155.1 billion cigarettes sold in the US market. The PHM estimates that adult cigarette smoking prevalence fell 62.5 percent between 2027 and 2028 in the primary impact policy scenario. Therefore, we estimate that 58.2 billion cigarette sticks were sold in 2028 in the primary policy impact scenario (155.1 billion x (100 - 62.5 percent) = 58.2 billion).

Figure 12 through Figure 15 below depict the expected units sold from 2025 to 2064 for cigarettes, RYO tobacco, pipe tobacco, and cigars, respectively. In 2028, the first year the policy impacts quantity, we estimate a reduction in quantity sold for affected combusted tobacco products of 4%, 60%, and 99% relative to baseline for the low, primary, and high impact policy scenarios. By 2064, we estimate a reduction of 55%, 96%, and 98% in quantity sold relative to baseline in the low, primary, and high impact scenarios.

Figure 12. Estimated Millions of Cigarette Sticks Sold at Baseline and Under the Low, Primary, and High Policy Impact Scenarios: 2025-2064

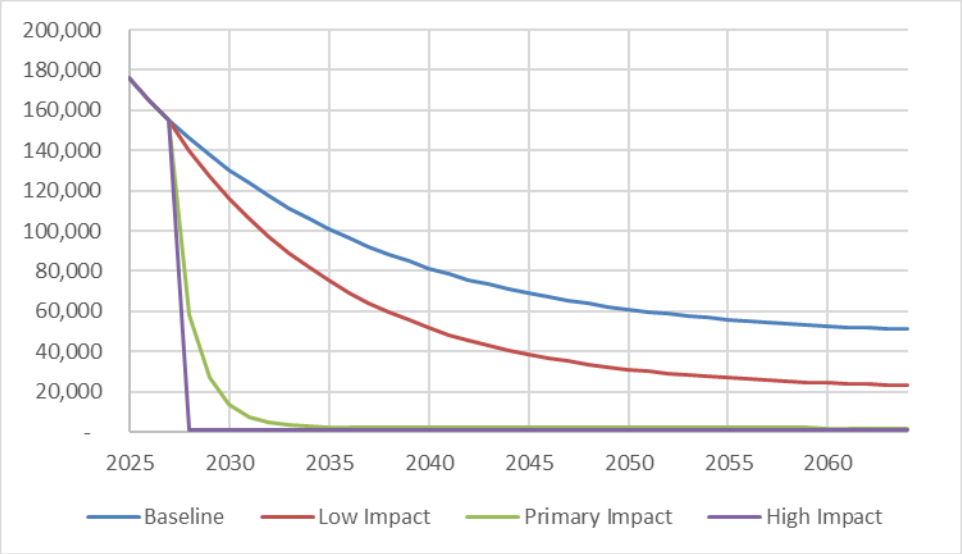


Figure 13. Estimated Millions of RYO Sticks Equivalents Sold at Baseline and Under the Low, Primary, and High Policy Impact Scenarios: 2025-2064

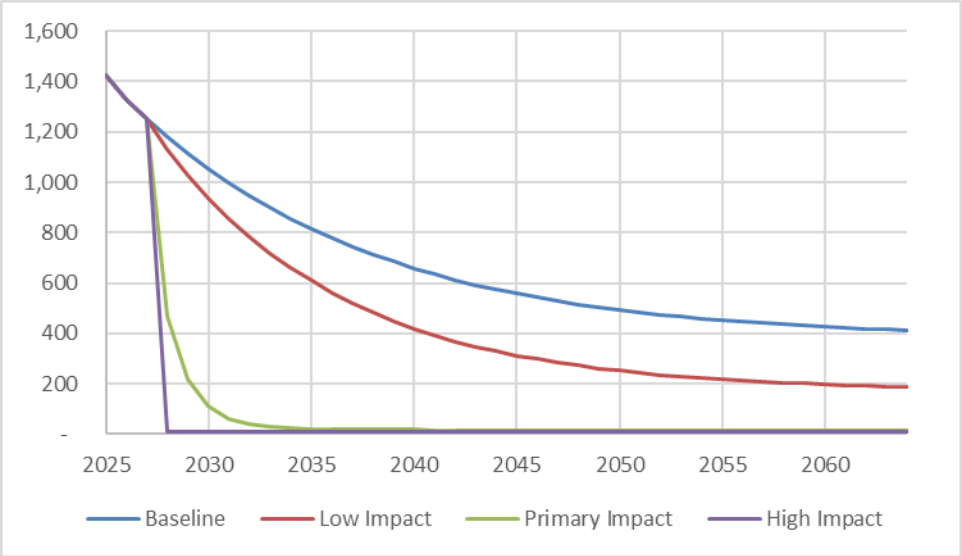


Figure 14. Estimated Metric Tonnes of Pipe Tobacco Sold at Baseline and Under the Low, Primary, and High Policy Impact Scenarios: 2025-2064

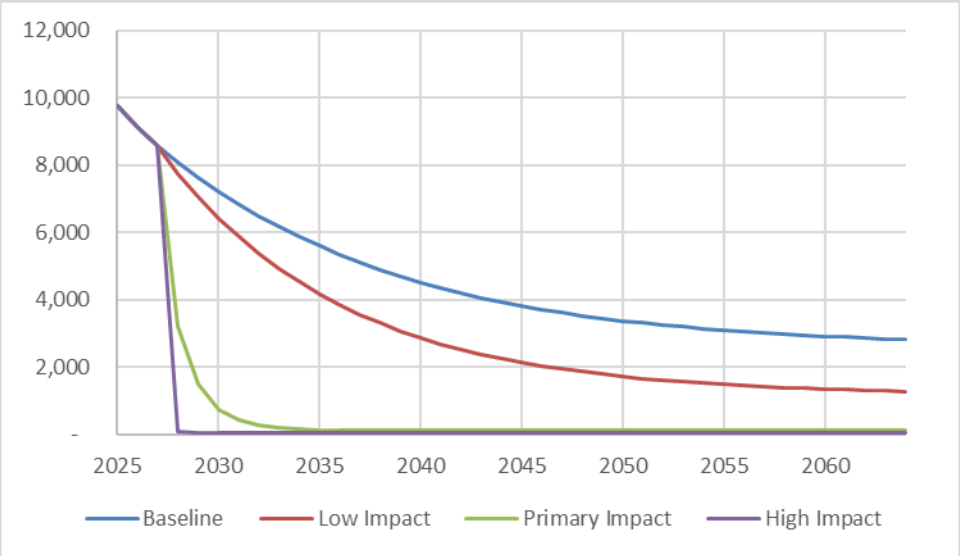


Figure 15. Estimated Millions of Non-Premium Tobacco-Flavored Cigars Sold at Baseline and Under the Low, Primary, and High Policy Impact Scenarios: 2025-2064

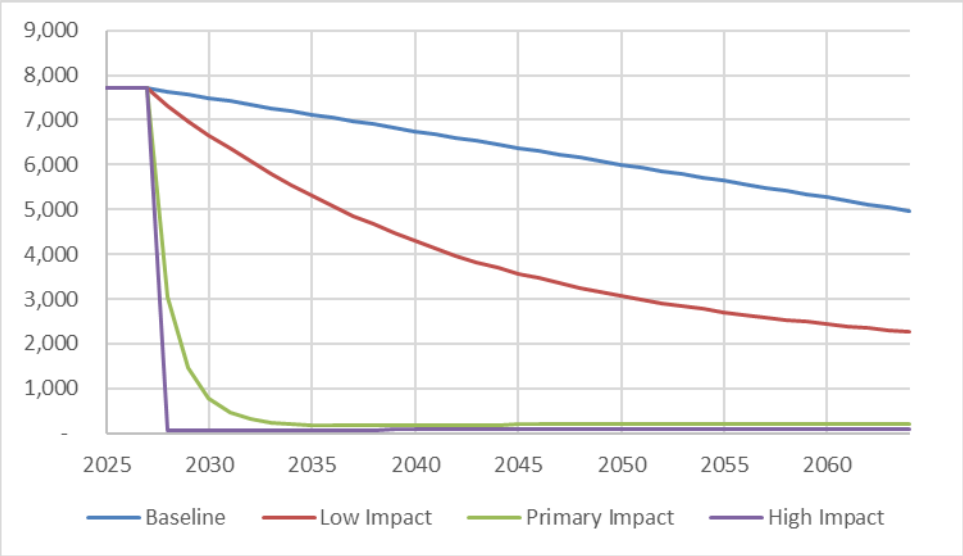
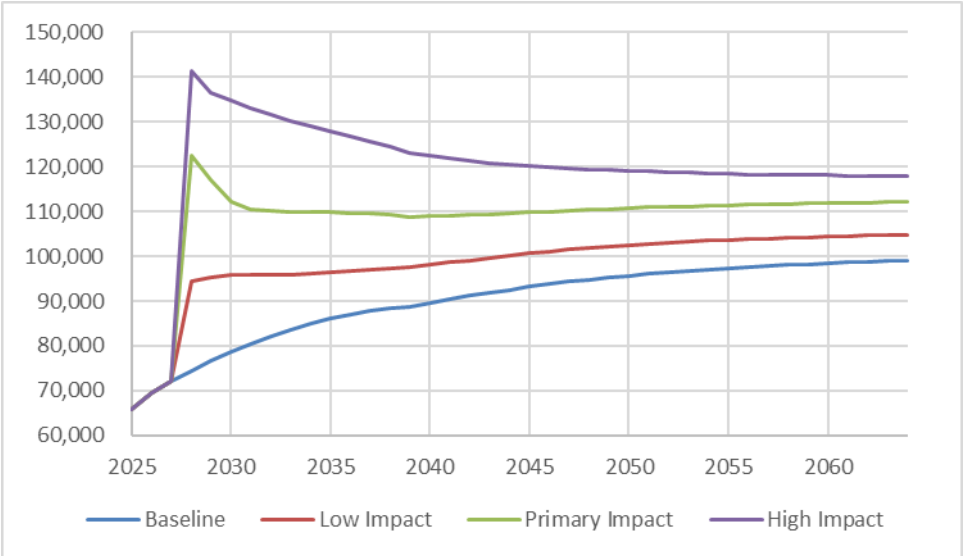


Figure 16 below shows expected units sold from 2025 to 2064 for SLT. Due to variation in how units are measured between product categories in the ENDS market, we assume the ENDS market remains proportional to SLT throughout the time horizon. In 2028, the first year the policy impacts quantity, we estimate an increase in quantity sold for noncombusted tobacco products of 27%, 64%, and 90% relative to baseline for the low, primary, and high impact policy scenarios. By 2064, we estimate an increase of 6%, 13%, and 19% in quantity sold relative to baseline in the low, primary, and high impact scenarios.

Figure 16. Estimated Metric Tons of Smokeless Tobacco Sold at Baseline and Under the Low, Primary, and High Policy Impact Scenarios: 2025-2064

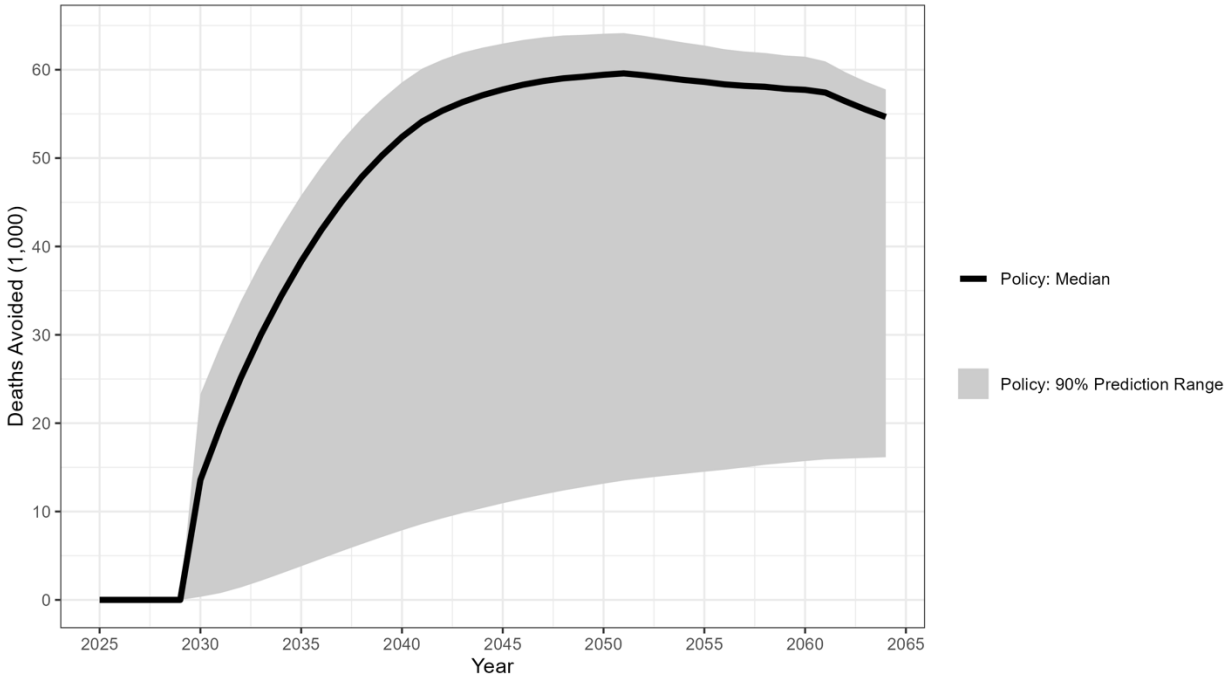


3. Premature Deaths Avoided

The PHM described in Section II.D and in greater detail in Center for Tobacco Products (2) also predicts the number of avoided deaths as a result of the proposed rule, if finalized. Specifically, for each time-step and iteration of the model, the PHM multiplies the projected prevalence of current tobacco use for the modeled tobacco product types, former tobacco product use, and never use by the number of people in the population to arrive at the number of people who currently use the modeled tobacco product types, who formerly used the modeled tobacco product types, or who never used the modeled tobacco product types. Each of these population groups in the PHM—defined by a unique combination of sex, age, and tobacco product use—have a specified probability of dying and set of probabilities for transitioning from one tobacco use state to another. In each year of the simulation, the model updates the number of members of each population group by calculating the number of individuals that transition into the population group and remain alive during the year. The sizes of the population groups are also updated by births and net international migration. The PHM then calculates the probability of dying for people who currently use and formerly used tobacco (based on relative risk of death) relative to each tobacco product type and multiplies the probability of dying under each tobacco use state by the corresponding populations to arrive at an estimated number of tobacco attributable deaths for each year in the analysis. In each year, the PHM finally compares the estimated number of tobacco-attributable deaths under the policy to the baseline estimated number of tobacco attributable deaths in the absence of the rule. The resulting estimates are the number of premature deaths we expect to avoid as a result of the proposed rule.

See Figure 17. Following the approach established in Apelberg et al. (2018), the PHM excludes any morbidity and mortality benefits accrued during the first three years after implementation of the product standard (30). Then, the PHM estimates the annual number of avoided premature deaths to increase from zero to approximately 14,000 in the fourth year (2030) and reaching approximately 60,000 in the 25th year (2052) after the implementation of the product standard before declining to approximately 54,000 by the end of the time horizon (2064). Over the 40-year time horizon, the PHM predicts a cumulative total of approximately 1.8 million averted premature deaths attributable to cigarettes and noncombusted tobacco use. We note that the predicted median (50th percentile) annual number of premature deaths avoided is closer to the upper bound of the prediction range (shaded in gray) than the lower bound. This is a direct result of the distribution of responses from the expert elicitation predicting the probability of changing smoking behavior as a result of the policy. Experts were asked to individually provide probability distributions of their responses, and when sampling across these various distributions, the PHM similarly reflects the same distributional shape present in the experts' responses.

Figure 17. Averted Annual Premature Mortality from Cigarettes and Noncombusted Tobacco Products, Adjusting for the Menthol and Cigar Flavors Proposed Rules



Using the PHM results, we also separately estimate the number of tobacco-attributable premature deaths avoided from various other sources including reduced exposure to secondhand smoke, reduced SIDS deaths, reduced smoking-related fires, reduced premature deaths from reduced pipe tobacco use, and reduced premature deaths from reduced cigar use (see Section II.D). Similar to the approach in estimating the baseline in Section II.E, the post-processing procedure scales the estimate of deaths annually attributable to direct cigarette smoking from 2005 to 2009 (3), according to the number of deaths attributed to use of other combusted tobacco products (e.g., cigars, pipe tobacco), exposure to secondhand smoke, SIDS, and smoking-related fires.[37] The mortality estimates attributable to the use of other combusted tobacco products (e.g., cigars, pipe tobacco), exposure to secondhand smoke, perinatal effects of smoking (e.g., SIDS), and smoking-related fires are explained in greater detail in Center for Tobacco Products (2).

[37] Specifically, from 2005 to 2009, there were 437,400 deaths annually attributable to cigarettes and 41,280 deaths annually attributable to secondhand smoke. Thus, after using the PHM to estimate the number of deaths attributable to cigarettes, we multiply those baseline deaths by 0.094 (= 41,280/437,400) to arrive at the estimated number of secondhand smoke-attributable deaths. Similarly, SIDS (0.001 = 400/437,400), fire-related (0.001 = 590/437,400), and pipe tobacco (0.003 = 1,095/437,400) -attributable deaths are estimated using the same ratio approach. Cigar deaths are estimated in two steps: 1) assuming a constant number of deaths (7,397) for the entire time horizon, then 2) phasing in the estimated number of avoided deaths from the product standard to prohibit all characterizing flavors (other than tobacco) in cigars (87 FR 26396, May 4, 2022).

See Figure 18. The PHM estimates annual premature deaths avoided from cigars to increase to approximately 3,000 each year by the end of the time horizon of the rule. The PHM predicts annual avoided deaths from secondhand smoke to increase to approximately 5,500 in the 20th year of the rule's implementation and remain relatively stable for the remainder of the time horizon. Using the PHM results, we also estimate that the proposed product standard would result in additional premature deaths avoided from reduced smoking-related fires, reduced SIDS deaths, and reduced pipe tobacco use.

Across the full 40-year time horizon, the PHM predicts a total of approximately 170,000 averted deaths attributable to secondhand smoke as a result of the rule. The same cumulative measure is approximately 1,600 for SIDS averted mortality, 2,400 for fire related averted mortality, 56,500 for cigar related averted mortality, and 4,500 for pipe tobacco related averted mortality.

Combined with the cumulative number of averted premature deaths attributable to cigarettes and noncombusted tobacco products, the PHM predicts a cumulative total of approximately 2 million averted premature deaths across all sources.

The PHM and underlying data support a year-by-year distribution of premature deaths avoided over time, including in the early years after the modeled policy takes effect. Studies of all cause smoking-attributable mortality risk, including cardiovascular disease risk, indicate that premature deaths are avoided early in the time horizon.

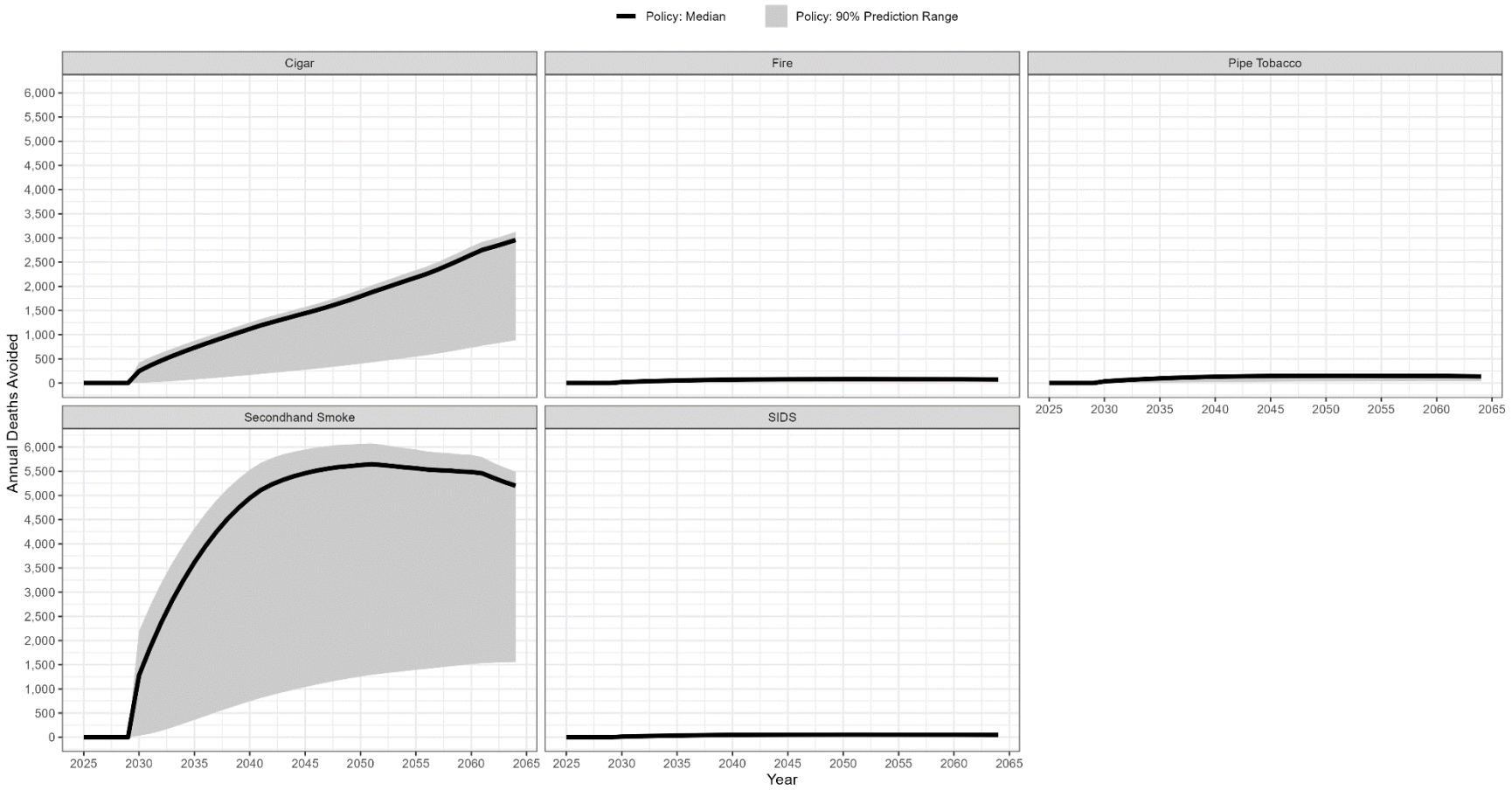
This mortality benefit is consistent data from the 2014 SGR on annual smoking-related mortality for adults aged 35 years and older, which shows that cancer accounts for 37.4% of smoking-attributable annual mortality (3). Cardiovascular (e.g., coronary heart disease, atherosclerosis, aortic aneurysm), metabolic (e.g., diabetes mellitus), and pulmonary (e.g., pneumonia, influenza, emphysema, bronchitis, chronic airways obstruction) diseases account for nearly two-thirds (62.6%) of annual smoking-related mortality (3). Cardiovascular diseases account for 34.7% of total annual smoking-related mortality, alone (3). Updated estimates of smoking-attributable mortality were published in the 2024 SGR "Eliminating Tobacco-Related Disease and Death: Addressing Disparities." Overall estimates of direct smoking-attributable mortality for U.S. adults aged 35 years and older were comparable in the 2014 and 2024 SGRs, with 437,400 deaths in the 2014 and 473,300 deaths in the 2024 reports (3 p. 660; 55 p. 495). We plan to incorporate these estimates into our analysis at the final rule stage.

Results from several studies support estimates of early reductions in mortality risk from cardiovascular disease including the 2010 SGR that states that "most risk reduction for mortality occurred in the first one to three years after smoking cessation…[i]t takes about three to five years of abstinence from smoking for most of the excess CVD [cardiovascular disease] risk to be gone" (24). More broadly, the 2020 SGR summarizes conclusions from previous Surgeon General's Reports on smoking cessation and cardiovascular disease, stating that "[t]he evidence is sufficient to infer that the relative risk of coronary heart disease among former smokers compared with never smokers falls rapidly after cessation and then declines more slowly" (6).

Specifically, “The excess risk of CHD [coronary heart disease] caused by smoking is reduced by about half after 1 year of smoking abstinence and then declines gradually” (6).

Overall, the 2020 SGR states that “the decline in risk of death compared with continuing smokers begins shortly after quitting,” indicating that some premature deaths are avoided early in the time horizon of analysis for this proposed product standard (6).

Figure 18. Averted Annual Premature Mortality from Additional Tobacco- Attributable Sources, Adjusting for the Menthol and Cigar Flavors Proposed Rules



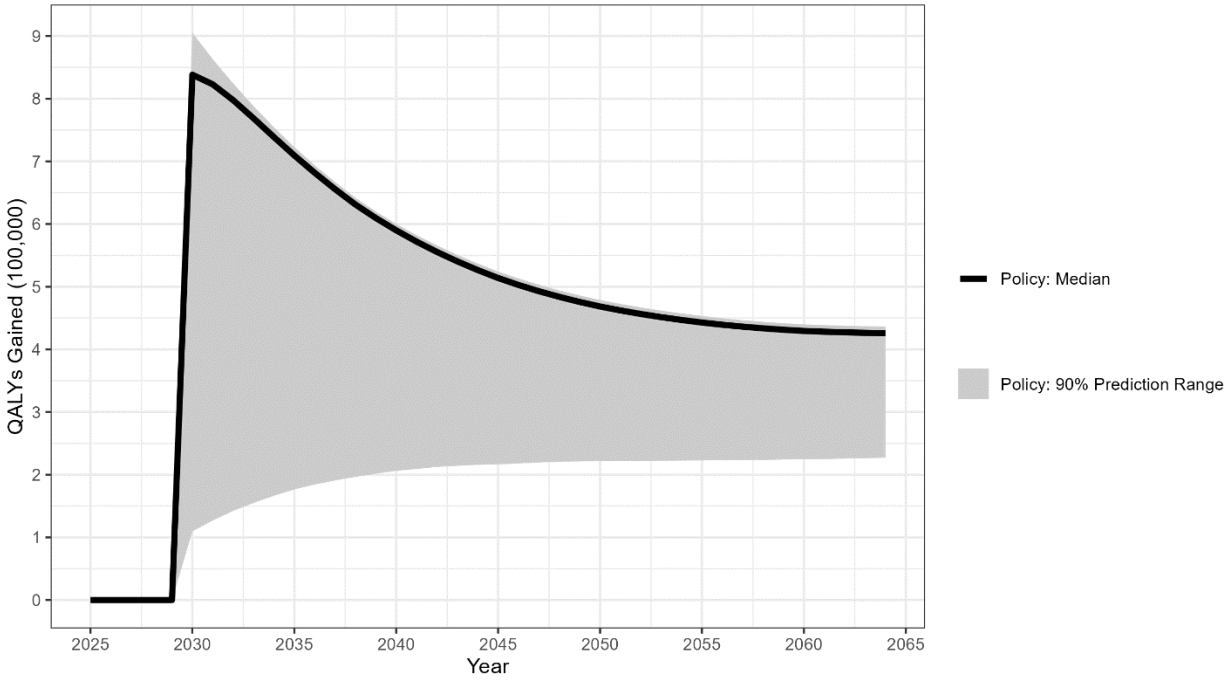
4. Quality-Adjusted Life Years Gained

The PHM described in Section II.D and in greater detail in Center for Tobacco Products (2) also predicts the number of QALYs gained from reduced smoking morbidity as a result of the proposed rule, if finalized. Specifically, to estimate the number of QALYs under the baseline and policy, the PHM first multiplies the difference in previously reported quality of life scores derived for people who smoke cigarettes and people who do not smoke cigarettes (56) by the number of people who currently smoke cigarettes according to age, sex, and model year. The difference between the number of QALYs under the baseline and each policy scenario during each year represents the number of QALYs expected to be gained in each year under the proposed rule. Jia and Lubetkin (2010) estimate mean EQ-5D[38] scores by age and smoking status from the Behavioral Risk Factor Surveillance System (BRFSS) (56). For people who smoke cigarettes, they find a mean EQ-5D score of 0.893 for ages 18-24, 0.864 for ages 25-44, 0.809 for ages 45-64, 0.799 for ages 65-74, and 0.753 for ages 75 and over. The mean EQ-5D scores for people who do not smoke cigarettes are 0.935 for ages 18-24, 0.913 for ages 25-44, 0.860 for ages 45-64, 0.831 for ages 65-74, and 0.773 for ages 75 and over. Using these scores, the PHM calculates the difference between the mean EQ-5D scores of people who smoke cigarettes and those who do not at each age. For example, the difference in mean EQ-5D score between a 55-year-old person who smokes cigarettes and a 55-year-old person who does not smoke cigarettes is 0.051 (= 0.860 – 0.809). The PHM incorporates these differences in EQ-5D scores, a QALY compatible instrument, to estimate QALYs gained for the adult population.

See Figure 19. Following the approach for mortality impacts established in Apelberg et al. (2018), the PHM excludes the number of QALYs gained during the first three years after the implementation of the product standard (30). Then, the PHM estimates the annual number of QALYs gained to increase from zero to approximately 850,000 in the fourth year (2030) after the implementation of the product standard. Annual QALYs gained are then projected to decrease to about 450,000 per year by the end of the time horizon (2064). We note that the predicted median annual number of QALYs gained is closer to the upper bound of the prediction range than the lower bound. This is a direct result of the distribution of responses from the PHM expert elicitation predicting the probability of changing smoking behavior as a result of the policy. Experts were asked to individually provide probability distributions of their responses, and when sampling across these various distributions, the PHM similarly reflects the same distributional shape present in the experts' responses.

[38] EQ-5D refers to the widely used measurement of quality of life, developed by the EuroQol Group (https://euroqol.org/euroqol/)

Figure 19. Projected Annual Quality-Adjusted Life Years Gained as a Result of the Policy



5. Limitations and Assumptions of this Modeling Approach

We note several limitations and assumptions in our approach to benefit, cost, and transfer estimates. First, because the PHM only considers two product types, we make assumptions about the relative rate of growth of the noncombusted tobacco product categories. This assumption has no impact on the estimated benefits because data limitations prevent us from distinguishing between the health consequences of various noncombusted products, however, these assumptions impact estimated costs and transfers. We assume that an increase in noncombusted prevalence scales to both the smokeless and ENDS categories. So, for example, a one percent increase in noncombusted prevalence would lead to a one percent increase in SLTs and a one percent increase in ENDS. The smokeless tobacco category is subject to Federal taxes and user fees, while the ENDs category is not.[39]

Second, we assume that this product standard does not impact the prevalence rates for waterpipe tobacco or premium cigars. As discussed in the NPRM, the Agency has determined that waterpipe tobacco involves profoundly different use behaviors than combusted cigarettes, which makes it an unlikely substitute for cigarettes. We therefore do not propose including

[39] ENDS products do not have quantity measures provided in the Euromonitor 2021 data. Therefore, we assume the ratio of ENDS to SLT revenue remains constant and use this ratio as a scalar to estimate expected ENDS unit sales between 2024 to 2063. The ratio of ENDS to SLT revenue in 2021 was about 0.69.

waterpipe tobacco products within the scope of this proposed rule. Further, and as also discussed in the NPRM and footnote 7 of this document, the U.S. District Court for the District of Columbia issued an order vacating FDA's rule deeming tobacco products to be subject to FDA's tobacco product authorities "insofar as it applies to premium cigars." *Cigar Ass'n of Am. v. FDA*, No. 16-cv-01460, 2023 WL 5094869 (D.D.C. Aug. 9, 2023), *appeal docketed*, No. 23-5220 (D.C. Cir. argued Sept. 13, 2024). FDA recognizes that, absent further relief, it is bound by the District Court's order. As such, cigar products that meet the above definition are excluded from the proposed rule. References to premium cigars in this document are included for explanatory purposes to clarify the proposed scope of products covered. Should FDA's regulatory authority over premium cigars change in the future, the Agency will address those changes at that time.

Third, the PHM relies on a complete list of transition probabilities, which refer to the probability that an individual would continue to use the two tobacco product types, switch products, quit, or not initiate at a given time. Most notably, cessation rates used by the PHM reflect successful smoking cessation for at least two years given that most relapse occurs during this period (57). However, the model does not allow for the possibility of relapse beyond 2 years. As Krall, Garvey, & Garcia (57) demonstrates, relapse rates fall over time, with most relapse occurring in the first two years following cessation. Beyond two years, they found smoking relapse rates of between 2-4 percent in between the 2^{nd} – 6^{th} years of cessation and relapse rates of less than one percent after 10 years of cessation. Given this behavior, the PHM sets the probability for relapse to zero and likely underestimate annual cessation rates within any two-year period.

Fourth, the transition probabilities used in the PHM are sourced from an expert elicitation rather than empirical studies and this introduces the opportunity for statistical bias. Because a nicotine product standard has not been implemented anywhere in the world, there are no empirical studies for measuring the transition probabilities for individuals under such a policy. Therefore, our results are based on the best available evidence.

Fifth, the expert elicitation used for the PHM did not include questions for understanding how transition probabilities may differ across additional demographics, such as race or ethnicity. Although the PHM does not directly estimate benefits to consumers of different demographic groups, we analyze and discuss distributional impacts of this rule for specific populations in Section II.K.

Sixth, the PHM assesses prevalence, but not intensity, of tobacco product consumption. To derive the market impacts from the model, we assume that, on average, individuals continue to consume at the average pre-policy rate. If the policy causes reductions in intensity, then our estimates may overstate the market size and could understate the morbidity and mortality benefits. We anticipate that any compensatory smoking caused by this rule will be transient and rapidly diminish to zero because the nicotine level is low enough in VLNCs that cravings cannot be satiated through continued consumption. Subsequently we do not anticipate an increase in smoking intensity.

Seventh, in an attempt to account for the uncertainty associated with the model-based estimates during the first years after the implementation of the nicotine standard, we exclude any morbidity and mortality benefits accrued during the first three years after the implementation of the product standard from our cumulative estimates of tobacco-attributable mortality, life years gained, and morbidity outcomes (30). This may reduce the estimated impact of the proposed standard.

Additionally, for several reasons, the estimates of the QALYs gained as a result of the policy are only an approximate measure of morbidity. First, there are limitations associated with the EQ-5D scores estimated by Jia and Lubetkin (2010) (56). The EQ-5D scores are not based on smoking-attributable illness or disease, but are instead estimated from a model using the Healthy Days measure (such as number of overall unhealthy days and self-rated health status) and age category from the Behavioral Risk Factor Surveillance System (BRFSS). The modeled EQ-5D scores are then compared by self-reported smoking status, and age category. Using self-reported smoking status could affect estimates of smoking prevalence.

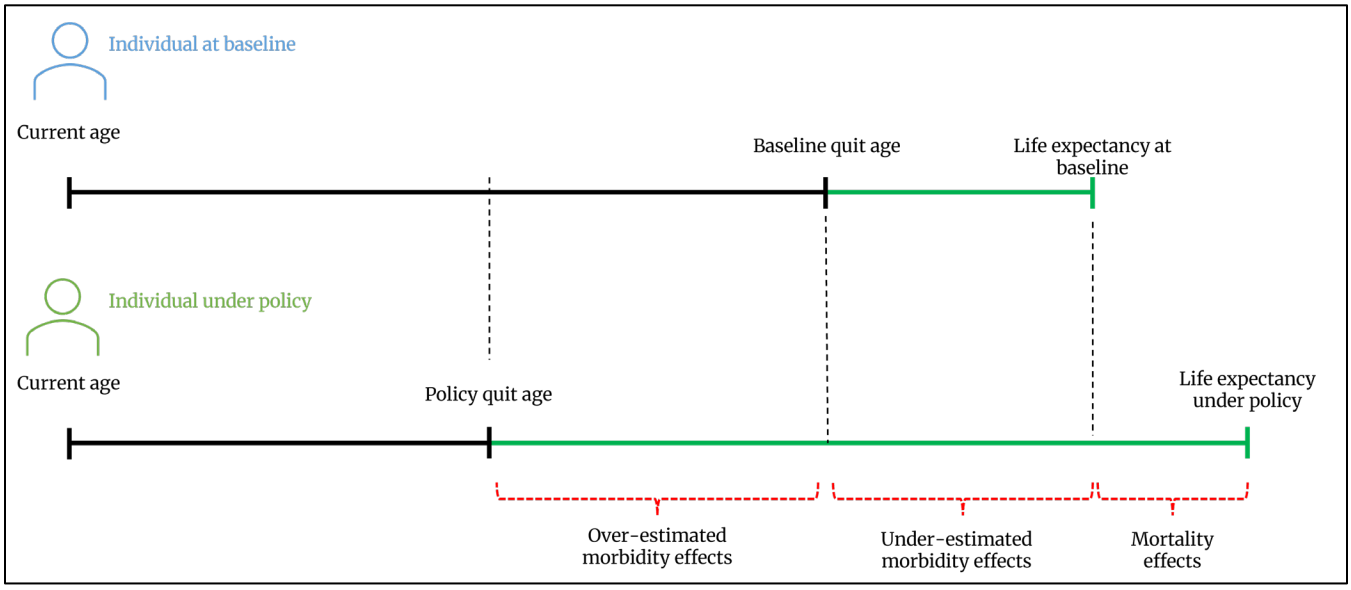
Second, the Jia and Lubetkin (2010) paper estimates the difference in modeled EQ-5D scores between people who smoke cigarettes and people who do not smoke cigarettes (never and former smokers) (56). This comparison allows the PHM to separate morbidity estimates from mortality estimates. However, it also tends to over-estimate morbidity for younger age categories and under-estimate morbidity for older age categories (as discussed more below for former smokers).

Third, residual confounding due to underlying characteristics could lead to bias in the estimates; however, this bias is expected to be minimal relative to the magnitude of the impact of smoking on mortality and morbidity (58; 59; 60; 61; 62).

Fourth, the PHM does not differentiate between quitting tobacco use entirely and switching from cigarettes to noncombusted use, giving the same morbidity impact to both populations. While evidence to date suggests that e-cigarettes are generally less harmful than combusted products (21), only complete cessation of all tobacco products fully eliminates all tobacco-related health risks (6).

Fifth, the effect of the product standard on morbidity may be underestimated because former smokers would be assigned the same EQ-5D scores regardless of time since cessation, even for people who would quit absent the product standard (e.g. at baseline). See Figure 20. Individuals may experience health improvements during the time between when they would have quit under the baseline scenario and their life expectancy under the baseline scenario. We request comment on the methods used, alternative studies, and data that may further inform and refine our estimates of overall population morbidity benefits.

Figure 20. Potential Sources of Over- and Under-Estimation of Morbidity



We request comment on the methods and assumptions used, including alternative studies and data, that may further inform and refine our estimates.

G. Benefits of the Proposed Rule

The proposed product standard, if finalized, would limit the addictiveness of cigarettes and certain other combusted tobacco products by limiting the level of nicotine in such products. As a result of the proposed product standard, we expect people who smoke cigarettes or use the other covered combusted tobacco products to reduce their use of combusted tobacco products, generating substantial health and other benefits. We quantify the benefits associated with the expected behavioral changes as a result of the rule. We request comment on all estimates in this section.

1. Monetized Avoided Tobacco Attributable Premature Deaths

In this section, we present the monetary value of avoided premature deaths from the proposed rule, if finalized. We use the PHM described in Section II.D to estimate the number of avoided premature deaths from the rule (see Section II.F for further description).

We estimate the monetary value of avoided tobacco-attributable premature deaths by multiplying the number of avoided premature deaths by the value of a statistical life (VSL), which is standard practice for monetizing changes in mortality risk. VSL estimates do not represent the dollar value of a person's life but instead represent the amount individuals are willing to pay for small reductions in mortality risk. We use VSL estimates recommended by the U.S. Department of Health and Human Services (HHS), which are based on a review of published studies. Please see our sensitivity analyses in Section II.M.5 and Section II.M.6 for a discussion of several sources of uncertainty that could result in the VSL approach

underestimating or overestimating the benefits of the proposed rule. The primary estimate of VSL following the rule's effective date (2027) is expected to be $13.5 million in 2023 U.S. dollars. The VSL in the first year of the time horizon and all subsequent years is adjusted for projected real income growth and income elasticity (1).[40] The Congressional Budget Office (CBO) currently projects real income growth at one percent per year through 2052 (63).[41] Since the time horizon for this rule extends to 2064, we assume a real income growth of one percent per year through 2064. HHS sets income elasticity to be equal to one (64).

a. Benefits from Avoided Tobacco-Attributable Premature Deaths

The primary benefit of the rule is the reduction in tobacco-attributable deaths. As mentioned previously, by "tobacco attributable," we mean attributable to the modeled tobacco product classes: cigarettes and noncombusted tobacco products. The proposed rule, if finalized, would reduce the addictiveness of cigarettes and other covered tobacco products, which we predict in the PHM would result in a reduction in the use of combusted tobacco products, which then results in fewer deaths associated with smoking. We monetize the avoided premature deaths by multiplying the predicted averted premature mortality from the PHM by the central VSL provided by HHS Guidelines, discounted for future years.[42] The results are then summarized by taking the 5th (low), 50th (primary), and 95th (high) percentiles of the resulting distribution of the value of averted premature mortality for each year in the time horizon. See Table 16. We present the present value, annualized value, and a figure showing the flow of the value of avoided premature mortality attributable to tobacco products over the time horizon of the rule.

Using a discount rate of 2 percent, we estimate that the present value of avoided tobacco-attributable premature deaths ranges from $3.7 trillion to $20.8 trillion, with a primary estimate of $18.7 trillion.

Using a discount rate of 2 percent, we estimate that the annualized value of avoided tobacco-attributable premature deaths ranges from $133 billion to $747 billion, with a primary estimate of $672 billion.

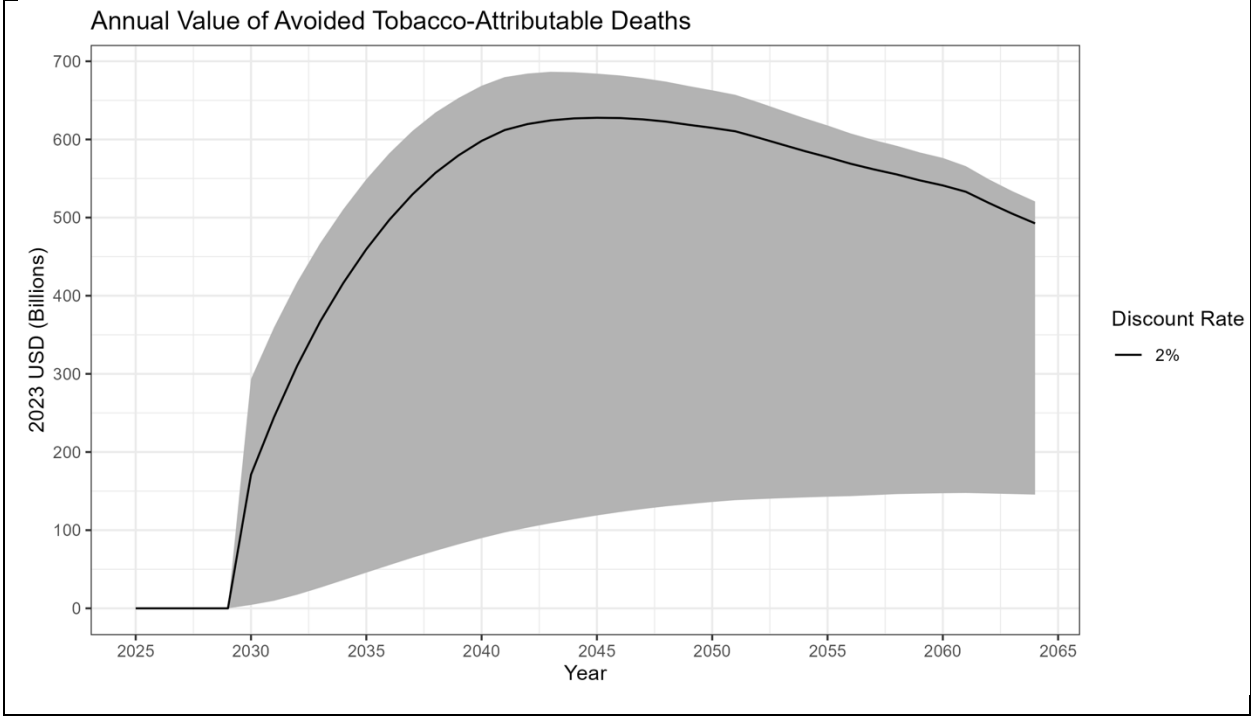
[40] The Department of Health and Human Services provides VSL values in 2023 dollars for changes in mortality risk occurring in 2023 through 2143: https://aspe.hhs.gov/reports/standard-ria-values.

[41] Congressional Budget Office. "The 2022 Long-Term Budget Outlook". Table B-1. Average Annual Growth Rates for Economic Variables That Underlie CBO's Extended Baseline Projections, by Calendar Year: Real Earnings per Worker, Overall, 2022-2052. https://www.cbo.gov/publication/58340. Accessed May 1, 2023.

[42] Discounting is used to account for time preferences for individuals so that the values in the future are discounted to current year dollars for consistent comparison. (124)

Table 16. Present and Annualized Value of Avoided Tobacco-Attributable Premature Deaths Using Central VSL Value (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$18,743.08	$3,716.36	$20,846.32
Annualized Value 2%	$672	$133	$747



b. Benefits from Avoided Premature Deaths due to Reductions in Secondhand Smoke Exposure

The proposed rule, if finalized, would reduce the addictiveness of cigarettes and other covered combusted tobacco products, which we predict would result in a reduction in the smoking of combusted products which then results in fewer deaths associated with exposure to secondhand smoke. Cessation or averted use among people who currently use or would use combusted tobacco products in the future would lead to improved health outcomes among people who do not use tobacco products but who regularly spend time in proximity to people who use combusted tobacco products at baseline. The Preamble provides detailed discussion on the health risks of exposure to secondhand smoke, such as premature death and disease in non-smoking youth and adults (see Preamble Section IV.D). We quantify these benefits for non-smokers, although we note that benefits from reductions in secondhand smoke exposure can accrue to both smokers and non-smokers. As with tobacco-attributed deaths, we monetize the avoided

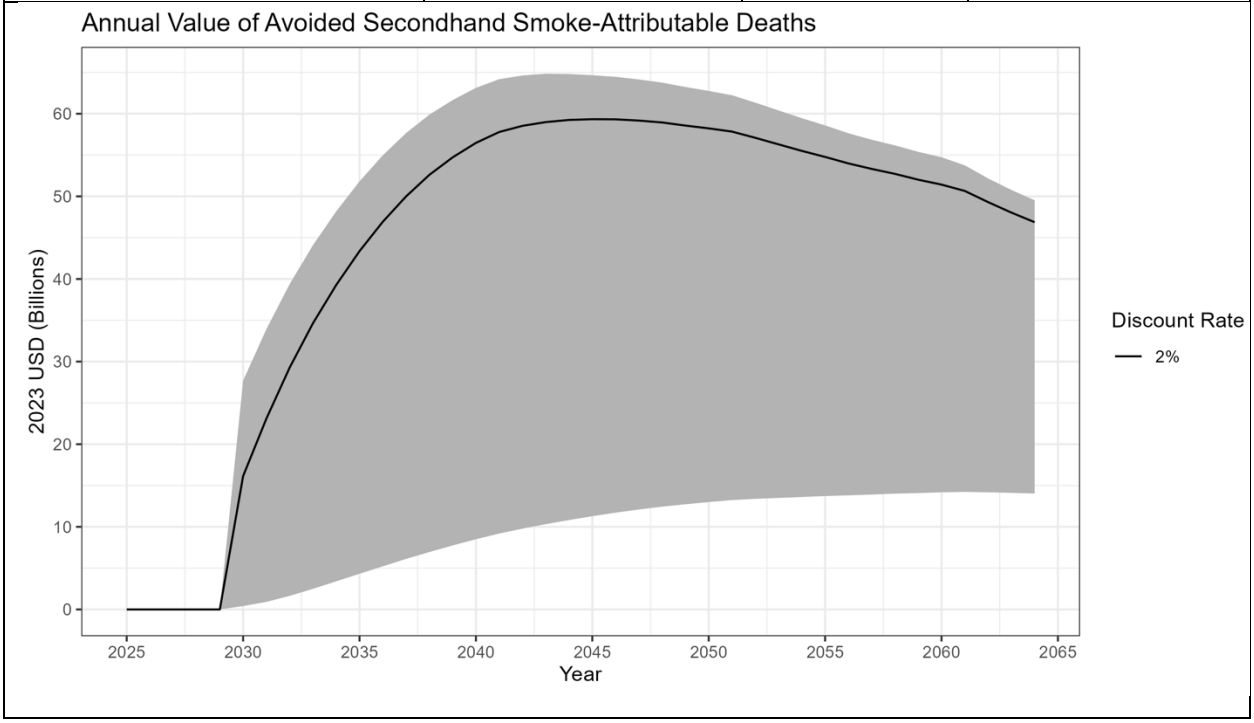
premature deaths by multiplying the number of averted premature deaths by the primary discounted VSL provided by HHS Guidelines. The results are then summarized by taking the 5th (low), 50th (primary), and 95th (high) percentiles of the resulting distribution of the value of averted premature mortality for each year in the time horizon. See Table 17. We show the present value, annualized value, and a figure showing the flow of the value of avoided premature mortality attributable to reductions in secondhand smoke exposure over the time horizon of the rule. We request comment on our assumptions regarding avoided premature mortality attributable to reductions in secondhand smoke exposure, including the timing of avoided premature mortality.

Using a discount rate of 2 percent, we estimate that the present value of avoided premature deaths due to reductions in secondhand smoke exposure ranges from $355 billion to $2.0 trillion, with a primary estimate of $1.8 trillion.

Using a discount rate of 2 percent, we estimate that the annualized value of avoided premature deaths due to reductions in secondhand smoke exposure ranges from $13 billion to $71 billion, with a primary estimate of $64 billion.

Table 17: Present and Annualized Value of Avoided Premature Deaths due to Reductions in Secondhand Smoke Exposure Using Central VSL Value (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$1,775	$355	$1,973
Annualized Value 2%	$64	$13	$71



c. Benefits from Avoided Smoking-Related SIDS Deaths

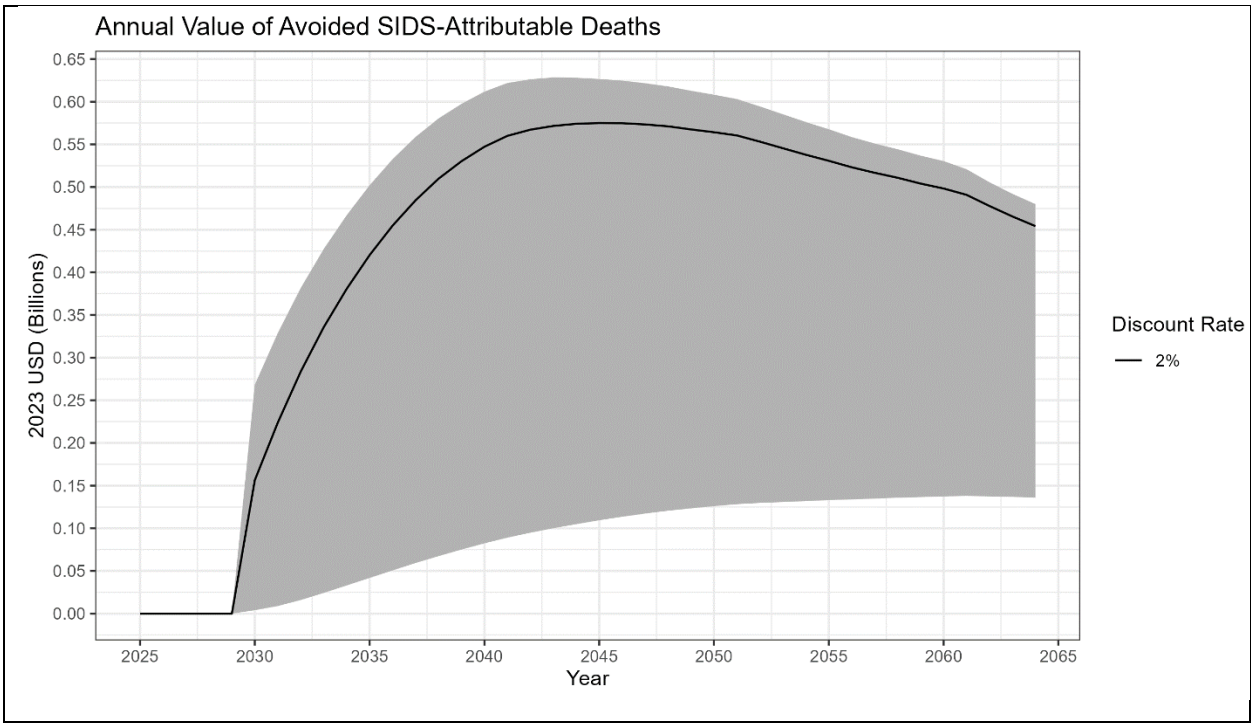
The proposed rule, if finalized, would reduce the addictiveness of cigarettes and other covered combusted tobacco products, which we predict would result in a reduction in smoking cigarettes, which then results in fewer deaths associated with smoking-related SIDS. Prenatal tobacco exposure and postnatal secondhand smoke exposure increase the risks of fetal deaths, fetal growth restriction/low birth weight, respiratory conditions, and SIDS (9; 3). We monetize the averted SIDS mortality discussed in Section II.F.0 by multiplying the averted mortality by the primary discounted VSL provided by HHS Guidelines. The results are then summarized by taking the 5^{th} (low), 50^{th} (primary), and 95^{th} (high) percentiles of the resulting distribution of the value of averted mortality for each year in the time horizon. See Table 18. We show the present value, annualized value, and a figure showing the flow of the value of avoided mortality attributable to smoking-related SIDS deaths over the time horizon of the rule. As discussed in Section II.F.3, we calculate smoking-related SIDS deaths avoided in a post-processing procedure based on the PHM mortality outputs and, thus, adopt similar timing assumptions. Estimated benefits from avoided smoking-related SIDS deaths may represent an underestimate of impacts as reductions in deaths will likely occur immediately following the rule. We request comment on our assumptions regarding the avoided smoking-attributable SIDS impacts, the relationship between reductions in smoking-attributable mortality and SIDS impacts, and the timing of reductions in SIDS deaths.

Using a discount rate of 2 percent, we estimate that the present value of avoided smoking-attributable SIDS deaths ranges from $3 billion to $19 billion, with a primary estimate of $17 billion.

Using a discount rate of 2 percent, we estimate that the annualized value of avoided smoking-attributable SIDS deaths ranges from $0.1 billion to $0.7 billion, with a primary estimate of $0.6 billion.

Table 18. Present and Annualized Value of Avoided Smoking-Attributable SIDS Deaths (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$17	$3	$19
Annualized Value 2%	$0.6	$0.1	$0.7



d. Benefits from Avoided Smoking-Related Fires

The proposed rule, if finalized, would reduce the addictiveness of cigarettes and other affected combusted tobacco products, which we predict would result in a reduction in smoking cigarettes, which then results in fewer smoking related fires. Benefits of reduced smoking related fires include reduced property damage, injury, and death. During 2012-2016, an estimated annual average of 18,100 reported home structure fires in the United States were caused by smoking materials, which killed an average of 590 people annually (28). Moreover, smoking materials remain a leading cause of fatal home fires in the United States, and people who smoke are not the only victims (65). The U.S Fire Administration estimates more than $361.5 million dollars in property damage from smoking-related fires in 2021. We are unable to quantify the averted property damage benefit that would result from this proposed rule, but we are able to monetize the averted mortality benefit.

We monetize the avoided premature deaths by multiplying the averted premature mortality estimated in Section II.F.0 by the primary discounted VSL provided by HHS Guidelines. The results are then summarized by taking the 5th (low), 50th (primary), and 95th (high) percentiles of the resulting distribution of the value of averted premature mortality for each year in the time horizon. See Table 19. We show the present value, annualized value, and a figure showing the flow of the value of avoided premature mortality attributable to reductions in smoking-related fires over the time horizon of the rule. As discussed in Section II.F.3, fire-related premature deaths avoided are calculated in a post-processing procedure based on the PHM mortality outputs and, thus, adopt similar timing assumptions. Estimated benefits from

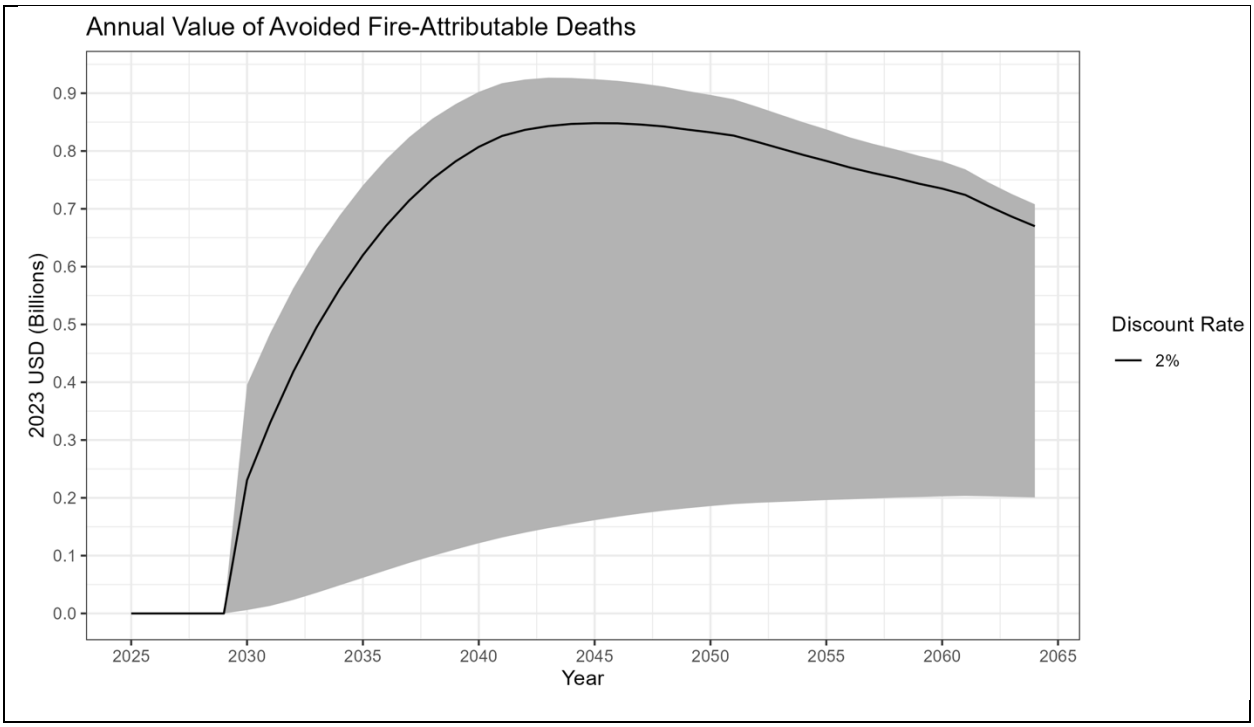
avoided smoking-related fires may represent an underestimate of impacts as reductions in smoking-related fires will likely occur immediately following the rule. We are unable to distinguish between avoided premature mortality attributable to reductions in smoking-related fires that are experienced by people who smoke from those experienced by people who do not smoke. This could lead to an overestimate of impacts, as this proposed product standard is estimated to reduce the population of people who smoke over time, thus reducing the causes of smoking-related fires and smoking-related deaths to those other than people who smoke. We request comment on our assumptions regarding averted smoking-related fire mortality, the relationship between reductions in smoking-attributable mortality and smoking-related fire mortality, the distribution of smoking-related fire damage experienced by people who smoke and people who do not smoke, and the timing of reductions in smoking-related fire mortality.

Using a discount rate of 2 percent, we estimate that the present value of avoided premature deaths due to reductions in smoking-related fires ranges from $5 billion to $28 billion, with a primary estimate of $25 billion.

Using a discount rate of 2 percent, we estimate that the annualized value of avoided premature deaths due to reductions in smoking-related fires ranges from $0.2 billion to $1 billion, with a primary estimate of $0.9 billion.

Table 19. Present and Annualized Value of Avoided Premature Deaths due to Reductions in Smoking-Related Fires (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$25	$5	$28
Annualized Value 2%	$0.9	$0.2	$1.0



e. Benefits from Avoided Cigar Attributable Premature Deaths

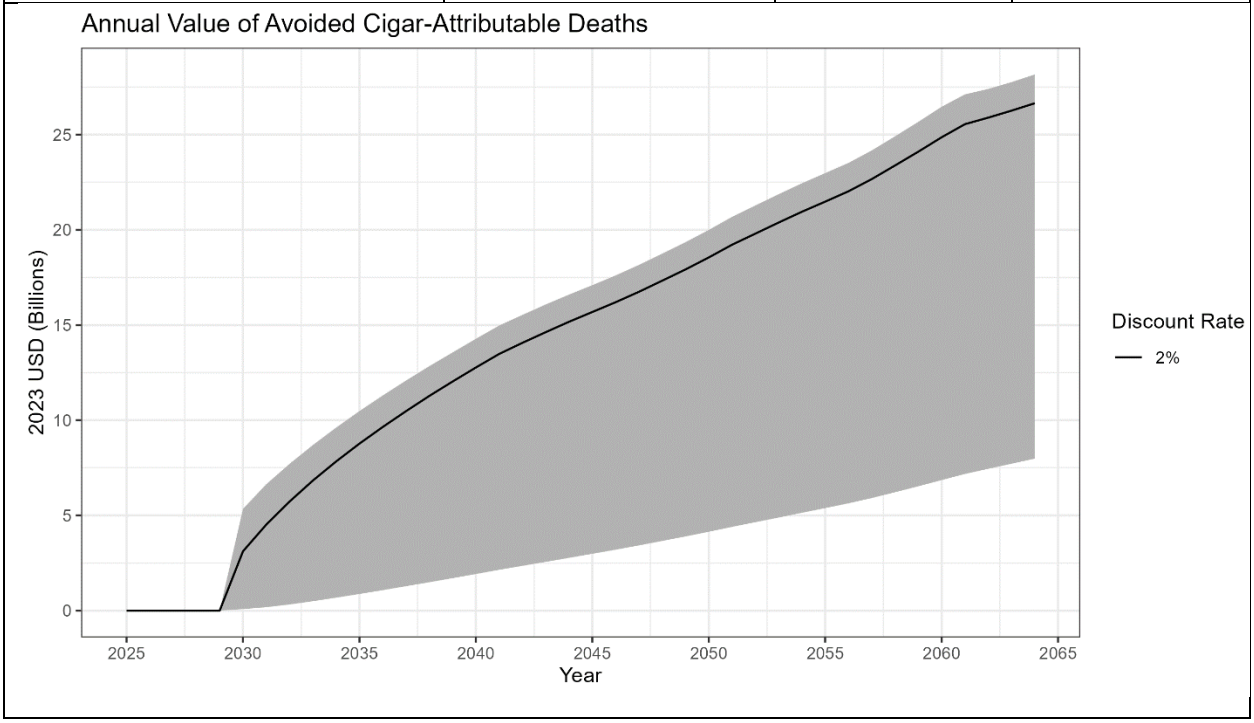
People who smoke cigars are at increased risk for many of the same diseases as people who smoke cigarettes, including oral, esophageal, laryngeal, and lung cancer; cardiovascular diseases; and chronic obstructive pulmonary disease (COPD) (66). The proposed rule, if finalized, would reduce the addictiveness of non-premium cigars and other affected combusted tobacco products, which we predict would result in a reduction in cigar smoking, which then results in fewer deaths associated with cigars. We monetize avoided premature deaths by multiplying the averted premature mortality discussed above in Section II.F.3 by the primary discounted VSL provided by HHS Guidelines. The results are then summarized by taking the 5th (low), 50th (primary), and 95th (high) percentiles of the resulting distribution of the value of averted mortality for each year in the time horizon. See Table 20. We show the present value, annualized value, and a figure showing the flow of the value of avoided premature mortality attributable to reduction in the use of cigars over the time horizon of the rule. We request comment on our assumptions regarding avoided premature mortality attributable to reductions in the use of cigars, including the timing of avoided premature mortality.

Using a discount rate of 2 percent, we estimate that the present value of avoided cigar-attributable premature deaths ranges from $127 billion to $631 billion, with a primary estimate of $576 billion.

Using a discount rate of 2 percent, we estimate that the annualized value of avoided cigar-attributable premature deaths ranges from $5 billion to $23 billion, with a primary estimate of $21 billion.

Table 20. Present and Annualized Value of Avoided Cigar-Attributable Premature Deaths (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$576	$127	$631
Annualized Value 2%	$21	$5	$23



f. Benefits from Avoided Pipe Tobacco Attributable Premature Deaths

Pipe smoking cause cancers of the lung and upper aerodigestive tract, including the oral cavity, oropharynx, hypopharynx, larynx, and esophagus (67). Additional evidence suggests that cigar and/or pipe smoking is causally associated with cancers of the pancreas, stomach, and bladder (68). The proposed rule, if finalized, would reduce the addictiveness of pipe tobacco and other affected combusted tobacco products, which we predict would result in a reduction in smoking pipe tobacco, which then results in fewer deaths associated with pipe tobacco. We monetize the avoided premature deaths by multiplying the number of averted premature deaths

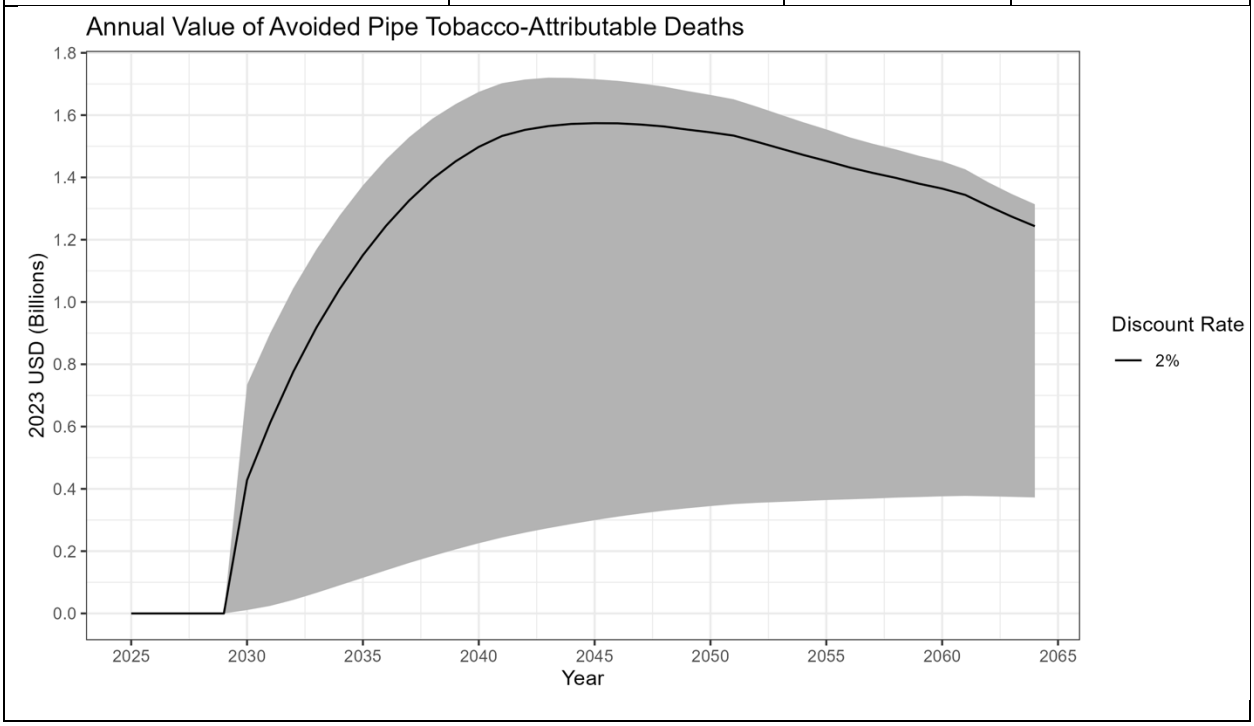
discussed in Section II.F.0 by the primary discounted VSL provided by HHS Guidelines. The results are then summarized by taking the 5th (low), 50th (primary), and 95th (high) percentiles of the resulting distribution of the value of averted premature mortality for each year in the time horizon. See Table 21. We show the present value, annualized value, and a figure showing the flow of the value of avoided premature mortality attributable to pipe tobacco overtime horizon of the rule.

Using a discount rate of 2 percent, we estimate that the present value of avoided pipe tobacco-attributable deaths ranges from $9 billion to $52 billion, with a primary estimate of $47 billion.

Using a discount rate of 2 percent, we estimate that the annualized value of avoided pipe tobacco-attributable deaths ranges from $0.3 billion to $1.9 billion, with a primary estimate of $1.7 billion.

Table 21. Present and Annualized Value of Avoided Pipe Tobacco-Attributable Deaths (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$47	$9	$52
Annualized Value 2%	$1.7	$0.3	$1.9



2. Monetized Morbidity Benefits

As discussed in the Preamble, quitting cigarette smoking substantially reduces the likelihood of tobacco-related death and disease. The 2020 SGR concludes, "[s]moking cessation is beneficial at any age. Smoking cessation improves health status and enhances quality of life." (6) According to the 2014 SGR, "The Health Consequences of Smoking: 50 Years of Progress," which summarizes thousands of peer-reviewed scientific studies and is itself peer-reviewed, smoking remains the leading preventable cause of death in the United States, and cigarettes have been shown to cause an ever-expanding number of diseases and health conditions (3). As stated in the report, "cigarette smoking has been causally linked to disease of nearly all organs of the body, to diminished health status, and to harm to the fetus" and "[t]he the burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products" (3). Please see the NPRM Section VIII.D for a complete discussion of averted tobacco-attributable morbidity. We request comment on our assumptions regarding averted tobacco-attributable morbidity attributable to reductions in the use of combusted tobacco products.

As discussed above in Section II.F, the PHM estimates the morbidity benefit of this proposed product standard as the difference in QALYs under in the baseline and policy for any given year. While this captures a significant morbidity impact of the policy, it likely does not capture some of the morbidity effects that are associated with many long-term illnesses, such as lung cancer and heart disease. The PHM also does not capture morbidity effects associated with improvements in mental health from smoking cessation. For additional discussion of benefits, see Section II.G.4.

To estimate the potential impact of the proposed standard on QALYs gained, we used QALY estimates from FDA's PHM, as discussed in Section II.F. To monetize the benefits of QALYs gained, we multiply the QALY estimates by the standard dollar value estimates for QALYs recommended by HHS (64). The primary estimate of the value of a QALY in the year following the rule's effective date (2027) using a discount rate of 2 percent is $608,512 in 2023 U.S. Dollars.

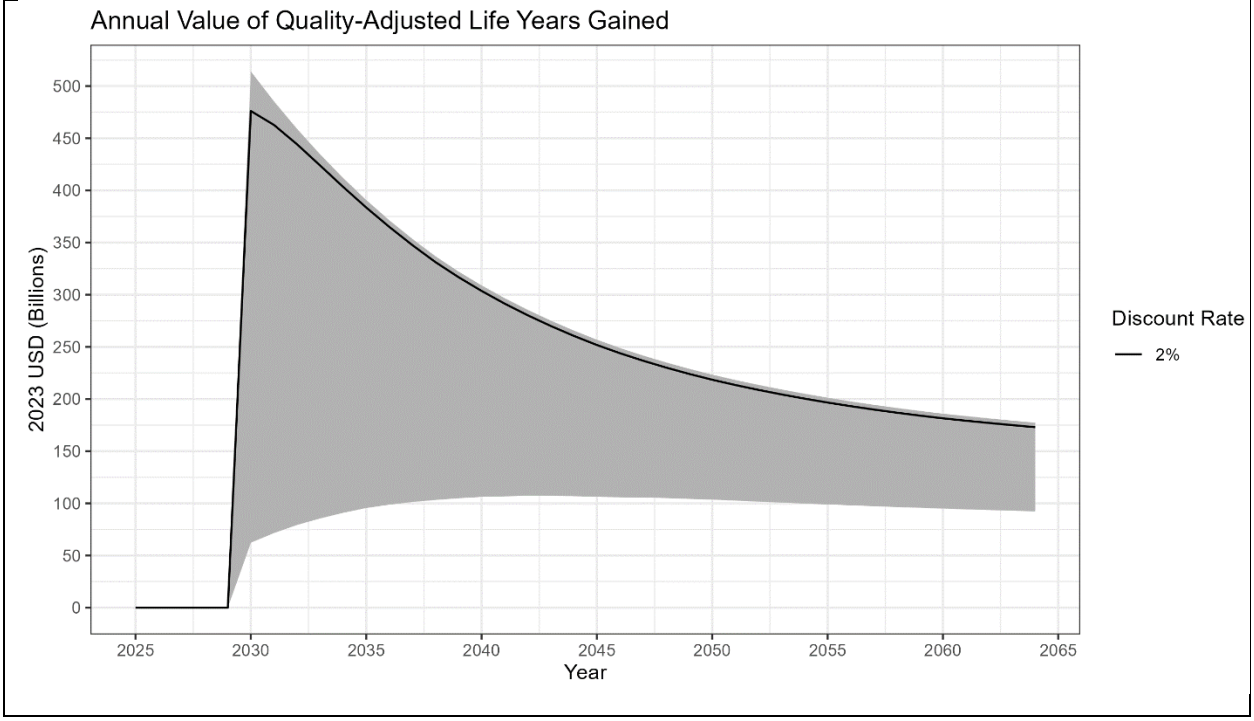
The results are then summarized by taking the 5th (low), 50th (primary), and 95th (high) percentiles of the resulting distribution of the value of QALYs gained for each year in the time horizon as our low impact, primary, and high impact scenarios. See Table 22. We show the present value, annualized value, and a figure showing the flow of the value of QALYs gained attributable to increased cessation of combusted tobacco products over the time horizon of the rule. We request comment on the estimates of QALYs gained and the monetized values.

Using a discount rate of 2 percent, we estimate that the present value of QALYs gained ranges from $3.4 trillion to $9.7 trillion, with a primary estimate of $9.4 trillion.

Using a discount rate of 2 percent, we estimate that the annualized value of QALYs gained ranges from $122 billion to $347 billion, with a primary estimate of $338 billion.

Table 22. Present and Annualized Value of Quality-Adjusted Life Years Gained (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$9,427	$3,415	$9,670
Annualized Value 2%	$338	$122	$347



3. Summary of Monetized Benefits

We summarize the total estimated benefits of the rule by adding up the monetary value of averted mortality from all sources: tobacco products, secondhand smoke, SIDS, fire, cigar, and pipe tobacco, as well as the QALYs gained from reduced cigarette smoking. See Table 23 for the total present and annualized values and Table 24 for present value and annualized value from each source.

Using a discount rate of 2 percent, we estimate that the present value of benefits ranges from $7.6 trillion to $33.2 trillion, with a primary estimate of $30.6 trillion.

Using a discount rate of 2 percent, we estimate that the annualized value of benefits ranges from $0.27 trillion to $1.2 trillion, with a primary estimate of $1.1 trillion.

Table 23. Present and Annualized Value of Mortality and Morbidity Using Central VSL Value (2023 USD Billions)

	Primary	Low	High
Present Value 2%	$30,611	$7,632	$33,220
Annualized Value 2%	$1,097	$274	$1,191

Table 24. Present and Annualized Value of Mortality and Morbidity by Source Using Central VSL Value (2023 USD Billions)

		Discounted Present Value (2%)			Annualized Benefits (2%)		
		Primary	Low	High	Primary	Low	High
Avoided Mortality	Modeled Tobacco Products	$18,743	$3,716	$20,846	$672	$133	$747
	Secondhand Smoke	$1,775	$355	$1,973	$64	$13	$71
	SIDS	$17	$3	$19	$0.6	$0.1	$0.7
	Fire	$25	$5	$28	$0.9	$0.2	$1.0
	Cigar	$576	$127	$631	$21	$5	$23
	Pipe Tobacco	$47	$9	$52	$1.7	$0.3	$1.9
Avoided Morbidity	Modeled Tobacco Products	$9,427	$3,415	$9,670	$338	$122	$347

4. Additional Discussion of Benefits

We provide additional discussion of potential benefits of this proposed rule, if finalized. Unless otherwise noted, all dollar values presented in this section are adjusted for inflation to reflect 2023 U.S. dollars.[43]

[43] Inflation adjustment done using the most recent medical care Consumer Price Index data from the Bureau of Labor Statistics (https://www.bls.gov, Data Series ID: CUUR0000SAM, CUUS0000SAM).

a. Medical Cost Savings

People who smoke cigarettes use more medical services during their lifetimes than people who do not smoke cigarettes; a 2012 CBO report uses regression analysis on two large national surveys to estimate the impact of smoking on annual health care spending (69). The CBO estimates that people who currently and formerly smoked cigarettes have higher annual health care spending per capita than similar people who have never smoked: about $1,507 for 45- to 64-year-olds; about $1,660 for 65–to 74-year-olds; and about $1,961 for ages 75 and older. The difference in annual spending is around $300 for 18- to 24-year-olds, and around $600 for 25- to 44-year-olds. The CBO finds that people who formerly smoked cigarettes have higher medical costs immediately after quitting than people who currently smoke cigarettes, which is likely due to poor health leading people who smoke cigarettes to quit, rather than a health disadvantage from quitting smoking. Like the CBO, we would expect that former smokers' annual health care spending converges toward health care spending by similar non-smokers as the number of years since cessation continue to increase.

The Surgeon General has estimated that smoking-attributable costs include nearly $164 billion annually for direct medical care for adults (3). Smoking-attributable costs included nearly $193 billion in lost productivity due to premature death and exposure to secondhand smoke. More specifically, productivity losses due to secondhand smoke-attributable deaths are estimated to cost the U.S. $7 billion each year.[44] The Surgeon General noted that, because these estimates do not include lost productivity due to illness, these costs significantly underestimate the full value of lost productivity costs due to smoking.

Xu et al. used data from the 2010-2014 Medical Expenditure Panel Survey and 2008-2013 NHIS to estimate the portion of annual healthcare spending potentially attributable to cigarette smoking (70). Their results suggested that, during 2010-2014, 11.7 percent of U.S. healthcare spending each year was attributable to adult cigarette smoking, with health care spending by people who currently smoke cigarettes accounting for 6.0 percent and health care spending by people who formerly smoked cigarettes accounting for 5.7 percent (1.3 percent quit in the last five years + 4.4 percent quit more than 5 years = 5.7 percent). Translating this smoking-attributable fraction into dollars, the authors estimated that smoking may have accounted for more than $283 billion (2023 USD) of total healthcare spending in 2014. Private insurance and out-of-pocket costs accounted for only $80.5 billion (2023 USD, 28 percent) of these costs during 2010 to 2014.

Bolnick et al. (71) used data from the 2017 Global Burden of Diseases, Injuries, and Risk Factors Study and the Disease Expenditure Project from the Institute for Health Metrics and Evaluation to estimate that healthcare spending attributable to tobacco smoking accounted for $154 billion dollars (2023 USD) in 2016 in the United States. Tobacco smoke ranked fifth highest in terms of all U.S. healthcare spending that could be attributed to modifiable risk

[44] Adjusted for inflation Consumer Price Index (CPI-U), all urban consumers data from the Bureau of Labor Statistics (https://www.bls.gov, Data Series ID: CUUR0000SA0).

factors, i.e., risk factors that may be mitigated through behavior. Cardiovascular disease (32.6 percent) and musculoskeletal disorders (21.4 percent) accounted for the largest portions of healthcare costs attributable to tobacco smoke.

Shrestha et al. (72) used a "human capital approach" to estimate the cost of productivity losses in the United States in 2018 from cigarette smoking-attributable morbidity among adults aged 18 and older. Their estimates of productivity losses include losses from absenteeism, presenteeism, household productivity changes, and inability to work. The authors find that the cost of these productivity losses totaled nearly $223 billion (2023 USD), with state-level total costs of morbidity-related productivity loss ranging from $351 million to $20.4 billion with a median cost of $3.3 billion (2023 USD).[45]

Using data from the 2008-2019 Medical Expenditure Panel Survey linked to the National Health Interview Survey, Valdez and Encinosa (73) provide an updated estimate of the national medical costs of smoking, including estimated racial and ethnic disparities in the excess healthcare costs and outcomes associated with smoking. In their study, the authors find that approximately 7.2 percent of national healthcare spending was associated with smoking, 42.0 percent of which was paid for by federal public programs (e.g., Medicaid, Medicare, the VA, etc.). With respect to per capita healthcare spending between adult current or former smokers (ever smokers) and never smokers, the average adult who ever smoked spent an additional $1,163 on annual medical care than adults who never smoked. The PHM predicts that the proposed rule may result in a primary estimate of approximately 6.9 million cumulative avoided initiates by year 40 (2065).[46] If we apply the Valdez and Encinosa estimates of medical cost savings, this would correspond to approximately $388.7 billion of undiscounted cumulative medical cost savings by 2065. Furthermore, the study estimates that medical cost-savings would be $151 million per year if a regulation averted 100,000 Hispanic, Black, Asian, and other non-Whites, and multi-race individuals from initiation into smoking, and $64 million per year if a regulation averted 100,000 non-Hispanic White individuals from initiation into smoking. The paper estimates that averting 100,000 adults from smoking would save federal healthcare programs $93 million per year. Dollar estimates have been inflation adjusted from 2019 to 2023 dollars.

Our main benefits estimates value mortality risk reductions using the VSL, and morbidity reductions using monetized QALYs. As discussed in the HHS Guidelines for RIAs, the VSL may include costs borne by affected individuals, including the allocation of work and non-work time (and associated productivity), and mortality-proximate out-of-pocket costs (see also (74). Therefore, to avoid double-counting, we do not include medical cost-savings as part of monetary

[45] Adjusted for inflation Consumer Price Index (CPI-U), all urban consumers data from the Bureau of Labor Statistics (https://www.bls.gov, Data Series ID: CUUR0000SA0).

[46] Valdez and Encinosa (73) estimate excess annual medical spending attributable to smoking for those aged 18 and older. However, the PHM estimates initiation and avoided initiation for the population aged 9-30 years old. The Valdez and Encinosa (73) paper notes that "…adults who started smoking regularly underage are almost twice as costly annually as those who started as adults ($1409 vs $718 per year in medical costs)."

benefits estimates. Cost-savings where third parties bear these costs in the absence of this proposed rule are discussed in Section II.I.1, below. We request comment on what portion of these medical cost-savings would be borne by third parties, and more generally, we request comment, including data and research, that would assist in refining quantification of benefits and transfers.

b. Reduced Exposure to Thirdhand Smoke

Thirdhand smoke—the chemical residue of combusted tobacco smoke that can become imbedded in the environment (e.g., carpet, dust) and may remain present for six months after someone has smoked in the home—also results in exposure to harmful tobacco smoke constituents such as tobacco-specific nitrosamines (75; 76; 77; 78; 79). In addition, research suggests that large quantities of thirdhand smoke (equivalent to 1 to 10 cigarettes of secondhand smoke) can also be introduced into indoor, nonsmoking environments by traveling on the clothing, belongings, or on the body of the person who smokes cigarettes (80). Exposure to thirdhand smoke is of particular concern to young children because of both their size and their behaviors, such as frequently putting their hands in their mouths (81). For example, nicotine exposure from thirdhand smoke residue can be 6.8 times higher in toddlers than what would be inhaled by passive (i.e., secondhand) smoke inhalation (82).

Thirdhand smoke can also harm overall health of pets through the presence of smoke residue. In the case of cats and dogs, they may ingest smoke particles which land on their fur through grooming themselves; by licking their owner's skin, hair, and clothes; or through inhalation of house dust (83; 84; 85). However, these effects are difficult to differentiate from secondhand smoke-related death and disease in humans and difficult to estimate for pets, and thus we qualitatively discuss the reduction in thirdhand smoke exposure.

c. Environmental Benefits – Changes in Tobacco Litter

Tobacco products, specifically cigarette butts, are one of the most frequently littered items (86; 87). For example, in 2023 the Ocean Conservancy found that cigarette butts were the most collected piece of coastal and waterway litter throughout North America, reaching over 780,000 items collected and double the amount of the next most littered item (bottle caps) (86). The cost of cleaning up the billions of cigarette butts improperly discarded every year usually falls on local communities. Cigarette butt abatement is estimated to cost the top 30 U.S. cities on average $306.7 million annually and an estimated annual mean of $7.49 per capita (88).[47] In addition, cigarette filters, which are made of plastic, may remain in the environment for many years, emitting and leaching toxic chemicals into the air and surrounding area, potentially

[47] Adjusted for inflation Consumer Price Index (CPI-U), all urban consumers data from the Bureau of Labor Statistics (https://www.bls.gov, Data Series ID: CUUR0000SA0).

threatening human health and the environment, especially marine ecosystems (89; 90; 91; 92; 93; 94).

We discuss qualitatively the impact of reduced tobacco product litter due to reductions in tobacco product use but note that this product standard could reduce litter. The net effect of the potential environmental benefits would depend on the behavioral response of baseline consumers of affected tobacco products, including those who switch to very low nicotine combusted products or other tobacco products. The environmental benefits would stem from those that stop or reduce tobacco use as estimated in the benefits section (see Section II.G), as well as from those who do not initiate tobacco use.

d. Improvements in Health-Related Quality of Life

We recognize that by 6 months of abstinence, most people who smoked cigarettes report less psychological distress than they experienced while they were still smoking (95 pp. 517-578) and showed improvements in measures of mental health compared with those who continued to smoke, including psychological well-being, anxiety, positive affect, cognitive functioning, energy, sleep adequacy, self-esteem, and sense of mastery (96). A 2014 meta-analysis of cessation literature concluded that smoking cessation is associated with reduced depression, anxiety, and stress and improved positive mood and quality of life compared with continuing to smoke (97). In studies of quality-of-life impacts after quitting, people who formerly smoked cigarettes reported no deterioration in quality of life and were more likely to see improvements and many people who no longer smoke cigarettes also reported that they were "happier" after quitting than they were before (98; 99). Finally, the PHM also does not capture some of the more immediate morbidity effects associated with improvements in quality-of-life, such as a decrease in coughing and shortness of breath that may first occur within 1 to 12 months of quitting (6), or general satisfaction smokers experience after quitting.

H. Costs of the Proposed Rule

This product standard would set a maximum nicotine level for cigarettes and certain other combusted tobacco products. We expect this proposed rule, if finalized, to impose costs on industry to follow the product standard, on the broader economy to repurpose land, labor, and capital, on consumers impacted by the product standard, and on FDA to enforce this product standard. To accurately quantify the costs of the rule we need to make sure that we do not inadvertently attribute any sales of illicit products to the formal marketplace. Doing so would inaccurately attribute the producer surplus value of illicit sales to the formal market which would give the impression that this rule is less costly than it is to the legal tobacco industry. Therefore, we use the "no illicit trade" scenario PHM output to restrict transitions to the legal market and

quantify the impact that this product standard would have on the legal marketplace. We request comment on all estimates in this section.

1. Cost to Industry

For all consumers who reduce or quit use of tobacco products as a result of this proposed product standard, if finalized, spending would shift from the tobacco sector to other sectors of the economy (including the banking sector in the form of savings or other financial services). This spending shift would result in land, labor, and capital inputs moving out of the tobacco sector of the economy and into other sectors. Additionally, this transition also includes firms transitioning resources within the tobacco industry to shift production to VLNC products or noncombusted tobacco products. The proposed rule results in three types of industry costs: 1) transition costs, which account for the cost to repurpose productive equipment and labor to new sectors, 2) producer surplus loss that results from the new equilibrium as combusted markets contract and noncombusted markets expand, and 3) compliance costs such as reading and understanding the rule, reformulating and labeling products to meet the standard, preparing and submitting premarket applications for new products, and testing costs to ensure combusted products meet the new standard.

a. Economic Transition Cost

Industry transitions resulting from this rule may take the form of firm closures, individual facility closure, and employment impacts across the tobacco supply chain including tobacco farming, tobacco product manufacturing, tobacco wholesalers, and tobacco retailers. We note that, rather than closing, some firms may shift their productive equipment and labor to the production and sale of compliant VLNC combusted products, noncombusted tobacco products, or nontobacco products. Firms that do not continue to operate in the market for combusted tobacco products would not be expected to face compliance costs, beyond reading and understanding the rule, as typically measured in Regulatory Impact Analyses. However, there would be costs related to the reallocation of productive resources to other sectors of the tobacco market or economy where consumers choose to spend the money that they previously spent on combusted tobacco products. The firms that transition their productive resources from the production of combusted tobacco products to noncombusted tobacco products also face transition costs as noncombusted tobacco products may require different equipment and labor than combusted tobacco products.

While we estimate significant costs to repurpose productive resources, such as capital, away from the combusted tobacco product industry, the literature on such significant shifts in the economy as a result of a regulation is relatively sparse. To develop the economic transition cost, we first completed a literature review, which is summarized in Appendix B. Given the limited

literature on the topic and the limited data that would allow us to estimate for firm/facility exit from the combusted tobacco market or other measures of the scale of the economic transition that may occur under this product standard, if finalized, we take a broad approach to the economy-wide transition of productive resources.[48]

We use data from the U.S. Census Bureau's 2022 Annual Capital Expenditures Survey (ACES) to estimate the annual amount that firms invest domestically in equipment and structures for all tobacco manufacturing under North American Industry Classification System (NAICS) code 3122 (100), inflation-adjusted to 2023 dollars. ACES reports that capital expenditures during 2013-2022 in the overall tobacco manufacturing industry ranged from $396 million to $647 million, with a 10-year average of $490 million, as seen in Table 25 below. We assume that one-time transition costs for capital would be equal to ten times the range stated above from $3,957 million to $6,467 million, with a primary estimate of $4,902 million. As we are unable to estimate what portion of the capital expenditures reported by ACES are solely related to manufacturing combusted products affected by this rule, we assume that annual capital expenditures by manufacturers of affected products are similar to those of the overall tobacco market.

Table 25. Capital Expenditures in the Tobacco Manufacturing Industry (NAICS 3122, Millions of 2023 Dollars)

Year	Structures	Equipment	Total[1]
2013	$80	$423	$503
2014 (max)	$82	$564	$647
2015	$221	$357	$578
2016	$107	$299	$406
2017	$128	$336	$465
2018 (min)	$121	$275	$396
2019	$91	$457	$548
2020	$115	$294	$408
2021	$108	$359	$467
2022	$85	$400	$485
10-Year Average	$114	$376	$490

[1] Totals may not add due to rounding.

[48] We note that that while the main analysis of the RIA is a Benefit-Cost Analysis that measures economic impacts from the standpoint of U.S. society as a whole, the Small Entities Analysis in Section III looks at the impacts from the standpoint of individual small entities. In this analysis we go into a more detailed discussion of impacts to firms. We also discuss reductions in tobacco firms' revenue in Section H.

We compute transition costs associated with labor in the following way. We estimate that the total number of employees working on affected products is 9,003 by multiplying the total tobacco manufacturing employment in the May 2023 National Industry-Specific Occupational Employment and Wage Estimates (101) of 11,280 by 79.8 percent, which is the share of revenue of affected products relative to total tobacco revenue. For the low, primary, and high scenarios, we use the estimated reduction in cigarette quantity, as discussed in section II.F.2, 5 years after the nicotine product standard effective date relative to baseline quantity and assume that firms scale down production proportional to this reduction. The low, primary, and high estimated reductions in quantity are 17 percent, 96 percent, and 99 percent, respectively. We estimate total employees facing transition for each scenario by multiplying the reduction in quantity by the total number of employees working on affected products.

We estimate the social cost of employee transition using estimates from the literature associated with mass layoffs (102; 103; 104). Walker (2013) estimates the present discounted cost of an employee separating from their job as a result of an environmental regulation to be about 120% of their pre-regulatory annual earnings at a 4% discount rate (104). Using the reported coefficients in Walker's Column 2 of Table III, we estimate the annualized cost to be 15.7% at a 2% discount rate. Davis & Von Wachter (2011) estimate the cost of an employee losing their job in a layoff to be about 11.9% of the present discounted value of counterfactual earnings over a 20-year period at a 5% discount rate or 171% of their predisplacement annual earnings (103). Bartik (2015) estimates the annualized cost to be 12.8% at a 3% discount rate for an area with average initial unemployment. For our analysis, we use the range of 11.9% to 15.7% as the low and high impact scenarios and take the midpoint of 13.8% as the primary impact scenario (102). We assume employees who lose their job as a result of the policy will face an annualized loss in wages of 11.9, 13.8, and 15.7 percent of their 2023 earnings over a 40 year time horizon, in the low, primary, and high impact scenarios, respectively. We estimate the potential multiple year impact on wages for transitioning employees as a one-time employment shock using the method explained below.

The 2023 annual mean wage for the Tobacco Manufacturing sector (NAICS 312200) is $67,570 (101). We calculate the annual lost wages due to an employee's transition by multiplying the annual wage by the annualized loss in wages, then discounting at a 2 percent rate over the 40 year time horizon. This yields a present discounted value per employee that ranges from $224,360 to $296,004, with a primary value of $260,182. We multiply the per employee cost by the number of affected employees in each policy impact scenario to compute the total transition cost of labor. The low, primary, and high estimates are $0.35 billion, $2.24 billion, and $2.64 billion, respectively. Refer to Table 26 below. We note that this approach may overestimate labor transition costs if firms that reallocate capital into the production of noncombusted tobacco products also retrain employees to manufacture them. We request comment on our approach, and for any additional literature on the topic.

Table 26. Transition Costs of Labor Under the Low, Primary, and High Policy Impact Scenarios (2023 Dollars)

	Primary	Low	High
Employees Working on Affected Products	9,003	9,003	9,003
Reduction in Smoking Prevalence 5 years Post-Policy	96%	17%	99%
Transitioning Employees	8,620	1,561	8,926
Social Cost Per Employee	$260,182	$224,360	$296,004
Total Cost	$2,242,782,659	$350,299,554	$2,642,118,350

We estimate the total one-time economic transition costs by summing costs associated with capital and costs associated with labor, as individually discussed above. We use a compliance period of 12 months (one year before the effective date), to allow firms time to reformulate and then submit a premarket application for their new tobacco product. Thus, we assume that costs occur one year following the publication date of the rule. Table 27 displays the estimates for the total economic transition costs. We estimate total economic transition costs to range from $4,307 million to $9,110 million, with a primary estimate of $7,145 million. We note that firms may be able to repurpose or reallocate capital to manufacture other noncombusted tobacco products or continue to domestically manufacture NNC combusted tobacco products for export to foreign countries. We request comment and data on the total value of tobacco-specific equipment, typical depreciation rates, potential resale value of various capital categories (including land), and typical expenditures on training new employees.

Table 27. One-Time Transition Costs ($ 2023, Millions)

	Primary	Low	High
Capital	$4,902	$3,957	$6,467
Labor	$2,243	$350	$2,642
Total	$7,145	$4,307	$9,110

b. Producer Surplus Loss

Producer surplus is determined by the difference between the price a producer receives for their product and the minimum price they would accept. When the amount of product sold in a market decreases, producers lose revenue, a portion of which is producer surplus. As this proposed product standard, if finalized, is expected to result in decreases in producer surplus for combusted products affected by this rule, this section discusses and estimates producer surplus in the market for combusted tobacco products. In Section II.I.2, we estimate the amount of revenue that would transfer from the tobacco market back to consumers. The policy's reduction in smoking prevalence is expected to lead to an associated producer surplus loss in the combusted tobacco market. There is also expected to be a supply shift in the noncombusted product market as a spillover effect from what is happening in the primary combusted market; some consumers of combusted tobacco products affected by the rule substitute into the noncombusted market to sustain their nicotine addiction. We discuss and quantify the change in the secondary-market for non-combusted tobacco products but do not include the monetized estimates from the spillover because the producer surplus effects may already be assessed in the primary-market analysis of combusted tobacco products.[49] We take this approach to avoid the potential for double counting but request comment on the extent to which the producer surplus in the noncombusted market would be double counted.

To estimate producer surplus changes as a result of this proposed product standard, we first consider the market structure and its impact on the magnitude of producer surplus. The tobacco market, and particularly the market for cigarette products, exhibits a high degree of market concentration and potential pricing power. Overall, the top three manufacturers/brand owners account for 87.8 percent of total cigarette sales by volume in the United States (44). We assume that in the other tobacco product markets such as non-premium cigars, pipe, and RYO tobacco, as well as noncombusted products, similar levels of concentration exist. This level of concentration is indicative of an oligopoly market structure. Oligopolies are challenging to assess as the market structure can range from competitive to monopoly.

Historical evidence suggests that producer behavior in the cigarette market differs from the typical relationship between quantity, minimum price accepted, and market price. A 1997 report prepared by the Federal Trade Commission (FTC) analyzed certain features of the tobacco Master Settlement Agreement (November 1998). This report suggested that the proposed settlement, particularly the antitrust exemption, had the potential to reduce competition and enhance the ability of the cigarette companies to "coordinate" price increases (105). As observed in more recent studies, the prices for cigarette packs have continued to rise as the number of cigarette packs sold have decreased, with cigarette prices typically increasing following

[49] See Ashley (109), Farrow and Rose (110), and Just, Hueth and Schmitz (111) for an explanation on potential double counting of producer surplus when looking at spillover markets.

government policies (20; 106; 107).[50,51,52] This evidence suggests that the tobacco industry may respond to the product standard by retaining or increasing market prices. We are uncertain about the overall price change, which would depend on responses from both consumers and manufacturers. We assume that price would remain constant after implementation of this product standard, based on shifts from both supply and demand. We request comment on potential pricing power of tobacco product manufacturers by product type and how such pricing power may be incorporated into this analysis.

However, as we do not have sufficient data to assess producer surplus under an oligopoly market structure, we present quantitative estimates of producer surplus under a hypothetical competitive market with a constant price as an approximation of changes in producer surplus due to this product standard. We then present a qualitative discussion of changes in producer surplus under a hypothetical monopoly market structure with a constant price, which would be more concentrated than an oligopolistic market structure. Additionally, we note that our estimates of producer surplus represent the surplus for the entire production chain (e.g., from manufacturer to retailer). We are unable to assess the extent to which concentration in a segment of the industry will impact the distribution of producer surplus across the supply chain. We request comment on the distribution of producer surplus across the tobacco supply chain, including the portion of tobacco product sales that may represent wholesale and retail margins.

1. Producer Surplus Assuming a Hypothetical Competitive Market and a Constant Price

We estimate the producer surplus associated with projected changes in combusted and noncombusted tobacco product consumption assuming a hypothetical competitive market in which price remains constant. Following the assumptions of a competitive market, we can calculate producer surplus based on initial firm revenue, the price elasticity of supply,[53] and the percent change in quantity in the market. We expect this proposed standard would result in leftward shifts in both supply and demand in the combusted tobacco market. We expect demand to have a parallel shift leftward due to consumer responses to reduced nicotine yield from

[50] See U.S. Department of Health and Human Services (20), page 525 Figure 5.2, where the graph reflects prices (the blue line) beginning to rise in the 1980's as the number packs (the red line) are seen decreasing. Prices rose significantly again after the enactment of the 2009 Tobacco Control Act and the "Special Rule for Cigarettes" (Section 907(a)(1)(A) of the FD&C Act). https://www.ncbi.nlm.nih.gov/books/NBK99238/figure/ch5.f2/.

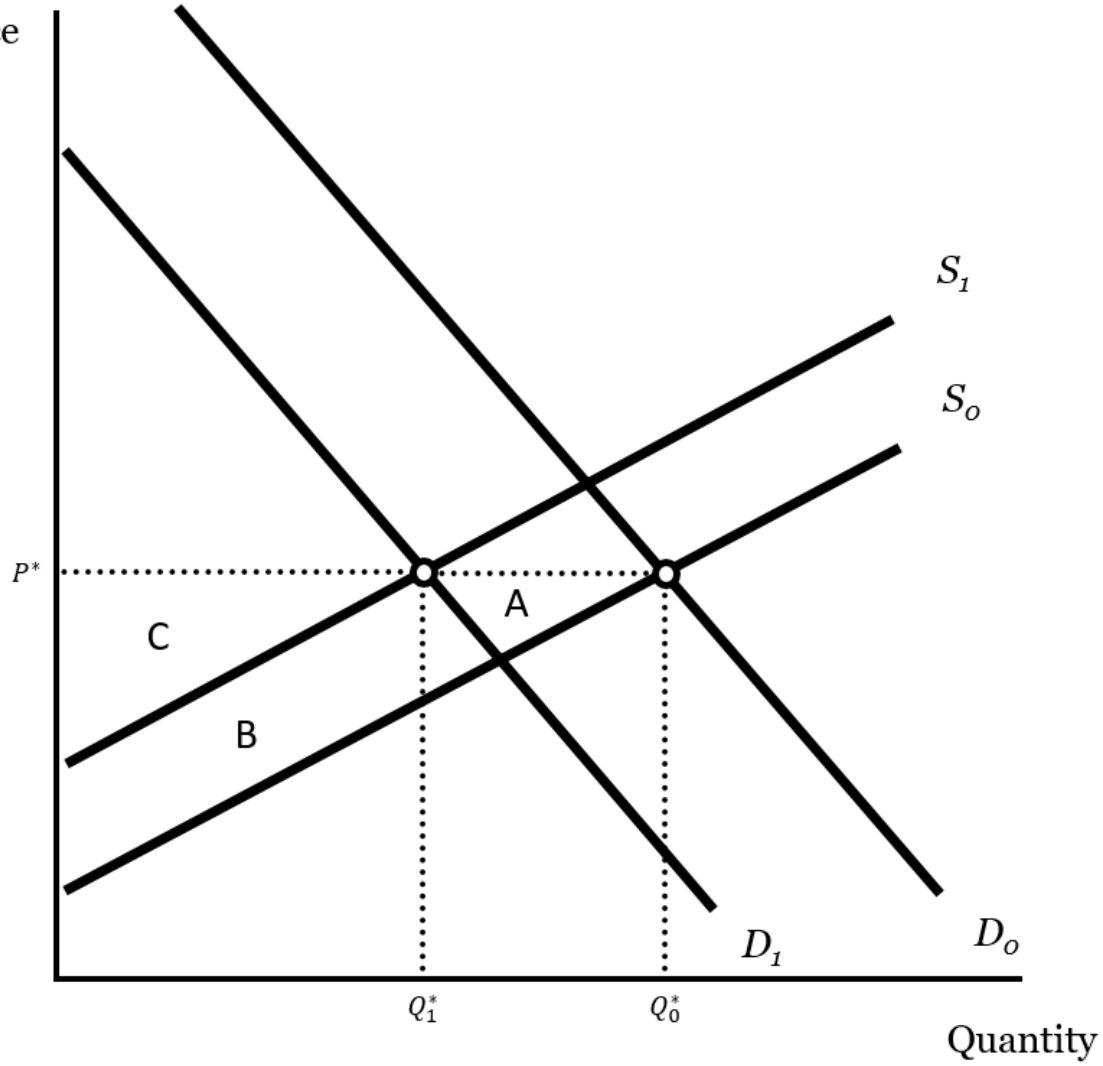
[51] "In April 2009, the federal cigarette excise tax in the United States was increased by US$0.6167 per pack, with US cigarette companies passing on the full amount of the tax increase and raising prices further (e.g., Philip Morris USA raised prices on its leading brands by US$0.71 per pack and on other brands by US$0.78 per pack)" (106 p. 31)

[52] "In light of the oligopolistic structure of the U.S. tobacco industry and price inelasticity of the demand for cigarettes, the tobacco industry has the ability to raise cigarette prices by more than the increase in marginal cost of cigarette production. Several empirical studies have found tax pass-through rates of 100% or greater in the cigarette industry (Barnett et al. 1995; Harris 1987)" (107 p. 702).

[53] Price elasticity is a measure of how the quantity supplied or demanded changes as a result of a change in price.

products with reduced content relative to current nicotine levels (that is, increased cessation and decreased initiation), and supply to have a parallel shift leftward due to firms' reallocating resources away from the production of combusted tobacco products based on expectations of consumer responses. Together, these shifts capture the projected declines in combusted tobacco product quantity consumed. We are uncertain about the overall price change, which would depend on the extent to which supply and demand shift relative to each other. Therefore, we assume that the supply and demand curves shift such that price remains constant after this proposed standard. This is shown in Figure 21 below, where we model the decrease in equilibrium quantity, assuming that price remains constant.

Figure 21. Graph of Producer Surplus Assuming a Hypothetical Competitive Market Structure and Combusted Tobacco Demand and Supply Shifts Under the Rule



Notes: D stands for demand, S stands for supply, Q stands for quantity, and P stands for price. Producer surplus without the policy is A + B + C, and producer surplus after the policy is area C. The lost producer surplus is A + B (= A + B + C – C). We note that our calculations depend solely on the decrease in quantity, our price assumption, and elasticity of supply. We make no assumptions on the demand for combusted tobacco products, with curves provided purely for illustration.

Previous empirical research has estimated the supply elasticity of tobacco farming at 7.0 (108). We use this supply elasticity to estimate the change in producer surplus in the markets for cigarettes and cigars, along with our estimates of change in quantity in those respective markets, and assuming parallel shifts in supply and demand such that price remains constant. We assume producer surplus loss in the market for pipe tobacco and RYO tobacco is proportional to the revenues of each product relative to cigarettes in the Euromonitor data in 2021, since they are assumed to follow the same trend in cigarette smoking prevalence as discussed in the baseline section above.[54] We request comment on this approach to producer surplus loss and on our supply elasticity estimate.

We calculate producer surplus losses from 2025 to 2064 by taking the difference between post-policy producer surplus and baseline producer surplus. We expect the policy to first impact sales beginning in 2028, as seen in Figure 12 of section II.F.2. In the absence of the policy, in our hypothetical analysis, each period smoking prevalence is declining, causing a leftward shift in demand and a simultaneous leftward shift in supply due to firms' expectations, resulting in constant price, lower equilibrium quantity, and a downward trend in producer surplus at baseline over the time horizon. In the first year, we assume the price elasticity of supply to be 7 at the hypothetical equilibrium price and quantity in the baseline. In each subsequent year, we dynamically calculate a new price elasticity of supply at that new equilibrium quantity with the same price.[55] In each given year and for each policy scenario (low, primary, and high policy impact scenarios), we calculate the relative difference between the baseline expected quantity sold and that policy scenario's expected quantity sold to establish the policy-induced decrease in quantity for each year. We then calculate the producer surplus loss in each year using the baseline firm revenue, price elasticity of supply, and the percentage change in quantity between the baseline quantity and the quantity of the respective policy scenario. The change in producer surplus loss, for year 't', under this framework is equal to

[54] The revenues of pipe tobacco and RYO as a percentage of cigarette revenues are 1.41 and 0.32 percent, respectively. Therefore, we assume the producer surplus loss for pipe tobacco is equal to 1.41 percent of the loss in the cigarette market and 0.32 percent for RYO.

[55] $Supply\ elasticity = \left(\frac{P}{Q}\right) x \left(\frac{1}{Slope\ of\ Supply\ Curve}\right)$. Given parallel shifts in supply, the slope of the supply curve remains constant from the first period. Slope is established at the initial equilibrium in the first period using the relationship, $Slope\ of\ Supply\ Curve = \left(\frac{P}{Q}\right) x \left(\frac{1}{supply\ elasticity}\right)$.

$$\text{PS Loss}_{\text{year t}} = 0.5 * \left(\text{Firm Revenue}_{\text{without rule,year } t}\right) * \left(\frac{1}{Supply\ Elasticity_{\text{year } t}}\right) * \left(1 - (1 - \%\Delta Q_{\text{year } t})^2\right).$$

We note that this calculation makes no direct use of estimates of the elasticity of demand for combusted tobacco products, and demand curves are provided purely for illustration.

Our estimate of annualized producer surplus loss in the cigarette market ranges from $159 million to $1,678 million, with a primary estimate of $1,435 million at a 2 percent discount rate. Cigar market annualized producer surplus estimates range from $35 million to $251 million, with a primary estimate of $228 million at a 2 percent discount rate. Annualized producer surplus loss estimates for the pipe tobacco market range from $2.2 million to $23.6 million, with a primary estimate of $20.2 million at a 2 percent discount rate. The annualized producer surplus loss estimates for the RYO tobacco market range from $0.5 million to $5.4 million with a primary estimate of $4.7 million at a 2 percent discount rate. We sum producer surplus losses for cigarettes, cigars, pipe, and RYO tobacco and display the total producer surplus loss for the combusted products affected by the rule in Table 28. Total present value of cost ranges from $5,479 million to $54,621 million, with a primary estimate of $47,076 million at a 2 percent discount rate. Annualized costs range from $196 million to $1,958 million, with a primary cost of $1,687 million at a 2 percent discount rate.

Table 28. Producer Surplus Loss in the Combusted Tobacco Products Market over 40 Years in Millions of 2023 Dollars at a 2% Discount Rate

	Primary	Low	High
Discounted Total Cost (40 years)	$47,076	$5,479	$54,621
Annualized Cost (40 years)	$1,687	$196	$1,958

As discussed above, we estimate the potential gains in producer surplus in the noncombusted market, however, we do not include these estimates in the form of a net producer surplus impact. We omit these monetized estimates from the spillover in the secondary noncombusted market because the producer surplus effects may already be assessed in the primary-market analysis of combusted tobacco products. That is, the producer surplus change in the market for noncombusted products may have been, implicitly, partially netted off from the long-run change in producer surplus in the primary market for combusted products (109; 110; 111). We request comment on the extent to which the producer surplus impact in the secondary market is already accounted for in the primary market estimates.

We compute producer surplus gain in the noncombusted tobacco product market with the same methods used to estimate producer surplus loss in the combusted tobacco product market discussed above (for example, the key change is modeled as a parallel rightward shift of the supply and demand curves such that equilibrium quantity increases, and price remains constant).

As discussed in the baseline, noncombusted tobacco product use prevalence is expected to continuously rise across the 40-year time horizon. We estimate that the policy would increase noncombusted tobacco product use relative to the baseline due to consumers switching from combusted to noncombusted tobacco products to sustain their nicotine addiction. The PHM estimates a sharp uptick in noncombusted tobacco use immediately following the policy relative to the baseline. Refer to Figure 16 in Section II.F.2 for the estimated quantity sold for smokeless tobacco products from 2025 to 2064. Following the same methodology for estimating baseline ENDS revenue, we estimate producer surplus gain for SLT and assume producer surplus gain in the market for ENDS is proportional to the ratio of ENDS to SLT revenues of 0.69 in the Euromonitor Passport data in 2021, as shown in Table 6.

Our estimate of annualized producer surplus gain in the smokeless tobacco market ranges from $42 million to $533 million, with a primary estimate of $206 million at a 2 percent discount rate. The annualized producer surplus gain for ENDS ranges from $29 million to $369 million, with a primary estimate of $142 million at a 2 percent discount rate. We sum the producer surplus gains for smokeless and ENDS to account for the entire noncombusted market and display the total producer surplus gain in Table 29. Total present value producer surplus gains range from $1,991 million to $25,168 million, with a primary estimate of $9,715 million at a 2 percent discount rate. Annualized producer surplus gains range from $71 million to $902 million, with a primary estimate of $348 million at a 2 percent discount rate.

Table 29. Producer Surplus Gain in the Noncombusted Tobacco Products Market over 40 Years in Millions of 2023 Dollars at a 2% Discount Rate

	Primary	Low	High
Discounted Total Gain (40 years)	$9,715	$1,991	$25,168
Annualized Gain (40 years)	$348	$71	$902

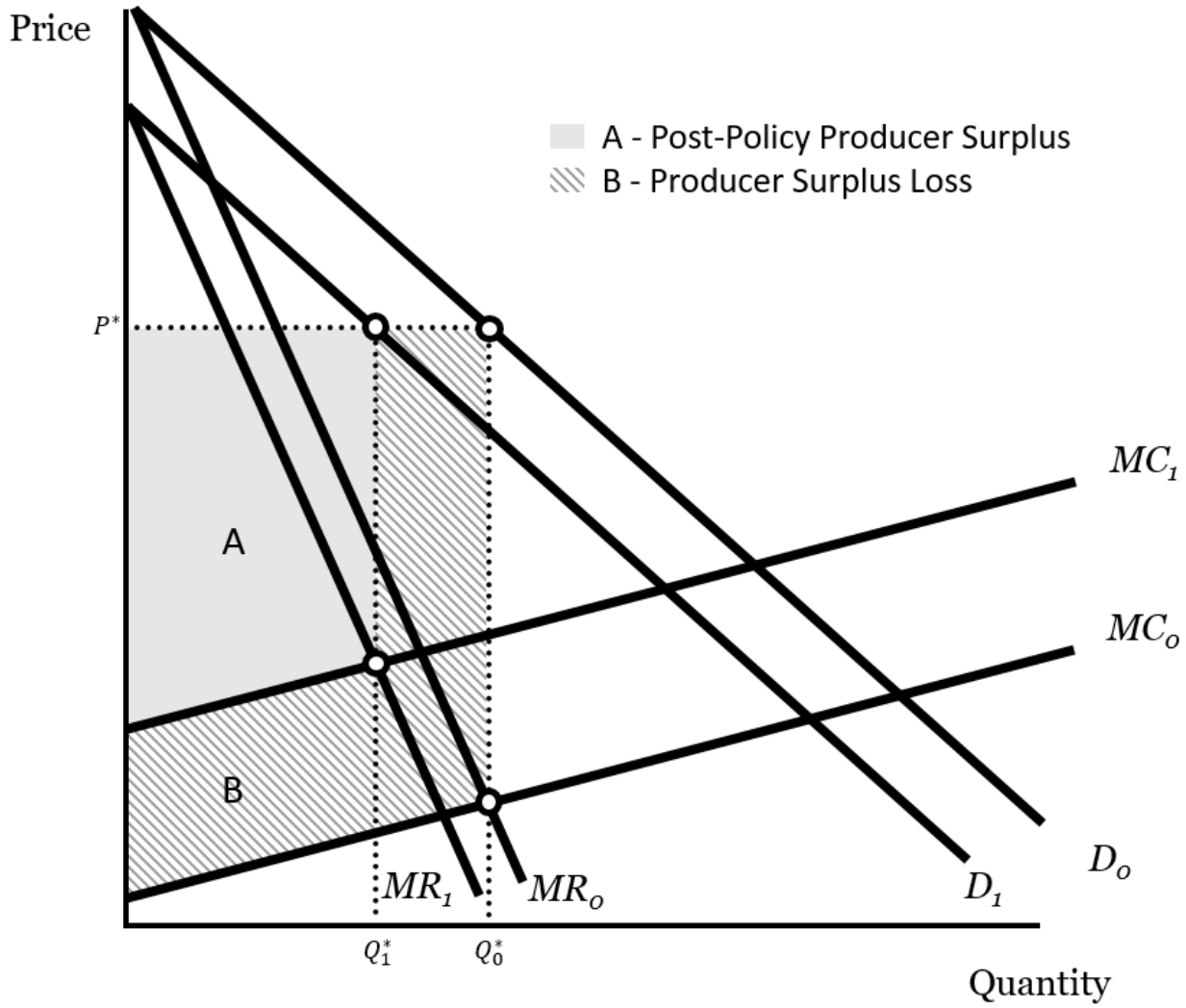
A limitation of our approach to estimating producer surplus is that it relies on an assumption of parallel supply curves (for every unit up to Q_1*) and on an estimate of supply elasticity which was estimated using data on tobacco growers in one state from 1950-1984. This estimate of supply elasticity may not generalize to other producers in the tobacco industry, including manufacturers, distributors, and retailers. More recent and regionally diverse data on supply elasticity may also generate different results. An additional limitation is that this analysis assesses the market as a whole. We do not have the data needed to assess the lost producer surplus at different points along the supply chain. The degree to which intermediaries in the market lose surplus depends on market structure and integration. Further, consumers who cease tobacco product use are expected to purchase other goods and services, resulting in reduced producer surplus for the tobacco industry but increased revenue and associated producer surplus for other industries. Additionally, we reiterate that the market for tobacco is highly concentrated,

with a small number of firms holding the majority share of tobacco product sales. We request comment on all assumptions and estimates in this section.

2. Producer Surplus Assuming a High Degree of Market Concentration and Constant Price

Depending on how the tobacco market is defined, the tobacco industry could be considered concentrated, which would imply producers could be cooperative and reach non-competitive outcomes. Oligopolies acting in a cooperative manner may be able to realize monopoly profits and subsequently may have greater changes in producer surplus relative to a competitive market as a result of this proposed product standard. However, since we do not have the data needed to estimate changes in producer surplus under a monopoly, we discuss it qualitatively. As discussed above, we are uncertain about the overall price change, which would depend on responses from both consumers and manufacturers. As with the hypothetical competitive market discussed above, historic data suggest that tobacco firms that manufacture combusted tobacco products often hold price constant after a policy shock, so we consider a simultaneous supply and demand shift that would reduce quantity while holding price constant. Since combusted tobacco markets are highly concentrated with only a few significant combusted tobacco product manufacturers making up a large percentage of the market, the markets may function closer to a monopoly structure than a competitive market. We show a monopoly structure in the combusted tobacco market in Figure 22 below, assuming simultaneous shifts in demand and marginal cost to illustrate how price could remain the same within a single, undifferentiated monopoly market. As depicted in Figure 22, the change in producer surplus would be the area B. We do not have enough information to derive the marginal cost or revenue curves used to determine the change in price under the rule and, subsequently, cannot estimate changes in producer surplus under this market structure. Thus, Figure 22 is used purely for illustration. We request specific data and information on the level of concentration in the tobacco market with and without this proposed policy, as well as data to estimate marginal cost and revenue curves for combusted and noncombusted tobacco products.

Figure 22. Graph of Producer Surplus in the Combusted Tobacco Market Assuming a High Degree of Market Concentration and Constant Price While Quantity Decreases Under the Rule



Notes: MC stands for marginal cost, MR stands for marginal revenue, D stands for demand, Q stands for quantity, and P stands for price. A and B are names assigned to represent the regions of the graph that define producer surplus post policy and the change in producer surplus.

c. Reading and Understanding the Rule

All entities affected by this proposed rule, if finalized, would spend time to read and understand the final rule, resulting in a one-time cost. The current Preamble and proposed codified together contain approximately 120,000 words; we use this as a proxy for the length of the final rule. Consistent with HHS guidelines, we assume that industry reviewers read at the average adult reading speed of approximately 200 words to 250 words per minute, so the time to read and understand the regulation would range from 8 hours to 10 hours per person (64). We

assume that one to five people would read the final rule at each entity manufacturing or importing affected products, wholesalers, and retail firms.

To value the time associated with reading and understanding the rule if finalized, we use composite wages calculated from the 2023 BLS national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry (101).[56] We use a mix of 50 percent management occupations (occupation code 11-0000) and 50 percent legal occupations (occupation code 23-0000). This mix yields a composite wage of $76.98 per hour for tobacco manufacturers, $80.64 per hour for wholesalers, and $47.39 per hour for retailers.[57] We double this to account for benefits and other indirect costs, yielding an hourly labor cost of $153.96 for tobacco manufacturers, $161.27 for wholesalers, and $94.77 for retailers.

We estimate the cost for one reviewer to read the rule, if finalized, to range from $1,231.68 to $1,539.60 for a manufacturer, from $1,290.16 to $1,612.70 for a wholesaler, and from $758.16 to $947.70 for a retail firm. Depending on the number of people who read the rule, these costs would range from $1,247.60 to $7,698 for manufacturers, from $1,244.32 to $8,063.50 for wholesalers, and from $708.08 to $4,738.50 for retailers. As previously discussed in Section II.E.4, we estimate that the rule if finalized would affect 293 entities manufacturing or importing tobacco products, 1,343 wholesalers, and 145,044 retailer firms. The total costs for reading and understanding the rule then range from approximately $112.1 million to $700.4 million with a primary estimate of $373.5 million. We assume this cost is incurred the year the rule publishes, in 2025. Table 30 includes a summary of these costs.

Table 30. One-time Costs for Reading and Understanding the Rule ($, 2023)

Costs	**Primary**	**Low**	**High**
Affected Entities (Manufacturers & Importers)	293	293	293
Affected Entities (Wholesalers)	1,343	1,343	1,343
Affected Entities (Retailers)	145,044	145,044	145,044
Number of People Reading per Entity	3	1	5
Word Count	120,000	120,000	120,000

[56] The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2022. We use instead, the legal occupation wage reported for the beverage and tobacco manufacturing industry (NAICS 312000). Additionally, wage estimates were not provided for tobacco-specific wholesalers or retailers. As such, we utilize the legal and management occupation wages for merchant wholesalers of nondurable goods (NAICS 4240A3) and all of retail (NAICS 44 and 45).

[57] The tobacco manufacturing management occupation average wage is listed at $73.88 per hour, and the legal occupation average wage is listed at $80.08 per hour. The calculation is 0.5 x ($73.88) + 0.5 x ($80.08) = $76.98. For wholesalers, the management occupation average wage is listed at $71.08 per hour, and the legal occupation average wage is listed at $90.19 per hour. The calculation is 0.5 x ($71.08) + 0.5 x ($90.19) = $80.64. For retailers, the management occupation average wage is listed at $49.75 per hour, and the legal occupation average wage is listed at $45.02 per hour. The calculation is 0.5 x ($49.75) + 0.5 x ($45.02) = $47.39.

Average Reading Speed (words per minute)	225	250	200
Reading Time (Hours)	8.9	8	10
Composite Wage ($ per hour) for Manufacturers & Importers	$153.96	$153.96	$153.96
Composite Wage ($ per hour) for Wholesalers	$161.27	$161.27	$161.27
Composite Wage ($ per hour) for Retailers	$94.77	$94.77	$94.77
Cost per Entity (Manufacturers & Importers)	$4,105.60	$1,231.68	$7,698.00
Cost per Entity (Wholesalers)	$4,300.53	$1,290.16	$8,063.50
Cost per Entity (Retailers)	$2,527.20	$758.16	$4,738.50
Total Costs for Manufacturers and Importers	$1,202,941	$360,882	$2,255,514
Total Costs for Wholesalers	$5,775,616	$1,732,685	$10,829,281
Total Costs for Retailers	$366,554,365	$109,966,309	$687,289,434
Total Cost	**$373,532,922**	**$112,059,876**	**$700,374,228**

d. Manufacturers: Reformulation Costs

This proposed product standard, if finalized, would cause a reduction in the number of tobacco products available on the market. The development of new, compliant VLNC products has costs to manufacturers, and tobacco products are required to go through one of several authorization pathways to enter the market. Please see NPRM Section IX.B ("Pathways to Market") for a complete discussion as it pertains to this proposed product standard. After implementation of the policy, manufacturers would face declining sales and would strategically decide how many new VLNC products to develop. In the text below, we discuss assumptions on the number of new VLNC products assumed to be developed under the low, primary, and high policy impact scenarios.[58] This exercise is intended to create a proxy to estimate the number of products that may remain post-policy and is not intended as an analysis of firm exit.

CTP experts assume that each manufacturer, on average, utilizes four different core blends per tobacco category that they manufacture. A "core blend" represents a mixture of tobacco to which different ingredients and processes are applied to produce a unique finished tobacco product. We use the number of core blends as the number of formulations that would have to be modified to comply with the proposed standard. For the low policy impact scenario, we assume that registered firms currently producing a tobacco product category reformulate four products for that tobacco category. There are currently 34 cigarette producing firms, 81 non-premium and premium cigar firms, 51 pipe tobacco firms, and 25 RYO firms. We have no information on the number of firms that only produce premium cigars, so we assume that all firms produce non-premium cigars.

[58] The "high impact scenario" corresponds to the scenario where the policy has the highest estimated averted mortality (95th percentile results projected by the PHM) and the lowest (5th percentile) post-policy combusted tobacco prevalence. For reformulation and some other costs, the "high impact scenario" or "upper bound" corresponds to the scenario with the fewest products and thus, reflects the lowest estimate of costs.

For our primary estimate, we assume that manufacturing of VLNC combusted tobacco products would decline to a handful of firms. We use the number of firms that have a high pre-policy market share as a proxy for the manufacturing capacity that may remain on the market, as discussed in Section II.H.1. We assume that four cigarette manufacturers and three cigar manufacturers remain on the market. Since an average manufacturer utilizes four different core blends per tobacco product category, as discussed in the previous paragraph, we assume that the high pre-policy market share firms that remain on the market would reformulate four products each. Since we lack data on the other product categories, we assume these categories are equally concentrated and estimate that three firms remain on the market in each of the other categories.

Finally, for the high policy impact scenario, we assume that only one product from each product category remains on the market, the minimum product variety needed to meet projected demand remaining after the proposed rule is finalized and in effect. There is already one firm with a VLNC cigarette on the market, so we assume that firm remains but introduces zero additional VLNC cigarettes. We assume one product from each of the other tobacco product categories remains on the market. See Table 31. We assume manufacturers would reformulate these products in the year before the effective date of any final rule and would not introduce additional VLNC combusted tobacco products later in the time horizon. We request comment on our assumptions and estimates in this section.

Table 31. Estimated Number of VLNC Combusted Tobacco Products that are Expected to be Reformulated and Seek Marketing Authorization Under the Policy

	Number of Products		
Product Type	Primary Impact	Low Impact	High Impact
Cigarette[1]	16	135	0
Cigar	12	324	1
Pipe	12	204	1
RYO	12	100	1
Total	52	764	3

[1]Note that 22nd Century Group, Inc. already produces a compliant VLNC cigarette, so no additional VLNC cigarettes are needed to ensure that one is available on the market in the high impact scenario. We subtract 1 from the low cigarette impact scenario to account for this, but do not do so in the primary estimate since this firm is not one of the 4 largest cigarette firms by market share.

In 2019, 22nd Century Group, Inc. received FDA marketing authorization and, in 2021, received exposure modification orders for VLNC cigarettes under the names VLN King and VLN Menthol King. VLNC cigarettes are currently being marketed and sold to consumers in select U.S. markets as cigarettes with 95 percent less nicotine than conventional cigarettes. These are currently the only products on the U.S. market that would comply with the proposed nicotine level of this product standard, if finalized. As discussed above, we expect some manufacturers to reformulate their combusted tobacco products to comply with this proposed rule, if finalized.

Manufacturers who choose to develop new VLNC products would have to reformulate their NNC products. To develop VLNC products, manufacturers could choose to use a variety of approaches to obtain the low nicotine tobacco inputs they need for production (See Preamble Section VII.E). Regardless of the approach chosen to acquire VLNC tobacco inputs, manufacturers may also choose to make additional changes to product formulation beyond what is required by the proposed product standard to account for any identifiable or detectable 'nicotine'-related impact on consumer perception or for any other characteristic affected by the nicotine reduction process. Therefore, manufacturers may choose to compensate for this by adding new ingredients or altering the quantity or concentration of existing ingredients added to combusted tobacco products. We estimate the cost of reformulation for each unique blend of compliant tobacco product expected to remain on the market following the proposed product standard.

FDA lacks data specific to the activities and resources that would be associated with reformulation of combusted tobacco products. Given this limitation, we estimate the costs of reformulating non-conforming combusted tobacco products using estimates from the FDA Reformulation Cost Model developed by RTI International (112). This model was initially developed to support food safety and nutrition regulations that require reformulation of affected products or induce manufacturers to reformulate because of changes in labeling requirements. The model provides cost estimates for different types of reformulation activities and compliance activities (such as product testing and premarket authorization of the new products) that take into account the complexity of the product and the company size at the product formulation level (i.e., one formula may be used to produce multiple products). In the model, the complexity of the product is determined by several product characteristics that facilitate or complicate reformulation processes such as number of ingredients, shelf stability, or storage condition. We recognize that food and tobacco products are not perfectly aligned in terms of production processes; below we describe how we use and adapt the model in the context of combusted tobacco products as well as limitations. FDA seeks comments or data to support alternative assumptions or estimates.

The reformulation cost estimates generated by FDA's Food Reformulation Model are largely driven by activities that are good proxies for what we expect to be incurred by covered combusted tobacco product manufacturers in response to this rule. The original model includes ten activities that food safety experts identified as key to the reformulation process. FDA tobacco subject matter experts identified three activities that are not expected to be relevant to reformulation activities in the context of combusted tobacco products. Specifically, we exclude packaging assessment and development and product and package performance testing because VLNC and NNC cigarettes can use the same type of packaging. Thus, the activities that we include in the analysis are determining response to regulation, project management, product reformulation, production scale-up testing, recordkeeping, analytic tests, and consumer tests (See Table 32). Given the variation in the product complexity and manufacturing steps for each combusted tobacco product subcategory, we find that the underlying activity cost estimates

produced by the FDA Food Reformulation Model (112) are reasonable proxies for related costs that may arise for combusted tobacco manufacturers affected by the proposed rule and request comment supported by data on our estimates.

To estimate the costs of reformulation in the FDA's Food Reformulation Model, RTI International worked with experts to determine the typical resources (types and quantity) required for labor, materials and utilities, analytical testing, and marketing testing, if applicable, for each of the activities and level of reformulation complexity that were identified. RTI International developed the estimates of market testing using information provided by three companies that conducted studies for manufacturers. Estimates of analytical testing costs were based on published prices from testing laboratories, and estimated market testing costs were based on information provided by vendors. Using the estimated labor hours, wage rates, and related testing costs, the model calculates per-formula reformulation costs for each reformulation activity. In addition, RTI International used the simulation model @Risk to generate the 5^{th}, mean and 95^{th} percentile for each of the activities. More details can be found in the model's documentation (112).

We recognize that food and tobacco products are not perfectly interchangeable in terms of production processes; however, the reformulation costs model was developed with recent (2014/2015) best industrial manufacturing practices in mind. We acknowledge that food manufacturing standards and processes have been established and in practice for some time and are regularly subject to review and revision given the importance of food safety to the United States, and it is only recently that FDA has issued a proposed rulemaking to assess tobacco product manufacturing practices (88 FR 15174, March 10, 2023) (TPMP) and move toward standardization. For this analysis, we assume that large tobacco product manufacturers, representing the bulk of tobacco product production capacity, adhere to industrial practices consistent with non-tobacco product manufacturing given their scale, reach for professional support, and the range of products produced by some of their larger parent companies. Although the total estimates produced by the model, which include inputs like size and structure of the food processing industry, would not be applicable to this rulemaking, the costs of individual activities, such as process modification, product performance testing, and project management could be applicable to any industrialized production of a consumable good. Thus, as discussed above, we apply only individual activity costs, which FDA's tobacco subject matter experts believe may be generally applicable, adjusted by considerations about the complexity of the tobacco product formulation and size of the operation, to the industry covered by this rulemaking.

As discussed in the Preamble, FDA's tobacco product scientists have identified multiple methods for altering the level of nicotine in cigarettes and certain other combusted tobacco products. FDA anticipates that manufacturers may choose to use a variety of approaches to meet the proposed maximum nicotine level. Significant reduction of nicotine in the tobacco products covered by this proposed product standard can be achieved principally through three main methods: tobacco blending, chemical extraction, and genetic engineering. Other practices, such

as modified growing conditions (e.g., discontinue the practice of topping where the flowering head of the tobacco plant is removed to produce leaves with a significantly higher nicotine content, increase plant density, decrease nitrogen application) as well as more novel techniques, can also help to reduce nicotine levels. One or more of these processes can be used to achieve the nicotine target level in this proposed product standard. The process we believe requires the fewest changes to general manufacturing practices and could be implemented for the lowest cost is switching from current tobacco blends to available strains of VLNC tobacco leaf. We expect that increased manufacturer interest in purchasing new tobacco blends with lower nicotine content will result in tobacco growers and distributors shifting tobacco crop inventories to meet this change in demand, following regular market forces. As we expect many manufacturers to primarily comply with this rule through changes in purchasing practices, we use the Food Reformulation Model's description of "major ingredient or process change" to capture the associated burden.[59]

We adapt the FDA Food Reformulation Model by using estimates of the number of new VLNC combusted tobacco product formulations that we expect to be developed to comply with this proposed product standard outlined in Table 31. Our estimates of the number of product formulations that may need to be reformulated may overestimate costs if manufacturers can create very low nicotine tobacco levels through changes in farming and curing practices prior to blending. Alternatively, these estimates may underestimate the reformulation costs if subsequent processing of the product is needed to alter nicotine levels or other characteristics beyond what may be resolvable through changes in blending.

As mentioned before, cost estimates developed in the FDA Food Reformulation Model also vary by the complexity of reformulation for each product subcategory to account for the fact that some products are more easily reformulated than others. For the purposes of this analysis, we assume that all combusted tobacco products are "low" complexity products. The complexity level criteria for foods are determined based on the number of ingredients that interact with other ingredients, and whether the manufacturing process is technologically challenging. Low complexity products, in this context, may be described as products where the manufacturing process is well understood, and one major ingredient is involved. For example, milk, cheese, packaged tea bags and low-calorie carbonated beverages are considered low complexity products because their finished product involves a manufacturing process that is predetermined, well understood, and involves mainly one ingredient. Products where the manufacturing process is more complex and involves few ingredients—such as regular (non-low-calorie) gum, dried fruit, chocolate and non-chocolate candy, powdered milk, or non-carbonated beverages—are considered medium complexity products. On the other hand, low-calorie gum, refrigerated

[59] In the Food Reformulation Model, a "major ingredient" is defined as one that is used at high levels with functional performance effect, food safety effect, or both types of effects (e.g., it is a macro component or it represents more than 2 percent by weight). In the model, a change in the production process cannot happen without a change in ingredient also occurring, but a major change in ingredient can occur without there being a change in process. A functional performance effect includes changes to the product related to sensory characteristics observable by the consumer. A food safety effect includes changes that can alter the product's safety such as shelf stability.

flavored milk or yogurt shakes are considered high complexity products because their manufacturing involves many ingredients and highly complex processes. The reformulation cost model also categorizes food products by acidity levels, shelf-stability and overall simplicity as determined by the number of ingredients in the product and the number of processing steps. Because combusted tobacco products generally have a relatively neutral pH, FDA believes this to be an area where the model guidelines of food product categories do not fit precisely for describing tobacco product categories. Acidity during processing and storage can have a large impact on shelf-stability and consistency for canned and jarred food products and is not a good indicator of manufacturing process complexity for tobacco products. Lacking a tobacco-specific reformulation cost model, FDA's tobacco product scientists reviewed combusted tobacco manufacturing processes in the context of the food reformulation cost model and determined that combusted tobacco would generally fall under the reformulation model's low complexity category of products, mainly based on the fact that the products are shelf-stable, consist of one major ingredient and involve few processing steps, not unlike a packaged tea bag, for example. Specifically, FDA tobacco product scientists have used the comparison of combusted tobacco to packaged tea bags in terms of manufacturing complexity. This is because combusted tobacco is largely dried tobacco leaf; cut, chopped, or shredded to varying degrees, possibly with flavors added; and then packaged in a shelf stable form. This contrasts with other products such as chewing gum, which are melted to strain natural impurities, mixed with sweeteners and flavors, flattened, mixed with additional sugars, and then packaged. The melting process and chemical mixing of additives in semi-liquid form of such products makes the overall process more complex. As another example, non-fat dried powdered milk manufacturing begins with the raw liquid milk, which is separated to remove cream or butterfat. The additional steps to reach a powder form include taking the resulting separated and condensed milk and either atomizing or spray drying the milk. Spray drying— the industry standard for a long time and still widely used—is where the condensed milk is sprayed through a nozzle into 400-degree swirling air where the moisture is separated from the milk particles. Those particles are collected as powdered milk. As a manufacturing process, this is significantly more complex than combusted tobacco manufacturing. Thus, the manufacturing process of combusted tobacco filler is quite different than the manufacturing processes of these food products.

Next, each VLNC formulation is assumed to be equivalent to a reformulation which the FDA Food Reformulation Model describes as a "change in production process (with an ingredient change)". The per-formulation costs include activities associated with determining response to regulation, project management, process modification, product reformulation, production scaleup testing, analytical and consumer testing, and recordkeeping. We update the per-formulation cost from 2014 dollars to 2023 dollars using the consumer price index. In addition, we note that the FDA Food Reformulation Model assumes a minimum of 24 months for reformulation for small and medium companies and a minimum of 36 months for large companies. Based on input from product formulation experts, we assume that large firms put substantially more effort into coordinating and planning a reformulation than small firms.

Shorter timelines can affect the availability of personnel to oversee and implement the changes, as well as availability of supply chain sources for ingredients and equipment, and the ability to conduct or contract research needed to implement the changes. Thus, shorter compliance periods would incur overtime and rush charges, thereby increasing costs. We use a compliance period of 12 months (one year before the effective date), to allow firms time to reformulate and then submit a premarket application for their new tobacco product. The report includes adjustment factors for a 12-month compliance period (the adjustment is 1.75 for small firms, 2.25 for medium firms, and 3 for large firms). We incorporate these adjustment factors in our estimates.

Using the per-formulation costs in Table 33 and the estimated number of new VLNC combusted tobacco products in Table 31, we estimate total reformulation cost as shown in Table 33. Total one-time reformulation costs are estimated to be between $35 million and $9 billion, with a primary estimate of $610 million. Most of the costs arise from cigarettes, followed by cigar and pipe tobacco.

The estimated costs are based on several key assumptions regarding anticipated industry response to reformulation decisions. FDA seeks comment and data supporting other assumptions regarding industry practice for reformulating products and their associated costs discussed in this section. First, in addition to the related activities mentioned above, manufacturers may need to discard or export unused inventory of raw materials. The reformulation model assumes that manufacturers would use any existing inventory of raw materials so that any potential costs of discarding or exporting them would not be incurred.[60] If manufacturers are not able to use existing raw materials, then the reformulation costs may be higher. Second, we assume any one-time reformulation costs are incurred in the first year after publication of the final rule, prior to the proposed product standard becoming effective, rather than spread out over the first and second years after publication. If additional time is available to implement a reformulation, then costs may be lower than what we have estimated. We request comment and data on our assumptions about the timing of costs for industry. Third, reformulation costs represented in the model are one-time costs of reformulation, and it does not include ongoing costs that may be associated with the reformulation. For example, if bringing the nicotine levels in compliance requires costly modifications to tobacco blends, then combusted tobacco product manufacturers would incur higher costs in the form of higher input prices that are not included in the underlying assumptions of the model and would thus result in this model underestimating the costs of reformulation. Fourth, capital equipment expenditures are not included in the model. The underlying assumption is that manufacturers would be able to use their current capital equipment to come in compliance. Finally, cost estimates assume that a moderate number of products are being reformulated at the same time. If all products within a product subcategory had to be

[60] A tobacco product intended for export is not deemed to be in violation of section 907 and can be exported under 801(e) of the FD&C Act if it (A) accords to the specifications of the foreign purchaser, (B) is not in conflict with the laws of the country to which it is intended for export, (C) is labeled on the outside of the shipping package that it is intended for export, and (D) is not sold or offered for sale in domestic commerce. If manufacturers were to export raw materials and incur costs associated with this activity, the reformulation model would be underestimated.

reformulated at the same time, manufacturers would incur a higher initial cost. There may, however, also be cost savings from manufacturing efficiencies when reformulating several related products at the same time.

Table 32. Reformulation Cost by Activity ($2023)

Reformulation Activity	**Cost**
Determine Response to Regulation	$164,088
Project Management	$861,302
Production scale-up testing	$1,305,689
Recordkeeping	$1,237,957
Analytical Tests	$3,765
Consumer Tests	$1,023,390
Product reformulation/process modification	$7,142,088
Total per-formulation cost	**$11,738,279**

Table 33. Reformulation Costs by Product Category ($2023, Millions)

	Primary	Low	High
Cigarette	$188	$1,596	$0
Cigar	$141	$3,803	$12
Pipe	$141	$2,395	$12
RYO	$141	$1,174	$12
Total	$610	$8,968	$35

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

As discussed above, there are several ways to reduce nicotine and reformulate products to comply with this proposed product standard. We request comment on the likelihood that each method would be used, and the costs associated with each method.

e. Labeling Cost

This proposed product standard, if finalized, would require manufacturers to include a manufacturing code on the packaging. See Section X.C.1 of the NPRM for details on the manufacturing code requirements. The manufacturing code would allow manufacturers and FDA to identify the production batch of a particular finished product that has been released for distribution. This labeling update is consistent with the labeling requirement laid out in the TPMP proposed rule (88 FR 15174, March 10, 2023). We anticipate that the TPMP rule will

finalize before this proposed product standard. Therefore, all potential labeling costs for this product standard are already accounted for.[61]

f. Cost to Submit Premarket Applications

Manufacturers for each new VLNC tobacco product would need to choose a pathway to market and submit a premarket application to FDA. Section IX.B of the NPRM discusses expected pathways to new VLNC products. We draw estimates of submission cost from the "Content and Format of Substantial Equivalence Reports" FRIA (86 FR 55224, October 5, 2021), since we expect most reformulated combusted tobacco products to use the substantial equivalence (SE) pathway. Table 2 of the SE FRIA presents time estimates for firms to develop SE submissions with a primary estimate of 193.5 hours. We develop a composite wage of 75 percent Chemical Technicians (average hourly wage $39.77) and 25 percent management (average hourly wage $83.42) from the NAICS 312200 – Tobacco Manufacturing wage data for a composite wage, including benefits and other indirect costs, of $101.37. This gives us an estimated cost of $19,614 per SE submission. We then apply the costs to the estimated number of products from Section II.H.1.d. See Table 34.

Table 34. Costs to Submit SE Reports for VLNC Products ($ 2023)

	Primary	Low	High
Hours per SE report	193.5	193.5	193.5
Composite wage per hour with overhead	$101.37	$101.37	$101.37
Cost per SE report	$19,614	$19,614	$19,614
Number of SE Submission	52	764	3
Total cost	$1,019,935	$14,985,193	$58,842

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

[61] If the TPMP rule is finalized *after* this product standard, we may expect the costs associated with Subpart F of TPMP to be incurred (at least in part) due to the nicotine product standard. In TPMP, we may estimate one-time labeling costs ranging between $2 million and $8 million, with recurring costs of approximately $0.5 million (undiscounted) each year. See Table 23a of the Requirement for Tobacco Product Manufacturing Practice, Preliminary Regulatory Impact Analysis (260). We expect labeling costs for the nicotine standard to be analogous to Subpart F of the TPMP rule. Except, we note that this estimate of labeling costs for the nicotine standard may be 1) overestimated because firms may exit the market as a result of the nicotine standard, so a direct transfer of costs from Subpart F of TPMP to this rule may not be appropriate, and 2) underestimated because firms may be required to engage in other activities analogous to other Subparts of TPMP. Further analysis would be needed to accurately assess the scenario where the nicotine standard publishes prior to TPMP.

We expect these costs to occur in year 1 of our time horizon, 2026, since all firms would want to have authorized tobacco products on the market before consumers begin switching to VLNC tobacco products at the effective date. We estimate a primary cost of $1 million with a lower and upper bound of $59 thousand and $15 million. We request comment on this approach.

g. Testing costs

The proposed rule requires manufacturers to test every batch of VLNC tobacco product subject to this standard. While manufacturers are required to develop their own testing procedures, or adopt one of FDA's suggested test methods, we make some assumptions about testing process here to estimate testing costs. Based on consultation with FDA tobacco product science subject matter experts, we assume the sample size a manufacturer uses for testing would need to be of sufficient size to ensure that the margin of error for a 95 percent confidence interval is no more than 0.06 milligrams of nicotine per gram of total tobacco.

Based on information from inspections and other FDA subject matter expertise, FDA estimates a batch size of 24 million cigarettes or 1.2 million packs for the largest cigarette manufacturers and 8 million cigarettes or 400,000 packs for smaller cigarette manufacturers. However, due to estimated decreases in quantity produced as a result of the product standard, we estimate that all manufacturers produce the smaller batch size of 8 million cigarettes or 400,000 packs after the final rule goes into effect. We request comment on the estimated batch size. Using our estimates for cigarette product unit sales under the proposed product standard, as shown in Figure 23, we estimate an annual production primary estimate of 155 billion cigarettes in the first year after the effective date and 2 billion by 2064.

Manufacturers are required to develop their own approach for a statistically valid sample. The product standard, if finalized, would establish a maximum nicotine level in a cigarette and certain other combusted tobacco products to be less than or equal to 0.70 mg of nicotine per 1 gram of total tobacco. Therefore, we assume manufacturers would use the upper bound of a 95 percent one-sided confidence interval of 0.76 (=0.70 + 0.06 margin of error). We request comment on this assumption. The number of samples required from each batch to meet this standard ranges from 76 with a nicotine level variance of 0.10, to 144 with a variance of 0.19. To meet a margin of error of 0.05, instead of 0.06, would require between 109 and 207 samples from each batch, depending on the variance. We estimate that between 76 and 207 samples of finished tobacco product would be tested from each batch. Our medium estimate is 113 samples, which we estimate using a margin of error of 0.06 and a variance of 0.15. A sample refers to the finished tobacco product in its final packaging, e.g., a pack of 20 cigarettes. FDA's Tobacco Products Laboratory estimates that the test costs $3.56 per sample when the sample size tested is over 20 units.

Using these assumptions, estimates, and testing costs, we estimate the testing cost per batch ranges from $269 to $737, with a medium estimate of $404. The PHM estimates that the first year the policy would impact cigarette quantity sold is 2028. We assume that the first-year

testing would take place is 2028, with a total of 7,270 batches required to be tested in the primary estimate. We estimate that by 2064, 246 batches would require testing. We show estimated number of batches required for testing below in Figure 23. We assume that the testing costs of affected combusted products that are not cigarettes are proportional to the revenues of each product relative to cigarettes in the Euromonitor data presented in Table 6.

Figure 23. Estimated Batches Required for Testing from 2025 to 2064 Under the Low, Primary, and High Policy Impact Scenarios

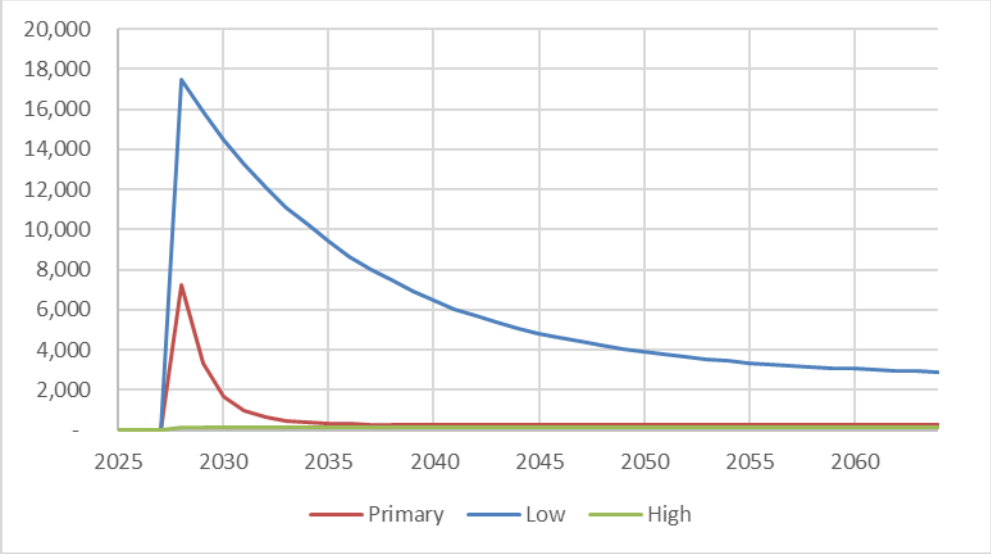


Table 35 shows the estimated annual testing cost for cigarettes. The estimated annualized testing cost for cigarettes ranges from $2 million in the low impact scenario to about $0.09 million in the high impact scenario with a primary estimate of around $0.31 million at a 2 percent discount rate.

Table 35. Testing Costs for Cigarettes over 40 Years in 2023 Dollars at a 2% Discount Rate

	Primary	Low	High
Discounted Total Cost (40 years)	$7,478,745	$47,956,037	$2,239,748
Annualized Cost (40 years)	$314,125	$2,014,264	$94,075

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

Table 36 shows the total cost of testing for all covered tobacco products, which includes cigarettes shown in Table 35, RYO tobacco, non-premium cigars, and pipe tobacco. The total annualized testing cost for all covered tobacco products ranges from $2.2 million in the low impact scenario to $0.1 million in the high impact scenario at a 2 percent discount rate.

Table 36. Testing Costs for All Covered Tobacco Products over 40 Years in 2023 Dollars at a 2% Discount Rate

	Primary	Low	High
Discounted Total Cost (40 years)	$8,223,977	$52,734,695	$2,462,932
Annualized Cost (40 years)	$345,426	$2,214,979	$103,449

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

The number of batches and the variance of the nicotine level per batch are uncertain. We request comment on the number of batches that would require testing, the number of samples per batch to meet the required confidence interval, and the cost of the testing method.

2. Costs to Consumers

a. Withdrawal Cost

As a result of this product standard many people who use combusted tobacco products will quit tobacco entirely. As discussed in NPRM Section IV.A, nicotine is addictive and, therefore, many who quit the use of nicotine products could experience withdrawal symptoms including cravings, irritability/anger/frustration, anxiety, depressed mood, difficulty concentrating, increased appetite, insomnia, and restlessness (113). We estimate the cost of experiencing withdrawal for those who quit all tobacco products, however, we qualitatively discuss withdrawal costs for those who switch to VLNC tobacco products, as these products may have mitigating effects on withdrawal symptoms, or those who switch to noncombusted products as it is unclear if these consumers switch immediately or have a failed quit attempt before switching. Overall, withdrawal costs are very small relative to the health gains from quitting smoking, which are discussed in Section II.G and include improvements in mental health (reduced depression, anxiety, and stress) and quality of life compared with continuing to smoke (97).

1. Withdrawal Symptoms and Cravings

The experience of nicotine withdrawal can manifest in two ways: withdrawal symptoms and cravings. Nicotine withdrawal symptoms are generally recognized to include irritability/anger/frustration, anxiety, depressed mood, difficulty concentrating, increased

appetite, insomnia, and restlessness.[62] Such symptoms typically emerge within the first 1-2 days following abstinence, peak within the first week, and last 2-4 weeks in total duration (114). The physiological basis of nicotine withdrawal is linked to the status of individuals' nicotine receptors in the brain, which appear to return to their normal state after 6-12 weeks of abstinence (115). The evidence noted here and discussed in more detail in the NPRM (IV.A) suggests that the strongest nicotine withdrawal symptoms can often appear quickly following nicotine or tobacco cessation and the duration of these symptoms last for a relatively limited time. Therefore, we assess the impacts of nicotine withdrawal over a short period of time.

While other nicotine withdrawal symptoms are associated with a relatively distinct trajectory over time, the trajectory of tobacco product craving is considerably more variable among individuals (116; 117; 118). Generally, craving has been shown to peak soon after quitting and then gradually decrease to baseline levels (i.e., levels observed while smoking) within the first week (117). However, for some individuals, prolonged cravings may persist intermittently for several years before eventually dissipating (119). These intermittent cravings are often in response to smoking cues such as certain environments or behaviors that can trigger impulses to again seek tobacco products. Given that cravings are most intense for most individuals in the first few weeks following cessation and occur concurrently with other physical and psychological nicotine withdrawal symptoms, we discuss the cost of cravings qualitatively. We request comment and research that may inform an analysis of the impacts such cravings may have on the quality-of-life following cessation experienced by people who quit all tobacco product use.

2. People Who Quit All Tobacco Use

To identify the population who may experience nicotine withdrawal symptoms, we use the PHM results to project the number of people using combusted tobacco products who would quit all tobacco use in the first year following the proposed product standard. The PHM projects a median of 4.3 million people who currently use combusted tobacco products would quit all tobacco product use in the first year under the proposed product standard, with a 90 percent prediction range of 45,000 to about 15.6 million. This estimate includes individuals who exclusively use combusted tobacco products at baseline as well as those who dual use with noncombusted tobacco products who then quit all tobacco product use under the proposed product standard.

Given the previous discussion of duration of nicotine withdrawal symptoms, we estimate a single, one-time impact of nicotine withdrawal symptoms attributable to the proposed product standard for the population projected to quit all tobacco product use. We quantify this impact by

[62] These symptoms have been recognized and attributed to nicotine and tobacco withdrawal since the 1980s (DSM-3) (257) and remain the standard set of symptoms used for identification of tobacco and nicotine withdrawal (113).

multiplying an estimate of the loss in quality of life experienced during nicotine withdrawal by the expected duration of these symptoms to produce estimates of the loss of quality-adjusted life days (QALDs). We monetize these impacts using a dollar value of a QALD. Recognizing that the number and types of nicotine withdrawal symptoms may vary widely across individuals, we allow for variance in our calculations in two ways. First, we split the population who are projected to quit all tobacco product use in the PHM into three nicotine withdrawal groups: 1) those who may report more nicotine withdrawal symptoms (i.e., report four or more physical or psychological withdrawal symptoms (120)), 2) those who may report fewer nicotine withdrawal symptoms (i.e., report fewer than four nicotine withdrawal symptoms), and 3) those who may not report any nicotine withdrawal symptoms while abstaining from tobacco product use. Second, we allow the loss in quality of life and duration of symptoms to vary across the individuals in each group. To estimate the total impact of nicotine withdrawal costs for the population who quits all tobacco product use, we perform a Monte Carlo simulation for each severity group individually and then sum across groups.

To identify the population withdrawal groups, we first rely on an analysis of data from a large, nationally representative sample of U.S. adults (National Epidemiologic Survey on Alcohol and Related Conditions, NESARC). In looking at Wave 1 (2001-2002) and Wave 2 (2004-2005) NESARC data, Garcia-Rodriguez et al. (121) found that 78.5 percent of individuals who reported tobacco product abstinence at Wave 1 of data collection also reported ever wanting "to stop or cut down on your tobacco product use" prior to their Wave 1 abstinence (García-Rodríguez et al., 2013).[63] Additionally, 65.2 percent of the participants in this study who were abstinent at Wave 1 of data collection reported "having experienced withdrawal symptoms when stopping or cutting down on tobacco use."[64] Another study of NESARC data covering the same years reported an additional breakdown relating to past year withdrawal symptoms, with 4,415 individuals who reported at least one withdrawal symptom in the past year (65.1%) and 1,048 individuals who reported a withdrawal-related relapse in the past year (15.3%) out of a sample size of 6,911 individuals who were fully abstinent from tobacco use at the time of the survey (122). This additional information of past year withdrawal-related relapse reported in this paper could potentially inform the severity of withdrawal symptoms experienced. For this analysis, we use the Garcia-Rodriguez et al. (2013) study and assume that 65.2 percent of individuals projected to cease all tobacco product use under this proposed product standard would also experience at least one reportable nicotine withdrawal symptom. We request comment, including additional data and studies, that may inform this analysis.

[63] From the study paper, this statistic is drawing from responses to "in your entire life, did you ever more than once want to stop or cut down on your tobacco use?"

[64] In Garcia-Rodriguez et al. (121), "having experienced withdrawal symptoms when stopping or cutting down on tobacco use" is based on response to the following question in the NESARC: "after stopping or cutting down on your tobacco use, did you ever (a) feel depressed, (b) have difficulty falling asleep or staying asleep? (c) have difficulty concentrating? (d) eat more than usual or gain weight? (e) become easily irritated, angry, or frustrated? (f) feel anxious or nervous? (g) feel your heart beating more slowly than usual? (h) feel more restless than usual?"

A study on abrupt cessation in 630 regular smokers that evaluated prevalence of tobacco withdrawal symptoms found that of the people who were abstinent from smoking and reported withdrawal symptoms, approximately 49% endorsed four or more withdrawal symptoms (i.e., met the DSM-III-R criteria for nicotine withdrawal) (120). Based on this study, we assume that, of the 65.2 percent of those abstinent from smoking who experience any reportable nicotine withdrawal symptoms, a little less than half (32 percent = 65.2 percent x 49 percent) would experience more nicotine withdrawal symptoms and the remainder (33.2 percent = 65.2 percent x 51 percent) would experience fewer nicotine withdrawal symptoms. We request comment on these data sources, estimates, our approach, and additional data and studies.

We utilize disutility values that measure the loss in quality of life associated with several chronic diseases that may function as proxies for some of the symptoms of withdrawal, including anxiety disorders and mood disorders (including depression) (123). Because the literature on how to estimate utilities (i.e., changes in quality of life) associated with disease conditions indicates that "there is no standardized method and a lack of consensus on how to estimate the utilities of comorbid disease conditions" (123), we apply the quality measure of one of the most widely reported withdrawal symptoms: anxiety (114). Additionally, we use the available measure of disutility of chronic disease for all anxiety disorders as a proxy for the relatively short-term nicotine withdrawal anxiety symptom.[65,66] Using recent empirical evidence on disutility experienced with chronic anxiety disorders (123), we assume that those individuals estimated to have more nicotine withdrawal symptoms experience an average quality-of-life loss of 0.053, with a standard deviation of 0.002. We assume that those individuals estimated to have fewer nicotine withdrawal symptoms experience an average loss in quality of life that is half of what those with more significant withdrawal symptoms experience, or 0.0265, with the same standard deviation of 0.002. We seek comment on this approach and request additional studies and data to

[65] It is important to note the limitations with using any particular anxiety disorder as a proxy for the anxiety symptoms experienced with tobacco withdrawal to draw conclusions on the quality-of-life or cost of illness impacts of tobacco withdrawal. The term "anxiety disorders," as used by Song et al. to calculate disutility experienced with anxiety, only encompasses the corresponding International Classification of Diseases, Ninth Revision (ICD-9) diagnostic codes that fall under the Clinical Classifications Software (CCS) Diagnosis Category Code 651 (123). Therefore, the Song et al. analysis of the impacts of anxiety disorders, and resulting disutility scores adopted in this analysis, does not include the impacts associated with the diagnosis codes related to tobacco use or withdrawal. Anxiety disorders are mental health diagnoses based on specific DSM-5 criteria that differ significantly from the tobacco withdrawal diagnostic criteria. As a result, the quality-of-life impacts of the conditions examined by Song et al. may be different than the quality-of-life impacts of the anxiety symptoms experienced with nicotine withdrawal.

[66] In section II.G.2, we qualitatively discuss the morbidity effects associated with improvements in mental health from smoking cessation. By 6 months of abstinence, most people who smoked cigarettes report less psychological distress than they experienced while they were still smoking (95 pp. 517-578) and showed improvements in measures of mental health compared with those who continued to smoke, including psychological well-being, anxiety, positive affect, cognitive functioning, energy, sleep adequacy, self-esteem, and sense of mastery (96). In studies of quality-of-life impacts after quitting, people who formerly smoked cigarettes reported no deterioration in quality of life and were more likely to see improvements and many people who no longer smoke cigarettes also reported that they were "happier" after quitting than they were before (98; 99).

inform this analysis, including more specific quality-of-life measures for nicotine withdrawal, or other disutility measures.

As described above, withdrawal symptoms typically emerge within the first 1-2 days following abstinence, peak within the first week, and last 2-4 weeks in total duration (114). For this reason, we assume that the duration of nicotine withdrawal costs for individuals across the withdrawal groups with non-zero losses in quality of life follow a triangular distribution with a minimum of 1 day, maximum of 30 days, and mode of 3 days.

Next, we multiply the expected loss in quality of life by the duration of withdrawal symptoms to produce estimates of the loss of quality-adjusted life days (QALDs). For those that report more withdrawal symptoms, we expect per-person QALD losses to range from 0.14 to 1.26, with a primary estimate of 0.55. For those who experience fewer withdrawal symptoms, we expect per-person QALD losses to range from 0.07 to 0.63, with a primary estimate of 0.27.

The dollar value of a QALD is calculated by dividing the value of a quality-adjusted life year (QALY) by 365 days. We use the value per QALY set by HHS Guidelines (1). The value per QALY depends on the discount rate used by the analyst, and we calculate nicotine withdrawal costs using 2 percent discount rates. For 2027, the first effective year of the policy, if finalized, the value per QALY using a 2 percent discount rate is approximately $608,512 in 2023 dollars. The value of a QALD is thus $608,512/365, or approximately $1,700.

Using the identified withdrawal groups, the estimates of the loss in quality of life for each grouping, the distribution of expected nicotine withdrawal symptom duration, and the estimated value of a QALD, we estimate the impact of nicotine withdrawal costs for the population who currently smoke and subsequently quit all tobacco use in the first year to be $1.4 billion (with a low of $15.4 million and a high of $9.2 billion).

3. People Who Switch to VLNC Exclusively

The PHM projects some of the population of people who smoke NNC tobacco products would switch to exclusive use of VLNC tobacco products, and thus continue using combusted tobacco products, in the year following the effective date of a final rule. The peer-reviewed FDA scientific assessment discussed in the Preamble provides an in-depth assessment of existing literature and research on the impacts of VLNC combusted product use on nicotine withdrawal and craving (see NPRM Section VII.B.11). Although some studies suggest brief and extended exposure to VLNC cigarettes can suppress craving and withdrawal just as effectively as NNC and usual brand cigarettes, there are several aspects of the available literature limiting our ability to quantify this effect and therefore the potential impact of nicotine withdrawal symptoms in this population. Studies that report quantitative data permitting an assessment of withdrawal at baseline (i.e., abstinent from tobacco) compared to withdrawal after use of VLNC cigarettes, often consist of specific participant populations, have small sample sizes, and/or use

methodologies that vary widely. These study characteristics limit our ability to make generalizations of the specific degree of withdrawal mediation for both symptom existence and intensity or reliable comparisons between studies.

Overall, we recognize that this population of people who exclusively smoke VLNC combusted tobacco products are among the population that FDA expects to significantly reduce their nicotine consumption following the effective date of a final rule. We request comment, including data, studies, or other information, which may inform FDA assessments of the potential impact of withdrawal symptoms experienced by those individuals switching to exclusive VLNC tobacco product use.

4. People Who Switch Between NNC Products

Among the population that continues to use NNC products following the product standard, either noncombusted or illicit, we qualitatively discuss potential nicotine withdrawal costs. Many consumers who currently use combusted tobacco products may switch directly to an available NNC tobacco product under the proposed product standard to continue nicotine consumption and, therefore, not experience nicotine withdrawal. Some people who currently use combusted tobacco products may first attempt to quit all tobacco product use before switching to an available NNC tobacco product.[67] These consumers may experience withdrawal costs during their quit attempt. However, the PHM projects tobacco product use transitions on an annual basis and does not differentiate, in a given year, between populations who switch directly to other NNC tobacco products and populations who switch to other NNC products after a quit attempt; therefore, we discuss nicotine withdrawal costs for this population qualitatively.

We request comment, including data, studies, or other information, on withdrawal symptoms and severity for people who switch directly to other available NNC tobacco products. We also request studies and data, on the potential population of individuals who may attempt to quit before switching to other NNC tobacco products, the duration of such potential quit attempts following the proposed product standard, as well as the comparability of nicotine withdrawal symptoms between people who switch to other available NNC tobacco products and people who switch to exclusive VLNC use that may result from this proposed product standard.

5. Summary

Overall, we recognize that for people who quit tobacco and nicotine consumption, nicotine withdrawal can represent a significant short-term impact. We value the impact of nicotine withdrawal for people who quit all nicotine consumption following this proposed product standard to be $1.4 billion (with a low of $15.4 million and a high of $9.2 billion). We request comment on our estimates of quantified withdrawal costs for those who quit all tobacco

[67] For a full discussion of cessation and relapse, see section IV.C of the NPRM

product use following the proposed standard, including studies and data regarding withdrawal symptom duration; the percentage of people who experience withdrawal symptoms when quitting; and the severity, type, and cost of such withdrawal symptoms. We also qualitatively discuss nicotine withdrawal costs for people who continue to smoke using VLNC combusted tobacco products or switch to other available NNC tobacco products. We request comment on withdrawal symptoms, duration, and severity for people who continue to smoke VLNC combusted tobacco products or switch to other available NNC tobacco products, including the percentage of people who may attempt to quit before continuing to use a tobacco product following the proposed standard.

b. One-Time Search Costs

Adult consumers who switch from a NNC tobacco product to a substitute tobacco product or those who try other tobacco products before quitting or search for a nicotine replacement therapy would incur search costs to look for substitute products in the year after the effective date (2027). Search costs may include the time it takes a person who formerly smoked cigarettes to research substitute products, including talking to other people who use tobacco products or nicotine replacement therapy, searching for reviews on the internet and social media, reviewing tobacco product or nicotine replacement therapy packages in the store, and assessing the value of products that were purchased. We lack data to estimate the opportunity cost to search for alternative products. Thus, we assume all adult covered tobacco product consumers would incur a one-time search cost equal to between 0.5 and 1.5 hours of free time. We request comment on possible sources of data on potential search costs and on our assumption.

To monetize these impacts, we adopt a value of time based on after-tax wages. Our approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an HHS report on "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices" (124). We start with a measurement of the usual weekly earnings of wage and salary workers of $1,115.75 (101). We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $27.89. We adjust this hourly rate downwards by an effective tax rate of about 17 percent, resulting in a post-tax hourly wage rate of $23.15 (124). We use this value for our low estimate and double it for our high estimate, $46.30. We use $34.73 as our primary estimate, the average of the low and high estimates.

We estimate the baseline number of affected individuals by using the estimates and trends described in our baseline section on prevalence trends (Section II.E.1). For cigarettes, we use estimates of the population of adults who exclusively smoke cigarettes from the PHM (people who smoke cigarettes – people who dual use cigarettes and noncombusted tobacco products) in the one year following the effective date of this proposed rule, if finalized. Our estimate for people who exclusively smoke cigarettes is around 23.9 million individuals. We

assume that individuals who use RYO tobacco are included in these estimates of people who smoke cigarettes. We also assume that the trend for pipe tobacco follows the trend for cigarettes. So, we estimate that there are around 337,000 affected people who smoke pipe tobacco. We estimate the number of people who smoke non-premium cigars to be around 17.4 million. We multiply the number of affected individuals for each product category by the estimated search time (low of 0.5 hour to high of 1.5 hours, 1 hour primary) with the corresponding per hour wage rate (low of $21.97 per hour to high of $43.94 per hour, $32.96 per hour primary). We estimate that the rule may result in approximately $1,446 million in one-time consumer search costs with a lower and upper bound of $482 million and $2,893 million. Table 37 summarizes the estimates of one-time search costs.

Table 37. One-Time Search Costs by Tobacco Product Category ($ Millions, 2023)

One-Time Search Costs ($ millions)	Primary	Lower	Upper
Exclusive Cigarette	$830.6	$276.9	$1,661.1
Non-Premium Cigar	$604.1	$201.4	$1,208.3
Pipe	$11.7	$3.9	$23.4
Total	**$1,446.4**	**$482.1**	**$2,892.8**

c. Utility Change for Consumers

Regulations that restrict availability or access to a product or that raise its market price may lead to changes in consumer surplus or consumer utility. For fully informed, rational consumers, consumer surplus reflects the difference between their willingness to pay for a product and the price they actually pay in the marketplace. A rational consumer is one whose choices maximize their utility, i.e., an individual who, when presented with a decision, chooses the option that maximizes their welfare. Circular A-4 (2023) states that regulatory impact analyses should consider including "gains or losses in consumers'…surpluses" as part of the economic analysis. This reduction or "loss" reflects consumers' diminished utility (i.e., a reduction in the sense of satisfaction or usefulness consumers obtain from using the good, above and beyond what they pay for it).

For people who use combusted tobacco products, early economic models explored the premise that people who use these products are rational in their decision-making about smoking, fully informed about the risks associated with smoking, and derive benefit from smoking above the price they pay; however, more recent works have added nuance that moves beyond these simplifying assumptions. There is a lack of consensus within the peer-reviewed economic

literature regarding how to account for changes in consumer surplus when analyzing the effect of regulations on tobacco products, which are highly addictive and generally initiated before adulthood—considerations that bear on assumptions of consumer rationality. We note that this proposed product standard would set the maximum level of nicotine in covered tobacco products to minimally addictive or nonaddictive levels, potentially addressing some of the many challenges identified below for covered products. See Section II.B for additional discussion.

In general, economic research has recognized significant challenges with modeling demand for tobacco products and associated changes in utility. These potential challenges include:

- the addictive nature of tobacco products;
- cigarette smoking initiation during adolescence when the brain is not yet fully developed;
- the developing nature of information about the health harms of smoking;
- tobacco product demand based on demand for other perceived benefits of smoking (derived demand); and
- the regret expressed by people who currently smoke cigarettes, desire to quit, and nicotine's negative impact on successful quitting.

These challenges are discussed in more detail in the following sections. In Appendix C, we provide a review of the literature and approaches to modeling tobacco product demand and associated changes in consumer surplus.

1. Addictive Nature of Tobacco Products

Tobacco use is the leading preventable cause of disease and death in the United States (3). Tobacco products also contain the highly addictive substance nicotine. Summarizing years of research and analysis in the field of smoking and tobacco product use, numerous SGRs from 1988 through 2024 have documented the many ways in which nicotine affects the brain and nicotine addiction drives smoking behavior. Seeking to address the primary question of why people smoke and use tobacco products, the 1988 SGR (titled "Nicotine Addiction") laid out primary criteria for dependence, including "highly controlled or compulsive use," "psychoactive effects," and "drug-reinforced behavior."[68] The report established three main conclusions: "1) Cigarettes and other forms of tobacco are addicting 2) [n]icotine is the drug in tobacco that causes addiction; and 3) [t]he pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine" (7). Speaking specifically to behavior and patterns of use, the report notes that "[p]atterns of tobacco

[68] The 1988 SGR further expands, stating that "[h]ighly controlled or compulsive use indicates that drug-seeking and drug-taking behavior is driven by strong, often irresistible urges. It can persist despite a desire to quit or even repeated attempts to quit" [(7) at p.7-8].

use are regular and compulsive, and a withdrawal syndrome usually accompanies tobacco abstinence" (7). The 2020 SGR discusses smoking cessation, asserting as a starting point that "[n]icotine addiction is now increasingly emphasized as a main driver of both the initiation and continuation of smoking" (6). Most recently, the 2024 SGR found that "menthol and other flavorants may potentiate the addictive effects of nicotine" and that "[r]educing nicotine in cigarettes and other combustible tobacco products to minimally addictive or nonaddictive levels should reduce tobacco use among many population groups experiencing tobacco-related disparities" (55).

The National Institute on Drug Abuse (NIDA) includes tobacco and nicotine among commonly used drugs (125), stating that nicotine stimulates "the adrenal glands to release the hormone epinephrine (adrenaline)" (126) and "activates reward pathways in the brain" (127) and that "[f]or many tobacco users, the long-term brain changes induced by continued nicotine exposure result in addiction."

As DiFranza et al. (2002) discuss, the onset of nicotine dependence is "the point of experiencing loss of autonomy over tobacco use" (128). Multiple studies have shown that symptoms of nicotine dependence can arise early after youth start smoking cigarettes, even among people who infrequently smoke cigarettes (129; 130; 131).[69] Further, a Federal court ruled that the major U.S. cigarette companies "have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction" (Tobacco Control Act 2009, §2(49) (reciting findings of fact in U.S. v. Philip Morris USA, 449 F. Supp. 2d 1 (D.D.C. 2006), aff'd in relevant part, 566 F.3d 1095 (D.C. Cir. 2009)).

The research presented above shows that combusted tobacco smoking is driven primarily by nicotine addiction and its resulting drug-reinforced and compulsive behavior, making it difficult to disentangle the consumption driven by addiction from the consumption that may be driven by rational or unbiased demand, meaning that determining the point at which addiction overtakes the choice to continue to smoke cigarettes poses a significant challenge.

2. Cigarette Smoking Initiation During Adolescence When the Brain Is Not Yet Fully Developed and How Most Addiction Begins in Adolescents

Based on over 50 years of published and peer-reviewed scientific evidence and data, the 2014 SGR concluded "[m]ost first use of cigarettes occur by 18 years of age (87%), with nearly all first use by 26 years of age (98%)" (3). Previous SGRs indicate that the percentage of people initiating tobacco product use before the age of 18 has remained mostly constant. The 1994 and 2012 SGRs on smoking and health note that almost 90 percent of adults who currently smoke

[69] The 1988 SGR (7) on page 9 states that the terms "drug addiction" and "drug dependence" are "scientifically equivalent and refer to the 'behavior of repetitively ingesting mood-altering substances by individuals.'" We note that referenced studies may employ one or both terms; thus, we use both terms interchangeably here.

regularly initiated smoking before age 18, and 99 percent initiated smoking before the age of 25, which is the approximate age at which the brain has completed development (19; 20). As nearly all people who smoke cigarettes begin before age 25, the approximate age at which the brain has completed development, such people are more vulnerable to developing nicotine dependence (3) (6; 132; 20). The report further notes that adolescence and young adulthood represents a time of "immaturity in consequential thinking, impulsivity, and decision-making skills" (20). Data reflect continued initiation by youth—the 2019 National Survey on Drug Use and Health (NSDUH) found that each day approximately 1,500 youth (those under the age of 18 years) and 2,600 young adults (those aged 18-25 years) first smoke a cigarette (133). More recently, a 2022 NSDUH report indicated that during 2022 a total of 437,000 adolescents aged 12 to 17 and 791,000 young adults aged 18 to 25 initiated cigarette smoking in the past year, with only around 10 percent of past year initiates (122,000) doing so after age 25 (134). Furthermore, almost three fourths (71.4 percent or 965,000 people) of the 1.4 million people who smoke cigarettes in 2022 who initiated in the past year did so before the age of 21 (134).

In the literature that discusses consumer welfare loss for individuals prevented from initiation, there is support for the position that consumer welfare losses for individuals prevented from initiating tobacco product use should not be considered within a welfare analysis (135; 136; 137). As summarized by Cutler et al. (2015), "because people deterred from starting to smoke never develop a special taste for tobacco products, they are able to get equal or better satisfactions from consuming other products, so a regulation that deters them from starting to smoke entails no utility loss" (135). In a later paper, Cutler et al. (2016) state:

> "...the strong 'taste' for cigarettes generally grows out of having become addicted to cigarettes. Thus, people who do not start consuming the good will not value it as highly as current users. If the average person deterred from starting to smoke finds a consumption bundle without cigarettes to be no less satisfying than one that includes them, a regulation that deters them from starting to smoke will cause no utility loss" (137).

Youth who smoke cigarettes are likely to enter adulthood with established nicotine dependence, compromising the ability to choose cigarette smoking in the absence of addiction. As Chaloupka et al. (2015) state, "most smoking initiation takes place during adolescence or young adulthood among individuals who are often less than fully aware of the health and economic consequences of smoking" (138). The authors conclude that "the decision to initiate smoking [among youth] is an irrational decision and any changes in their conventionally calculated consumer surplus resulting from changes in their tobacco use… should not be counted..." (138).

3. Developing Nature of Information About the Health Harms of Smoking

Since the first SGR published in 1964, evidence of the negative health consequences of cigarette smoking and secondhand smoke has expanded dramatically. As noted in the 2010 SGR, there is "overwhelming and conclusive biologic, epidemiologic, behavioral, and pharmacologic evidence that tobacco use is deadly" (24). The health conditions established to be causally linked to cigarette smoking in the 2014 SGR are in addition to the more than 40 unique health consequences of cigarette smoking and exposure to secondhand smoke determined by earlier studies (3).

Many of the economists developing methods of analysis of consumer surplus effects have attempted to generate some proxy for fully informed and nonaddicted rational consumers who are able to accurately assess available information on the negative health harms of tobacco product use. However, new information about the health harms of tobacco product use continues to be identified. Additionally, research has shown that being a member of specific populations is associated with having lower knowledge of the negative health consequences of smoking (see 85 FR 15638, Mar. 18, 2020 – Tobacco Products; Required Warnings for Cigarette Packages and Advertisements for a more detailed discussion). How such ongoing information development is assimilated by different individuals, updating their judgment about the risk of tobacco product use as new information about health harms continues to be identified, and incorporated into modeling results presents additional challenges and sources of uncertainty.

4. Tobacco Product Demand Based on Demand for Other Perceived Benefits of Smoking (Derived Demand)

Often, the nature of tobacco product experimentation and initiation into regular use, especially in adolescents, is based on demand for other perceived benefits of tobacco product use rather than demand for the tobacco product itself (e.g., weight loss, social status, peer effects that may have positional externalities). This makes it difficult to model the demand for tobacco products separate from the demand for other perceived benefits of use. Evidence of this derived demand comes from surveys in which adolescents are asked about their motivations for initiating smoking (139; 140; 141).

Over time, the original derived demand rationale for tobacco product use (such as peer acceptance) may no longer be relevant, but people who use tobacco products may be unable to stop due to the development of addiction. This suggests an additional explanation of derived demand: nicotine. In addition to the people who use tobacco products' demand for nicotine, sensorimotor stimuli (e.g., smell/taste of smoke, inhaling/exhaling, airway sensations such as "throat hit") repeatedly occur during smoking tobacco products that contain nicotine (142). The sensory aspects of smoking, such as taste and sensations of smoking (e.g., "throat hit"), though initially unpleasant, become reinforcing because they have been paired repeatedly with nicotine exposure (143). These stimuli often act as secondary or conditioned reinforcers that contribute to the smoking "reward" and dependence (142; 144) and may also serve as another source of derived demand. Thus, it is difficult to disentangle the demand for combusted tobacco products

from the demand for other perceived benefits of smoking, demand for nicotine, demand for the addiction-associated sensorimotor stimuli, or demand for simply avoiding withdrawal. We request comment on issues of derived demand associated with tobacco initiation and continued use.

5. Regret Expressed by People Who Currently Smoke Cigarettes, Desire to Quit, and Cognitive Bias

The significant level of regret experienced by most people who smoke cigarettes also plays a role in welfare analysis. It is difficult to estimate unbiased demand, and in particular consumer surplus, when most people who smoke cigarettes state that they regret having ever started smoking and wish to quit. Adults who use tobacco products, most of whom want to quit, are often unsuccessful because of the highly addictive nature of these products (145). More recently, analyses of 2022 NHIS and 2018-2019 Tobacco Use Supplement to the Current Population Survey (TUS-CPS) data indicate that 67.7 and 76.6 percent of adults who smoke cigarettes wanted to quit (146; 147), respectively, while 2022 NHIS data (146) and 2018-2019 TUS-CPS data (147) show that 53.3 and 51.3 percent, respectively, of adults who smoke cigarettes in the United States actually made a quit attempt within the past year. However, an analyses of NHIS and TUS-CPS data for these years indicate that only 8.8 and 7.5 percent of adults had successfully quit smoking cigarettes, respectively (146; 147).

A study by Pechacek et al. (148) found that "more than 80 percent of current smokers report high (22.5 percent) or very high (59.8 percent) discontent due to inability to quit, perceived addiction and regret about having started to smoke". The authors conclude that "the proportion of smokers who might be characterized as having a preference to continue smoking are greatly outnumbered by addicted, discontent, and concerned smokers who want to quit and regret ever having started to smoke" (148). These people "could have a substantial net welfare gain if new regulations helped them escape their concerns about the health effects from continuing smoking" (148). These surveys of people who smoke cigarettes consistently reflect that smoking preference and smoking behavior do not align, meaning empirical evidence shows that their decision utility is not aligned with their experience utility (terms that are now common in behavioral economics) and confirms the cognitive biases in the demand further complicating estimation of consumer surplus loss or gain.[70]

6. What Role Does Nicotine Play in Discussions of Consumer Surplus for Combusted Tobacco Products?

As addressed by the potential challenges above, it is difficult to disentangle the consumption driven by nicotine addiction from that which may be driven by demand for

[70] Decision utility refers to an individual's perceived utility prior to experience, whereas experience utility is the realized utility after making the decision to consume a particular product.

combusted tobacco products. Thus, modeling consumers' willingness to pay for addictive products and, in particular, isolating the value consumers place on the key characteristic of an addictive product—the nicotine level—is a major source of uncertainty regarding the estimation of consumer utility.

To the extent that the demand for combusted tobacco products stems from the demand for nicotine or other combusted product attributes, substitutes for these attributes are readily available (e.g., other tobacco products or VLNC combusted products). Substitute products could potentially provide the same or more consumer surplus for some people who, due to a *status quo bias*,[71] continued using combusted tobacco products because these products were the tobacco product with which they initiated (149). However, people currently using combusted tobacco products who continue to use VLNC combusted products or premium cigars will not experience the health benefits associated with reduced consumption of combusted tobacco products.

Following the reduction in nicotine to minimally addictive or nonaddictive levels, current combusted tobacco product consumers can choose to continue the use of minimally addictive or nonaddictive combusted tobacco products, cease all tobacco product use, or switch to another NNC tobacco product. For instance, these consumers could seek nicotine from smoking cessation products (e.g., NRTs) and/or continue obtaining nicotine from other tobacco products such as ENDS or smokeless tobacco.

However, it is difficult to distinguish between the reasons people who smoke may continue to demand minimally addictive or nonaddictive combusted tobacco products following implementation of a proposed product standard. Continued consumer demand after implementation of the product standard could reflect a step toward "unbiased" demand or simply be an artifact of former addiction. Studies of VLNC cigarettes show that some people who smoke will continue to use the product even without enough nicotine to sustain addiction. While this may represent some partial "unbiased" demand, it might also be a byproduct of previous use of an addictive tobacco product including the pairing of sensorimotor stimuli with nicotine consumption that may be reinforcing on its own for some length of time. Sensorimotor stimuli (e.g., smell/taste of smoke; airway sensations; holding the cigarette) repeatedly occur when using smoking products that contain nicotine (150). These stimuli often act as secondary or conditioned reinforcers that contribute to the smoking "reward" and dependence (150). As discussed in more detail in the Preamble (Section VI.A.3.c), this conditioning can suppress craving and some withdrawal symptoms even in the absence of nicotine.

Additionally, consumers may mistake the reduction in the addictive properties of the product for some other change that impacts other characteristics of the product. It is difficult to determine if any "taste" differences or "liking" are the result of actual changes to the product,

[71] In their influential 1988 paper, Samuelson and Zeckhauser (149) discuss "status quo bias," or a bias towards maintaining one's current or previous decision. The authors further note that "…the initial purchase and use of a brand significantly increase the likelihood of repurchase in a subsequent consumption decision. Clearly, status quo effects contribute to this behavior."

beyond the loss of addictiveness and the effects one associates with the nicotine consumption. Studies that have used the same research cigarette, but with variations in the nicotine level, found that the decrease in "liking" for cigarettes tracked the decline in nicotine level (151; 152). In other words, as the nicotine level declined, demand also declined. However, in a study of people who smoke cigarettes comparing their usual brand with research cigarettes having a similar level of nicotine, the same decline in "liking" was not seen, suggesting that taste or flavor perceptions for the research cigarette were similar to the participant's usual brand (153), which suggests that the "liking" of a cigarette is largely connected to nicotine content rather than brand or packaging in this study. In addition, study participants reported higher positive product ratings when told that they were receiving a nicotine-containing cigarette, regardless of the actual nicotine content of the cigarette (154; 155; 156; 157; 158). Note that these studies imply that "taste" or "flavor" perceptions are associated with nicotine level, making it difficult to identify how much a reduction in nicotine level might impact demand or reflect "unbiased demand".

While the proposed rule does address one significant source of "internalities" in the market for combusted tobacco products (addiction to nicotine), it is important to note that this rule does not fully address information asymmetries or provide additional ways to improve consumer understanding of the health effects from combusted tobacco product use. As such, some information-related "internalities" may persist in creating "bias" in the demand for combusted tobacco products even with this proposed product standard.

7. Summary

FDA does not believe that any reasonable consideration of consumer utility change, even if such a change were negative, would change our Executive Order 12866 determination that benefits associated with this rule clearly justify the costs.[72] While FDA believes that consumer utility change can be considered qualitatively for the product standard, we do not estimate the direction or magnitude of any potential consumer utility changes due to the high level of uncertainty and challenges regarding approaches to consumer surplus estimation. This conclusion is driven by the findings noted above, including that: a) cigarette and other combusted tobacco product use is driven primarily by nicotine addiction; b) the vast majority of adults who smoke cigarettes and other combusted tobacco products become addicted to nicotine at young ages, before the brain has completed development; c) many who smoke did not fully understand the information available about the health harms of smoking when they began

[7272] FDA reiterates that the benefits of this rule are expected to be very large. For example, the present discounted value of avoided premature deaths due to secondhand smoke exposure alone, for which estimating changes in consumer surplus would not apply under any scenario (since these benefits are an externality), is $1,692 billion (at a 2 percent discount rate), while the present discounted value of total costs is $1.58 billion (at a 2 percent discount rate). This is in addition to the value of all prevented premature deaths and qualitative benefits arising from firsthand smoking. As should be clear, while we are not able to quantify the value of any consumer utility changes, we do not believe that any reasonable consideration of such impacts would affect the determination that benefits associated with this rule justify the costs.

smoking, and many still do not fully understand this information today; d) a person who smokes cigarettes' original derived demand rationale for tobacco product use (such as peer acceptance) may no longer be relevant to an individual, and it is difficult to disentangle the demand for cigarettes from the demand for other perceived benefits of smoking, including simply avoiding withdrawal symptoms; e) evidence of regret shows that the decision utility of people who smoke cigarettes is not aligned with their experience utility; and f) the role of nicotine specifically, including the possibility that switching products could provide the same or more utility for some due to status quo bias.

Given the challenges and uncertainties outlined above, and the breadth of literature and approaches discussed in Appendix C (Consumer Surplus), this regulatory impact analysis qualitatively discusses, but does not quantitatively estimate, changes in consumer surplus stemming from the proposed product standard. We continue to research these issues and request comment and/or data to assist in future application of potential modeling approaches.

3. Government Enforcement Costs

a. Federal Enforcement Costs

With a new product standard, we expect some reallocation of CTP's resources to enforce the standard. Thus, we estimate the opportunity cost to reallocate these resources.

The cost of enforcement includes one-time tasks such as updating inspector training materials and websites to reflect the new product standard. In addition, there could be ongoing costs for detecting violations through in-person inspections of tobacco manufacturing establishments and retail distribution outlets, as well as additional monitoring of retail internet sites. CTP currently undertakes these inspection and monitoring activities while enforcing the Tobacco Control Act. We anticipate that CTP investigators may include additional criteria to monitor for non-compliance in covered tobacco products during inspections and investigations. The enforcement of the proposed rule, if finalized, would also include investigating, drafting, and processing warning letters and taking enforcement actions as necessary, such as civil money penalties, criminal prosecution, seizure, and injunction.

Based on subject matter expertise, CTP estimates that 13 to 30 full-time equivalent (FTE) employees would be required for the enforcement activities described above in the first two years after the effective date of this proposed standard, if finalized. From year three onward, CTP estimate that 11 to 23 FTE's would be required for ongoing enforcement. We use an annual wage based on an Agency-wide estimate of the average cost for FTE employees to value this effort. The fully-loaded (inclusive of benefits and other indirect costs) cost per FTE in 2023 equals $320,080. Therefore, we estimate that the annual cost of enforcement in year 1 and 2 after the effective date ranges from $4.2 million to $9.6 million, with a primary estimate of $6.9 million. From year three onward, we estimate that the annual cost of enforcement ranges from

$3.5 million to $7.4 million, with a primary estimate of $5.4 million. While existing staff could conduct this work they are considered as costs because we are shifting our resources to better serve the needs of the Agency. We note that these costs would not affect the total amount of user fees, overall FDA accounting costs, the size of the federal budget, or the amount of tobacco industry user fees. The TCA requires that industry user fees fully fund our regulation of tobacco products. Therefore, these costs represent an opportunity cost for Agency resources.

We note between our counting of potentially affected combusted tobacco products (Section II.E.4.b) and our proxy estimates for the number of combusted products that may reformulate and seek marketing authorization following the proposed product standard (Section II.F.4), this proposed rule has the potential to decrease FDA enforcement costs after the first few years by reducing the number of tobacco product records inspectors may need to review during inspections, decreasing the number and frequency of combusted tobacco products being imported, and reducing the number of product listing submissions in TRLM NG.

In addition, FDA may work with federal partners to help identify and enforce against illicit markets if they develop. For example, as we have in the past, we may work with the U.S. Department of Justice to initiate enforcement actions for injunctive relief against tobacco product manufacturers and retail distribution outlets that illegally manufacture, sell, and/or distribute violative products, and seizure of violative products.

b. State and Local Enforcement

If the proposed rule is finalized, it would prohibit the supply chain distribution and retail sale of non-compliant tobacco products under federal law. It would not prohibit or criminalize the possession or use of such products by individual consumers. State and local law enforcement agencies do not enforce the FD&C Act and FDA regulations under that Act. Thus, we do not estimate costs for state and local jurisdictions to enforce this proposed rule. Due to the lack of enforcement authority, this proposed product standard, if finalized, also should not impact State and local law enforcement work or priorities. To the extent any existing State and local laws would be violated by the manufacture, distribution, sale, possession, or use of tobacco products that do not comply with this product standard, or if new State and local laws are enacted, if resources are limited, law enforcement generally possesses the discretion to not prioritize enforcement of those laws in favor of enforcing laws that have higher priority. We acknowledge that the proposed rule has the potential to impact illicit trade in non-compliant products, but FDA does not anticipate that the rule will induce a surge in illicit trade for the reasons described in Section IX.D of the proposed rule; if as small in magnitude as anticipated by FDA, the potential impacts that illicit sales of non-compliant products might have on State and local law enforcement agencies would be outside the scope of this analysis. We request comment on the potential impacts on state and local enforcement.

c. Costs for Premarket Review of New Tobacco Products

Each new VLNC product would need to choose a pathway to market and submit an application to FDA. Section IX.B of the NPRM discusses expected premarket application pathways for new VLNC products that comply with this product standard, if finalized. We use estimates of FDA review times from the SE FRIA, since we expect most products to use the SE pathway (159)(86 FR 55224, October 10, 2021). We use the SE FRIA Table 9 to estimate of 133 hours for FDA to review an SE application. We apply the fully loaded FDA hourly wage rate of $153.88 per hour to get the per SE review cost of $20,467. We then apply the per SE cost estimate to the number of expected VLNC products from Section II.H.1.d. See Table 38.

Table 38. Premarket Review Costs (2023 USD)

	Primary	Low	High
Hours to Review an SE report	133	133	133
FDA Wage	$153.88	$153.88	$153.88
Cost per SE Review	$20,467	$20,467	$20,467
Number of SE Reports	52	764	3
Total Cost	$1,064,267	$15,636,539	$61,400

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

We expect these costs to occur in year 1 of our time horizon, 2026, since all firms would want to have authorized products before consumers begin switching to VLNC tobacco products at the effective date. We estimate a primary cost of $1.1 million with a low impact scenario cost of $15.6 million and a high impact scenario cost of $0.06 million. We request comment on this approach.

4. Summary of Costs

Using a 2 percent discount rate, the present value of the quantified costs of the proposed rule are approximately $57,964 million (with a lower bound of $19,259 million and an upper bound of $76,149 million). The corresponding annualized costs of the proposed rule are approximately $2,077 million (with a lower bound of $690 million and an upper bound of $2,729 million).

Table 39. Summary of Present Value of Quantified Costs (Millions of 2023 Dollars over a 40-Year Time Horizon, 2 percent discount rate)

Cost Category		Present Value Costs		
		Primary	Low	High
Industry	Economic Transition Cost	$7,005.0	$4,222.4	$8,930.9

	Producer Surplus Loss	$47,076.1	$5,478.7	$54,621.5
	Reading and Understanding the Rule	$373.5	$112.1	$700.4
	Manufacturers: Reformulation Costs	$598.4	$8,792.2	$34.5
	Cost to Submit Premarket Applications	$1.0	$14.7	$0.1
	Testing Costs	$8.2	$52.6	$2.5
Consumer	Withdrawal Costs	$1,366.5	$14.8	$8,883.3
	Search Costs	$1,390.2	$463.4	$2,780.5
Government Enforcement Costs	Federal Enforcement Costs	$143.8	$92.5	$195.1
	Costs for Premarket Review of the New Tobacco Products	$1.0	$15.3	$0.1
Total Present Value Quantified Costs		*$57,963.9*	*$19,258.8*	*$76,148.7*

Table 40. Summary of Annualized Quantified Costs (Millions of 2023 Dollars over a 40-Year Time Horizon, 2 percent discount rate)

Cost Category		Annualized Value Costs		
		Primary	Low	High
Industry	Economic Transition Cost	$251.1	$151.3	$320.1
	Producer Surplus Loss	$1,687.2	$196.4	$1,957.6
	Reading and Understanding the Rule	$13.4	$4.0	$25.1
	Manufacturers: Reformulation Costs	$21.4	$315.1	$1.2
	Cost to Submit Premarket Applications	$0.04	$0.5	$0.002
	Testing Costs	$0.3	$1.9	$0.1
Consumer	Withdrawal Costs	$49.0	$0.5	$318.4
	Search Costs	$49.8	$16.6	$99.6
Government Enforcement Costs	Federal Enforcement Costs	$5.2	$3.3	$7.0
	Costs for Premarket Review of the New Tobacco Products	$0.04	$0.5	$0.002
Total Annualized Quantified Costs		$2,077.4	$690.2	$2,729.1

I. Transfers Caused by the Proposed Rule

We analyze the amount of excise taxes and combusted tobacco product revenues that would have been associated with purchased NNC products in the absence of the rule. Consumers who quit use of tobacco products (or do not initiate) are expected to use the transferred value to purchase non-tobacco products (including savings). If the proposed rule is finalized, we expect transfers from (1) the Federal Government and State Governments to consumers in the form of

reduced excise tax revenue[73], and from (2) affected tobacco product manufacturers in the form of reduced revenue.

The proposed product standard would limit the addictiveness of the most toxic and widely used tobacco products and is estimated to reduce overall consumption of tobacco products. This reduction would lead to reduced tax revenue for governments that tax tobacco products. We do not include excise tax transfers associated with purchases of VLNC tobacco products by former consumers of NNC tobacco products in our analysis of transfers.

In addition to excise taxes, most jurisdictions also collect sales taxes on tobacco transactions. We expect that reductions in sales tax collections are likely to be offset as consumers would increase purchases and consumption of other taxable products, which may include VLNC tobacco products. We therefore do not expect State sales tax revenue collections to be affected by the proposed rule.

We also do not estimate change in other transfers that may occur between people who smoke and Federal and State governments, such as medical costs and other financial effects of smoking, in this section (see discussion in II.G.4.a).

1. Estimation of Federal and State Excise Tax Revenue Transfers

In Section II.E.5, we estimate baseline Federal excise tax revenues over a 40-year time horizon. Using estimates presented in Table 10 through Table 14 and applying the three policy projections (low impact scenario, primary impact scenario, and high impact scenario) from the PHM (discussed in Section II.F of this analysis), we estimate the total undiscounted value of transfers from the Federal Government in the form of reduced excise tax collections. We utilize the PHM to calculate the percentage change in the number of people who use the covered tobacco products from the baseline to the estimated number of people who use these products in the three estimated policy scenarios (see Section II.E.1). This yields a percentage change in the number of people who use these products for each covered tobacco product (cigarettes, non-premium cigars, smokeless products, and pipe/RYO products) over the 40-year horizon of this analysis. We then scale each estimate of baseline excise tax revenues by the corresponding percentage change in people who use these products to yield estimated excise tax revenues for the three policy scenarios. We subtract the estimated excise tax revenue under these policy scenarios from baseline excise tax revenues to yield the estimated transfer of excise tax revenues.

We estimate that the 40-year cumulative total undiscounted value of the transfer of federal excise tax revenues is approximately $55.5 billion in the low policy impact scenario, $150.7 billion in the primary policy impact scenario, and $158.9 billion in the high policy impact scenario for cigarettes; $8.6 billion in the low policy impact scenario, $22.0 billion in the

[73] "In April 2009, the federal cigarette excise tax in the United States was increased by US$0.6167 per pack, with US cigarette companies passing on the full amount of the tax increase and raising prices further (e.g., Philip Morris USA raised prices on its leading brands by US$0.71 per pack and on other brands by US$0.78 per pack)" (106 p. 31). Therefore, we expect excise taxes to be transferred back to consumers.

primary policy impact scenario, and $23.0 billion in the high policy impact scenario for covered cigars; -$1.1 billion in the low policy impact scenario, -$2.4 billion in the primary policy impact scenario, and -$3.9 billion in the high policy impact scenario for smokeless tobacco; and $1.9 billion in the low policy impact scenario, $5.1 billion in the primary policy impact scenario, and $5.4 billion in the high policy impact scenario for pipe/RYO products. Table 41 through Table 44 present baseline estimates of affected tobacco product sales and Federal excise tax revenues, as well as excise tax transfers under the three policy impact scenarios, over a 40-year time horizon for affected cigarettes (Table 41), cigars (Table 42), smokeless tobacco products (Table 43), and pipe/RYO tobacco products (Table 44).

Table 41. Transfer of Federal Excise Tax Revenues Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Cigarette Excise Tax Revenues)

Year Count	Year	Volume Sales of Cigarettes (Millions of Sticks)	Sales Volume in Pack Equivalents (Millions)	Federal Excise Tax Rate (2023)	Baseline Federal Excise Tax Revenue ($2023, Billions)	Transfer of Federal Excise Tax Revenues ($2023 Billions, Undiscounted)		
						Low Transfer	Primary Transfer	High Transfer
Year 0	2025	176,358	8,818	$1.01	$8.9	-	-	-
Year 1	2026	164,714	8,236	$1.01	$8.3	-	-	-
Year 2	2027	155,114	7,756	$1.01	$7.8	-	-	-
Year 3	2028	146,258	7,313	$1.01	$7.4	$0.3	$4.4	$7.3
Year 4	2029	138,083	6,904	$1.01	$7.0	$0.5	$5.6	$6.9
Year 5	2030	130,565	6,528	$1.01	$6.6	$0.7	$5.9	$6.5
…	…	…	…	…	…	…	…	…
Year 39	2064	51,430	2,572	$1.01	$2.6	$1.4	$2.5	$2.6
Year 40	2065	51,063	2,553	$1.01	$2.6	$1.4	$2.5	$2.5
Total		3,367,342	168,367	-	$170.1	$50.0	$135.9	$143.2

Table 42. Transfer of Federal Excise Tax Revenues Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Cigar Excise Tax Revenues)

Year Count	Year	Volume Sales of Cigars (Millions of Cigars)	Federal Excise Tax Rate (2023)	Baseline Federal Excise Tax Revenue ($2023, Billions)	Transfer of Federal Excise Tax Revenues ($2023 Billions, Undiscounted)		
					Low Transfer	Primary Transfer	High Transfer
Year 0	2025	7,716	$0.10	$0.8	-	-	-
Year 1	2026	7,716	$0.10	$0.8	-	-	-
Year 2	2027	7,716	$0.10	$0.8	-	-	-
Year 3	2028	7,642	$0.10	$0.8	$0.03	$0.5	$0.8
Year 4	2029	7,568	$0.10	$0.8	$0.1	$0.6	$0.7
Year 5	2030	7,493	$0.10	$0.7	$0.1	$0.7	$0.7

…	…	…	…	…	…	…	…
Year 39	2064	5,045	$0.10	$0.5	$0.3	$0.5	$0.5
Year 40	2065	4,971	$0.10	$0.5	$0.3	$0.5	$0.5
Total		256,484	-	$25.6	$8.6	$22.0	$23.0

Table 43. Transfer of Federal Excise Tax Revenues Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Smokeless Excise Tax Revenues)

Year Count	Year	Volume Sales of Smokeless Products (Millions of Units)	Federal Excise Tax Rate (2023)	Baseline Federal Excise Tax Revenue ($2023, Billions)	Transfer of Federal Excise Tax Revenues ($2023 Billions, Undiscounted)		
					Low Transfer	Primary Transfer	High Transfer
Year 0	2025	2,421	$0.08	$0.2	-	-	-
Year 1	2026	2,576	$0.08	$0.2	-	-	-
Year 2	2027	2,696	$0.08	$0.2	-	-	-
Year 3	2028	2,811	$0.08	$0.2	-$0.06	-$0.1	-$0.2
Year 4	2029	2,918	$0.08	$0.2	-$0.06	-$0.1	-$0.2
Year 5	2030	3,017	$0.08	$0.2	-$0.06	-$0.1	-$0.2
…	…	…	…	…	…	…	…
Year 39	2064	3,721	$0.08	$0.4	-$0.02	-$0.04	-$0.1
Year 40	2065	3,740	$0.08	$0.4	-$0.02	-$0.04	-$0.1
Total		126,006	-	$12.2	-$1.1	-$2.4	-$3.9

Table 44. Transfer of Federal Excise Tax Revenues to Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Pipe/RYO Excise Tax Revenues)

Year Count	Year	Volume Sales of Pipe/RYO Products (Millions of Units)	Federal Excise Tax Rate (2023)	Baseline Federal Excise Tax Revenue ($2023, Billions)	Transfer of Federal Excise Tax Revenues ($2023 Billions, Undiscounted)		
					Low Transfer	Primary Transfer	High Transfer
Year 0	2025	56	$5.38	$0.3	-	-	-
Year 1	2026	53	$5.38	$0.3	-	-	-
Year 2	2027	50	$5.38	$0.3	-	-	-
Year 3	2028	48	$5.38	$0.3	$0.01	$0.2	$0.3
Year 4	2029	45	$5.38	$0.2	$0.02	$0.2	$0.2
Year 5	2030	43	$5.38	$0.2	$0.03	$0.2	$0.2
…	…	…	…	…	…	…	…
Year 39	2064	20	$5.38	$0.1	$0.1	$0.1	$0.1
Year 40	2065	20	$5.38	$0.1	$0.1	$0.1	$0.1
Total		1,168	-	$6.3	$1.9	$5.1	$5.4

Using the same methodology, we multiply baseline State excise tax revenue from affected tobacco products in each year from Table 45 through Table 48 by the assumed

percentage of State excise tax revenue. By applying the same three policy scenarios (low, primary, and high) of transfers, we estimate an undiscounted value for affected cigarettes, cigars, smokeless products, and pipe/RYO products. We estimate the cumulative 40-year total undiscounted value of transfers from State governments in the form of reduced excise tax collections of approximately $104.9 billion in the low policy impact scenario, $285.1 billion in the primary policy impact scenario, and $300.4 billion in the high policy impact scenario for cigarettes; approximately $16.1 billion in the low policy impact scenario, $41.2 billion in the primary policy impact scenario, and $42.9 billion in the high policy impact scenario for cigars; approximately -$2.0 billion in the low policy impact scenario, -$4.5 billion in the primary policy impact scenario, and -$7.2 billion in the high policy impact scenario for smokeless products; and approximately $3.1 billion in the low policy impact scenario, $8.3 billion in the primary policy impact scenario, and $8.7 billion in the high policy impact scenario for pipe/RYO products.

Table 45 through Table 48 presents baseline estimates of affected tobacco product sales and State excise tax revenues, as well as excise tax transfers under the three policy impact scenarios over a 40-year time horizon for cigarettes (Table 45), cigars (Table 46), smokeless products (Table 47), and pipe/RYO (Table 48).

Table 45. Transfer of State Excise Tax Revenues Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Cigarette Excise Tax Revenues)

Year Count	Year	Volume Sales of Cigarettes (Millions of Sticks)	Sales Volume in Pack Equivalents (Millions)	Average State Excise Tax Rate (2023)	Baseline State Excise Tax Revenue ($2023, Billions)	Transfer of State Excise Tax Revenues ($2023 Billions, Undiscounted)		
						Low Transfer	Primary Transfer	High Transfer
Year 0	2025	176,358	8,818	$2.12	$18.7	-	-	-
Year 1	2026	164,714	8,236	$2.12	$17.5	-	-	-
Year 2	2027	155,114	7,756	$2.12	$16.4	-	-	-
Year 3	2028	146,258	7,313	$2.12	$15.5	$0.7	$9.3	$15.4
Year 4	2029	138,083	6,904	$2.12	$14.6	$1.2	$11.8	$14.5
Year 5	2030	130,565	6,528	$2.12	$13.8	$1.5	$12.4	$13.7
…	…	…	…	…	…	…	…	…
Year 39	2064	9,793,879	29,937	$2.12	$5.4	$3.0	$5.2	$5.4
Year 40	2065	9,759,731	29,833	$2.12	$5.4	$3.0	$5.2	$5.4
Total		581,116,793	168,367	-	$356.8	$104.9	$285.1	$300.4

Table 46. Transfer of State Excise Tax Revenues Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Cigar Excise Tax Revenues)

Year Count	Year	Volume Sales of Cigars	Average State Excise	Baseline State Excise Tax	Transfer of State Excise Tax Revenues ($2023 Billions, Undiscounted)

		(Millions of Cigars)	Tax Rate (2023)	Revenue ($2023, Billions)	Low Transfer	Primary Transfer	High Transfer
Year 0	2025	7,716	$0.19	$1.4	-	-	-
Year 1	2026	7,716	$0.19	$1.4	-	-	-
Year 2	2027	7,716	$0.19	$1.4	-	-	-
Year 3	2028	7,642	$0.19	$1.4	$0.1	$1.0	$1.4
Year 4	2029	7,568	$0.19	$1.4	$0.1	$1.1	$1.4
Year 5	2030	7,493	$0.19	$1.4	$0.1	$1.2	$1.4
…	…	…	…	…	…	…	…
Year 39	2064	5,045	$0.19	$0.9	$0.5	$0.9	$0.9
Year 40	2065	4,971	$0.19	$0.9	$0.5	$0.9	$0.9
Total		256,484	-	$47.8	$16.1	$41.2	$42.9

Table 47. Transfer of State Excise Tax Revenues Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Smokeless Excise Tax Revenues)

Year Count	Year	Volume Sales of Smokeless (Millions of Units)	Average State Excise Tax Rate (2023)	Baseline State Excise Tax Revenue ($2023, Billions)	Transfer of State Excise Tax Revenues ($2023 Billions, Undiscounted)		
					Low Transfer	Primary Transfer	High Transfer
Year 0	2025	2,421	$0.15	$0.4	-	-	-
Year 1	2026	2,576	$0.15	$0.4	-	-	-
Year 2	2027	2,696	$0.15	$0.4	-	-	-
Year 3	2028	2,811	$0.15	$0.4	-$0.1	-$0.3	-$0.4
Year 4	2029	2,918	$0.15	$0.4	-$0.1	-$0.2	-$0.3
Year 5	2030	3,017	$0.15	$0.5	-$0.1	-$0.1	-$0.2
…	…	…	…	…	…	…	…
Year 39	2064	4,396	$0.15	$0.7	-$0.04	-$0.1	-$0.1
Year 40	2065	4,418	$0.15	$0.7	-$0.04	-$0.1	-$0.1
Total		148,848	-	$22.6	-$2.0	-$4.5	-$7.2

Table 48. Transfer of State Tax Revenues Under the Proposed Product Standard Under the Low, Primary, and High Policy Impact Scenarios (Change in Overall Pipe/RYO Excise Tax Revenues)

Year Count	Year	Volume Sales of Pipe/RYO (Millions of Units)	Average State Excise Tax Rate (2023)	Baseline State Excise Tax Revenue ($2023, Billions)	Transfer of State Excise Tax Revenues ($2023 Billions, Undiscounted)		
					Low Transfer	Primary Transfer	High Transfer
Year 0	2025	56	$8.72	$0.5	-	-	-
Year 1	2026	53	$8.72	$0.5	-	-	-
Year 2	2027	50	$8.72	$0.4	-	-	-
Year 3	2028	48	$8.72	$0.4	$0.02	$0.3	$0.4
Year 4	2029	45	$8.72	$0.4	$0.03	$0.3	$0.4
Year 5	2030	43	$8.72	$0.4	$0.04	$0.3	$0.4
…	…	…	…	…	…	…	…

Year 39	2064	20	$8.72	$0.2	$0.1	$0.2	$0.2
Year 40	2065	20	$8.72	$0.2	$0.1	$0.2	$0.2
Total		1,168	-	$10.2	$3.1	$8.3	$8.7

We discount the streams of Federal and State excise tax revenue transfers presented in Table 41 through Table 48 using a 2 percent discount rate to estimate the present value and annualized values of Federal and State excise tax revenue transfers. The present value of total Federal excise tax revenue transfers from the proposed product standard is approximately $37.9 billion (low policy impact scenario), $111.9 billion (primary policy impact scenario) and $118.0 billion (high policy impact scenario), totaled over all affected tobacco product categories at a 2 percent discount rate. The annualized value of total Federal excise tax revenue transfers is approximately $1.4 billion (low policy impact scenario), $4.1 billion (primary policy impact scenario), and $4.3 billion (high policy impact scenario) at a 2 percent discount rate.

The present value of total State excise tax revenue transfers from the proposed product standard is approximately $77.9 billion (low policy impact scenario), $230.2 billion (primary policy impact scenario) and $242.8 billion (high policy impact scenario), totaled over all affected tobacco product categories at a 2 percent discount rate. The annualized value of total State excise tax revenue transfers is approximately $2.8 billion (low policy impact scenario), $8.4 billion (primary policy impact scenario), and $8.9 billion (high policy impact scenario) at a 2 percent discount rate. These estimates are summarized in Table 49.

Table 49. Present and Annualized Value of Federal and State Excise Tax Revenue Transfers Under the Low, Primary, and High Policy Impact Scenarios

Category	Discount Rate	Transfers of Federal Excise Tax Revenue ($2023, Billions)			Transfers of State Excise Tax Revenue ($2023, Billions)		
		Low	Primary	High	Low	Primary	High
Undiscounted Value	-	$59.4	$160.6	$167.6	$122.1	$330.0	$344.8
Present Discounted Value	2%	$37.9	$111.9	$118.0	$77.9	$230.2	$242.8
Annualized Value	2%	$1.4	$4.1	$4.3	$2.8	$8.4	$8.9

The present value of total Federal and State excise tax revenue transfers from the proposed product standard is approximately $115.8 billion (low policy impact scenario), $342.1 billion (primary policy impact scenario) and $360.8 billion (high policy impact scenario), totaled over all affected tobacco product categories at a 2 percent discount rate. The annualized value of total Federal and State excise tax revenue transfers is approximately $4.2 billion (low policy impact scenario), $12.5 billion (primary policy impact scenario), and $13.2 billion (high policy impact scenario) at a 2 percent discount rate. These estimates are summarized in Table 50.

Table 50. Present and Annualized Value of Total Excise Tax Revenue Transfers Under the Low, Primary, and High Policy Impact Scenarios

Category	Discount Rate	Total Transfers of Excise Tax Revenue ($2023, Billions)		
		Low	Primary	High
Undiscounted Value	-	$181.5	$490.6	$512.5
Present Discounted Value	2%	$115.8	$342.1	$360.8
Annualized Value	2%	$4.2	$12.5	$113.2

In Section II.G.4, we discuss medical cost savings due to reductions in smoking and smoking-attributable illness. Xu et al. (70) uses data from the 2010-2014 Medical Expenditure Panel Survey and 2008-2013 National Health Interview Survey to estimate the portion of annual healthcare spending potentially attributable to cigarette smoking. Their results suggest that, during 2010 to 2014, 11.7 percent of U.S. healthcare spending each year was attributable to adult cigarette smoking. Translating this smoking-attributable fraction into dollars, the authors estimate that smoking may have accounted for more than $225 billion of total healthcare spending in 2014. With respect to public healthcare expenditures, the authors find "[m]ore than 60% of annual smoking-attributable healthcare spending in the U.S. was paid through public health insurance programs, including either Medicaid, Medicare, or other federal health insurance programs," with Medicaid and Medicare alone paying for more than half of the smoking-attributable expenditures ($125.7 billion dollars in 2014) (70).

While we do not separately estimate reductions in smoking-attributable medical costs due to this product standard (as noted in Section II.G.4), we expect Federal and State governments would realize benefits from medical cost savings that reduce public healthcare expenditures and offset the transfers of tax revenues estimated in this section.

We request comment on this analysis, including estimates of the portion of excise tax transfers back to consumers that may be spent on products subject to excise tax, such as other tobacco products.

2. Transfer of Revenue from Tobacco Products Market to Consumers

Under the proposed product standard, covered tobacco product manufacturers' revenues, exclusive of excise taxes and lost producer surplus estimated in Section II.H.1, would transfer from covered products manufacturers to consumers. We expect that some consumers would use the transferred value to purchase VLNC tobacco products manufactured by the same entities. For this analysis, we do not consider consumer purchases of VLNC tobacco products to result in a net transfer of revenues, as these purchases would stay within the market for covered tobacco products. We estimate transfers from the covered tobacco products market to consumers who purchase other tobacco products authorized for market or other non-tobacco goods and services.

In Section II.E.5, we estimate baseline sales (revenues) in the affected tobacco product market over the 40-year time horizon used in analysis of the proposed rule. Similarly, we estimate baseline Federal and State excise tax revenues from affected tobacco products over the 40-year time horizon in II.E.5 and lost producer surplus from Section II.H.1. From these sections, we use the estimates in Table 10 through Table 14 (baseline revenues and excise taxes) and subtract baseline total Federal and State excise tax revenues from baseline tobacco product revenues in each year to generate annual estimates of affected tobacco product revenues, exclusive of excise taxes. This adjustment is summarized in Table 51 through Table 54 for affected cigarettes (Table 51), cigars (Table 52), smokeless tobacco products (Table 53), and pipe/RYO tobacco products (Table 54).

Table 51. Baseline Industry Revenue Projections for Affected Cigarettes, With and Without Excise Taxes ($2023 Billions, undiscounted)

Year Count	Year	Total Product Revenue (Billions)	Total Product Excise Tax Revenue (Billions)	Total Product Revenue, Exclusive of Excise Taxes (Billions)
Year 0	2025	$80.8	$27.6	$47.6
Year 1	2026	$76.3	$25.8	$45.4
Year 2	2027	$72.5	$24.3	$43.6
Year 3	2028	$68.9	$22.9	$41.8
Year 4	2029	$65.6	$21.6	$40.1
Year 5	2030	$62.4	$20.4	$38.6
…	…	…	…	…
Year 39	2064	$28.5	$8.0	$20.5
Year 40	2065	$28.4	$8.0	$20.4

Table 52. Baseline Industry Revenue Projections for Affected Cigars, With and Without Excise Taxes ($2023 Billions, undiscounted)

Year Count	Year	Total Product Revenue (Billions)	Total Product Excise Tax Revenue (Billions)	Total Product Revenue, Exclusive of Excise Taxes (Billions)
Year 0	2025	$8.5	$2.2	$6.1
Year 1	2026	$8.4	$2.2	$5.9
Year 2	2027	$8.2	$2.2	$5.8
Year 3	2028	$7.4	$2.2	$5.0
Year 4	2029	$7.0	$2.2	$4.7
Year 5	2030	$6.7	$2.1	$4.3
…	…	…	…	…
Year 39	2064	$1.5	$1.4	$0.7
Year 40	2065	$1.4	$1.4	$0.2

Table 53. Baseline Industry Revenue Projections for Affected Smokeless Tobacco Products, With and Without Excise Taxes ($2023 Billions, undiscounted)

Year Count	Year	Total Product Revenue (Billions)	Total Product Excise Tax Revenue (Billions)	Total Product Revenue, Exclusive of Excise Taxes (Billions)
Year 0	2025	$22.3	$0.6	$21.0

Year 1	2026	$23.8	$0.6	$22.4
Year 2	2027	$24.9	$0.6	$23.5
Year 3	2028	$25.9	$0.7	$24.4
Year 4	2029	$26.9	$0.7	$25.3
Year 5	2030	$27.8	$0.7	$26.0
…	…	…	…	…
Year 39	2064	$40.6	$1.0	$37.1
Year 40	2065	$40.8	$1.0	$37.3

Table 54. Baseline Industry Revenue Projections for Covered Pipe/RYO Tobacco Products, With and Without Excise Taxes ($2023 Billions, undiscounted)

Year Count	Year	Total Product Revenue (Billions)	Total Product Excise Tax Revenue (Billions)	Total Product Revenue, Exclusive of Excise Taxes (Billions)
Year 0	2025	$3.4	$0.8	$2.5
Year 1	2026	$3.2	$0.7	$2.4
Year 2	2027	$3.0	$0.7	$2.2
Year 3	2028	$2.9	$0.7	$2.1
Year 4	2029	$2.7	$0.6	$2.0
Year 5	2030	$2.6	$0.6	$1.9
…	…	…	…	…
Year 39	2064	$1.2	$0.3	$0.9
Year 40	2065	$1.2	$0.3	$0.9

This estimate of market revenue excluding excise taxes may be further split between manufacturers, distributors, and retailers; however, we estimate that manufacturers capture the largest portion of revenues and assume affected tobacco product revenues, exclusive of excise taxes, represent manufacturer revenues. We apply our three-policy scenario (low, primary, and high) range of revenue less lost producer surplus transfers away from manufacturers in each tobacco product category and to consumers over the 40-year time horizon. We estimate that the cumulative 40-year total undiscounted present value of this transfer is approximately $354.0 billion in the low policy impact scenario, $925.8 billion in the primary policy impact scenario, and $970.0 billion in the high policy impact scenario for cigarettes; $16.4 billion in the low policy impact scenario, $57.4 billion in the primary policy impact scenario, and $61.6 billion in the high policy impact scenario for cigars; -$112.4 billion in the low policy impact scenario, -$250.5 billion in the primary policy impact scenario, and -$399.8 billion in the high policy impact scenario for smokeless tobacco products; and $16.5 billion in the low policy impact scenario, $43.9 billion in the primary policy impact scenario, and $46.1 billion in the high policy impact scenario for pipe/RYO tobacco products. These estimates are summarized in Table 55 through Table 58 for affected cigarettes (Table 55), cigars (Table 56), smokeless tobacco products (Table 57), and pipe/RYO tobacco products (Table 58).

Table 55. Transfer of Revenue from Cigarette Product Manufacturers to Consumers over 40-Year Time Horizon Under the Low, Primary, and High Policy Impact Scenarios ($2023 Billion, Undiscounted)

Year Count	Year	Total Product Revenue, Exclusive of Excise Taxes and Producer Surplus (Billions)	Transfer of Revenue from Affected Tobacco Product Manufacturers ($2023, Billions)		
			Low	Primary	High
Year 0	2025	$47.6	-	-	-
Year 1	2026	$45.4	-	-	-
Year 2	2027	$43.6	-	-	-
Year 3	2028	$41.8	$1.9	$25.2	$41.4
Year 4	2029	$40.1	$3.2	$32.3	$39.8
Year 5	2030	$38.6	$4.3	$34.6	$38.3
…	…	…	…	…	…
Year 39	2064	$20.5	$11.1	$19.7	$20.1
Year 40	2065	$20.4	$11.2	$19.7	$20.1
Total		$1,134.7	$359.5	$940.6	$985.5

Table 56. Transfer of Revenue from Cigar Product Manufacturers to Consumers over 40-Year Time Horizon Under the Low, Primary, and High Policy Impact Scenarios ($2023 Billion, Undiscounted)

Year Count	Year	Total Product Revenue, Exclusive of Excise Taxes and Producer Surplus (Billions)	Transfer of Revenue from Affected Tobacco Product Manufacturers ($2023, Billions)		
			Low	Primary	High
Year 0	2025	$6.1	-	-	-
Year 1	2026	$5.9	-	-	-
Year 2	2027	$5.8	-	-	-
Year 3	2028	$5.0	$0.2	$3.0	$4.9
Year 4	2029	$4.7	$0.3	$3.8	$4.6
Year 5	2030	$4.3	$0.4	$3.9	$4.3
…	…	…	…	…	…
Year 39	2064	$0.7	$0.4	$0.6	$0.6
Year 40	2065	$0.2	$0.1	$0.2	$0.2
Total		$80.3	$16.5	$57.6	$61.9

Table 57. Transfer of Revenue from Smokeless Tobacco Product Manufacturers to Consumers over 40-Year Time Horizon Under the Low, Primary, and High Policy Impact Scenarios ($2023 Billion, Undiscounted)

Year Count	Year	Total Product Revenue, Exclusive of Excise Taxes and	Transfer of Revenue from Affected Tobacco Product Manufacturers ($2023, Billions)		
			Low	Primary	High

		Producer Surplus (Billions)			
Year 0	2025	$21.0	-	-	-
Year 1	2026	$22.4	-	-	-
Year 2	2027	$23.5	-	-	-
Year 3	2028	$24.4	-$6.5	-$15.7	-$21.9
Year 4	2029	$25.3	-$6.1	-$13.3	-$19.7
Year 5	2030	$26.0	-$5.7	-$11.1	-$18.5
…	…	…	…	…	…
Year 39	2064	$37.1	-$2.2	-$5.1	-$7.3
Year 40	2065	$37.3	-$2.2	-$5.1	-$7.2
Total		$1,257.4	-$112.4	-$250.5	-$399.8

Table 58. Transfer of Revenue from Pipe/RYO Tobacco Product Manufacturers to Consumers over 40-Year Time Horizon Under the Low, Primary, and High Policy Impact Scenarios ($2023 Billion, Undiscounted)

Year Count	Year	Total Product Revenue, Exclusive of Excise Taxes and Producer Surplus (Billions)	Transfer of Revenue from Affected Tobacco Product Manufacturers ($2023, Billions)		
			Low	Primary	High
Year 0	2025	$2.5	-	-	-
Year 1	2026	$2.4	-	-	-
Year 2	2027	$2.2	-	-	-
Year 3	2028	$2.1	$0.1	$1.3	$2.1
Year 4	2029	$2.0	$0.2	$1.6	$2.0
Year 5	2030	$1.9	$0.2	$1.7	$1.9
…	…	…	…	…	…
Year 39	2064	$0.9	$0.5	$0.9	$0.9
Year 40	2065	$0.9	$0.5	$0.9	$0.9
Total		$53.6	$16.5	$43.9	$46.1

We discount the stream of revenue transfers presented in Table 55 through Table 58 using a 2 percent discount rate to estimate the present value and annualized value of revenue transfers from tobacco product manufacturers to consumers for all covered tobacco products.

The present value of the revenue transfer from tobacco product manufacturers to consumers under the proposed product standard is approximately $170.6 billion (low policy impact scenario), $546.2 billion (primary policy impact scenario), and $481.6 billion (high policy impact scenario), discounted at 2 percent. The annualized value of revenue transfers from tobacco product manufacturers to consumers is approximately $6.2 billion (low policy impact scenario), $20.0 billion (primary policy impact scenario), and $17.6 billion (high policy impact scenario), discounted at 2 percent. Estimated transfers in the high impact scenario are higher than transfers in the primary scenario; this is driven by the estimate net negative transfers associated with smokeless tobacco products. These estimates are summarized in Table 89.

Table 59. Present and Annualized Values of Revenue Transfers to Consumers from Tobacco Product Manufacturers to Consumers Under the Proposed Product Standard ($2023, Billions)

Category	Discount Rate	Revenue ($2023, Billions)		
		Low	Primary	High
Undiscounted Value of Revenue Transfer	-	$280.1	$791.5	$693.6
Present Value of Revenue Transfer	2%	$170.6	$546.2	$481.6
Annualized Value of Revenue Transfer	2%	$6.2	$20.0	$17.6

We total the estimated present value and annualized value of the transfers from Federal and State excise tax revenues and tobacco product manufacturers to consumers under the proposed product standard. The present value of all transfers is approximately $286.4 billion (low scenario), $888.3 billion (primary policy impact scenario), and $842.4 billion (high policy impact scenario), discounted at 2 percent. The annualized value of all transfers is approximately $10.5 billion (low policy impact scenario), $32.5 billion (primary policy impact scenario), and $30.8 billion (high policy impact scenario), discounted at 2 percent. These estimates are summarized in Table 60.

Table 60. Present and Annualized Values of Total Transfers to Consumers Under the Proposed Product Standard ($2023, Billions)

Category	Discount Rate	Revenue ($2023, Billions)		
		Low	Primary	High
Undiscounted Value of Revenue Transfer	-	$461.6	$1,282.1	$1,206.1
Present Value of Revenue Transfer	2%	$286.4	$888.3	$842.4
Annualized Value of Revenue Transfer	2%	$10.5	$32.5	$30.8

We request comment on this analysis, including estimates of the portion of transfers back to consumers that may be spent on tobacco products not covered by the proposed product standard.

3. Tobacco Manufacturers, Distributors, Retailers, and Growers

The proposed rule, if finalized, would eliminate the revenues that firms currently receive from the sale of certain NNC combusted tobacco products. This revenue would transfer to consumers who could either save this money or spend it on other goods and services. We lack information that could be used to project which sectors might benefit from this spending shift.

The distributional effects may not impact all sectors equally. For example, consumers who continue to use tobacco products might purchase products manufactured or offered for sale

by the same entity that lost revenues from NNC combusted products. The extent to which those entities could obtain lost NNC combusted tobacco profits from other products would determine the magnitude of the distributional effect on those entities. Consumers who stop or reduce their use of tobacco products in response to this product standard would reallocate their resources to non-tobacco industries (or savings). In addition, employees and owners of firms that currently produce those tobacco products would have less resources to spend elsewhere.

We expect that the product standard limiting nicotine to minimally addictive or nonaddictive levels in certain combusted tobacco products would create transfers from retailers to consumers. Prior to the effective date of the product standard, retailers and related entities may continue to sell available stock of affected NNC combusted tobacco products. With many retailers under contract to provide dedicated shelf space for tobacco products, we expect that retailers would be stocked with other tobacco products to fill the shelf space previously reserved for NNC products.[74] As consumers use the money they were previously spending on NNC combusted tobacco products on other products, including non-tobacco products, some retailers may see an overall reduction in sales while others experience an increase in overall sales. This shift between product categories may also include ancillary sales, and people who formerly used combusted tobacco products may change their retail habits following the proposed product standard. We do not separately estimate transfers from retailers and distributors to consumers because of this product standard.

This proposed rule, if finalized, may also have an effect on tobacco farmers. FDA does not regulate production of tobacco crops. The proposed nicotine product standard is expected to impact demand for tobacco products beyond the continued decline in tobacco product consumption already expected in the United States. In this section, we analyze the impacts on U.S. tobacco leaf growers due to an expected reduction in demand for combusted tobacco products, and potential offsetting impacts of increased demand for noncombusted tobacco products or nontobacco products. These impacts are transfers because acreage no longer used to grow tobacco for combusted tobacco products, would be put to some other use, such as growing tobacco for noncombusted tobacco products, growing other nontobacco crops, or a purpose outside of agriculture.

The three primary types of tobacco used in manufacturing of all cigarettes and RYO are bright (also known as flue-cured), burley, and oriental; dark and oriental tobacco is used in cigar manufacturing. Bright, burley, and dark types of tobacco are grown in the United States, while oriental tobacco type is imported, mostly from Turkey (160). Over the past five years, tobacco leaf production in the United States has decreased from 710 million pounds in 2017 to about 447 million pounds in 2022—a reduction of over 35% (See Table 61) (161)(162). In 2022, bright and burley tobacco production represented about 81% of total U.S. tobacco leaf production (See

[74] These tobacco company incentive programs require retailers to follow specific product placement and advertising placement for the manufacturer's specific brands. Plaintiffs' 2018 Supplemental Brief On Retail Point Of Sale Remedy, United States v. Philip Morris USA, Inc., No. 99-CV-2496 (D.D.C. Aug. 3, 2018) (ECF No. 6276).

Table 61) (162). Additionally, in 2017 (the most recent year with data) cigar type tobacco (Types 4-6) comprised approximately 0.61 percent of all tobacco leaf production in the United States (See Table 62) (163). Cigar tobacco accounted for less than 1 percent of the tobacco market in 2017 (163).

Table 61. United States Total Bright and Burley Tobacco Production, 2017-2022 (1,000 lbs.)

	2017	2018	2019	2020	2021	2022
Class 1, Flue-cured (Bright)	460,650	338,690	297,170	227,555	301,975	302,640
Class 3A, Light air-cured, Types 31 and 32 (Burley)	161,140	100,435	92,830	80,332	77,826	58,607
Total U.S. Production of Bright and Burley Tobacco	626,110	442,205	392,300	308,807	380,571	361,247
Total U.S. Tobacco Leaf Production	710,161	533,241	467,956	372,877	458,126	447,367
Total Bright and Burley Production as a Share of Total U.S. Tobacco Production	88%	83%	84%	83%	83%	81%

Source: FDA analysis of USDA Annual Crop Production Summary reports (161) (162).
Note: USDA Annual Crop Production Summary reports list two types of light air-cured tobacco; both Type 31 and Type 32 are types of burley tobacco.

Table 62. U.S. Tobacco and Cigar Tobacco Production, 2013-2017 (1,000 lbs.)

	2013	**2014**	**2015**	**2016**	**2017**
All Tobacco	724,266	876,689	719,563	628,720	710,161
Cigar Type Tobacco	8,573	9,313	8,718	3,840	4,320
Cigar Type Tobacco (%)	1.18%	1.06%	1.21%	0.61%	0.61%

Source: U.S. Department of Agriculture, National Agricultural Service (163)

The number of U.S. farms growing tobacco has decreased over the past few decades. In 2022, owners and employees of approximately 3,000 farms were growing tobacco—a dramatic drop from approximately 93,000 tobacco farms in 1997 and 10,000 farms in 2012 (162). The consolidation in the tobacco farm sector is, in part, due to two major changes in tobacco policy that directly impacted tobacco growers: The Master Settlement Agreement of 1998 (MSA) and the elimination of the Federal Tobacco Price Support Program. Both of these programs combined provided over $15 billion dollars to tobacco growers to transition to growing other crops. As part of the MSA agreement, $5.15 billion was allocated to aid tobacco growers who would suffer losses because of declining consumption.

The second major change was the elimination of the Federal Tobacco Price Support Program, a price support and tobacco quota program system for U.S. tobacco growers to assist them in transitioning to growing other crops. The 2004 tobacco crop was the last crop year eligible for Federal support and payments. Buyout payments to farmers began in 2005 and continued through 2014 with total payment from the buyout program estimated to be around $10 billion (164). Since 2018, some tobacco growers have switched to hemp production as it uses the same equipment and many of the same growing techniques as tobacco (165).

The impact of the proposed rule on U.S. raw leaf tobacco growers may be mitigated by the demand for low nicotine content tobacco varieties. To the extent that cigarette manufacturers use genetically modified (GM) or bioengineered (BE) tobacco to comply with the proposed product standard and replace conventional tobacco leaf, domestic tobacco leaf growers would be able to use current acreage to grow the low nicotine tobacco leaf for the VLNC cigarettes. Genetically modified or bioengineered tobacco are often covered by patents which can add some amount of cost per acre, further reducing the expected profitability of existing tobacco crop assuming the market price of VLNC tobacco leaf is equivalent to NNC tobacco leaf. We are unable to estimate how the potential for VLNC tobacco leaf could offset decreased demand for NNC tobacco leaf (see NPRM section VII.E). We request comment on VLNC tobacco leaf potential pricing.

Available raw tobacco leaf may be used in an extraction process to create reconstituted VLNC tobacco. Liquid nicotine, a by-product of the extraction process, may also be used for the production of e-liquids used in e-cigarettes. Additionally, such available existing leaf may be exported to other markets.

The changing landscape of the tobacco farm sector over the past several decades in response to declining demand and policies supporting transition away from tobacco leaf growing are expected to mitigate the impact of the proposed rule on tobacco leaf growers. Potential cultivation of low nicotine content varietals, tobacco used in noncombusted products, or other high-value replacement agricultural products may also mitigate the impact of the proposed rule on U.S. raw tobacco leaf growers. For additional discussion of the cultivation methods for low nicotine content varietals see Preamble Section VII.E. We request comment, including additional data or studies, regarding impacts of this proposed rule on U.S. tobacco farmers and the U.S. farming industry as a whole.

4. Impact on Tobacco User Fees

Changes in tobacco product user fees are not a social cost of the rule; instead, reallocation of user fees between and within tobacco product classes represent a transfer between tobacco companies (or segments within one company if they produce multiple product categories). However, the increased burden of user fees could impose an additional strain on individual businesses already facing economic transition costs estimated in Section II.H.1.a. A decrease in

market share resulting from the proposed product standard and, thus, a decrease in assessed user fees collected from a particular tobacco product class results in a corresponding reallocation of user fees assessed for manufacturers and importers of other tobacco product classes subject to user fees. We note that estimating changes in any user fee assessments for any particular entity that manufactures or imports both combusted and smokeless tobacco products is challenging. Similarly, any decrease in market share and, thus, user fees collected from domestic manufacturers and importers within a tobacco product class subject to user fees results in a reallocation of user fees to other domestic manufacturers and importers within that class. This analysis focuses on the allocation by product category rather than by specific manufacturers who may manufacture or import tobacco products in multiple categories.

We expect this proposed product standard, if finalized, to significantly reduce cigarette, RYO tobacco, cigar, and pipe tobacco use and increase use of smokeless and ENDS products as some consumers switch from covered products to non-covered tobacco products. Therefore, we expect the amount of user fees paid by cigarette, RYO tobacco, non-premium cigar, and pipe tobacco manufacturers and importers to decline, while the amount of user fees paid by manufacturers and importers of smokeless (snuff and chewing tobacco) to increase. While ENDS products are subject to FDA authority and are impacted by the proposed product standard, FDA does not currently have the authority to assess user fees on manufacturers of ENDS products. We note that a single manufacturer may produce tobacco products across a range of tobacco product classes that are subject to user fees, resulting in net transfers of user fees within firms. As seen in Table 83, there are 143 total tobacco product manufacturers on the market (excluding manufacturers that only produce ENDS), 125 of which produce only combusted products, 10 produce only smokeless products, and 8 produce both combusted and smokeless products. To the extent that large manufacturers may operate in both combusted and noncombusted tobacco product categories, this analysis cannot predict how their overall user fee assessments may change under the proposed product standard.

Figure 24. Tobacco Product Categories Classifications by Covered Product and User Fee Classification

	Subject to User Fees	Not Subject to User Fees
Subject to the Nicotine Product Standard	- Cigarettes - Cigars - RYO - Pipe tobacco[A]	
Not Subject to the Nicotine Product Standard	- Smokeless (Snuff, chewing tobacco)	- ENDS

[A]As discussed above our data on pipe tobacco includes waterpipe tobacco; however, waterpipe tobacco is not subject to this product standard.

Because tobacco revenues would decline as a result of the product standard while the total amount of tobacco user fees assessed declines in real 2023 dollars only as a result of projected inflation, we expect the user fee assessment per category as a percent of post-tax revenue to increase significantly. As discussed in the baseline section, Section II.E.6, user fee assessments by product category are determined by the total amount of federal excise tax collected on each product category. See Table 63 for the estimated dollar valued owed by each product class under the primary policy scenario.

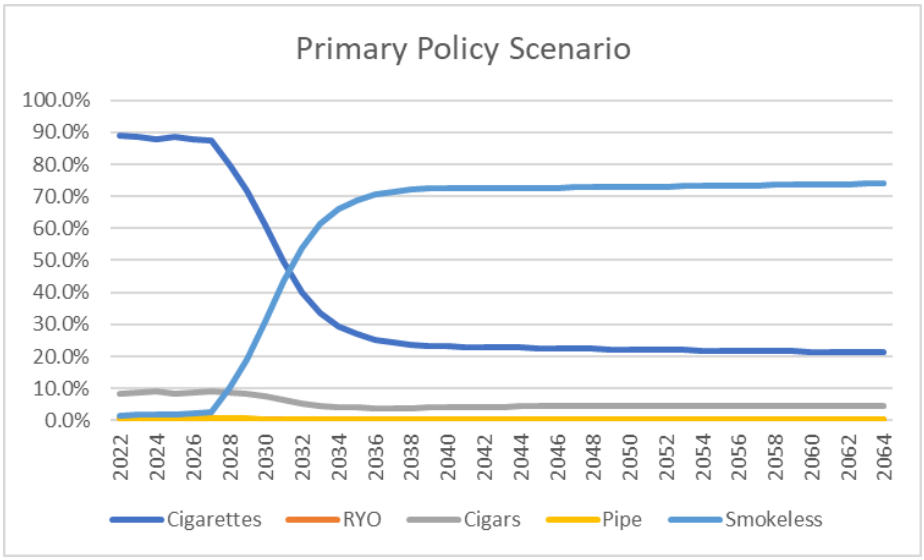
Table 63. Total Projected Primary Policy User Fee Allocation by Product Category, Following the Proposed Product Standard (2023, $)

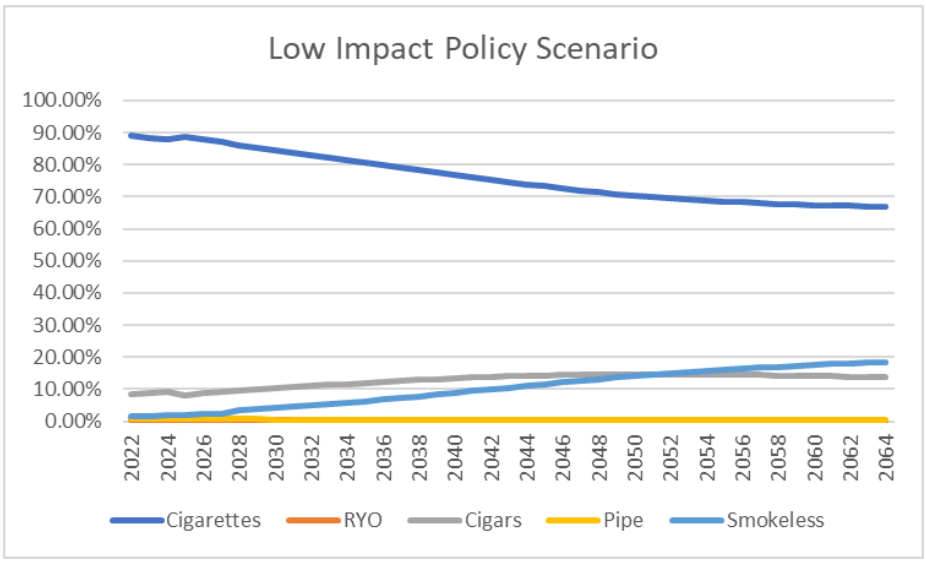
	Total Allocation for				
Year	Cigarettes	RYO	Cigars	Pipe	Smokeless
2025	605,563,358	3,703,374	62,842,681	4,143,691	12,447,642
2030	484,925,700	2,965,604	55,929,812	3,318,203	128,287,301
2035	196,730,409	1,203,122	28,104,752	1,346,168	440,917,796
2040	154,744,600	946,354	26,221,973	1,058,872	480,450,260
2045	149,600,174	914,893	28,587,948	1,023,670	479,586,137
2050	146,257,019	894,447	30,001,265	1,000,794	478,569,800
2055	143,135,993	875,360	30,261,949	979,437	478,968,289
2060	140,589,093	859,785	29,645,454	962,010	480,013,994

To evaluate the impact of the proposed rule on user fees, we use the approach discussed in Section II.E.6. Table 63 and Figure 25 shows that most of the user fee obligation moves to smokeless products once the proposed rule is implemented and prevalence rapidly moves from combusted to noncombusted products.

Figure 26 shows the difference between the policy and baseline scenarios for the percent of user fees owed by each product category.

Figure 25. Percent of Total User Fees Owed by Product Category





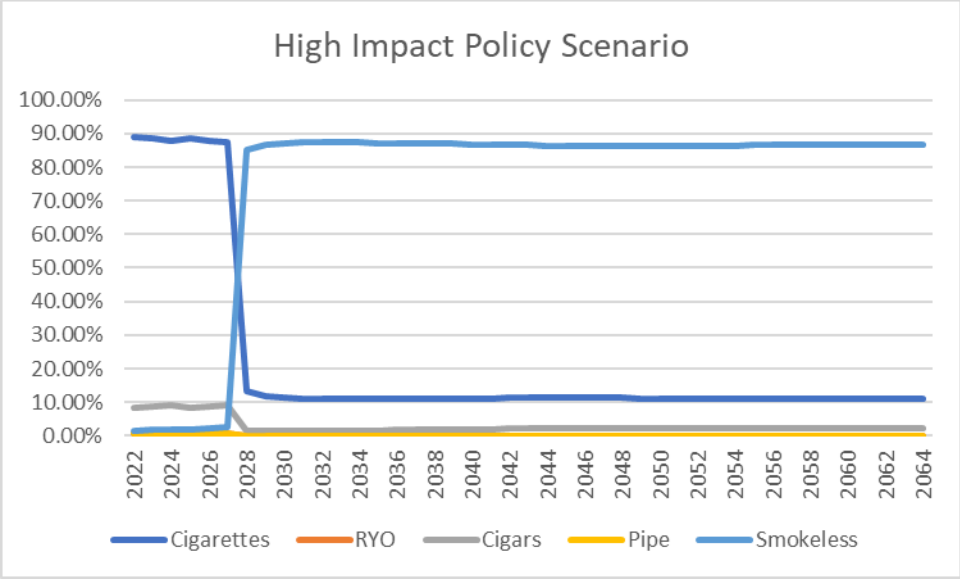
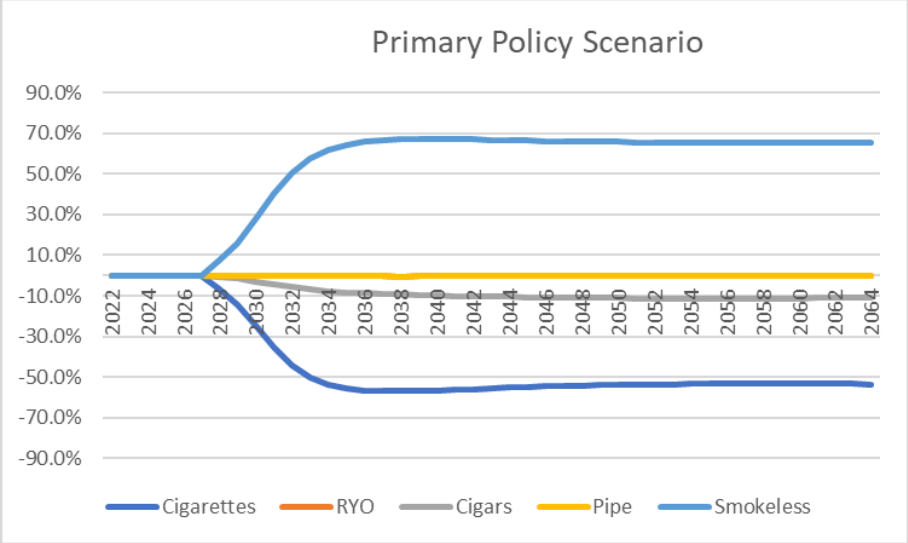
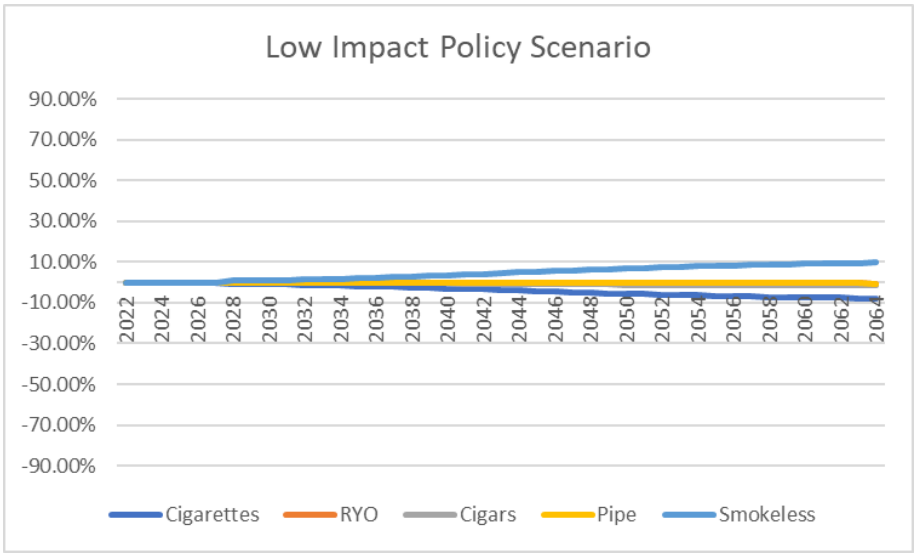
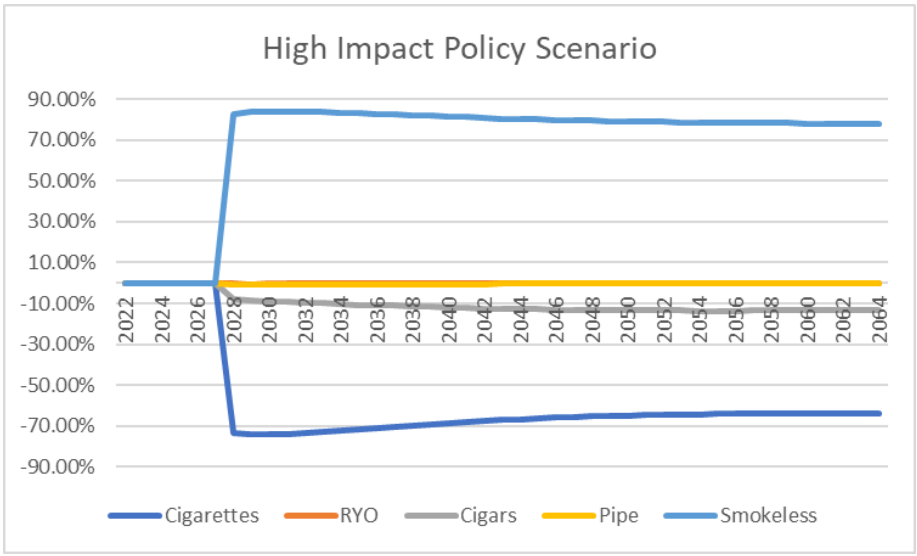


Figure 26. Percent Change of Total User Fees by Product Category – Difference Between Policy Scenario and Baseline







Overall, this proposed product standard, if finalized, would cause a shift in user fee obligations from combusted product manufacturers to smokeless tobacco product manufacturers. The primary policy scenario results in an annualized transfer of user fee assessments from combusted to smokeless tobacco firms of $333 million at a 2 percent discount rate. In the low impact scenario, the annualized transfer of user fee assessments is $26 million at a 2 percent discount rate. In the high impact scenario, the annualized transfer of user fee obligation is $461 million at a 2 percent discount rate.

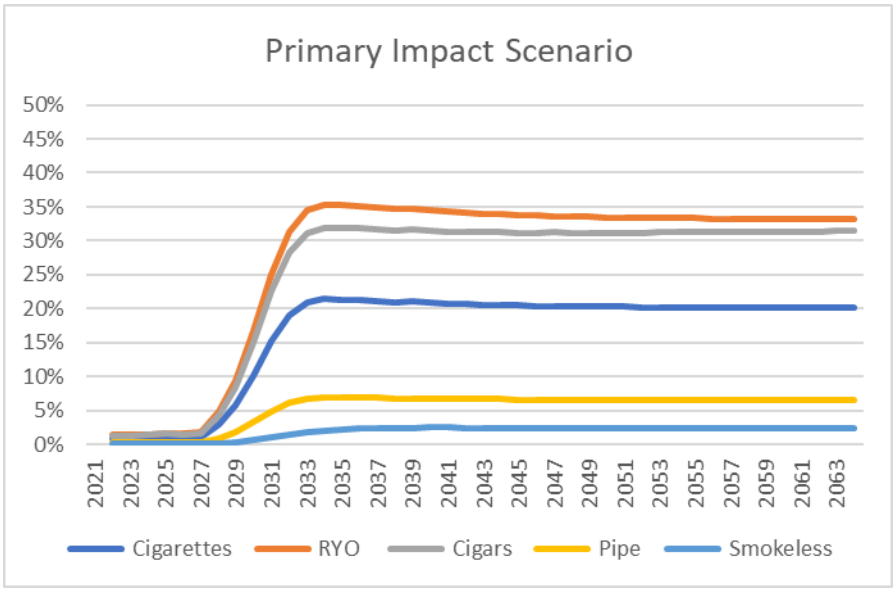
Additionally, while the proposed product standard may result in a decrease in total tobacco spending and revenue (all classes), the TCA specifies the total amount of user fees assessed, subsequently resulting in a higher ratio of user fee assessments as compared to post-tax revenue for each product category. We note that all of these assumptions are based around several critical assumptions, including an assumption that market prices of both combusted and noncombusted tobacco products remain constant (in real dollars) over the years following the

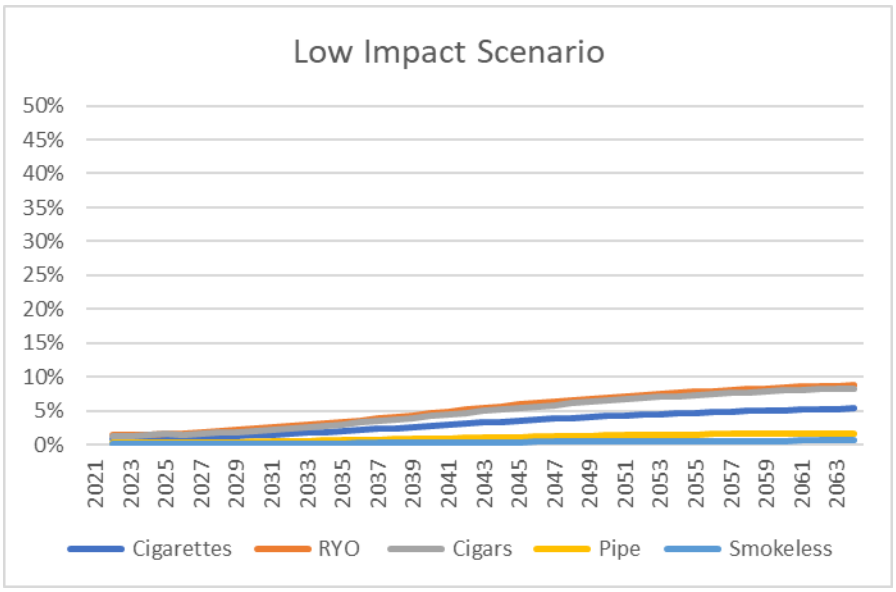
proposed product standard. As discussed with more detail in section II.H.1.0 (Producer Surplus Loss), the tobacco industry generally operates in an oligopolistic manner and retains pricing power resulting in relatively frequent price increases. Increases in tobacco prices would increase manufacturer revenue and reduce any proportional impact of a user fee assessment. Additionally, to the extent that a manufacturer may operate in both combusted and smokeless tobacco product categories, this analysis cannot predict how their overall user fee assessments may change under the proposed product standard.

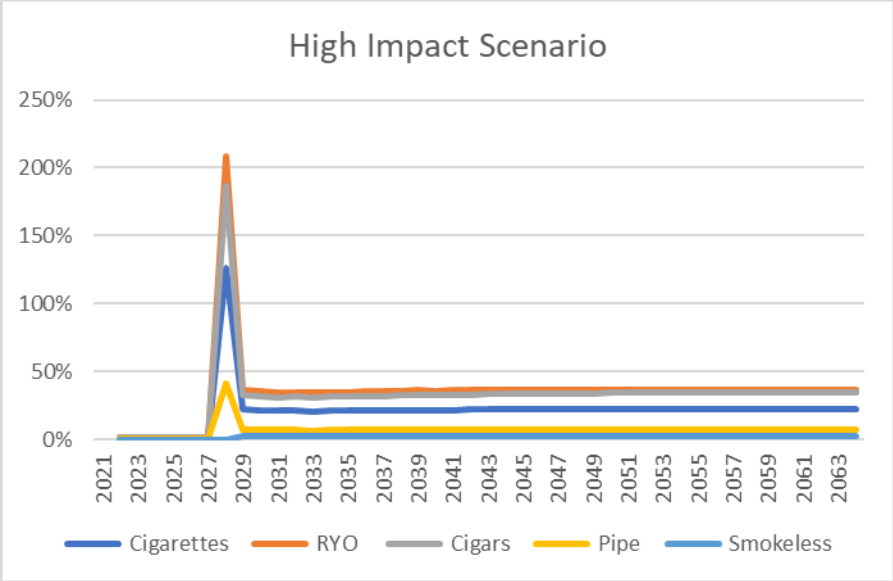
By 2037, in the primary impact scenario, the relative user fee burden has leveled out to about 21.2 percent of post-tax revenue for cigarettes, 34.9 percent of post-tax revenues for RYO, 31.7 percent of post-tax revenue for cigars, 6,8 percent of post-tax revenues for pipe tobacco and 2.4 percent of post-tax revenue for smokeless products. See Figure 27. Since tobacco revenues are already decreasing at baseline, in 2037 policy impact on user fee obligation is about 19.5 percent of post-tax revenue for cigarettes, 32.1 percent of post-tax revenues for RYO, 29.2 percent of post-tax revenue for cigars, 6.3 percent of post-tax revenues for pipe tobacco and 2.2 percent of post-tax revenue for smokeless products. See Figure 28. We note that each firm may produce multiple product categories or may have lines of business outside of the tobacco industry. This analysis does not reflect the percent of total firm revenue owed in user fees, but rather the percent of the tobacco product-derived revenue within a tobacco product category that may be assessed in user fees.

Since the total user fee assessment assigned to each class of tobacco products for a given fiscal year is based on the class's tax burden for the most recent calendar year, the first year that the policy impacts producers and importers they are paying user fees based on the pre-policy world with post-policy revenues. In both the low and primary impact scenarios revenues drop off quickly but over several years, such that the user fee obligation as a percent of revenue from the tobacco category ramps up to a relatively stable point about 15 years after implementation. However, based on the PHM's predicted impact on combusted prevalence, in the high impact scenario revenues drop off so rapidly in the first year of market impact that user fees spike to well over 100 percent of revenue for the combusted product categories before stabilizing to levels comparable to the primary policy scenario.

Figure 27. Percent of Post-Tax Revenue of a Product Category Needed to Meet User Fee Obligation Post (Primary) Policy

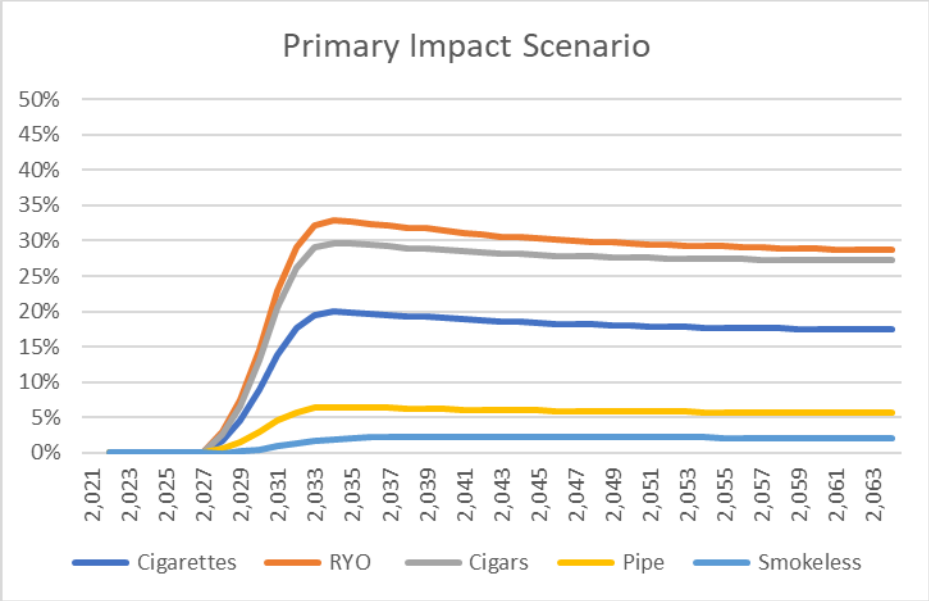


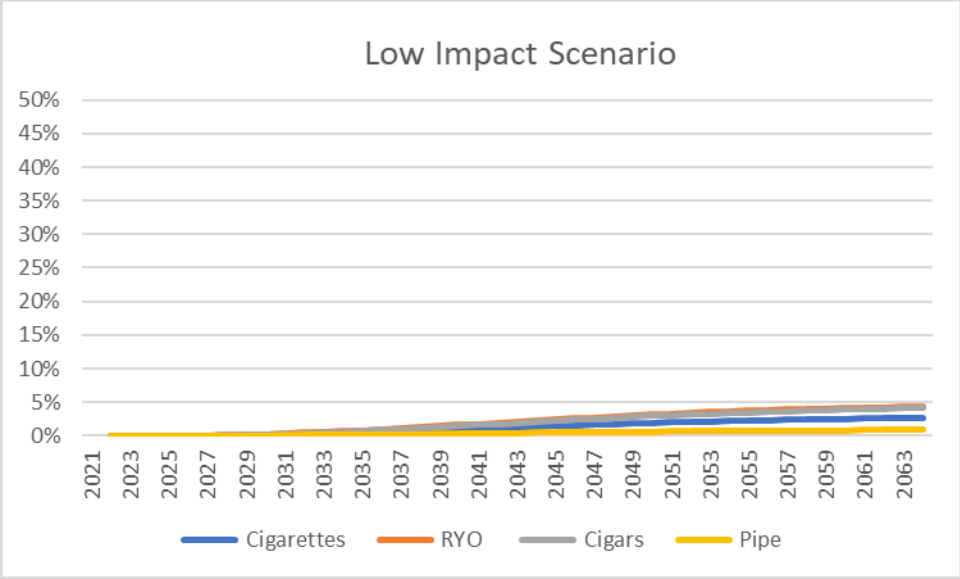


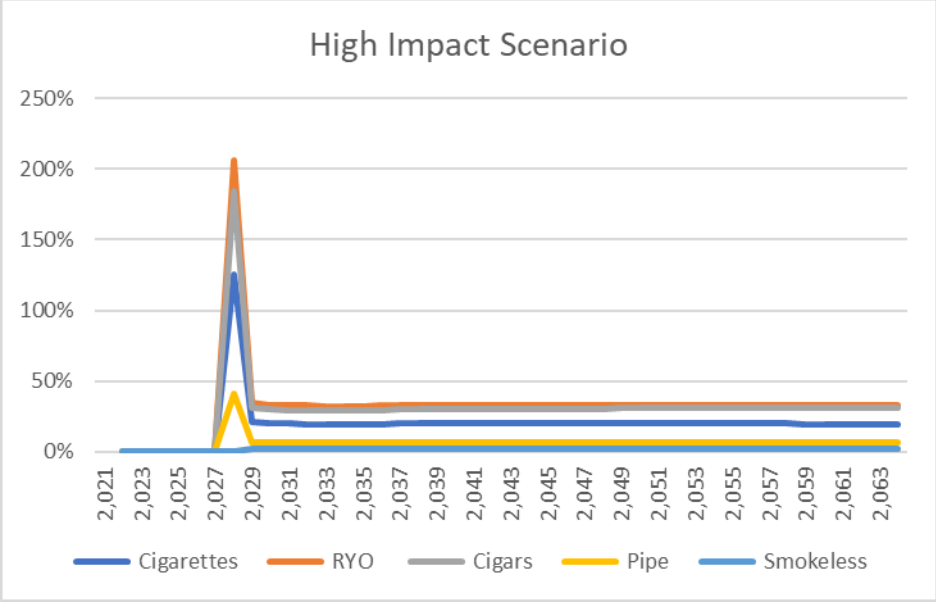


Note: The scale for the "High Impact Scenario" figure differs from the other two.

Figure 28. Percent of Post-Tax Revenue of a Product Category Needed to Meet User Fee Obligation Difference Between Primary Policy and Baseline







Note: The scale for the "High Impact Scenario" figure differs from the other two.

As noted above, although this is not a social cost, the increase in user fee burden would increase the financial constraints on domestic manufacturers and importers. This financial constraint would impact all firms subject to user fees including firms with covered products and smokeless products. While we lack information to fully assess firms' shutdown point, we note that for firms that manufacture or import combusted tobacco products declining revenue and relative growth of user fee obligations are likely to create additional strain. We expect smaller firms to have lower net profit margins than large firms. See Section III below for a more complete discussion of the impacts of the product standard on small entities.

We note that this analysis assumes that there are no changes to the user fee structure or federal tax structure during the time horizon of the analysis. As part of its budget requests since fiscal year 2020, FDA has requested that Congress provide the Agency with authority to assess and collect user fees for all regulated products, including ENDS products. Congress may choose to update the user fee structure or tax structure at any time, which would alter our analysis. We are unable to assess any potential action by Congress. We request comment on how this policy may impact user fees and the burden they have on firms.

J. Analysis of Regulatory Alternatives to the Proposed Rule

We analyze several alternatives to the proposed rule: extending the effective date to six years, including waterpipe tobacco in the proposed standard, allowing for a gradual reduction in nicotine, and allowing for acceptance testing of the nicotine level.

1. Gradual Reduction in Nicotine

FDA is proposing an immediate nicotine reduction rather than a gradual (i.e., stepped down) approach. In this analysis, we assess the alternative of a gradual reduction. Specifically, we consider a two-step scenario where in 2027 a first step down in nicotine becomes effective and, four years later, in 2031 the final nicotine level, in line with this proposed rule, is implemented.

a. Literature on Gradual versus Immediate Nicotine Reduction

Most studies comparing dependency outcomes between immediate nicotine reduction via VLNC cigarettes and gradual nicotine reduction find evidence that switching to VLNC cigarettes decreases dependence (32; 166; 11; 167; 168). Further, evidence suggests that immediate nicotine reduction is more likely to lead to decreases in dependence than gradual reduction (32; 166; 169). We expect that there would be little or no compensatory smoking of VLNC cigarettes under the proposed immediate approach, while evidence suggests that a gradual approach could lead to compensatory smoking as the nicotine levels are reduced but remain above VLNC levels (32; 166). Therefore, the gradual reduction approach could lead to increased combusted tobacco consumption and, consequently, increased morbidity and mortality during the reduction period relative to the proposed immediate reduction approach. We request comment on these data sources and our assumptions.

b. Gradual Reduction Alternative Estimation

From the literature on immediate versus gradual nicotine reduction, it is evident that consumers are likely to compensate with more cigarettes until nicotine levels have been reduced to nonaddictive or minimally addictive levels and consumers can no longer compensate by

smoking more (see Section VII.C of the NPRM). Although there may be increases in quantity of affected tobacco products sold resulting from increases in intensity among smokers, the PHM does not capture this change quantitatively. As such, we assume that the policy has no impact on smoking prevalence under the gradual reduction alternative in the first step and consequently, no change in quantity of affected tobacco products.-We request comment on these data sources and our assumptions.

Under the gradual reduction alternative, we assume that costs for firms to reformulate products, submit premarket applications to FDA, and the cost for FDA to review these applications will be incurred both in 2026 and 2030 relative to only once in the main analysis. In the low, primary, and high impact scenarios for the first nicotine reduction step, we assume there are the same amount of VLNC products reformulated as there are in the low impact scenario of the main analysis, along with the corresponding costs to submit premarket applications and for FDA to review. See section II.H.1.d for the number of VLNC products reformulated, section II.H.1.d for reformulation costs, section II.H.1.f for application submission costs, and section II.H.3.c for government review costs. We also assume that in 2027, consumers incur search costs associated with a decrease in the number of products on the market. We estimate that search costs to consumers for the first nicotine reduction step are half of the search costs for each respective impact scenario of the main analysis. See section II.H.2.b for search costs. In the second nicotine reduction step, we assume that firms incur the same costs for reformulation, application submission, and the cost for FDA application review as in the main analysis. We assume that in 2031, consumers incur the same search cost as in the main analysis. Lastly, we assume firms incur the one-time cost of reading and understanding the rule upon its publication date in 2025, one-time economic transition costs one year prior to the second step of nicotine reduction in 2030, and that consumers incur a one-time withdrawal cost in 2032. Recurring costs of nicotine content testing to firms and government enforcement costs begin in 2028, and recurring changes in producer surplus begin in 2032. See Table 64 for the sequencing of costs in the gradual reduction scenario.

Table 64. Sequencing of Costs Associated with Gradual Reduction

Affected Entity	Type	2025 **Publication**	2026	2027 **Step 1**	2028	2029	2030	2031 **Step 2**	2032 to 2064
Firm	Reading and Understanding	X							
	Economic Transition						X		
	Reformulation		X				X		
	Application Submission		X				X		
	Nicotine Testing				X	X	X	X	X

	Producer Surplus*								X
Govt	Review		X				X		
	Enforcement				X	X	X	X	X
Consumer	Withdrawal							X	
	Search			X				X	

*Note: Producer surplus represents the net effect of firms, which includes losses to firms selling combusted tobacco products affected by the rule as well as gains to firms selling noncombusted tobacco products

Under the gradual reduction alternative, 40-year annualized benefits range from $197 billion to $855 billion, with a central estimate of approximately $787 billion, discounted at 2 percent. Annualized costs under this alternative range from $0.9 billion to $2.4 billion, with a central estimate of approximately $1.9 billion, discounted at 2 percent. Annualized transfers of excise tax revenues from Federal governments to consumers under this alternative range from $1.1 billion to $3.3 billion, with a central estimate of approximately $3.2 billion, discounted at 2 percent. Annualized transfers of excise tax revenues from State governments to consumers under this alternative range from $2.2 billion to $6.9 billion, with a central estimate of approximately $6.5 billion, discounted at 2 percent. Annualized transfers of revenues from firms to consumers under this alternative range from $4.9 billion to $14.0 billion, with a central estimate of approximately $15.7 billion, discounted at 2 percent. The present and annualized values of the gradual reduction alternative and the difference between the proposed rule and the gradual reduction alternative are summarized in Table 65.

Table 65. Summary of Benefits, Costs, and Transfers for the Gradual Reduction Alternative ($2023 Millions)

		Gradual Reduction Alternative			Difference Between Gradual Reduction Alternative and Proposed Rule
	Discount Rate	Primary	Low	High	Primary
Benefits					
Present Discounted Value	2%	$21,953,457	$5,498,042	$23,860,498	-$8,657,159
Annualized Value	2%	$786,789	$197,044	$855,136	-$310,264
Costs					
Present Discounted Value	2%	$51,754	$25,784	$66,148	-$6,209
Annualized Value	2%	$1,855	$924	$2,371	-$223
Transfers: From Federal Governments to Consumers					
Present Discounted Value	2%	$88,537	$30,160	$93,300	-$25,632
Annualized Value	2%	$3,173	$1,081	$3,344	-$919
Transfers: From State Governments to Consumers					
Present Discounted Value	2%	$181,747	$61,897	$191,697	-$53,020
Annualized Value	2%	$6,514	$2,218	$6,870	-$1,900
Transfers: From Firms to Consumers					
Present Discounted	2%	$438,936	$135,902	$391,147	-$118,118
Annualized Value	2%	$15,731	$4,871	$14,018	-$4,233

Table 66 (analogous to Table 41 in section II.H) presents the annualized costs associated with the gradual reduction alternative broken down by category. Although some costs are reduced in this alternative, much of that is offset by increased costs associated with reformulation, submission, and premarket review of additional products.

Table 66. Summary of Annualized Quantified Costs under Gradual Reduction Alternative (Millions of 2023 Dollars over a 40-Year Time Horizon, 2 percent discount rate)

Cost Category		Annualized Value Costs		
		Primary	Low	High
Industry	Economic Transition Cost	$231.9	$139.8	$295.7
	Producer Surplus Loss	$1,157.6	$143.0	$1,330.5

	Reading and Understanding the Rule	$13.4	$4.0	$25.1
	Manufacturers: Reformulation Costs	$334.9	$606.2	$316.2
	Cost to Submit Premarket Applications	$0.56	$1.01	$0.528
	Testing Costs	$1.2	$1.9	$1.7
Consumer	Withdrawal Costs	$39.0	$0.4	$252.1
	Search Costs	$70.9	$23.6	$141.9
Government Enforcement Costs	Federal Enforcement Costs	$4.6	$3.0	$6.4
	Costs for Premarket Review of the New Tobacco Products	$0.58	$1.06	$0.551
Total Annualized Quantified Costs		$1,854.8	$924.1	$2,370.7

On net, we expect the gradual reduction approach to have lower benefits than the proposed rule. We also expect transfers of Federal and state excise tax revenues to consumers and transfers of user fees owed by combusted tobacco firms to noncombusted tobacco firms to be lower than with the proposed rule.

2. Change the Effective Date

The proposed rule, if finalized, would become effective 2 years after publication of the final rule. In this analysis, we consider an effective date of 6 years (See Table 67). For the 6-year effective date, we use much of the same approach as the Gradual Reduction in Nicotine Alternative as estimated in Section II.J.1. As discussed in the gradual reduction alternative, we do not estimate health benefits until nicotine levels reach minimally or non-addictive levels. So, while the gradual reduction and 6-year effective date are different from a policy standpoint the impacts are similar. We estimate the 6-year effective date to have the same benefits as the gradual reduction alternative and the same costs except those associated with the first round of reformulation. We assume that the change in effective date does not have a substantial impact on the baseline. Specifically, we assume for this analysis that no tobacco regulation issued prior to the publication of this final rule other than the Menthol and Cigar Flavors Product Standards, that would result in major changes to the tobacco market.

Given that smoking rates are declining at baseline the policy has a lower averted mortality impact with a longer effective date. We expect costs to decrease because 1) the costs also occur further in the future and 2) some of the costs are lower because combusted tobacco prevalence is declining at baseline which results in lower lost producer surplus. However, given the relative magnitudes of the monetized benefits and costs of this rule, the decline in benefits far exceeds the reduced cost burden.

The 6-year effective date has a decrease in annualized value of the monetized benefits relative to the 2-year effective date of approximately $310 billion at a 2 percent discount rate. The monetized annualized costs under this alternative decrease by $558 million and a 2 percent discount rate.

Table 67. Benefits and Costs Under the Alternative Effective Date of 6 Years ($ Millions, 2023 $)

	Alternative Compliance Date			Difference between Proposed Rule and Alternative Compliance Date
	Primary	Low	High	Primary
Benefits				
Present discounted Value	$21,953,457	$5,498,042	$23,860,498	$8,657,159
Annualized Value	$786,789	$197,044	$855,136	$310,264
Costs				
Present discounted Value	$42,403	$16,706	$57,077	$15,561
Annualized Value	$1,520	$599	$2,046	$558

3. Include Waterpipe Tobacco

FDA considered including waterpipe tobacco products within the scope of this proposed product standard and received comment that waterpipe tobacco use among young people may cause similar or more severe health effects than cigarette smoking. A waterpipe smoking session typically lasts 20 to 80 minutes, with a person using the waterpipe taking 50 to 200 puffs, while smoking a cigarette typically takes 5 to 7 minutes, with a person who smokes cigarettes taking 8 to 12 puffs. (170; 171). However, FDA decided to not include waterpipe tobacco products in this proposed standard because the Agency has determined that waterpipe tobacco involves profoundly different use behaviors than combusted cigarettes, which makes it an unlikely substitute for cigarettes. Findings from 2024 NYTS data suggest that 0.7 percent of middle and high school students reported using waterpipe tobacco within the past 30 days (172). Data drawn from the 2022 NHIS suggest that 0.8 percent of adults reported daily or occasional pipe, waterpipe, or hookah smoking, while 13.9 percent of adults reported ever smoking a pipe, waterpipe, or hookah. Because the NHIS survey data asks one combined question about whether respondents have smoked regular pipes, waterpipe, or hookah, these prevalence estimates may overstate the number of individuals who currently or have ever smoked only waterpipes.

Waterpipe tobacco is significantly less likely to be smoked daily. Multi-wave PATH Study data (173) (Wave 1, 2013-2014; Wave 2, 2014-2015) indicates that among adults who used waterpipes in the past year, 77.1 percent report less than monthly use in Wave 1, and 44.9 percent report less than monthly use in Wave 2. In Wave 3, 0.1 percent of youth, 0.3 percent of young adults, and 0 percent of adults reported daily waterpipe use (174). For comparison, 59.1 percent of adults in the 2018 NHIS who smoke cigarettes report daily use (175).

Our analysis of the costs of the proposed rule uses Euromonitor Passport data, which includes waterpipe tobacco (shisha) in its definition of pipe tobacco. We therefore expect that

our estimates of the costs of the proposed product standard partially consider the waterpipe tobacco market. Due to the low prevalence of waterpipe smoking and its profoundly different use topography, we do not expect the inclusion of waterpipe tobacco to significantly impact estimated benefits of the proposed product standard; however, we lack data that would allow us to quantify this impact. Specifically, we lack data on the extent to which waterpipe tobacco use leads to morbidity or mortality. Further, we lack data on the extent to which waterpipe use may be used as a substitute for other NNC combusted tobacco products if this standard is finalized. We request comment on these topics.

4. Allow for Acceptance Testing of the Nicotine Level

This proposed rule, if finalized, would require product testing on each batch of finished cigarettes and certain other finished combusted tobacco products prior to commercial distribution in the United States to prevent nonconforming tobacco products from entering the stream of commerce and reaching consumers. This regulatory alternative would allow manufacturers to test tobacco filler and other ingredients for nicotine prior to putting them in the finished product or in final packaging through incoming and in-process acceptance activities. Incoming acceptance would confirm that incoming materials from suppliers (e.g., cut filler, cigar wrapper) meet established specifications using purchasing documents such as a Certificate of Acceptance (COA). In-process testing would allow manufacturers that manufacture their own materials to demonstrate, through testing, that their products meet established specifications. Regardless of when testing occurs, however, it would remain the manufacturer's responsibility to ensure that finished tobacco products subject to this proposed nicotine yield product standard comply with the proposed maximum nicotine content set forth in proposed §1160.10.

Under this regulatory alternative, manufacturers who use the same filler for different finished tobacco products would be able to test finished products that apply to multiple different finished products without additional samples. For these products that use the same filler, the ability to test the filler rather than every batch of finished tobacco product reduces waste of final packaged products. We calculate testing costs using a batch size of 24 million cigarettes, or 1.2 million packs, as a proxy for running samples of filler over larger batches relative to the main analysis of 8 million cigarettes, or 400,000 packs. Refer to Section II.H.1.g for a detailed explanation of estimating testing costs in the main analysis.

Table 68 below displays the testing cost estimates for allowing acceptance testing of nicotine levels as well as the difference between costs for acceptance testing and the final product testing requirement used in the main analysis. At a 2 percent discount rate, annualized acceptance testing would cost $1,476,653, $230,284, and $68,966 less in the low, primary, and high estimates relative to final product testing.

Table 68. Summary of Testing Cost of Nicotine Level with Acceptance Testing at a 2% Discount Rate over a 40 Year Time Horizon

Cost for Acceptance Testing All Affected Combusted Products			
	Primary	Low	High
Discounted Total Cost	$2,741,326	$17,578,232	$820,977
Annualized Cost	$115,142	$738,326	$34,483
Difference between Acceptance Testing and Final Product Testing			
	Primary	Low	High
Discounted Total Cost	-$5,482,651	-$35,156,463	-$1,641,954
Annualized Cost	-$230,284	-$1,476,653	-$68,966

This regulatory alternative would present multiple challenges and potentially would increase government costs to enforce this product standard. One such challenge would be in evaluating premarket tobacco product applications with multiple nicotine COAs (e.g., COAs for Bright, Burley, and Oriental tobacco leaf inputs). The COAs for one finished tobacco product may include multiple different test methods using different detectors (i.e., an instrument used to measure how much nicotine is present). Each of these test methods would need to be validated for precision, accuracy, selectivity, and sensitivity to ensure they are fit for purpose. In addition, for each test method, the manufacturer would need to submit sufficient information about the nicotine testing so FDA could fully evaluate the submitted data. Finally, unless every COA was reported in identical units of nicotine concentration for each ingredient, component, and part of the finished tobacco product, there may not be a clear or reliable way to calculate the total nicotine concentration in the finished tobacco product other than testing the final, finished tobacco product (as required by the proposed rule).

As discussed in the proposed rule, the scope of this nicotine product standard would include components and parts of cigarettes and certain other combusted tobacco products, meaning that reliance on acceptance testing of some, but not all, materials used to manufacture a covered tobacco product may not accurately represent the total nicotine content in the finished tobacco product. For example, nicotine may be added to cigarette paper, or the mouthpiece or filter of a cigar. Similarly, additives used in the manufacturing process, such as the processing of reconstituted tobacco or modified tobacco after acceptance, may impact the total nicotine content of the finished tobacco product. Another potential complication is that cross-contamination of manufacturing equipment containing nicotine residues that are not properly cleaned can affect the nicotine content of finished tobacco products.

Due to challenges related to premarket review of acceptance activities as well as the potential for the nicotine content of the finished tobacco product to vary based on subsequent manufacturing practices after acceptance activities, the Agency has determined to not adopt this alternative and proposed that each batch of finished tobacco products be tested to determine the total nicotine content of the finished tobacco product. We request comment and data on the

comparative costs and benefits that might be associated with allowing for acceptance testing in lieu of batch testing of the finished tobacco product.

K. Distributional Effects

1. Specific Populations

The quantified benefits and costs of the proposed product standard across the U.S. population and industry are discussed in Section II.G and II.H. FDA expects that the public health benefits of this rule would be particularly pronounced for specific populations, including children and adolescents; Black, non-Hispanic American Indian/Alaska Natives (AI/AN), and other racial and ethnic minority populations; individuals with lower socioeconomic status (SES), household income, and educational attainment; individuals with behavioral health disorders, including mental illness and substance use disorders; and individuals who identify as lesbian, gay, bisexual, transgender, queer, intersex, and other sexual and gender minority populations (LGBTQI+). Similarly, the quantified costs of the proposed product standard, such as withdrawal costs and search costs, may also be disproportionately incurred by specific populations. Withdrawal costs, relating to degree of addiction and intensity of use, may follow the distribution of health benefits and be particularly pronounced for those specific populations whose patterns of tobacco product use differ from the general population. Additionally, individuals in specific populations with less access to information may incur higher hourly search costs as they may expend additional time seeking information on substitute products.

a. Children and Adolescents

Data indicate that nicotine has stronger rewarding effects in adolescents than in adults, and that the adolescent brain is more vulnerable to developing nicotine dependence (20). Additionally, the earlier individuals begin smoking, the less likely they are to quit successfully (176). Evidence suggests that adolescents who use tobacco and initiate tobacco use at earlier ages are more likely to report symptoms of dependence than those who initiate at older ages (129). Further, the 2010 SGR notes that adolescents report symptoms of dependence even at low levels of cigarette smoking and may be particularly vulnerable to addiction (24). FDA expects that this proposed product standard, if finalized, would have significant benefits for youth and young adults by reducing the risk that those who experiment with cigarettes and certain other combusted tobacco products would progress to regular use as a result of nicotine dependence. See Section II.G.1.c for an analysis of benefits from avoided smoking-related SIDS deaths and Section II.M.7 for an extended analysis of the impacts due to this proposed product standard on youth. We request comment on the impacts of this proposed product standard on youth.

b. Race and Ethnicity

Black adults, and in particular Black men, experience the highest rates of incidence and mortality from many tobacco-related cancers, such as lung and bronchial cancer and head and neck cancer, compared to those from other racial and ethnic groups (177; 178; 179). Deaths from other tobacco-related conditions such as heart disease, stroke, and hypertension are higher among Black individuals compared to other racial and ethnic groups regardless of tobacco use status (180; 181; 182; 183; 184; 185). Compared to persons identifying as non-Hispanic White, Hispanic and Black persons smoke fewer cigarettes and are more likely to be people who do not smoke daily, yet have greater risk of lung cancer morbidity and mortality (186; 187; 188; 189; 190; 191; 3; 192). Additionally, AI/AN populations have the highest cigarette use prevalence (193) and are more likely to suffer disproportionate rates of tobacco-related death (194).

The 2014 U.S. SGR reported 2,326,810 annual deaths among the U.S. population aged 35 and older, of which 437,400 deaths were attributed to cigarette smoking (3). While this provides a population level estimate of smoking-attributable mortality, we are unable to determine a distribution of smoking-attributable mortality across race and ethnicity from this data. Thus, to estimate reductions in mortality risk for specific populations, we take the following approach. First, we establish adult smoking prevalence by race and ethnicity using data from the 2021 NHIS, shown in column 1 of Table 69 (195).[75] Then, we use CDC WONDER data to determine the percent of the adult population that each race and ethnicity group represents, shown in column 2 of Table 69 (196). Combining smoking prevalence with the prevalence of the associated race and ethnicity group in the overall US population, we calculate the distribution of the smoking population across race and ethnicity. For example, total smoking prevalence in 2021 NHIS is 11.5% and smoking prevalence among the non-Hispanic White population is 12.9% (column 1 of Table 69). The non-Hispanic White population accounts for 61.6% of the US adult population in that year (column 2 of Table 69). Therefore, the non-Hispanic White population represents 69.2% ([=12.9% x 61.6%] / 11.5%) of the smoking population in 2021. The share of the cigarette smoking population by race and ethnicity is shown below in Table 69.

Table 69: Cigarette Smoking among Adults in the US by Race and Ethnicity, 2021

Race, Ethnicity	(1) Cigarette Smoking Prevalence	(2) Percent of Adult Population	(3) Percent of Smoking Population

[75] We use the Sample Adult dataset of the 2021 NHIS. Current cigarette smoking was defined as smoking 100 or more cigarettes during a person's lifetime and now smoking cigarettes "every day" or "some days" and adjusted for nonresponse by removing respondents with indeterminate smoking status (i.e., "unknown if ever smoked" and "smoker current status unknown"). Race and ethnicity were defined using the variable "HISPALLP_A." We calculate the cigarette smoking prevalence by race and ethnicity in column 1 of Table 69 by applying the Final Annual Weight, WTFA_A, to general national estimates.

White (non-Hispanic)	12.9%	61.6%	69.2%
Black/African American (non-Hispanic)	11.7%	12.3%	12.6%
Asian (non-Hispanic)	5.4%	6.0%	2.8%
AIAN (non-Hispanic)	19.0%	0.7%	1.2%
Hispanic or Latino	7.7%	17.3%	11.6%
Other	14.9%	2.0%	2.6%
Total	11.5%	100.0%	100.0%

To account for differences in mortality by race and ethnicity, we leverage the age-adjusted all-cause death rates from CDC WONDER, shown in column 1 of Table 71 (196).[76] Age-adjusted all-cause mortality for adults in the United States in 2021 was 1,106 deaths per 100,000 people. The age-adjusted all-cause death rate among the non-Hispanic White population was 1,126, which relative to the US population is a ratio of 1.02 (1,126 / 1,106). For each race and ethnicity group, we multiply the ratio of age-adjusted all-cause deaths among that race and ethnicity group relative to the total population (column 2 of Table 71) by their share of the smoking population (column 3 of Table 71) and normalize the values to compute an age-adjusted distribution of deaths weighted by smoking prevalence across race and ethnicity (column 4 of Table 71). We multiply this distribution by the cumulative avoided tobacco-attributable mortality estimated by the PHM over the period from 2025 to 2064 to estimate an approximate distribution of tobacco-attributable avoided deaths by specific population (column 5 of Table 71). We assume these weights computed in 2021 remain representative over the 40-year time horizon of our analysis. For example, the PHM model estimates there to be 1,786,164 avoided premature deaths from 2025 to 2064 (Median estimate—50th Percentile). Thus, we estimate there to be approximately 282,968 (1,786,164 x 15.8%) cumulative avoided smoking-attributable deaths for the non-Hispanic Black population resulting from the policy over this time frame. A similar approach yields 26,858 cumulative avoided smoking-attributable deaths for the non-Hispanic AI/AN population and 170,095 cumulative avoided smoking-attributable deaths for the Hispanic/Latino population by 2064. We present a summary of these estimates by race and ethnicity in Table 71. While we adopt these assumptions, we note that rates of smoking-

[76] The rates of almost all causes of disease, injury, and death vary by age. Age adjustment is a technique for "removing" the effects of age from crude rates so as to allow meaningful comparisons across populations with different underlying age structures. Age-adjusted rates are calculated by applying the age-specific rates of various populations to a single standard population. Standard age-adjusted rates (calculated with standard populations) are only available for Ten-Year Age Groups and the lowest age band that captures adults 18+ ranges from 15-24 years. Thus, to be inclusive in our analysis of all adults in the US population, the data used from CDC WONDER ranges from 15 to 85+ years of age. However, we note that the PHM estimates tobacco-attributable avoided deaths for adults aged 35+. For a more detailed explanation of how age-adjusted death rates are computed in CDC WONDER, please refer to https://wonder.cdc.gov/wonder/help/ucd-expanded.html#.

attributable mortality may differ from smoking prevalence across race and ethnicity and may vary over time. Thus, estimates presented in Table 71 represent an approximation of tobacco-attributable mortality avoided by specific populations under this proposed rule. We request comment on these assumptions and additional data on the distribution of tobacco-attributable deaths across race and ethnicity.

Table 70. Cumulative Tobacco Attributable Avoided Premature Deaths Under the Product Standard for Specific Adult Populations from 2025 to 2064

Race, Ethnicity	(1) Age-Adjusted Death Rates per 100,000	(2) Ratio of Age-Adjusted Death Rate to Total Population	(3) Share of Smoking Population	(4) Smoking Prevalence Weighted Distribution of Deaths[3]	(5) Distribution of Tobacco Attributable Avoided Deaths by Specific Population[4]
White (non-Hispanic) [1]	1,126	1.02	69.2%	70.3%	1,256,331
Black/African American (non-Hispanic) [1]	1,395	1.26	12.6%	15.8%	282,968
Asian (non-Hispanic) [1]	580	0.52	2.8%	1.5%	26,563
AIAN (non-Hispanic) [1]	1,392	1.26	1.2%	1.5%	26,858
Hispanic or Latino[1]	911	0.82	11.6%	9.5%	170,095
Other (non-Hispanic) [2]	567	0.51	2.6%	1.3%	23,348
Total	1,106	1.00	100.0%	100.0%	1,786,164

1 These categories exclude deaths for individuals recorded as having "More than one race."

2 This category includes remaining non-Hispanic populations, including those listed as more than one race and populations where Hispanic origin was "Not Stated."

3 We note the distribution of deaths is computed using smoking prevalence across race and ethnicity and may not represent smoking-attributable mortality by race and ethnicity. The distribution was also normalized to ensure estimates presented in column 4 total to 100 percent.

4 Tobacco attributable avoided deaths in column 5 are calculated by multiplying the smoking attributable death weights in column 4 by the 1,786,164 cumulative avoided premature deaths due to the product standard by 2064 (Median – 50th Percentile estimate from a PHM modeling scenario that incorporates the impacts of a menthol product standard in the baseline).

Using data from the 2008-2019 Medical Expenditure Panel Survey linked to the National Health Interview Survey, Valdez and Encinosa (73) estimate that Hispanic, Black, Asian, and other non-Whites and multi-race people who have ever smoked spent an excess of $1,697 per adult smoker on annual medical care when compared to adult never smokers, while non-Hispanic

White ever smokers spent less than half the amount or an excess of $985 per adult smoker. The share of total healthcare spending attributable to smoking was estimated to be 6.2 percent among non-Hispanic White adults and 10.2 percent among Hispanic, Black, Asian, and other non-White and multi-race adults (65% larger than the non-Hispanic White population's estimated spending). Based on their inflation-adjusted estimates, the authors also suggest that if a tobacco regulation averted 100,000 individuals from initiation into smoking, cost savings would be $151 million per year for 100,000 Hispanic, Black, Asian, and other non-White and multi-race adults averted from smoking, $87 million or 135 percent more per year than the $64 million saved per year for 100,000 non-Hispanic White adults averted from smoking.

Disparities in secondhand smoke exposure exist across various environmental settings, and inequities in places where members from underserved communities are likely to reside, spend time, and work may influence secondhand smoke exposure (197). Findings from 2011-2018 NHANES data indicate that non-smoking, non-Hispanic Black respondents had higher overall levels of secondhand smoke exposure. Evidence from 2013-2016 NHANES data indicate that non-Hispanic Black respondents are more likely to be exposed to secondhand smoke in homes other than their own compared to non-Hispanic White respondents (198). Data from the 2010 and 2015 NHIS show that workplace secondhand smoke exposure is disproportionately high among non-Hispanic Black respondents and Hispanic respondents.

Research has found that retail advertising for tobacco products, including cigarettes and other combusted tobacco products, is more common in neighborhoods with greater proportions of Black residents and households with lower income (199; 200; 201). Additionally, storefront and outdoor tobacco marketing, as well as point-of-sale marketing, are disproportionately present in Black, Hispanic/Latino, AI/AN, and low-income communities (202; 199; 203; 201; 204; 205; 206; 207). Tobacco industry marketing tactics include culture-specific imagery, traditional practices, and cultural events targeting specific racial and ethnic groups. For instance, tobacco industry documents revealed the use of American Indian imagery such as traditional headdresses and other cultural symbols in cigarette branding and the portrayal of harmful stereotypes of Native people in cigarette advertising (208). The historical and cultural significance of traditional tobacco was used to validate the authenticity of commercially available cigarettes, thus exploiting the traditions of Native people to encourage cigarette use (208). Moreover, tobacco companies market cigarettes to specific racial and ethnic populations by sponsoring cultural events (e.g., Cinco de Mayo, Chinese New Year, Black History Month) (209).

FDA expects that the proposed product standard, if finalized, would have significant benefits for the aforementioned populations. Because these populations experience higher incidence rates of tobacco-related disease, higher rates of secondhand smoke exposure, and are disproportionately targeted by marketing by tobacco companies, we expect that the proposed will have increased benefits for these groups. We request comment on the benefits to these specific populations. We also request comment on the effects experienced by any other specific populations not mentioned here.

c. Socioeconomic Status, Household Income, and Educational Attainment

Disparities in tobacco-related morbidity and mortality have also been observed for population groups with lower SES, household income, and educational attainment. Studies have consistently shown a strong relationship between lower SES and prevalence of cigarette and other combusted tobacco product smoking, such that higher educational attainment and total family income are inversely associated with smoking prevalence (210; 211; 212). Individuals with lower levels of household income and educational attainment bear a disproportionate burden of heart disease, stroke incidence, and mortality (213; 214). Cigar smoking also occurs disproportionately among individuals of lower educational attainment and lower annual household income (215; 216). People who exclusively use RYO tobacco tend to be of lower socioeconomic status, older, and male; however, young adults who smoke cigarettes also use RYO for financial reasons (35).

Findings from 2011-2018 NHANES data indicate that non-smoking respondents living below the poverty level had the highest levels of secondhand smoke exposure (27). Data from the 2010 and 2015 NHIS show that secondhand smoke exposure in the workplace also varies across population groups and is disproportionately high among lower education, lower income workers[77] (217).

FDA expects that the proposed product standard, if finalized, would have significant benefits for individuals with lower socioeconomic status, household income, and educational attainment who disproportionally bear the burden of smoking-related disease, are more likely to be exposed to secondhand smoke, and are disproportionately targeted by tobacco companies' marketing. We request comment on the effects and additional data associated with socioeconomic status, household income, and educational attainment.

d. Mental Illness and Substance Use

Research has shown that individuals with behavioral health conditions and other medical comorbidities have higher prevalence of combusted tobacco use compared to those without these conditions and have increased risk of tobacco-related morbidity and mortality (218; 219; 220; 3; 221). The prevalence of cigarette smoking is higher among adults with mental health symptoms or substance use (222; 223; 224; 225), resulting in increased risk for tobacco-related morbidity and mortality (226). Data from the 2014 NSDUH show cigarette smoking prevalence is higher among persons with mental health and/or substance use problems than among persons who do not report these conditions (38.5 and 15.4 percent, respectively) (225). Similarly, 26.9 percent of adults who report depression currently smoke cigarettes, compared to 11.8 percent among those

[77] Prevalence of exposure to secondhand smoke decreases across the observed education categories (less than high school; GED or high school; some college; college or higher) and observed income categories (0-$34,999; $35,000-$74,999; $75,000-$99,000; $100,000 and above) (216).

who do not report depression (222). Additionally, findings from the 2021 NHIS show that 28.1 percent of individuals reporting serious psychological distress also reported smoking cigarettes, compared to 10.9 percent of individuals not reporting serious psychological distress (227). Analyses of data from the 2015 and 2016 NSDUH also show that cigarette smoking is significantly more prevalent among persons who use cannabis and alcohol as compared to those who do not report using these products (223; 224). Tobacco industry documents show that the tobacco companies have strategically marketed their products to people experiencing homelessness and people with mental illness (228; 229).

FDA expects that the proposed product standard, if finalized, would have significant benefits for specific populations that disproportionately use affected tobacco products and experience the highest incidence rates of tobacco-related disease, including mental health disorders and substance use disorders. We request comment on the effects and additional data associated with mental illness and substance use.

e. LGBTQI+ Individuals

Industry documents showed that tobacco companies were aware of the higher prevalence of tobacco use among LGBTQI+ groups compared to the general population (230; 231). The LGBTQI+ community is targeted by cigarette marketing through direct and indirect advertising, community outreach and promotions, and event sponsorships (230). Study findings indicate that individuals who identify as lesbian, gay, or bisexual are more likely to report smoking cigarettes as compared to those who identify as heterosexual (232; 210; 233; 234). Among adults in the 2021 NHIS, cigarette smoking was more prevalent among persons identifying as lesbian, gay, and bisexual versus those identifying as heterosexual (15.3 and 11.4 percent). Further, among adults in the 2022 wave 4 PATH Study data, individuals who identify as transgender or gender diverse have current cigarette/e-cigarette/cigar use rates ranging from 32.6 percent to 39.7 percent (235). FDA expects that the proposed product standard, if finalized, would have significant benefits for specific populations that disproportionately use affected tobacco products, including LGBTQI+ individuals. We request comment on the effects and additional data associated with LGBTQI+ individuals.

2. Impact on Tribal Governments

The proposed product standard, if finalized, would apply to all manufacturers of combusted cigarettes, cigarette tobacco, RYO tobacco, cigars (including little cigars, cigarillos, and large cigars, but excluding premium cigars), and pipe tobacco (other than waterpipe tobacco), including those manufacturers that are tribally-affiliated or operating on tribal land. Under Section 905 of the FD&C Act, owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco

products are required to register with FDA and to list their products. However, FDA does not require information on tribal affiliation or tribal ownership as part of our TRLM NG data. Under Section 704 of the FD&C Act, FDA inspects such establishments registered under Section 905 of the FD&C Act, to evaluate whether the establishments, including those that are tribally-affiliated and/or operating on tribal land are in compliance with the FD&C Act and FDA's implementing regulations. Therefore, because persons submitting registration and listing data to FDA under Section 905 of the FD&C Act do not designate whether they are tribally-affiliated and/or operating on tribal land, FDA's estimate is based on the addresses of registered establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products; its determination of whether the address is on tribal land; and inspection history.[78]

Of domestic manufacturers potentially affected by the product standard, FDA estimates that there are 12 manufacturers that are tribally-affiliated and/or operate on tribal land, all of which manufacture products affected by this product standard. The majority of these establishments are believed to be individually, rather than tribally, owned, though it is not clear what, if any, revenue from such individually-owned establishments on tribal lands may go to tribal governments.

We do not have information about the manufacturing volume of these establishments. However, the 12 establishments referenced above as tribally affiliated and/or operating on tribal land are small entities, based on data from Dun & Bradstreet, the number of employees included in establishment inspection reports, or FDA's determination based on receipt of submission information under timelines for small-scale tobacco product manufacturers. We request comment on our estimates of the potential impacts of the proposed product standard on manufacturers, including those that are tribally-affiliated or operating on tribal land.

3. Regional Effects

If finalized, the proposed product standard would affect the demand for covered tobacco products. We expect that this would disproportionally affect the regions of the United States that have a disproportionately high rate of combusted tobacco product use, as well as have a disproportionate impact on the regions where tobacco is grown and produced to supply the combusted tobacco market.

Table 71 shows tobacco leaf production in the U.S. over time by state. U.S. bright and burley type tobacco leaf growers are primarily located in seven states, most of which are in the

[78] FDA's Registration and Product Listing database may provide an over- or underestimate of the number of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products operating on tribal land. Information in the database is confirmed upon inspection, at which time FDA may request that the person who registers under Section 905 of the FD&C Act update registration and/or product listing information. As an example of how the registration information may provide an overestimate, some firms may have erroneously registered establishments not engaged in the manufacture, preparation, compounding, or processing of tobacco products, such as certain warehouses, due to confusion.

South (Georgia, Kentucky, North Carolina, Pennsylvania, South Carolina, Tennessee, and Virginia) (See Table 72). The largest share of tobacco leaf production in a single state is that of North Carolina; based on USDA Annual Crop Production Summary reports, North Carolina accounts for approximately 56 percent of domestic tobacco leaf production by weight. We therefore expect these regions and states to be disproportionately affected by decreased demand for tobacco products as a result of the proposed product standard.

Table 71. U.S. Tobacco Leaf Production, 2017-2022, (1,000 lbs.)

State	2017	2018	2019	2020	2021	2022
Georgia	26,250	23,750	18,900	19,355	13,090	12,600
Kentucky	183,300	134,370	123,390	102,395	110,515	96,640
North Carolina	360,040	251,925	234,700	178,727	244,270	249,672
Pennsylvania	18,990	17,400	14,300	13,440	14,020	13,020
South Carolina	25,200	22,140	15,770	6,600	12,045	11,600
Tennessee	43,000	39,610	30,490	27,940	30,225	33,965
Virginia	53,381	44,046	30,406	24,420	33,961	29,870
United States	710,161	533,241	467,956	372,877	458,126	447,367

Source: FDA analysis of USDA Annual Crop Production Summary reports (162)

Table 72. Bright and Burley Tobacco Production by State, 2017-2022 (1,000 lbs.)

	2017	2018	2019	2020	2021	2022
Class 1, Flue-cured (Bright)						
Georgia	26,250	23,750	18,900	19,355	13,090	12,600
North Carolina	358,600	250,800	234,000	178,200	243,950	249,400
South Carolina	25,200	22,140	15,770	6,600	12,045	11,600
Virginia	50,600	42,000	28,500	23,400	32,890	29,040
United States	460,650	338,690	297,170	227,555	301,975	302,640
Class 3A, Light air-cured, Types 31 and 32 (Burley)						
Kentucky	129,150	80,000	77,900	68,250	66,000	50,400
North Carolina	1,440	1,125	700	527	320	272
Pennsylvania	10,350	8,800	6,500	7,000	7,000	3,250
Tennessee	18,000	9,010	6,400	3,875	3,750	4,185
Virginia	2,200	1,500	1,330	680	756	500
United States	161,140	100,435	92,830	80,332	77,826	58,607

Source: FDA analysis of USDA Annual Crop Production Summary reports (162).

Note: USDA Annual Crop Production Summary reports list two types of light air-cured tobacco; both Type 31 and Type 32 are types of burley tobacco. We present production by State in this table, aggregating both types of burley tobacco.

We expect this proposed standard to increase demand for noncombusted tobacco products. Smokeless tobacco products use fire-cured tobacco leaf. So, raw leaf tobacco growers in Tennessee and parts of Kentucky and Virginia, where fired-cured tobacco leaf type is grown may experience increased demand for their tobacco crop. In 2019, 6,500 acres of fire-cured tobacco were harvested in Tennessee, almost 64% of total tobacco acreage harvested in the State. In Kentucky, 8,000 acres of fire-cured tobacco were harvested in 2019, or 15% of total tobacco acreage harvested in the State. Parts of Virginia also are dedicated to the fire-cured tobacco cultivation. We request comment, including additional data or studies, regarding geographic impacts of this proposed rule on raw leaf tobacco growers in the United States.

The prevalence of cigarette smoking varies by State. Based on data from the Behavior Risk Factor Surveillance System in 2019, the lowest prevalence of cigarette use among adults is in Utah at 7.9 percent, and highest in West Virginia at 23.8 percent.[79] The number of people who smoke cigarettes does not vary exactly with prevalence because of differences in population size by state. However, in general, we expect that there may be disproportionate impacts on certain states, based on level of baseline cigarette prevalence. We request comment on the differential impacts this product standard might have on different regions of the United States.

L. International Effects

We expect that the proposed rule, if finalized, would have the same impact on foreign firms that sell products in the U.S as domestic firms. While foreign firms do not bear the burden of user fees, we expect affected importers will pass on user fee costs to foreign firms so they will face similar impacts overall as domestic firms. We use the Tobacco Import data from 2021[80] to evaluate the distribution of dollar sales of imports across countries and product categories. See Table 73. On its own, the highest value tobacco import category is premium and non-premium cigars. The sum of cigarette tobacco, cigarettes, smokeless tobacco, RYO tobacco, and components is approximately $881 million, which is less than the value of premium and non-premium cigar imports, at $1,327 million. The sum of the value of ENDS products and ENDS components is approximately $1,188 million, still less than the value of cigar imports but greater than the value of cigarette and cigarette-related imports.

We also present the major countries of origin, by percent of the value of imports in Table 73. Brazil, Turkey, and the Dominican Republic are responsible for the largest value of cigarette and cigarette-related imports. The Dominican Republic is a major source of premium and non-premium cigar imports. China is the major source of ENDS and ENDS components imports.

[79] See https://www.cdc.gov/statesystem/cigaretteuseadult.html

[80] Prepared by U.S. Food and Drug Administration, June 9, 2023. Data is supplied by the import filer and is not verified by FDA.

We lack the data to predict how international markets would respond to the rule, but in general we expect the Dominican Republic to experience larger than average negative effects of the rule, based on our data on tobacco imports. However, given that we cannot break cigar imports down by premium and non-premium, the extent to which cigar imports from the Dominican Republic may be disrupted is unclear. On the other hand, China may experience larger than average positive effects under the proposed standard, if finalized, as we expect the prevalence of ENDS product usage to increase over the time horizon. Similarly, demand for smokeless products may increase imports of these products under the proposed product standard, if finalized, potentially increasing imports of smokeless tobacco products, primarily from Sweden and India. Attributing the effects of the rule to specific countries is uncertain. We request comment on anticipated international effects of the rule.

Table 73. Value of Tobacco Imports in 2021 (2022 USD, millions) and Major Trading Partners

	Value (Millions USD)	Major Trading Partners (Percent of total imports by declared value)
Cigarette Tobacco	$339.00	Brazil (29%); Turkey (22%)
Cigarettes	$143.72	Canada (56%); Turkey (21%)
Smokeless Tobacco	$63.36	Sweden (37%); India (37%)
RYO Tobacco	$40.92	The Dominican Republic (61%)
Cigarette Component, Part, or Accessory	$157.54	France (23%); The Dominican Republic (14%)
RYO Tobacco Component, Part, or Accessory	$216.49	Spain (31%); Indonesia (31%)
Cigar	$1,326.88	The Dominican Republic (57%); Nicaragua (26%)
Cigar Component or Part	$32.90	The Dominican Republic (36%); Indonesia (29%)
Pipe Tobacco	$18.02	Denmark (49%)

Waterpipe Tobacco	$41.75	United Arab Emirates (87%)
Waterpipe Tobacco Component or Part	$9.48	China (61%)
Electronic Nicotine Delivery System	$366.53	China (97%)
Electronic Nicotine Delivery System Component/Part	$821.07	China (95%)
Nicotine Delivery Product	$54.98	India (40%); Switzerland (28%); Sweden (24%)
Pipe, Pipe Component or Part	$9.90	China (47%); Italy (17%)
Grand Total	*$3,642.52*	

M. Uncertainty, Sensitivity, and Extended Analyses

1. Estimates of this Proposed Standard without Adjusted Baseline

The PHM was initially developed to model the impact of the nicotine product standard prior to the development of the Menthol and Cigar Flavors Product standards. Therefore, we present an additional analysis of the nicotine product standard in the absence of the Menthol and Cigar Flavors Product Standards. We use the same methods described in the main analysis above, but using baseline PHM output that is not adjusted for the Cigar Flavors or Menthol Rules. In Table 74 we present the total annualized and present value for the costs, benefits, and transfers under this alternative baseline assumption and the difference between these estimates and the estimates in the main analysis. The present and annualized values are higher here than in the main analysis because under this alternative baseline, the people who are expected to quit as a result of the Menthol or Cigar Flavors Product Standard would still be smoking. We request comment on these estimates.

Table 74. Summary of Benefits, Costs, and Transfers at a 2% Discount Rate Without Adjusting for Menthol and Cigar Flavors Proposed Rules ($2023 Millions)

	Unadjusted "No Menthol, No Cigar Flavors" Baseline			Difference between Proposed Rule and Unadjusted Baseline		
	Primary	Low	High	Primary	Low	High
Benefits						
Present Discounted Value	$37,070,042	$9,875,979	$40,500,827	-$6,459,426	-$2,244,034	-$7,280,493
Annualized Value	$1,328,552	$353,945	$1,451,508	-$231,499	-$80,424	-$260,925
Costs						
Present Discounted Value	$83,962	$24,322	$106,977	-$25,998	-$5,064	-$30,828
Annualized Value	$3,009	$872	$3,834	-$932	-$181	-$1,105
Transfers: Federal Governments to Consumers						
Present Discounted Value	$114,954	$39,813	$123,498	-$784	-$1,147	-$3,152
Annualized Value	$4,120	$1,427	$4,426	-$28	-$41	-$113
Transfers: State Governments to Consumers						
Present Discounted Value	$235,471	$81,463	$253,284	-$703	-$1,999	-$5,582
Annualized Value	$8,439	$2,920	$9,077	-$25	-$72	-$200
Transfers: From Firms to Consumers						
Present Discounted Value	$806,539	$288,785	$739,586	-$249,485	-$114,811	-$248,425
Annualized Value	$28,906	$10,350	$26,506	-$8,941	-$4,115	-$8,903
Transfers: From User Fees owed by Combusted Tobacco to Noncombusted Tobacco						
Present Discounted Value	$8,483	$633	$12,735	$798	$101	$131
Annualized Value	$304	$23	$456	$29	$4	$5

2. Sensitivity Analysis of PHM Modeling Assumptions

The PHM output included several sensitivity analyses considering baseline conditions without adjusting for the menthol and cigar flavors proposed rules. These analyses accounted for the following: an increase in noncombusted product initiation; different assumptions of people who smoke cigarettes switching to noncombusted products per year; decrease in cigarette smoking initiation; lower and higher noncombusted product mortality risk compared to baseline; different assumptions for dual product use mortality risk; and changes in baseline mortality rate projections. In general, these various assumptions in the PHM are discussed in detail in Section VIII.D.1 and Table 6 of the Preamble of the Proposed Rule. We have re-produced Table 6 from the Preamble below as Table 75.

Table 75. Impact of Varying Unadjusted Baseline Assumptions on Projected Smoking Prevalence and Avoided Mortality and Morbidity by 2100. Median (5^{th}, 95^{th} Percentiles) Estimates

Scenario	Projections Through Year 2100			
	Cigarette Smoking Prevalence (%)	Cumulative Tobacco-Attributable Mortality Avoided (Millions)	Cumulative Life Years Gained (Millions)	Cumulative QALYs Gained from Reduced Smoking Morbidity (Millions)
Main scenario	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	76.4 (26.5, 82.5)	53.1 (27.5, 54.4)
Baseline noncombusted tobacco product trajectory				
Increased noncombusted initiation	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	76.5 (26.7 82.5)	53.1 (27.5, 54.4)
50% increased complete switching	0.13 (0.06, 1.7)	4.2 (1.7, 4.5)	74.9 (28.6, 80.7)	51.9 (29.0, 52.9)
100% increased complete switching	0.12 (0.06, 1.5)	4.2 (1.8, 4.4)	73.6 (30.3, 79.0)	50.8 (30.2, 51.6)
Baseline smoking initiation trajectory				
25% decrease in smoking initiation during the period 2021-2030	0.13 (0.1, 1.6)	4.1 (1.5, 4.4)	72.9 (24.3, 79.0)	45.2 (22.9, 46.4)
Baseline smoking cessation				
10% increase in smoking cessation	0.15 (0.1, 1.8)	4.0 (1.5, 4.3)	70.9 (24.9, 76.4)	50.1 (26.3, 51.2)
Baseline noncombusted mortality relative risk (RR)				
Higher RR than main scenario (RR=1.3)	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	75.0 (26.0, 81.4)	53.1 (27.5, 54.4)
Lower RR than main scenario (RR=1.1)	0.2 (0.1, 1.9)	4.4 (1.6, 4.7)	77.2 (26.9, 83.2)	53.1 (27.5, 54.4)
Baseline dual use RR				

Dual use RR is 18% greater than for cigarette smoking	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	75.9 (25.0, 82.4)	53.1 (27.5, 54.4)
Dual use RR is the average of cigarette and noncombusted use RR	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	77.0 (28.6, 82.6)	53.1 (27.5, 54.4)
Dual use RR is equal to the noncombusted use RR	0.2 (0.1, 1.9)	4.3 (1.6, 4.6)	77.6 (30.7, 82.7)	53.1 (27.5, 54.4)
Baseline mortality rate projections				
Keep mortality rates constant starting at 2060	0.2 (0.1, 2.0)	4.7 (1.9, 5.1)	77.9 (28.2, 83.9)	53.0 (27.4, 54.2)

3. Illicit Trade and Adverse events

In Section II, we use the PHM primary illicit trade scenario that assumes 5.9 percent of people who are predicted to quit smoking in the PHM output would instead continue smoking NNC combusted tobacco products through an illicit market, and 2.6 percent of youth and young adults would seek to smoke NNC cigarettes via illicit trade (2). The 5.9 percent estimate is based on findings from the International Tobacco Control United States Survey (227), estimating that 5.9 percent of U.S. citizens who smoke cigarettes last purchased cigarettes from low-tax locations. The PHM also presents estimates under two alternate illicit trade assumptions about the proportion of people who smoke cigarettes who would use illicit cigarettes instead of quit smoking. Specifically, the PHM considers a low-end estimate of 3.8 percent based on 2017 estimates of illicit trade volume in cigarettes from Euromonitor International (236). This estimate excludes inter-state smuggling for purposes of tax avoidance. The PHM uses 21 percent as a high-end estimate based on the difference in non-compliance rates between reduced nicotine intervention groups (78 percent) and control groups assigned to NNC cigarettes (57 percent) in clinical trial data from Nardone et al. (237) and Donny et al. (32). Participants had easy access to legal NNC cigarettes when the trial was conducted. The difference in non-compliance rates reflects the increased likelihood that participants assigned to VLNC cigarettes would seek NNC cigarettes that are easily accessible. This estimate of 21 percent also represents the high-end of the range of illicit cigarette sales in the U.S. estimated in the National Research Council report (238). Finally, the PHM incorporates changes in smoking initiation assuming that youth and young adults who would have initiated NNC cigarettes (in the absence of a rule) would seek to smoke NNC cigarettes via illicit trade. We request comment on these estimates and assumptions. The model also uses findings from an expert elicitation developed to gauge the impact of Menthol Cigarette Product Standard in the United States (37), which indicate that among people ages 12-24 who would have otherwise initiated menthol cigarette use, 2.6 percent (primary

estimate) would initiate illicit menthol cigarette use (experts' estimates ranged from 0 percent (low estimate) to 10 percent (high estimate)).

The PHM estimates of illicit trade do not include any countervailing health impacts, beyond the change in prevalence. That is, the PHM assumes that the health risks of illicit NNC combusted tobacco products is the same as the risks of NNC combusted products legally marketed without the proposed standard. We request comment and data on any health impacts associated with illicitly traded combusted tobacco products or the availability of products and components that individuals could use to boost nicotine in a combusted product for their personal consumption.

In our main analysis, which uses the primary level (5.9 percent of smokers may divert to use of NNC cigarettes, and 2.6 percent of youth and young adults would seek to smoke NNC cigarettes) of illicit trade for benefits estimates, we estimate the total present value of benefits of the rule to be approximately $30.6 trillion discounted at 2 percent. Assuming a low level of illicit trade (3.8 percent of smokers may divert to use of NNC cigarettes, and 10 percent of youth and young adults would seek to smoke NNC cigarettes), that same measure is approximately $30.7 trillion, which is an increase of approximately 0.3 percent. Assuming a high level of illicit trade (21 percent), total benefits are estimated to be $29.7 trillion (discounted at 2 percent), which is a decrease of approximately 3 percent.

The level of illicit trade also affects our low and high estimates of benefits. In general, assuming a low level of illicit trade would increase our low estimates by 6.4 percent, and increase the high estimates by 0.1 percent, compared to the primary level of illicit trade. Conversely, assuming a high level of illicit trade would decrease our low estimates by 47 percent, and decrease the high estimates by 1 percent, compared to the primary level of illicit trade.

Our estimates of the benefits of the rule are not generally sensitive to the level of illicit trade assumed in the PHM. A notable exception is in the case of a high level of illicit trade, the lower bound estimates are 47 percent lower than the estimates we use in our main results. Nonetheless, the primary estimates of benefits are roughly similar across all illicit trade scenarios.

Table 76. Total Benefits (All Mortality + Morbidity, 2023 USD Billions) Comparing Illicit Trade Scenarios Under the Low, Primary, and High Impact Policy Scenarios

Total Benefits (All Mortality + Morbidity) (2023 USD Billions)			
Primary Illicit Trade Scenario[1]			
	Primary	Low	High
Present Value 2%	$30,611	$7,632	$33,220

Annualized Value 2%	$1,097	$274	$1,191
Low Illicit Trade Scenario[2]			
Present Value 2%	$30,720	$8,121	$33,256
Annualized Value 2%	$1,101	$291	$1,192
High Illicit Trade Scenario[3]			
Present Value 2%	$29,685	$4,055	$32,901
Annualized Value 2%	$1,064	$145	$1,179

[1] 5.9 percent of smokers may divert to use of NNC cigarettes, and 2.6 percent of youth and young adults would seek to smoke NNC cigarettes.
[2] 3.8 percent of smokers may divert to use of NNC cigarettes, and 0 percent of youth and young adults would seek to smoke NNC cigarettes.
[3] 21 percent of smokers may divert to use of NNC cigarettes, and 10 percent of youth and young adults would seek to smoke NNC cigarettes.

We note that we estimate costs in the main analysis using the zero illicit trade PHM output to ensure that we do not attribute any illicit market sales to the participants in the legal marketplace. We do, however, note that there could be varying levels of enforcement costs across the illicit trade scenarios. Enforcement costs are a small fraction of total costs and subsequently would not change the overall impact of this product standard. We request comment on enforcement costs under different levels of illicit trade.

4. Effect of the Policy with Other Tobacco Control Policies

In recent years, state and local tobacco control policies have proliferated. In this section, we summarize policies in two areas: increasing the minimum age for sale of tobacco products and implementing excise taxes on ENDS products. In addition to the policies discussed here, we note that there have been state and local policies banning characterizing flavors in tobacco products; however, some of these policies may be superseded by the Menthol and Cigar Flavors Product Standards, if finalized. The Menthol and Cigar Flavors Product Standards are already built into the baseline of our analysis.

The first policy trend noted above is increasing the minimum age for sale of tobacco products. By July 2019, seventeen states and over 475 localities had increased the minimum age of sale to 21 (239). Then, in December 2019, the President signed the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94, div. N, tit. I, subt. F, sec. 603, 133 Stat. 2534, 3123-24), making 21 the minimum age of sale at a national level. The PHM includes tobacco use

inputs from 2020, accounting for early impacts of the increase in the minimum age of sale. We request comment on methods and evidence—for example, extrapolation from state-derived empirical evidence, such as (240) —that might be relevant in accounting for increasing numbers of cohorts being subject to the increased minimum age of sale.

The second recent policy trend has been for states to collect excise taxes on ENDS products and other changes to the ENDS landscape. As of October 2022, 30 states, the District of Columbia, and Puerto Rico have enacted excise tax legislation for ENDS products (241; 242). This proposed rule, if finalized, may increase ENDS use due to those who smoke NNC cigarettes and certain other combusted tobacco products switching to ENDS products and therefore generate additional tax revenue in these jurisdictions. In 2021 and 2022, FDA issued negative marketing determinations for many ENDS premarket tobacco product applications, which required the products to be taken off or not introduced to market.[81]

This complicated patchwork of rules makes it difficult to estimate the exact impact of this proposed rule, if finalized, given that the baseline set of tobacco control policies varies across jurisdictions and continues to evolve. Moreover, we anticipate that additional jurisdictions may enact rules that would limit access to various tobacco products prior to a nicotine final rule. This suggests that the proposed rule, if finalized, may have a smaller impact than we estimate if newly enacted state or local policies deter combusted tobacco consumption. We request comment on how state and local policies may impact our analysis.

However, while state and local policies are important, we note that they can potentially be avoided by simply making purchases outside of the locality with the tobacco control policy. A national rule provides a more uniform product standard, making compliance and enforcement approaches more consistent.

5. Estimating Monetized Benefits with VSL Range

In the analysis in Sections II.G, we report a range of health benefits that result from the primary, low, and high PHM output and use the central VSL to monetize these benefits. In Table 77, we include a sensitivity analysis of the total monetary value of health benefits using a range of VSL and value per QALY estimates. Specifically, we simulate VSL using a triangular distribution with minimum, maximum, and modal values specified by the low, high, and central VSL values provided by HHS (64) and multiply the simulated VSL by the estimated averted deaths predicted by the PHM. We use the same simulation approach to value the QALYs gained by multiplying the estimated QALYs gained from the PHM by a simulated value per QALY.

Total benefits using a central VSL are presented again, along with the total benefits using the full VSL range. See Table 77. The present discounted value of benefits using the central VSL

[81] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders

ranges from approximately $7.6 trillion to $33.2 trillion, with a primary estimate of $30.6 trillion at a 2 percent discount rate. The present discounted value of benefits using the simulated VSL ranges from approximately $7.2 trillion to $41.8 trillion, with a primary estimate of $27.7 trillion at a 2 percent discount rate. The annualized values of the primary estimates are approximately $1.1 trillion using a 2 percent discount and central VSL and $994 billion at a 2 percent discount rate and simulated VSL.

Using the full range of VSL values to value premature averted mortality results in a greater range of benefits, with a slightly smaller primary estimate due to the shape of the distributions of averted mortality and VSL.

Table 77. Total Benefits Using Central and Simulated VSL Values (2023 USD, Billions)

Total benefits using the primary VSL			
	Primary	Low	High
Present Value 2%	$30,611	$7,632	$33,220
Annualized Value 2%	$1,097	$274	$1,191
Total benefits using a range of VSL			
	Primary	Low	High
Present Value 2%	$27,722	$7,210	$41,815
Annualized Value 2%	$994	$258	$1,499

6. Sensitivity Analysis on the Value per Statistical Life

In our main analysis, we monetize benefits of the proposed rule from tobacco-attributable mortality avoided using a VSL approach. Our primary estimates apply HHS's central estimate of VSL. This central estimate reflects the mid-point of measured population willingness to pay for mortality risk reductions reported in several revealed-preference studies, stated-preference studies, and a meta-analysis identified in an HHS-commissioned review of the VSL literature (243). We address uncertainty in measurements of population willingness to pay for mortality risk reductions by applying a range of VSL estimates when reporting our range of benefits in a previous sensitivity analysis (See Section II.M.5). For reference, the low and high estimates of VSL are about 47% and 152% of the central estimate of VSL, respectively.[82]

Several additional sources of uncertainty could result in VSL estimates that differ from those used in the main analysis of benefits for this proposed rule. In this section, we discuss the 2021 HHS Guidance "Valuing COVID-19 Mortality and Morbidity Risk Reductions in U.S.

[82] HHS's estimates of VSL are based on low, central, and high estimates from the literature review of $4.2 million, $9.0 million, and $13.7 million, reported in 2013 dollars. HHS updates these estimates for inflation and real income growth to produce a range of year-specific VSL estimates. The magnitudes of the low, central, and high estimates of VSL have a constant ratio. As an example calculation, $4.2 million / $9.0 million ≈ 47%.

Department of Health and Human Services Regulatory Impact Analyses" that explores a quantitative adjustment to the VSL in the context of assessing polices that result in large risk reductions, such as those associated with COVID-19. Several characteristics of the risks associated with tobacco-attributable mortality may differ from the types of risks typically considered in VSL studies, which might introduce bias into our benefit estimates. Individual characteristics of the population experiencing the benefits of the proposed rule may also differ from the typical population underlying studies that estimate VSL, which could also introduce bias.

First, the mortality risks associated with long-term tobacco product use are substantial. The PHM, adjusted to account for the potential impacts of the Menthol proposed product standard, projects a baseline annual average of about 41.4 million U.S. adults will use cigarettes and noncombusted tobacco products over the 40-year time horizon, with a baseline annual average of about 272,564 tobacco-attributable deaths, excluding deaths from secondhand smoke. As a rough comparison that ignores the timing and duration of the cumulative exposure to risk from tobacco use, these estimates indicate an average of about 0.66% of people who use cigarettes and noncombusted tobacco products will die of tobacco-related diseases every year.[83] This annual mortality risk, about 1 in 152, exceeds the types of risks considered in most of the studies that underlie the HHS VSL estimates, which are generally on the order of 1 in 10,000 . Hammitt (244) suggests that policies addressing mortality risks of this magnitude can potentially exceed the magnitude of the risks for which monetizing benefits using the VSL approach is appropriate, without considering adjustments to the choice of VSL (244). In the context of recommending an approach to assessing policies that address risks associated with COVID-19, ASPE noted that "the average rate at which an individual is willing to pay for risk reduction (willingness to pay divided by the risk reduction) decreases as the risk reduction increases," and provided the following guidance for HHS analysts developing regulatory impact analyses (245):

> "Under the standard theoretical model underlying VSL, the rate does not fall very sharply until the individual's willingness to pay rises to 10 percent or more of his or her ability to pay… While the relationship between willingness to pay and the size of the risk reduction depends on the assumptions used in the calculations (especially the income elasticity of VSL), the rate is not likely to decrease substantially until the risk change exceeds about 1 in 1,000; for larger risk reductions, the ratio of willingness to pay to risk reduction will be much smaller than VSL. Since most analyses conducted by HHS are likely to yield mortality risk changes smaller than 1 in 1,000, no adjustment in the VSL for the size of the risk reduction will be needed. In the rare case that a policy leads to a larger risk change, analysts may wish to follow the approach in Hammitt (244) to adjust VSL in sensitivity analysis."

Therefore, we request comment on whether and how VSL estimates should be adjusted to address large mortality risk reductions specifically for the population of those who use tobacco products.

[83] 272,564 / 41,419,769 ≈ 0.66%.

7. Estimated Monetized Benefits from 2065 to 2100

a. Estimated Avoided Premature Mortality from 2065 to 2100

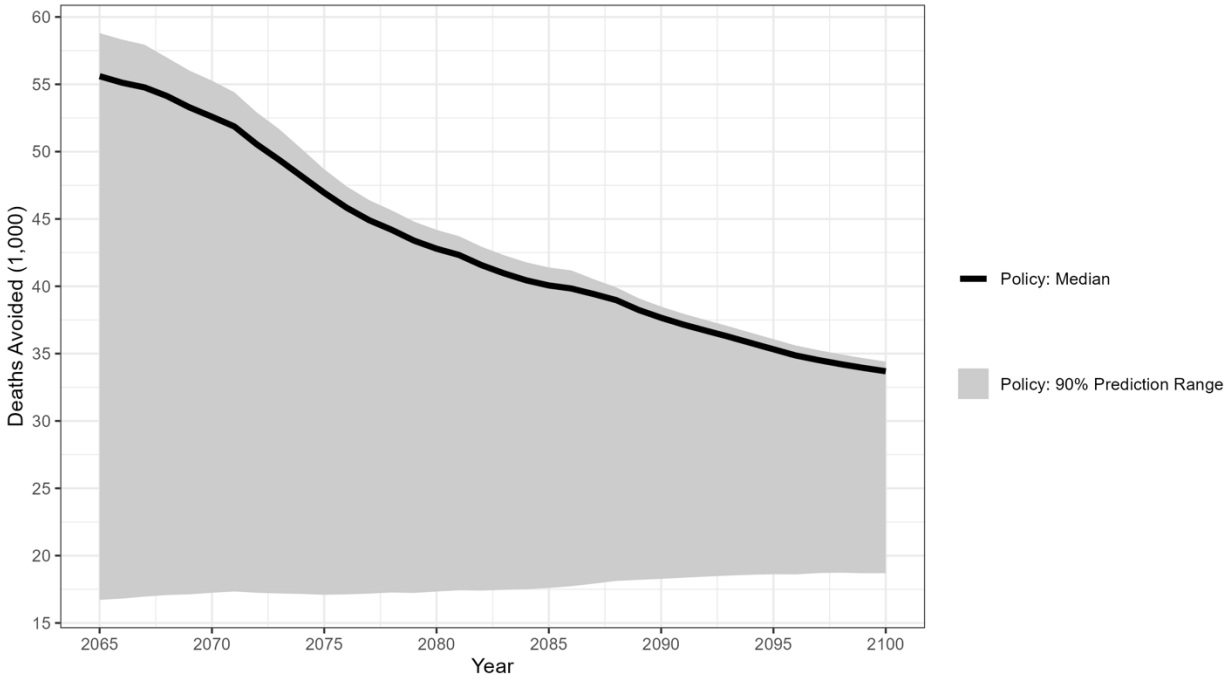
While the analysis in Section II.G.1 monetized avoided premature mortality up to year 2064, this section estimates benefits of avoided premature mortality in later years. We use the extended output from the PHM for the years 2065- 2100 which falls directly after the 40-year time horizon used in the main analysis. Given the structure of the PHM we are unable to distinguish averted mortality that occurs from averted initiation rather than quitting or switching between tobacco products. Therefore, we note that, given the extended time frame analysis only, most of this section's averted mortality come from averted initiation but some may come from tobacco product cessation and switching. This section's analysis predominantly captures mortality benefits due to avoided youth initiation.

As noted in the Institute of Medicine report on raising the minimum legal sale age to 21, impacts on youth related to reductions in smoking-related mortality would "not be observed for at least 30 years after the increased MLA takes effect" (176). Therefore, the additional years (2065 – 2100) capture the increasing impact of the rule on individuals who would be youth during the time horizon of the analysis and would therefore avoid initiation. The PHM's endpoint is 2100, therefore we choose this as the endpoint of this analysis.

In the NPRM, we discuss evidence that the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain, and the earlier an individual begins smoking the less likely they are to quit (246). The maximum nicotine content requirement proposed in this product standard to address nicotine yield would help make cigarettes and certain other combusted tobacco products minimally addictive or nonaddictive, limiting the number of youth and young adults who move beyond experimentation, develop nicotine dependence, and progress to regular use and reducing their risk for smoking-related diseases.

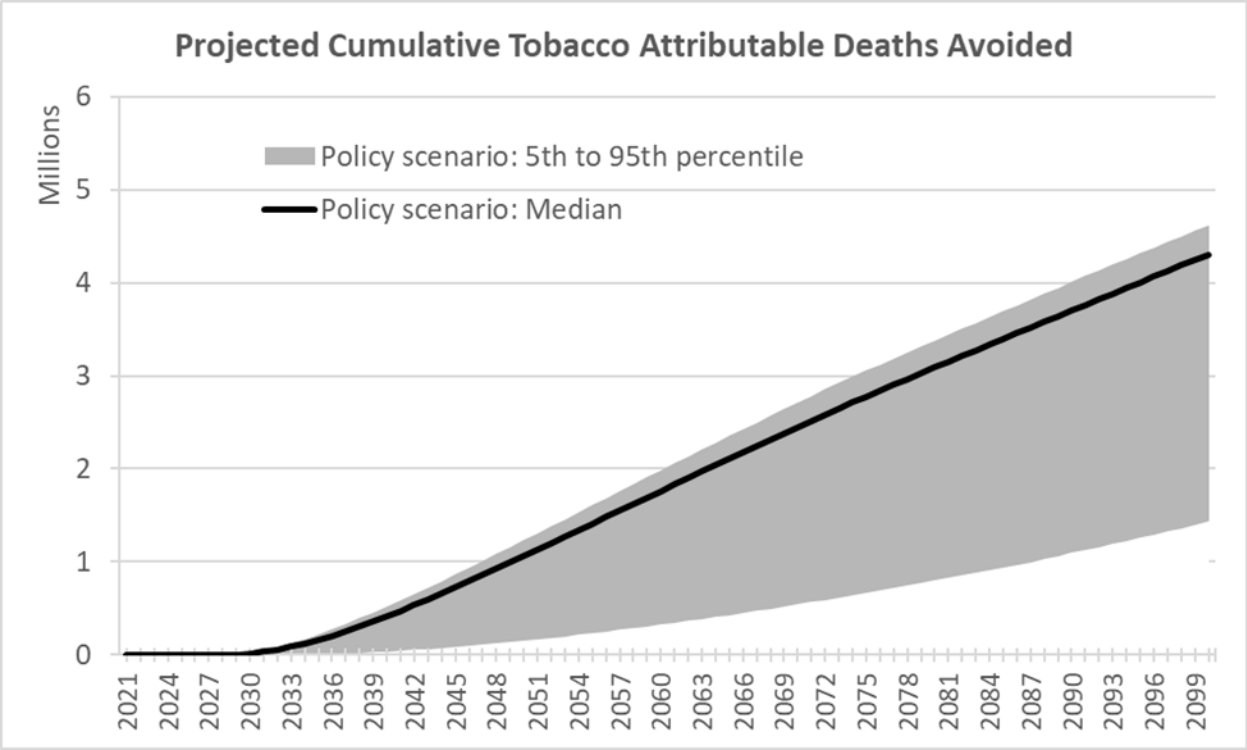
See Figure 29. Across the 2065-2100 time horizon, annual averted tobacco-attributable mortality relative to baseline is estimated to decrease from approximately 55,000 in 2065 to approximately 35,000 by 2100.

Figure 29. Tobacco-Attributable Averted Mortality for Years 2065 - 2100



Although we present the extended modeling output directly following the 40-year time horizon used in the main analysis, estimates in each year depend on how the population changes during the preceding periods; as such, the estimates over 2065-2100 are a direct consequence of outcomes occurring over the initial 40 years and do not represent an independent set of results. Looking across an extended time horizon, the PHM predicts a cumulative total of approximately 4.3 million tobacco-attributable deaths avoided from tobacco product cessation, avoided initiation, and switching to noncombusted tobacco products by 2100. See Figure 30.

Figure 30. Cumulative Tobacco-Attributable Averted Mortality by 2100



b. Extended Analysis of Monetized Benefits

We use the same approach described in Section II.G to monetize the averted mortality described in the previous section. Specifically, we multiply the estimated averted premature mortality by a central value of VSL as recommended by HHS (64).

We summarize our monetized averted mortality in Table 78. The present discounted value using a 2 percent discount rate of total avoided deaths, including those from averted youth initiation, ranges from approximately $8.5 trillion to $19.8 trillion, with a primary estimate of $19.1 trillion.

As discussed above, benefits from 2065 to 2100 are lifetime benefits that accrue mostly to individuals who would be youth, and subsequently avoided initiation, during the initial 40-year time horizon of the analysis. Therefore, we continue to annualize using our initial 40-year time horizon. Using a discount rate of 2 percent, we estimate that the annualized value of benefits, including those from reduced youth initiation, ranges from $303 billion to $707 billion, with a primary estimate of $684 billion.

Table 78. Present Discounted Value and Annualized Value of Quantified Benefits from 2065 to 2100 (2023 $ Billions)

	Primary	Low	High
Present Value 2%	$19,079	$8,463	$19,732
Annualized Value 2%	$684	$303	$707

8. Accounting for Effects on Capital

Regulations that displace or induce capital investments at a point in time may affect present and future consumption differently than regulations that increase or decrease consumption at a point in time. This arises because the return on capital need not equal the social rate of time preference, as taxes on capital, other economic distortions, risk premia, and missing markets can create a sustained divergence between these rates of return and among rates of return to different capital.

The analytically preferred method of handling temporal differences between benefits and costs is to adjust all the benefits and costs to reflect their value in equivalent units of consumption before discounting them. This approach to discounting is sometimes called the "shadow price" approach. Drawing from the recommended rates in OMB's Circular A-4 (247), for the main analysis we use a shadow price of capital of 1.0, which reflects an economy with perfect capital mobility, and for this sensitivity analysis we consider a shadow price of 1.2 which reflects a closed economy with no foreign capital flows.

We identify economic transition costs, producer surplus, and reformulation cost as the impacts that are most likely displace capital investments. We do not evaluate the shadow price of capital for VSL gained from averted mortality as we already discuss uncertainty around VSL in Section II.M.5. We analyze the shadow price of capital by multiplying the undiscounted flow of costs with capital implications by 1.2, then discounting all benefits and costs by our standard 2 percent discount rate. See Table 79. We note that even at the upper bound of the shadow price of capital this policy still has benefits that far outweigh the costs.

Table 79. Shadow Price of Capital Analysis (Applied only to Costs, Millions of 2023 Dollars)

	Primary	**Low**	**High**
Costs: Assuming SPC=1			
Present Discounted Value	$57,964	$19,259	$76,149
Annualized Value	$2,077	$690	$2,729
Costs: Assuming SPC=1.2			
Present Discounted Value	$68,900	$22,958	$88,866

Annualized Value	$2,469	$823	$3,185
Difference between SPC of 1 and SPC of 1.2			
Present Discounted Value	-$10,936	-$3,699	-$12,717
Annualized Value	-$392	-$133	-$456

9. Declines in Baseline Cigarette Product Dollar Sales and Unit Sales

In Section II.H.0.1, we estimate changes in producer surplus under the assumption of a constant price for all combusted and noncombusted products impacted by the rule. However, historical Euromonitor Passport data on cigarette sales and revenue between 2010 to 2021 suggest that revenues and units change at differing rates. For example, cigarette revenue decreased at an annual rate of about 1% between 2010 and 2021 while cigarette units sold decreased at a rate of about 3.3% for an annual increase in the price of cigarettes of about 2.4%. See Table 80 below.

Table 80. Historical Euromonitor Passport Cigarette Revenue and Quantity: 2010 to 2021 in 2023 Dollars

Year	Revenue ($ millions)	Quantity (Millions of sticks)	Average Price (per Pack of 20 sticks)
2010	$125,440	309,124	$8.12
2011	$123,093	300,615	$8.19
2012	$121,951	292,721	$8.33
2013	$119,340	279,539	$8.54
2014	$116,701	270,639	$8.62
2015	$120,017	269,894	$8.89
2016	$119,928	262,468	$9.14
2017	$118,406	252,609	$9.37
2018	$115,683	240,821	$9.61
2019	$111,799	225,528	$9.91
2020	$114,748	225,753	$10.17
2021	$110,836	213,751	$10.37
Mean	$118,162	261,955	$9.11
Slope of Best Fit Line[1]	-$1,119	-8560.5518	$0.22
Slope Relative to Mean	-0.95%	-3.27%	2.36%

[1]The slope of the best fit line is the linear regression coefficient from regressing 'year' on 'revenue', 'quantity', and 'average price', respectively using the 'least squares' method.

In this sensitivity analysis, we estimate producer surplus loss experienced by firms producing cigarettes using a baseline where annual revenues decrease at a rate of 1% and annual units sold decrease at a rate of 3.3%. That is, in this baseline, the average price of cigarettes is increasing annually at a rate of about 2.4% as opposed to the constant price assumption used in the main analysis. In Section II.H.0.1, we compute producer surplus loss for combusted tobacco firms, producer surplus gain for noncombusted tobacco firms, and the net change in producer

surplus for the entire tobacco market. Based on Euromonitor data, the historical trend of increasing pricing only applies to cigarettes and not to all other tobacco products. Consequently, we only focus on producer surplus loss for cigarettes in this sensitivity analysis. Results are shown in Table 81 below. Annualized producer surplus losses in the cigarette market at a 2 percent discount rate for the increasing cigarette price assumption baseline range from $255 million to $1,894 million, with a primary estimate of $1,631 million. The increasing price assumption baseline results in an additional $196 million of annualized costs or about 14% higher than the constant price assumption in the main analysis for the primary estimate.

Table 81. Producer Surplus Loss in the market for Cigarettes under an Increasing Price Assumption: 2025 to 2064 in Millions of 2023 Dollars

	Primary	Low	High
Constant Cigarette Price Baseline			
Present Discounted Value	$40,032	$4,437	$46,807
Annualized Value	$1,435	$159	$1,678
Increasing Cigarette Price Baseline			
Present Discounted Value	$45,499	$7,110	$52,851
Annualized Value	$1,631	$255	$1,894
Difference between Constant Price and Increasing Price Baseline			
Present Discounted Value	-$5,467	-$2,672	-$6,043
Annualized Value	-$196	-$96	-$217

III. Initial Small Entity Analysis

We have examined the economic implications of this proposed rule for small entities as required by the Regulatory Flexibility Act. If a proposed rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the final rule on small entities. FDA finds that this rule will have a significant economic impact on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this document and the Preamble of the Proposed Rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

Table 82. Initial Regulatory Flexibility Analysis Elements

Element	Location
Reasons action is being considered and object of the rule	Section II.A-II.C. of the PRIA
Legal basis for the rule	Section I.C. of the Preamble to the Proposed Rule

Estimate of the small entities impacted	Section II.D. and this section of the PRIA
Compliance requirements	Section II.H. and this section of the PRIA for small business specific estimates
Significant alternatives considered	Section II.J. and this section of the PRIA
Duplicative overlapping and conflicting rules	Section II.M.2. of the PRIA

A. Description and Number of Affected Small Entities

1. Tobacco Product Manufacturers

The data on affected entities comes from CTP's Tobacco Registration and Listing Module Next Generation (TRLM NG) data and Dun & Bradstreet firm data (D&B). We merge TRLM NG data with D&B firm data to identify firm-level characteristics. According to the Small Business Administration (SBA), a small tobacco manufacturer is any firm with under 1,500 employees (248).[84] Because the tobacco manufacturing firms do not all have tobacco manufacturing as their primary business in the D&B data and different lines of business have varying standards to determine small businesses, we determine the number of small businesses by relying on the D&B created small business indicator which D&B determines using the SBA definitions and primary business for each firm. For firms that had missing data for the small business indicator but did have data on the number of employees at the establishment, that data was used to make the determination. We then took the following additional steps to identify small businesses. First, we used data from D&B Ultimate Family Trees to identify TRLM NG registered firms that are owned by larger non-small business organizations and determined them not to be small businesses. We also used Euromonitor Passport data on Company Share of the market to create a list of companies that control significant shares of the market for each of the affected tobacco products. We matched Global Brand Owner and National Brand Owner names to the TRLM NG registered firms list to identify large business when D&B lacked data. 15 firms from the TRLM NG data did not match to D&B data.

At baseline there are 143 registered firms that manufacture affected tobacco products, of which 102 are small, and 41 are non-small[85]. Table 83 summarizes firm size based on whether

[84] Under section 900(16) of the FD&C Act (21 U.S.C. 387(16)), tobacco product manufacturers (and importers) are considered small if they employ "fewer than 350 employees". Note that, "[f]or purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer". 21 U.S.C. 387(16). However, the Small Business Administration's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

[85] Of the 158 firms that manufacture combusted and/or SLT products in the TRLM NG data, only 143 firms were available in the D&B data, Thus some of our analysis is limited to 143 firms.

the firm produces only combusted tobacco products, only noncombusted tobacco products, or both. There are 125 firms that produce only combusted tobacco products, of which 92 are small businesses. There are 10 firms that produce only noncombusted tobacco products, of which 4 are small businesses. Finally, 8 firms produce both combusted and noncombusted tobacco products, of which 6 are small businesses. We note that this may be a lower bound number of entities due to limitations in the data available for this analysis. We request comment on data sources and methods for identifying tobacco manufacturing small businesses.

Table 83. Manufacturing Firms by Tobacco Product Category

Product Category	Small	Non-Small	Total
Combusted Only	92	33	125
Noncombusted Only	4	6	10
Dual Operation	6	2	8
Total	102	41	143

The distribution of the size of small firms is presented Table 84. Most small firms (69 of 102) have fewer than 10 employees.

Table 84. Distribution of Small Tobacco Manufacturers and Revenue by Employee Size in 2023 Dollars

Number of employees	Number of Firms	Average Revenue per Firm ($)
0 to 4	41	$220,449
5 to 9	28	$587,290
10 to 19	11	$1,842,879
20 to 49	14	$4,577,789
50 to 99	5	$13,246,993
100 to 249	1	$31,207,414
250 to 1500	2	$32,060,582

Note: Data on number of firms and revenue are from Dun & Bradstreet accessed in October 2023.

2. Retailers and Wholesalers

To estimate the number of small wholesale and retail entities that may be affected by the proposed product standard, if finalized, we use the estimated number of tobacco-selling wholesale and retail firms and their associated SBA size thresholds by NAICS code from Section

II.E.4. Incorporating 2017 SUSB employment data for tobacco wholesalers and 2017 Economic Census data on firm and establishment counts by size of sales, value of shipments, or revenue for retailers, we match 2023 SBA size thresholds to Census thresholds and estimate the percentage of firms that may be small for each wholesale or retail NAICS code (47) (163).[86] For each wholesaler and retailer NAICS code, we note that the closest Census size threshold is below the SBA size threshold for identifying small businesses. For this reason, our estimate of the percentage of small firms in each category likely represents an underestimate. These calculations can be found in Table 85.

Table 85. SBA Size Standards and Census Size Categories for Wholesale and Retail Categories, 2017

NAICS	Description of NAICS	SBA Standard (employees or $million)	Census Size Category, (employees or $million)	Total Number of Firms	Total Number of Establishments	Firms Below Census Standard	% Small Firms
424940	Tobacco and Tobacco Product Merchant Wholesalers	250	200	1,285	1,513	1,240	96.5
445110	Supermarkets and Other Grocery (except Convenience) Stores	$40.0	$25.0	40,981	65,141	28,897	70.5
445120	Convenience Stores	$36.5	$25.0	25,844	28,460	17,191	66.5
445300	Beer, Wine, and Liquor Stores[a]	$10.0	$10.0	30,313	34,440	25,456	84.0
446110	Pharmacies and Drug Stores	$37.5	$25.0	19,259	45,358	16,609	86.2
447110	Gasoline Stations with Convenience Stores	$36.5	$25.0	56,926	98,788	48,344	84.9
447190	Other gasoline stations	$33.5	$25.0	10,084	16,581	8,683	86.1
452311	Warehouse Clubs and Supercenters	$47.0	$25.0	9	8,202	0	0.0
452319	All other general merchandise stores	$40.0	$25.0	7,857	41,241	6,284	80.0

[86] NAICS codes changed from 2017 to 2022 for Convenience Stores (445131 in 2022), Beer, Wine, and Liquor Stores (445320 in 2022), Pharmacies and Drug Stores (456110 in 2022), Gasoline Stations with Convenience Stores (457110 in 2022), Other gasoline stations (457120 in 2022), Warehouse Clubs and Supercenters (455211 in 2022), All other general merchandise stores (455219 in 2022), and Tobacco Stores (459991 in 2022).

453991	Tobacco Stores[b]	$11.5	$10.0	8,286	10,415	5,646	68.1

[a] Small Business Administration size threshold available for 445310 NAICS code, which is the only detailed code under the aggregate 445300 code.

[b]We note that "Tobacco Stores" may sell a variety of tobacco products including cigarettes, cigars, tobacco, pipe, and other smokers' supplies. We request comment on data with additional specificity that would allow us to identify the number of entities that only sell premium cigars.

In Table 86, we apply the percentage of firms that may be small from the 2017 data to our estimates of firms that sell tobacco products in 2021 and estimate that about 113,000 small wholesale and retail firms may be impacted by the product standard.

Table 86. Estimate of Small Wholesale and Retail Establishments with Tobacco Sales in 2020

NAICS	NAICS Description	Total Firms with Tobacco Sales	Share of Small Firms	Small Firms with Tobacco Sales
42494	Tobacco and Tobacco Product Merchant Wholesalers	1,343	96.5	1,296
44511	Supermarkets and Other Grocery (except Convenience)	18,054	70.5	12,728
44512	Convenience Stores	28,414	66.5	18,895
44530	Beer, Wine, and Liquor Stores	17,103	84	14,366
44611	Pharmacies and Drug Stores	8,172	86.2	7,045
44711	Gasoline Stations with Convenience Stores	51,305	84.9	43,558
44719	Other gasoline stations	2,036	86.1	1,753
452311	Warehouse Clubs and Supercenters	30	0	0
452319	All other general merchandise stores	6,094	80	4,875
453991	Tobacco Stores	12,492	68.1	8,507
	Total	**145,044**		**113,024**

3. Small Governmental Jurisdictions

Small governmental jurisdictions are considered a "small entity" under the Regulatory Flexibility Act (RFA) (see Sections 601(5-6 (5 U.S.C. 601)). Small governmental jurisdictions are defined as "governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand." We do not have data to estimate how many small governmental jurisdictions would be affected by this proposed rule.

B. Description of the Potential Impacts of the Rule on Small Entities

In this section, we separately consider impacts to small entities for the three different types of firms as discussed above, small businesses that manufacture only combusted tobacco

products, small businesses that manufacture only noncombusted tobacco products, and dual operation small businesses that manufacture both combusted and noncombusted tobacco products. In this analysis, we project impacts to small businesses from the standpoint of how businesses look forward to make decisions to remain in the market, assuming small businesses of all sizes continue to operate and comply with this product standard. We note that this may differ from assumptions and results in other parts of this regulatory impact analysis. For the purpose of the small entity analysis, we consider all lost revenue to be a cost to the firms. We expect many small firms selling only or primarily combusted tobacco products would decide to shut down or shift industries rather than experience the costs of this regulation. We request comment on how best to present the impacts to small entities.

1. Combusted Tobacco Product Manufacturers

Small businesses manufacturing only combusted products are subject to the costs to firms as described in the cost section (see Section II.H.1). This includes the cost of reading and understanding the rule, reformulation costs, the cost to submit pathways to market application, testing costs as well as reductions in revenue and potentially increased user fee assessments as discussed in the transfer section (see Section II.I).

We discuss the cost to read and understand the final rule in Section II.H.1.c. We estimate a one-time cost of reading and understanding the rule that is incurred in year zero of between $1,212 to $7,698 per affected entity with a primary estimate of $4,106.

To comply with the nicotine yield product standard, small entities would need to reformulate their current products to meet the new nicotine content thresholds. Using the FDA Food Reformulation Model, as discussed in Section II.H.1.d, we estimate the cost for a small company to reformulate at $115,885 per product. In the upper bound (related to the high impact policy scenario), we assume firms would reformulate 1 product. For the lower bound (related to the low impact policy scenario), we assume firms would reformulate 4 products. We use the midpoint of 2.5 products as the primary estimate. We multiply the cost per product reformulation by the number of expected products to estimate the reformulation cost per small entity. We estimate that reformulation costs for the average small entity would range between $463,542 and $115,885, with a primary estimate of $289,714. We note that these costs may be overestimated for some small businesses that do not engage in certain types of manufacturing activities such as importers or re-packagers currently registered as tobacco manufactures. For example, small business that purchase pre-blended tobacco for rolling or packaging may not incur the full cost of a product reformulation, although they would be expected to pay a higher cost for that tobacco due to the reformulating firms passing costs through the supply chain, which we are unable to measure quantitatively. Reformulation costs are a one-time cost that occur in 2026 (year 1) of the policy. See Table 87 below.

Table 87. Reformulation Costs per Small Entity

	Primary	Low	High
Number of Products	2.5	4	1
Cost per Reformulation	$115,885	$115,885	$115,885
Total Cost	$289,714	$463,542	$115,885

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

Each new VLNC product would need to choose a pathway to market and submit a premarket application to FDA. We discuss the pathways and their associated costs in Section II.H.1.f. We assume all small entities would choose to use the SE pathway. We draw our estimate from the "Content and Format of Substantial Equivalence Reports" Final Rule to estimate the cost to submit one SE submission at $19,614 (159) (86 FR 55224, October 10, 2021). We estimate the cost of submitting market applications for reformulated products by multiplying the estimated number of reformulated products under the low, primary, and high estimates by the cost per SE submission. We estimate a primary cost of $49,035 with a range of $78,457 to $19,614, as shown below in Table 88. Application submission costs are a one-time cost that occurs in 2026 (year one) of the policy.

Table 88. Application Submission Costs per Small Entity

	Primary	Low	High
Number of Products	2.5	4	1
Cost per Reformulation	$19,614	$19,614	$19,614
Total Cost	$49,035	$78,457	$19,614

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

Small entities manufacturing combusted tobacco products affected by this proposed rule would be subject to nicotine content testing to ensure their product offerings are compliant with the proposed product standard. Using Euromonitor Passport data on Company Share of the market by Global Brand Owner, we assume that small entities are represented by the "Others" category and therefore sold 4.6 percent of total volume of cigarettes in 2021. We then multiply the small entities percentage of the market by the total number of cigarettes sold under the low, primary, and high policy impacts, in each year of the 40-year time horizon, as shown in Figure 12. As discussed in Section II.H.1.g, we assume a batch size of 8 million cigarettes. We divide the total cigarette volume for small entities by 8 million to compute the required number of batches for testing each year. The testing cost per batch ranges from $269 to $737, with a medium estimate of $404. We multiply testing cost per batch by the number of batches each year to calculate the total annual cost of testing for small entities. To assess the impact on the average

small entity, we divide the total annual cost for small entities by the 92 small entities producing only combusted tobacco products discussed above. We assume that testing costs of affected combusted products that are not cigarettes are proportional to the revenues of each product relative to cigarettes in the Euromonitor data presented in Table 6, consistent with the methods for computing testing costs in Section II.H.1.g.

Table 89 shows the estimated testing cost for all combusted products produced by the average small entity producing only combusted tobacco products. Testing is a recurring cost that begins in 2027 and continues until the end of the 40-year time horizon. Testing costs decline over time as fewer combusted tobacco products are manufactured and sold due to ongoing reductions in projected smoking prevalence. We note that the 'low policy impact scenario' has the highest relative combusted tobacco use prevalence and quantity of combusted tobacco products sold and consequently has the highest testing costs for affected combusted tobacco products. In 2028, testing costs range from $2,353 to $61 per small entity, with a primary cost of $1,469. By 2064, testing costs range from $390 to $41, with a primary estimate of $50.

Table 89. Testing Costs for All Affected Combusted Products per Small Entity

Year	Primary	Low	High
2025	$0	$0	$0
2026	$0	$0	$0
2027	$0	$0	$0
2028	$1,469	$2,353	$61
2029 (5 years)	$679	$2,142	$53
2034 (10 years)	$75	$1,377	$45
2044 (20 years)	$52	$684	$44
2054 (30 years)	$51	$465	$42
2064 (40 years)	$50	$390	$41

Note: The low estimates relate to the low policy impact scenario (e.g., lowest estimate of averted deaths) from the PHM, while the high estimates relate to the high policy impact scenario (e.g., highest estimate of averted deaths) from the PHM.

We expect this proposed product standard, if finalized, to significantly reduce cigarette, RYO tobacco, non-premium cigar, and pipe tobacco use and increase use of smokeless and ENDS products as some consumers switch from covered products to non-covered tobacco products. Therefore, we expect the absolute amount of user fees assessed for domestic manufacturers and importers of cigarette, RYO tobacco, non-premium cigar, and pipe tobacco domestic manufacturers and importers to decline, while the amount of user fees assessed for domestic manufacturers and importers of smokeless tobacco to increase. Because combusted tobacco revenues would decline as a result of the product standard while the total amount of user fees collected remains fixed, we expect the user fee assessment per firm as a percent of post-tax

revenue to increase significantly, as seen below over the 40-year time horizon. Please refer to Section II.I.4 of the PRIA for additional discussion on user fees.

We lack individual sales data for small businesses in order to assess individual firm user fee obligations by product category. Therefore, we assume that the product portfolio of each small business is proportional to the market share of total sales for each product category as shown in Table 6. We compute the user fee obligation as a percentage of revenues for the individual small business by multiplying the market share of sales for each product category by the user fee obligation for that product category in each year of the 40-year time horizon. We then take the difference between user fee obligations under the policy scenario and the baseline to find the policy effect on user fee obligations for the average small business as a percentage of revenue. Table 90 presents the additional user fee obligation as a percentage of revenue by year. Increased user fee assessments as a percentage of post-tax revenue are first experienced in 2028 and range from, 0.05 percent to 111.47 percent, with a primary estimate of 1.55 percent. By 2064, they range from 2.31 percent to 17.23 percent, with a primary estimate of 15.19 percent.

Table 90. Additional Combusted User Fee Obligation as Percentage of Revenue over a 40-year time horizon

Year	Primary	Low	High
2025	0.00%	0.00%	0.00%
2026	0.00%	0.00%	0.00%
2027	0.00%	0.00%	0.00%
2028	1.55%	0.05%	111.47%
2029 (5 years)	4.02%	0.08%	18.78%
2034 (10 years)	17.77%	0.37%	17.51%
2044 (20 years)	16.13%	1.20%	17.51%
2054 (30 years)	15.49%	1.91%	17.39%
2064 (40 years)	15.19%	2.31%	17.23%

We expect that small firms would experience long-term changes to their revenue due to the proposed product standard, if finalized. For the purpose of the small entity analysis, we consider all lost revenue to be a cost to the combusted tobacco manufacturing firms. We estimate the lost revenue using reductions in smoking prevalence from the PHM under each policy scenario relative to baseline smoking prevalence for both cigarettes and cigars. As discussed in Section II.E.3, we assume price for each tobacco product is held constant, and therefore measure lost revenues in each year as equal to the relative difference between baseline quantity and the quantity under each of the policy scenarios with the assumption that each firm retains their market share of volume of affected products after the policy. We request comment on our approach.

Table 91 shows the percentage reduction in combusted tobacco product revenue relative to baseline. The policy first impacts revenues in 2028, resulting in a 4 percent, 60 percent, and 99 percent reduction in revenue relative to baseline for the low, primary, and high impact policy scenarios, respectively. By the end of the 40-year time horizon, revenues are reduced by 20 percent, 97 percent, and 99 percent relative to baseline for the low, primary, and high impact policy scenarios.

Table 91. Percentage Reduction in Combusted Revenue Relative to Baseline over a 40-Year Time Horizon

Year	Primary	Low	High
2025	0%	0%	0%
2026	0%	0%	0%
2027	0%	0%	0%
2028	60%	4%	99%
2029 (5 years)	81%	8%	99%
2034 (10 years)	90%	11%	99%
2044 (20 years)	94%	14%	99%
2054 (30 years)	96%	17%	99%
2064 (40 years)	97%	20%	99%

Table 92 presents the average cost (i.e., costs, reductions revenue) of the proposed standard per small entity that manufacture only combusted tobacco products over the 40-year time horizon. Annualized costs range from $5.5 million to $18.2 million, with a primary estimate of $17 million at a 2 percent discount rate. The average small tobacco product manufacturer has annual revenue of $2,660,851 based on the Dun & Bradstreet data used to identify registered small firms described and presented above in Table 84. Given that these costs are averaged across all small tobacco product manufacturers, they may represent an overestimate for firms of the smallest size and an underestimate for relatively larger small tobacco product manufacturers.

Table 92. Estimated Average Cost per Small Combusted only Manufacturer over a 40-Year Time Horizon at a 2% Discount Rate (2023 $)

	Primary	Low	High
Discounted Total Cost (40 years)	$406,050,497	$138,110,023	$432,451,739
Annualized Cost (40 years)	$17,055,058	$5,800,940	$18,163,971

Note: The average small firm has annual revenue of $2,660,851 based on Dun & Bradstreet data presented in Table 84.

Table 93 presents the undiscounted costs as a percentage of revenue by number of employees. Reading and understanding costs are a one-time cost that occurs in 2025 (year 0). There is a two-year period before full implementation of the policy during which firms are

assumed to engage in compliance activities (such as product testing and premarket authorization of the new products). Reformulation and application submission costs are a one-time cost that occur in 2026 (year 1). Firms experience recurring costs of testing nicotine content, increased user fee obligations, and lost revenues beginning in 2028 and continuing throughout the remainder of the 40-year time horizon. For firms of the smallest size, reformulation and application submission costs in 2026 represent a significant burden, as high as 246 percent of revenue in the low policy impact estimate and 154 percent of revenue in the primary policy impact estimate. As noted previously, these calculations are estimates for those small tobacco product manufacturers that may remain in the market for combusted tobacco products. Recurring costs gradually increase across time as lost revenue relative to baseline grows and user fee obligations as a percentage of revenue increases. By 2064, costs of the policy are 23 percent of revenue in the low estimate and 112 percent of revenue in the primary estimate. The high policy impact scenario exceeds the primary policy impact scenario in all cases, so we show only the low and primary estimates for brevity. Given the substantial estimated impacts of the proposed standard expressed as a percentage of revenues to small entities, we anticipate the proposed product standard would likely result in firm closures as small manufacturers of combusted tobacco products seek alternative business opportunities. We request comment on this conclusion.

Table 93. Undiscounted Costs to Small Combusted Only Tobacco Manufacturers as a Percentage of Revenue by Employee Size Under the Low and Primary Policy Impact Scenarios in Certain Years

Year	2025	2026	2027	2028	2029 (5 yr)	2034 (10 yr)	2044 (20 yr)	2054 (30 yr)	2064 (40 yr)
Cost Drivers	Reading and Understanding (One-time)	Reformulation, Application Submission (One-time)	None	Testing, Increased User Fee Assessments, Lost Revenue (Recurring 2028 to 2064)					
Number of employees	**Panel A: Undiscounted Low Cost as Percentage of Revenue**								
0 to 4	2%	246%	0%	6%	9%	12%	16%	19%	23%
5 to 9	1%	92%	0%	5%	8%	12%	16%	19%	23%
10 to 19	0%	29%	0%	5%	8%	12%	16%	19%	23%
20 to 49	0%	12%	0%	5%	8%	12%	16%	19%	23%
50 to 99	0%	4%	0%	5%	8%	12%	16%	19%	23%
100 to 249	0%	2%	0%	5%	8%	12%	16%	19%	23%
250 to 1500	0%	2%	0%	5%	8%	12%	16%	19%	23%
Panel B: Undiscounted Primary Cost as Percentage of Revenue									
0 to 4	1%	154%	0%	62%	85%	107%	110%	111%	112%
5 to 9	0%	58%	0%	62%	85%	107%	110%	111%	112%
10 to 19	0%	18%	0%	62%	85%	107%	110%	111%	112%
20 to 49	0%	7%	0%	62%	85%	107%	110%	111%	112%
50 to 99	0%	3%	0%	62%	85%	107%	110%	111%	112%
100 to 249	0%	1%	0%	62%	85%	107%	110%	111%	112%
250 to 1500	0%	1%	0%	62%	85%	107%	110%	111%	112%

2. Noncombusted Tobacco Product Manufacturers

Small businesses that manufacture only noncombusted tobacco products are expected to experience two offsetting impacts from the rule: increased revenue from policy induced increases in noncombusted tobacco use prevalence, and increased user fee assessments for smokeless tobacco products as a percentage of revenues. We make a simplifying assumption in this analysis that the representative non-combusted tobacco only manufacturer sell all noncombusted products. As shown in Figure 16, we estimate large increases in SLT sales relative to baseline resulting from people who use combusted tobacco products switching into the noncombusted market following implementation of the policy. As previously discussed in Section II.H.1.b.1, we assume increases in sales of ENDS products proportional to the ratio of ENDS to SLT of 0.69. Since we do not have sales data by product for individual small businesses, we assume all small entities selling only noncombusted products have a product portfolio of noncombusted products representative for each product of the percent of noncombusted revenue in Table 6. That is, we assume about 41 percent of sales are from ENDS and 59 percent of sales are from SLT. Table 94 shows the percentage gain in revenue relative to baseline for noncombusted products. There is a sharp uptick in noncombusted sales relative to baseline in 2028, when the policy impact simultaneously causes a large decline in combusted tobacco use of affected products. Revenue gains in 2028 are 27 percent, 64 percent, and 90 percent higher than baseline in the low, primary, and high estimates, respectively. Baseline noncombusted tobacco use is increasing annually, and by 2064, revenue gains are 15 percent, 32 percent, and 56 percent higher relative to baseline for the low, primary, and high estimates.

Table 94. Percentage Gain in Noncombusted Revenue Relative to Baseline

Year	Primary	Low	High
2025	0%	0%	0%
2026	0%	0%	0%
2027	0%	0%	0%
2028	64%	27%	90%
2029 (5 years)	52%	24%	78%
2034 (10 years)	42%	22%	71%
2044 (20 years)	37%	19%	65%
2054 (30 years)	34%	17%	60%
2064 (40 years)	32%	15%	56%

User fees are not assessed for ENDS products, so we compute user fee assessments as a percentage of post-tax revenue for SLT in Section II.I.4 and multiply by 59 percent to account for the percent of total revenues that come from SLT products as discussed above. Table 95 shows the additional user fee assessment as a percentage of noncombusted tobacco product only manufacturer's revenue. By 2028, additional user fee obligations as a percentage of revenue

range from -0.02 percent to -0.04 percent, with a primary estimate of -0.03 percent. By 2064, additional user fee obligations as a percentage of revenue range from 0.19 percent to 1.42 percent, with a primary estimate of 1.25 percent.

Table 95. Additional Noncombusted User Fee Assessment as Percentage of Revenue over a 40-Year Time Horizon

Year	Primary	Low	High
2025	0.00%	0.00%	0.00%
2026	0.00%	0.00%	0.00%
2027	0.00%	0.00%	0.00%
2028	-0.03%	-0.02%	-0.04%
2029 (5 years)	0.12%	0.00%	1.34%
2034 (10 years)	1.15%	0.03%	1.42%
2044 (20 years)	1.33%	0.09%	1.45%
2054 (30 years)	1.27%	0.15%	1.43%
2064 (40 years)	1.25%	0.19%	1.42%

Table 96 shows the costs to small noncombusted only manufacturers. We display the net cost of the increased user fee assessments and the increase in revenues. We express increases to revenue as a negative percentage. For example, manufacturers with 0 to 4 employees have 27 percent higher revenue in 2028 relative to baseline. In every year, there is a net revenue increase for noncombusted only small manufacturers due to the overcompensating increase in revenue relative to the increased user fee assessments.

Table 96. Undiscounted Costs to Small Noncombusted Only Tobacco Manufacturers as a Percentage of Revenue by Employee Size Under the Low and Primary Policy Impact Scenarios in Certain Years

Year	2025	2026	2027	2028	2029 (5 yr)	2034 (10 yr)	2044 (20 yr)	2054 (30 yr)	2064 (40 yr)
Cost Drivers	None	None	None	Increased User Fee Assessment, Increased Revenue (Recurring 2028 to 2064)					
Number of employees	**Panel A: Undiscounted Low Policy Impact Net Cost as Percentage of Revenue**								
0 to 4	0%	0%	0%	-27%	-24%	-22%	-19%	-17%	-14%
5 to 9	0%	0%	0%	-27%	-24%	-22%	-19%	-17%	-14%
10 to 19	0%	0%	0%	-27%	-24%	-22%	-19%	-17%	-14%
20 to 49	0%	0%	0%	-27%	-24%	-22%	-19%	-17%	-14%
50 to 99	0%	0%	0%	-27%	-24%	-22%	-19%	-17%	-14%
100 to 249	0%	0%	0%	-27%	-24%	-22%	-19%	-17%	-14%
250 to 1500	0%	0%	0%	-27%	-24%	-22%	-19%	-17%	-14%
	Panel B: Undiscounted Primary Policy Impact Net Cost as Percentage of Revenue								
0 to 4	0%	0%	0%	-65%	-52%	-41%	-36%	-33%	-30%
5 to 9	0%	0%	0%	-65%	-52%	-41%	-36%	-33%	-30%
10 to 19	0%	0%	0%	-65%	-52%	-41%	-36%	-33%	-30%
20 to 49	0%	0%	0%	-65%	-52%	-41%	-36%	-33%	-30%
50 to 99	0%	0%	0%	-65%	-52%	-41%	-36%	-33%	-30%
100 to 249	0%	0%	0%	-65%	-52%	-41%	-36%	-33%	-30%
250 to 1500	0%	0%	0%	-65%	-52%	-41%	-36%	-33%	-30%

Note: Negative cost represents a gain in revenue relative to baseline.

Table 97 presents the average costs per small entity that manufactures only noncombusted tobacco products over the 40-year time horizon. Annualized costs range from -$4.6 million to -$15.5 million, with a primary estimate of -$9.5 million at a 2 percent discount rate. In all policy impact scenarios, small manufacturers of only noncombusted products gain considerable amounts of revenue relative to the baseline. The average small firm has annual revenue of $2,660,851 based on the Dun & Bradstreet data used to identify registered small firms described and presented above in Table 84. Given that these costs are averaged across all small manufacturers, they may represent an overestimate for firms of the smallest size and an underestimate for relatively larger small manufacturers.

Table 97. Estimated Average Cost per Small Noncombusted only Manufacturer over a 40-Year Time Horizon at a 2% Discount Rate (2023 $)

	Primary	Low	High
Discounted Total Cost (40 years)	-$224,911,608	-$110,440,821	-$368,764,372
Annualized Cost (40 years)	-$9,446,807	-$4,638,769	-$15,488,955

Note: The average small firm has annual revenue of $2,660,851 based on Dun & Bradstreet data presented in Table 84.

3. Combusted and Noncombusted Tobacco Product Dual Operation Manufacturers

We assess policy impacts to small dual operation manufacturers who produce combusted and noncombusted tobacco products by assuming that half of their sales revenue is from combusted products and the other half is from noncombusted product sales. We lack data on the individual sales of dual operation facilities and request comment on this assumption. Thus, we compute costs of the rule to small dual operation manufacturers by multiplying combusted only costs by 50 percent, multiplying noncombusted only costs by 50 percent, and summing them together. We assume that the reading and understanding one-time cost is equal to the full value incurred by combusted only firms.

Table 98 shows undiscounted policy impact costs as a percentage of revenue for small dual operation manufacturers. Since these facilities manufacture combusted products, they experience one-time costs of reading and understanding the rule as well as reformulation and application submission costs. They also have recurring testing costs, increased user fee burden, and lost revenue associated with their combusted line of products. However, they have an increase in revenue associated with their noncombusted line of products, which fully offsets the additional increase in user fee burden paid for their noncombusted products. For firms of the smallest size with 0 to 4 employees, one-time reformulation and application submission costs are a considerable burden, accounting for up to 123 percent of revenue in the low policy impact scenario. In the primary policy impact scenario, these one-time costs are as high as 77 percent for

firms with 0 to 4 employees. The recurring costs occur between 2028 to the end of the 40-year time horizon. In the low policy impact scenario, the losses to revenue from combusted products are outweighed by the increases in revenue from noncombusted products the first 20 years after policy implementation. However, due to increasing user fee assessments for combusted and noncombusted products, as well as increasing baseline noncombusted use prevalence trends, the large losses from combusted tobacco product revenue results in large costs relative to revenue for the final 20 years of the 40-year time horizon, ranging from 1 to 4 percent. In the primary policy impact scenario, increased noncombusted revenues fully offset losses from combusted revenue and firms gain revenue relative to baseline by the second year of recurring cost, in 2029. For all remaining years of the 40-year time horizon, firms experience large costs relative to revenue ranging from 16 to 41 percent.

Table 98. Undiscounted Costs to Small Dual Operation Tobacco Manufacturers as a Percentage of Revenue by Employee Size Under the Low and Primary Policy Impact Scenarios for Certain Years

Year	2025	2026	2027	2028	2029 (5 yr)	2034 (10 yr)	2044 (20 yr)	2054 (30 yr)	2064 (40 yr)
Cost Drivers	Reading and Understanding (One-time)	Reformulation, Application Submission (One-time)	None	Testing, Increased User Fee Assessment for Combusted and Noncombusted, Lost Combusted Revenue, Increased Noncombusted Revenue (Recurring 2028 to 2064)					
Number of employees	**Panel A: Undiscounted Low Cost as Percentage of Revenue**								
0 to 4	2%	123%	0%	-11%	-8%	-5%	-2%	1%	4%
5 to 9	1%	46%	0%	-11%	-8%	-5%	-2%	1%	4%
10 to 19	0%	15%	0%	-11%	-8%	-5%	-2%	1%	4%
20 to 49	0%	6%	0%	-11%	-8%	-5%	-2%	1%	4%
50 to 99	0%	2%	0%	-11%	-8%	-5%	-2%	1%	4%
100 to 249	0%	1%	0%	-11%	-8%	-5%	-2%	1%	4%
250 to 1500	0%	1%	0%	-11%	-8%	-5%	-2%	1%	4%
Panel B: Undiscounted Primary Cost as Percentage of Revenue									
0 to 4	1%	77%	0%	-1%	16%	33%	37%	39%	41%
5 to 9	0%	29%	0%	-1%	16%	33%	37%	39%	41%
10 to 19	0%	9%	0%	-1%	16%	33%	37%	39%	41%
20 to 49	0%	4%	0%	-1%	16%	33%	37%	39%	41%
50 to 99	0%	1%	0%	-1%	16%	33%	37%	39%	41%
100 to 249	0%	1%	0%	-1%	16%	33%	37%	39%	41%
250 to 1500	0%	1%	0%	-1%	16%	33%	37%	39%	41%

Note: Negative cost represents a gain in revenue relative to baseline.

We believe that dual operation small manufacturers of combusted and noncombusted tobacco products would cease production of affected combusted tobacco products. Given our assumption that 50 percent of dual operation firms' revenue is from the sale of combusted tobacco products, if they cease production of affected combusted tobacco products, they may close and seek alternative business opportunities or increase their volume of sales for noncombusted products.

Table 99 presents the average costs per small entity that manufactures both combusted and noncombusted tobacco products as a dual operation organization over the 40-year time horizon. Annualized costs range from $0.6 million to $1.3 million, with a primary estimate of $3.8 million at a 2 percent discount rate. The average small firm has annual revenue of $2,660,851 based on the Dun & Bradstreet data used to identify registered small firms described and presented above in Table 84. Given that these costs are averaged across all small manufacturers, they may represent an overestimate for firms of the smallest size and an underestimate for relatively larger small manufacturers.

Table 99. Estimated Average Cost per Small Dual Operation Manufacturer over a 40-year time horizon Under the Low, Primary, and High Policy Impact Scenario at a 2% Discount Rate (2023 $)

	Primary	Low	High
Discounted Total Cost (40 years)	$90,569,445	$13,834,601	$31,843,684
Annualized Cost (40 years)	$3,804,126	$581,085	$1,337,508

Note: The average small firm has annual revenue of $2,660,851 based on Dun & Bradstreet data presented in Table 84.

4. Retailers and Wholesalers

As estimated in Section II.H.1.c, we estimate small retailers and wholesalers to face one-time costs of reading and understanding the rule of between $1,232 and $7,698 per retailer and wholesaler. Additionally, retailers and wholesalers could face lost revenue from their combusted tobacco product sales, although that lost revenue could, in part, be offset with increased revenue from whatever products the consumer purchases with money previously spent on combusted tobacco products affected by this rule or increased sales of noncombusted tobacco products.

5. Small Governmental Jurisdictions

In general, we do not believe that small governmental jurisdictions directly tax tobacco products; however, they may receive tobacco product tax revenue from other jurisdictions.[87] Any

[87] Small governmental jurisdictions are considered a "small entity" under the Regulatory Flexibility Act (RFA) (see Sections 601(5-6 (5 U.S.C. 601)). Small governmental jurisdictions are defined as "governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand."

decrease in tobacco product tax revenue may impact these jurisdictions, although we do not have detailed data to estimate this impact. We discuss impacts on taxes in Section II.I. We also do not expect these entities to incur enforcement costs. State and local law enforcement agencies do not enforce the tobacco product authorities in the FD&C Act and do not, and cannot, take enforcement actions against any violation of FDA's tobacco authorities, including its regulations, on FDA's behalf. We request comments and data on any impacts of this proposed product standard on small governmental jurisdictions.

C. Alternatives to Minimize the Burden on Small Entities

One alternative that could reduce the impact to small entities would be a delayed effective date for all entities. The proposed product standard has a 2-year effective date. With a 6-year effective date, manufacturers would have the same cost structure except lower one-time reformulation costs. Following FDA's Reformulation Cost Model, as discussed in Section II.H.1.d, we estimate lower reformulation costs when firms have additional time to reformulate. Under a 2-year effective date in the main analysis, we estimated the cost per reformulation to be $115,885 for a small firm and with an extended time horizon we estimate the cost per reformulation to be $66,220. All other costs and benefits are estimated to remain the same as in the main analysis except that they occur 4 additional years into the future beyond the effective date in the main analysis.

Table 100 presents the primary estimate of the discounted cost per small combusted only manufacturer under the alternative effective date of 6 years and the difference from the 2-year effective date in the proposed rule. While extending the effective date to 6 years would decrease the burden on small business, it also would decrease the benefits of a final rule by delaying the benefits for an additional 4 years. For example, public health benefits in terms of lives saved resulting from smoking cessation would not be realized during the 4-year delay, resulting an increase to public health costs relative to the implementation date in the main analysis.

Table 100. Costs of the Final Rule per Small Combusted Only Manufacturers in 2023 Dollars at a 2% Discount Rate

Under 72-Month Effective Date	Cost Per Firm
Present Discounted Value ($)	$312,033,028
Annualized Value	$13,106,108
Difference between Proposed Rule and 72-Month Effective Date	
Present Discounted Value ($)	-$92,420,153
Annualized Value	-$3,881,860

Note: Negative cost represents a gain relative to baseline.

Table 101 presents the primary estimate of the discounted cost per small noncombusted only manufacturer under the alternative effective dates of 6 years and the difference from the 2-year effective date in the rule. Extending the effective date to 6 years increases the burden on small business who manufacture combusted only products relative to the 2-year effective date in the rule because it delays the increased revenues that these firms stand to receive following implementation of the rule. In addition, it also decreases the benefits of this final rule by delaying the benefits.

Table 101. Costs of the Final Rule per Small Noncombusted Only Manufacturers in 2023 Dollars at a 2% Discount Rate

Under 72-Month Effective Date	Cost Per Firm
Present Discounted Value ($)	$209,635,085
Annualized Value	$8,805,158
Difference between Proposed Rule and 72-Month Effective Date	
Present Discounted Value ($)	$432,656,470
Annualized Value	$18,172,571

Note: Negative cost represents a gain relative to baseline.

Table 102 presents the primary estimate of the discounted cost per small dual operation combusted and noncombusted manufacturer under the alternative effective dates of 6 years and the difference from the 2-year effective date in the rule. Since the rule is a net cost for dual manufacturers, extending the effective date decreases the burden. However, it also decreases the benefits of this final rule by delaying the benefits.

Table 102. Costs of the Final Rule per Small Dual Operation Manufacturer in 2023 Dollars at a 2% Discount Rate

Under 72-Month Effective Date	Cost Per Firm
Present Discounted Value ($)	$260,834,056
Annualized Value	$10,955,633
Difference between Proposed Rule and 72-Month Effective Date	
Present Discounted Value ($)	$170,118,158
Annualized Value	$7,145,355

Note: Negative cost represents a gain relative to baseline.

IV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restrictions. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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254. *Retrospective and Prospective Benefit-Cost Analyses of U.S. Anti-Smoking Policies.* **Jin, L., et al.** 1, 2015, Journal of Benefit Cost Analysis, Vol. 6, pp. 154-186.

255. *Measuring Consumer Surplus in the Case of Addiction: A Re-examination of the Rational Benchmark Algebra.* **Massin, S. and Miera, M.** 4, 2020, Economics Bulletin, Vol. 40, pp. 3171-3181.

256. *Mortality and Economic Costs from Regular Cigar use in the United States, 2010.* **Nonnemaker, J, et al.** 9, 2014, American Journal of Public Health, Vol. 104, pp. e86-e91.

257. ***** *Estimating the potential public health impact of prohibiting characterizing flavors in cigars throughout the US.* **Rostron, Brian L., et al.** 18, 2019, International Journal of Environmental Research and Public Health, Vol. 16, p. 3234.

258. **American Psychiatric Association Committee on Nomenclature and Statistics.** *Diagnostic and Statistical Manual of Mental Disorders, Ed. 3.* s.l. : American Psychiatric Association, 1980.

259. *A Novel Approach to Estimating the Prevalence of Untaxed Cigarettes in the USA: Findings from the 2009 and 2010 International Tobacco Control Surveys.* **Fix, B V, et al.** suppl 1, 2021, Tobacco Control, Vol. 23, pp. i61-i66.

260. *Time to First Cigarette in the Morning as an Index of Ability to Quit Smoking: Implications for Nicotine Dependence.* **Baker, T.B., et al.** Suppl_4, 2007, Nicotine & Tobacco Research, Vol. 9, pp. S555-S570.

261. *** U.S. Food & Drug Administration.** *Requirement for Tobacco Product Manufacturing Practice, Preliminary Regulatory Impact Analysis.* 2023.

262. *Comparison of the Yield of Very Low Nicotine Content Cigarettes to the Top 100 United States Brand Styles.* **Carmines, E and Gillman, IG.** 6, 2019, Contributions to Tobacco & Nicotine Research, Vol. 28, pp. 253-266.

263. *** 22nd Century Group Inc.** *22nd Century Group Inc. Modified Risk Tobacco Product (MRTP) Applications. Section IV Part 1 - Descriptive Information - Updated February 22, 2021.* s.l. : HHS, FDA, 2019.

V. Appendix

A. Main Analysis and Section II.M.1 Analysis under 3 and 7 Percent Discount Rates

The updated OMB Circular A-4 (247) changed the discount rate used in RIAs from 3 and 7 percent to 2 percent. We conduct our main analysis with a 2 percent discount rate to be consistent with the updated Circular A-4 (247). However, due to this recent change and to allow for comparison across FDA rules, we present the analysis with the alternative discount rates of 3 and 7 percent here. We present both the main analysis and the analysis with the baseline unadjusted for menthol and cigar flavors (Section II.M.1) under these alternative discount rates.

Table 103. Policy Impact under the Main Analysis Baseline Discounted at 3 and 7 Percent

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $M/year	$1,117,406	$268,259	$1,211,484	2023	7%	40 years	
		$1,101,433	$273,653	$1,195,427	2023	3%	40 years	
	Annualized Quantified							
	Qualitative							
Costs	Annualized Monetized $M/year	$2,647	$1,065	$4,181	2023	7%	40 years	
		$2,195	$759	$2,986	2023	3%	40 years	
	Annualized Quantified							
	Qualitative							
Transfers	Federal Annualized Monetized $M/year	$4,093	$1,113	$4,430	2023	7%	40 years	
		$4,114	$1,332	$4,359	2023	3%	40 years	
	From/ To	From: Federal Government			To: consumers			
	Other Annualized Monetized $M/year	$8,427	$2,292	$9,129	2023	7%	40 years	
		$8,463	$2,738	$8,975	2023	3%	40 years	
	From/ To	From: State Governments			To: consumers			
	Other Annualized Monetized $M/year	$19,418	$4,294	$17,513	2023	7%	40 years	
		$19,967	$5,837	$17,672	2023	3%	40 years	
	From/ To	From: Retailers			To: Consumers			
	Other Annualized Monetized $M/year	$263	$17	$406	2023	7%	40 years	
		$319	$24	$451	2023	3%	40 years	

	From/ To	From: User fees owed by combusted tobacco	To: User fees owed by noncombusted tobacco	

Table 104. Policy Impact under the Unadjusted Baseline Discounted at 3 and 7 Percent

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $M/year	$1,348,486	$348,444	$1,475,688	2023	7%	40 years	
		$1,334,604	$355,218	$1,458,728	2023	3%	40 years	
	Annualized Quantified							
	Qualitative							
Costs	Annualized Monetized $M/year	$3,388	$1,182	$5,143	2023	7%	40 years	
		$3,095	$926	$4,084	2023	3%	40 years	
	Annualized Quantified							
	Qualitative							
Transfers	Federal Annualized Monetized $M/year	$4,058	$1,134	$4,528	2023	7%	40 years	
		$4,130	$1,369	$4,470	2023	3%	40 years	
	From/ To	From: Federal Government			To: consumers			
	Other Annualized Monetized $M/year	$8,327	$2,326	$9,302	2023	7%	40 years	
		$8,462	$2,801	$9,170	2023	3%	40 years	
	From/ To	From: State Governments			To: consumers			
	Other Annualized Monetized $M/year	$25,994	$6,865	$24,565	2023	7%	40 years	
		$28,420	$9,608	$26,194	2023	3%	40 years	
	From/ To	From: Retailers			To: Consumers			
	Other Annualized Monetized $M/year	$231	$15	$394	2023	7%	40 years	
		$289	$21	$445	2023	3%	40 years	
	From/ To	From: User fees owed by combusted tobacco			To: User fees owed by noncombusted tobacco			

B. Literature Review on Economic Transition Costs

This proposed product standard is expected to cause a significant shift away from the combusted tobacco industry. There are a limited number of regulations that have had a similar impact on an industry and therefore there are limited studies and data from which to draw cost estimates. Here, we present the relevant literature available on costs of significant industry disruption. We note that none of these studies present estimates that would be applicable to the context of economic transition cost for this proposed product standard. We request comment on additional literature that may help to calibrate the transition cost estimates in Section II.H.1.a.

Citation	**Product Banned/ Restricted**	**Cost Estimations**
Mahaffey, H., Taheripour, F. & W.E. Tyner. 2016. "Evaluating the Economic and Environmental Impacts of a Global GMO Ban". *Journal of Environmental Protection*, vol 7: 1522-1546. http://dx.doi.org/10.4236/jep.2016.711127	Genetically Modified Organism (GMO) Foods	The authors evaluate the impact of a global ban on GMOs. A global ban on GMOs would cause food price increases ranging from an increase of 0.27% to 2.2%, depending on the region. Total welfare losses associated with loss of GMO technology total up to $9.75 billion.
Vanatta, M., Craig, M. T., Rathod, B., Florez, J., Bromley-Dulfano, I., & D. Smith. 2022. "The costs of replacing coal plant jobs with local instead of distant wind and solar jobs across the United States". *iScience*, 25(8). https://doi.org/10.1016/j.isci.2022.104817.	Coal	The authors evaluate the costs of switching energy production from coal to renewable sources (wind or solar). Switching from energy production from one coal plant to a renewable source would cost $6.4 million to $8.4 billion depending on the region.
Holland, Stephen P., Erin T. Mansur, and Andrew J. Yates. 2021. "The Electric Vehicle Transition and the Economics of Banning Gasoline Vehicles". *American Economic Journal: Economic Policy*, 13(3): 316-44.	Gasoline Vehicles	The authors evaluate the deadweight loss (DWL) of several policies to promote electric vehicles (Evs) including bans on gas vehicles, Pigouvian tax, and quotas. There is significant variation in DWL under different policy options.
Pollin, R., & Callaci, B. 2019. The Economics of Just Transition: A Framework for Supporting Fossil Fuel–Dependent Workers and Communities in the United States. *Labor Studies Journal*, *44*(2), 93-138. https://doi.org/10.1177/0160449X18787051	Fossil Fuels	The authors examine the cost of an effective job guarantee program for displaced fossil fuel workers which includes compensation insurance, retraining, relocation, pension, and community transition. Costs are estimated to be between $300 – $600 million per year.
Louie, E., & J. M. Pearce. 2016. "Retraining investment for U.S. transition from coal to solar photovoltaic employment". *Energy Economics*, vol 57: 295-302. https://doi.org/10.1016/j.eneco.2016.05.016.	Coal	The authors examine a hypothetical case where the coal industry shuts down and workers are retrained into the solar photovoltaic industry (PV). The cost of transitioning employees ranges from estimates $5,756 to $20,863 per person.

Taheripour, F., Mahaffey, H., and E. Tyner, 2016. "Evaluation of Economic, Land Use, and Land-use Emission Impacts of Substituting Non-GMO Crops for GMO in the United States". *AgBioForum*, vol 19(2): 156-172.	GMOs	The authors examine the economic and land-use impacts of banning GMO corn, soybean, and cotton, in the United States. Using a general equilibrium model simulation, their results show a GMO ban would have significant impacts on land use, emissions, commodity and good prices, and economic welfare losses. They estimate an increase in US food spending of about $14-24 billion per year and average US welfare losses of about $0.6-2.6 billion.
Lesser, W. 2014. "Costs of Labeling Genetically Modified Food Products in N.Y. State". http://publications.dyson.cornell.edu/docs/LabelingNY.pdf.	GMOs/ Genetically Engineered (GE) food	The cost to replace GE food production with non-GE production is estimated to range from $11 to $103 per capita for New York State and range from $3.6 billion to $33 billion for the United States. Replacing all GE production with the production of organic alternatives would cost between $29 billion to $126 billion for the United States.

C. Consumer Surplus

Regulations that reduce the demand for a product or that raise its market price may lead to reductions in consumer surplus or consumer utility. We include a brief discussion of this topic under the heading of Costs of the Proposed Rule in section II.H.2 (Costs to Consumers). This appendix provides additional background information and explores the challenges of addressing potential gains and losses in consumer surplus from this proposed product standard. At a high level, the purpose of this section is to discuss the uncertainty and practical challenges surrounding consumer demand estimation, which complicates the ability to provide a quantified analysis. To do so, we provide a comprehensive review of available literature on the topic of demand and consumer surplus estimation for tobacco products and outline some of the open questions for consideration.

For fully-informed, rational consumers, consumer surplus reflects the difference between their maximum willingness to pay for a product and the price they pay in the marketplace. A rational consumer is one whose choices maximize their utility, i.e., an individual who, when presented with a decision, chooses the option that maximizes their welfare. Circular A-4 states that regulatory impact analyses should consider including "gains or losses in consumers'…surpluses" as part of the economic analysis (247).

As with other tobacco products, consumer behavior in the market for combusted tobacco products is distorted by addiction, imperfect information, and internalities. Section II.B (Need for Federal Regulatory Action) of this PRIA describes the internalities that influence demand for tobacco products. These complexities and other challenges are discussed in the main analysis

II.H.2 (Costs to Consumers) and also briefly described in this appendix. The focus of this appendix is to provide additional background, especially on relevant literature on approaches to modeling demand and associated consumer surplus for tobacco products, which are highly addictive and generally initiated before adulthood. A review of the literature highlights the lack of consensus regarding how to account for lost consumer surplus in analyzing the effect of regulations on tobacco products.

1. Summary Literature Review: Consumer Surplus in Tobacco Product Use

Early economic modelers of cigarette consumption noted that cigarette demand decreased as price increased, similar to other products on the market, and attempted to fit a model of rational addiction to cigarette use (249). These models simplified cigarette demand in ways that allowed application of classic economic theory and concepts, such as consumer preference, demand, and willingness to pay for cigarettes. Under this rational addiction approach, people who smoke cigarettes were seen to derive a surplus from smoking equal to the difference between the price they were willing to pay for cigarettes and the shadow, or full, price of cigarettes. For harmful addictive goods, the shadow price includes both the market price and the present value of future costs resulting from current consumption. Thus, under this rational addiction approach, any reduction in cigarette use caused by regulation, seen as a cost to the consumer, would create a loss in surplus.

However, because consumers face the internality problems discussed above, it is difficult to disentangle consumption driven by addiction from that which may be driven by rational demand. For this reason, there is a lack of consensus about how to quantify forgone consumer surplus in tobacco regulation impact analyses (250). In contrast to the rational addiction approach above, some argue that most consumers do not experience utility losses from reduced use because they derive little to no pleasure from consumption (138; 251). The authors assert that forgone consumption would not be a cost to consumers who regularly smoked cigarettes during adolescence (before the legal age of smoking), as these consumers would not be considered rational at the time of initiation. Others argue that some consumers who reduce their cigarette use do experience some disutility (e.g., Ashley et al. (252), Cutler et al. (135), and DeCicca et al (253)).

Even among those who conclude that some consumer utility loss exists, there is a lack of consensus about how to meaningfully incorporate it into welfare analysis (250). As Levy, Norton, & Smith (250) note, there is an open question of how best to quantitatively assess welfare and lost consumer surplus when consumers are not fully-informed and rational (250). One approach is to offset health gains by some factor intended to represent consumer surplus loss. This approach has been used in the past where data and methods did not allow for direct estimation of the consumer surplus change due to specific tobacco regulations. As a result, studies have increasingly aimed to identify utility losses by comparing the demand of consumers with and without internality problems, though doing so creates additional challenges.

In contrast, Levy, Norton, & Smith (250) asserts that the "correct approach to evaluating the economic impact of regulation is to calculate changes in the welfare of a rational and fully informed consumer, rather than first calculating the value of health gains and then offsetting them by some amount" (250). The paper identifies three main questions framing the assessment of welfare[88] and lost consumer surplus:

- "First, under the assumption that consumers are fully informed and rational, what is the appropriate framework for welfare analysis of government regulations that yield both health gains and potentially large losses in consumer surplus?"
- "Second, *are* consumers fully informed and rational?" [emphasis added]
- "Third, what is the appropriate framework for welfare analysis if consumers are *not* fully informed and rational?" [emphasis added]

In response to the second question, the authors note that "to date no research has developed an empirical test that distinguishes clearly between rational and quasi-rational models of smoking behavior" (250). In response to the third question, the authors propose a model for performing a welfare analysis when consumers are not rational, arguing that "even if consumers are not rational, the correct response from an economic perspective is not to abandon welfare analysis in favor of policies that maximize health" (250). Instead, Levy, Norton, & Smith (2018) outline further research that would help "figure out how to perform welfare analysis when consumers are not rational" but note that they do not "claim to have solved the practical question of how the FDA should carry out regulatory impact analysis of anti-smoking policies" (250).

2. Approaches to Modeling Demand for Tobacco Products

Several studies consider how to measure unbiased demand that reflects a rational and fully informed consumer, as compared with biased demand based on current consumption. As Levy, Norton, & Smith (250) note, bias increases demand above and beyond unbiased demand levels, which could be due to many factors such as "…they do not know how bad it is for them, do not realize how hard it will be to quit down the road, or simply cannot control themselves". The driving idea behind these models is that any regulation that moves consumer demand closer to an unbiased demand curve would be welfare improving from the consumer's perspective. We discuss these studies to present a range of approaches. We conclude with the most recent model by Levy, Norton, & Smith (2018) because using an unbiased demand curve appears to be an improvement over models that do not consider the bias in tobacco product demand caused by nicotine addiction, noting that some of the questions posed by Levy, Norton, & Smith (250) would first need to be resolved before a model could be constructed.

[88] We note that Levy, Norton, & Smith (249) uses the economic meaning of the term "welfare". For purposes of this discussion, we define welfare to be overall well-being, including economic, health, and social well-being. Although text in this appendix may refer to the welfare of people who smoke cigarettes specifically, social welfare analysis in tobacco regulations encompasses overall well-being of both people who smoke cigarettes and those who do not.

In the context of addictive products, a white paper drafted by the Office of the Assistant Secretary for Planning and Evaluation at HHS (ASPE) (136) and Cutler, Jessup, Kenkel, & Starr (135) and Cutler, Jessup, Kenkel, & Starr (137) outlines an approach for analyzing utility, or consumer surplus, offsets to health benefits of smoking regulations based on the identification of a subset of people who smoke cigarettes most likely to be rational – i.e., fully-informed to choose their consumption levels in ways that rationally weigh benefits, costs, and risks – and whose impacts should be assessed separately and differently from non-rational people who smoke cigarettes. Cutler, Jessup, Kenkel, & Starr (135) uses several proxies for rationality, including people who smoke cigarettes who self-report not smoking within 30 minutes of waking[89] and those aged 30-45 with a college degree, regardless of age of initiation. The authors assume that the 30-45 age cohort would have initiated well after the health risks of smoking became well-publicized and use a college degree as a proxy for awareness of public information.[90] Individuals aged 30 or below were excluded from the analysis as their education levels had not yet been established Cutler, Jessup, Kenkel, & Starr (135). However, the authors acknowledge that their estimated "rational" smoking rate is likely too high as "some well-educated young smokers probably initiated 'accidentally' in their teens and now would prefer to quit" Cutler, Jessup, Kenkel, & Starr (135). Cutler, Jessup, Kenkel, & Starr (135) estimate uses withdrawal costs as a proxy for utility impacts for the population of "rational" people who smoke cigarettes. By considering these short run withdrawal costs relative to the lifetime health benefits of quitting, they conclude that, for most regulations, "a population-level estimate of the offset ratio will be closer to 5%" Cutler, Jessup, Kenkel, & Starr (135).

In Jin, Kenkel, Liu, & Wang (254), the authors acknowledge that an individual's initiation decisions are likely mistaken and that "individual failures stem from some combination of poor information about the health consequences of smoking, other decision-making errors that lead to imperfect optimization, and bounded self-control". In response to irrational initiation, the authors adopt a framework that attempts to eliminate these difficulties by considering an individual's decision-making process *post* initiation (254) (emphasis added). Simulations in Jin, Kenkel, Liu, & Wang (254) are predicated on an assumption that past cigarette consumption is a determinate of future demand, regardless of whether past consumption decisions were rational. However, the authors also admit that "rational demand might be mainly driven by the value of cigarettes as a means to reduce the utility losses from withdrawal" (254). While Jin, Kenkel, Liu, & Wang (254) conclude—in an addendum that segments into gross and net results their primary reduced-form estimates—that "about 94% of the gross health benefits from past anti-smoking policies are offset by losses of consumer surplus in the cigarette market," the authors calculate

[89] "A widely used measure of nicotine addiction is whether the person has their first cigarette within one-half hour of waking…" [Cutler et al. (137), citing 2014 SGR]. Smoking within 30 minutes of waking (time to first cigarette) is a widely used measure of nicotine dependence (259).

[90] The 30-45 age cohort analyzed by Cutler et al. (137) using data from the 2010-11 Tobacco Use Supplement to the Current Population Survey from the U.S. Census Bureau would have likely reached adulthood during the 1990s. It is unclear what public information would have been most salient to this population at time of initiation.

that about 33 percent of estimated health benefits from future, hypothetical tobacco regulations would be offset by losses in consumer surplus from reduced cigarette use.

With respect to tobacco product cessation, these studies and others identify a subset of people who smoke cigarettes that may be considered rational and present a wide array of potential values for consumer surplus estimates that offset public health benefits: ranging from 5 percent to 99 percent (135; 252; 254). Chaloupka, Warner, & Acemoglu (138) identify only a "small fraction" of people who smoke cigarettes that "made what might be interpreted as a rational decision" to smoke, without offering an estimate of the potential size of this lost consumer surplus. Chaloupka, Gruber, & Warner (251), however, conclude "that the 'lost pleasure' from tobacco use, as represented by conventionally measured consumer surplus, should not be included as a cost in FDA economic impact analyses of tobacco regulations". Previous regulatory impact analyses evaluating rules regulating the use of tobacco products have estimated potential consumer surplus loss for those who quit as a percentage of the health benefits attributable to the rule. For example, based on their analysis of literature, the Department of Housing and Urban Development's regulatory impact analysis of the Smoke-Free Public Housing Final Rule, considered potential offsets totaling 5 percent to 33 percent of the health benefits attributable to the rule as the consumer surplus loss associated with the rule.[91] This broad range of values for consumer surplus estimates that offset public health benefits from cessation demonstrate the uncertainty with an offset approach, and later sections of this appendix discuss additional uncertainty with an offset approach in the context of tobacco products.

DeCicca, Kenkel, Liu, & Wang (253) developed a two-period model based on internalities, or the long-term costs to oneself resulting from consumption of a harmful good, to estimate the impact of tobacco control policies on social welfare, assuming that smoking only creates adverse health consequences in the second period, and that if people who smoke cigarettes quit by the end of the first period, which studies have shown to be around age 40, most of the excess mortality risk of smoking is avoided. The authors argue that "[m]ortality risks are valued so much more heavily than morbidity risks that they dominate consumer decision-making and social welfare calculations." Ultimately, DeCicca, Kenkel, Liu, & Wang (253) attempts to correct for some of the flaws in previous rational addiction modeling by allowing for the

[91] The literature cited in the HUD RIA, which also included an analysis using the rental premium on smoke-free apartments to estimate benefits (without the separate steps of monetizing health and longevity benefits and then subtracting shorter-term utility loss), includes Levy, Helen, et al. (249). "Tobacco Regulation and Cost-Benefit Analysis: How Should We Value Foregone Consumer Surplus?" NBER Working Paper No. 22471. http://www.nber.org/papers/w22471; DeCicca, Philip, et al. (252). "Behavioral Welfare Economics and FDA Tobacco Regulations". NBER Working Paper No. 22718. http://www.nber.org/papers/w22718; Cutler, D. et al. (135); Valuing Regulations Affecting Addictive or Habitual Goods. Journal of Benefit-Cost Analysis 6 (2): 247-280, and; Jin, L. et al. (253)). Retrospective and prospective benefit-cost analyses of U.S. anti-smoking policies. Journal of Benefit-Cost Analysis 6(1): 154-186. The utility-loss estimate of 33% of health benefits is based on a hypothetical prospective regulation that cuts the smoking initiation rate in half, increases the smoking cessation rate by one-third and reduces the average quantity of cigarettes smoked by one-third. HUD's rule is not expected to have an identical impact on smoking activity and thus the loss in consumer utility may be different than 33% of health benefits.

existence of internalities, moving consumer surplus evaluation of tobacco policy towards directly modeling the utility in the market.

In furthering this discussion, Levy, Norton, & Smith (250) identify the main questions that would need to be answered in order to create an "unbiased" demand curve that represents demand for a fully informed and rational consumer. These questions include what framework to use in building an "unbiased" demand curve (i.e., the demand of people who use tobacco products who are fully informed of the health effects to tobacco product use and rational in deciding to use these products); whether tobacco product usage can be considered fully informed and rational; and how to evaluate welfare when consumers are not fully informed and rational (250). The authors conclude that moving consumers closer to the unbiased demand curve can be welfare improving, while also noting the limitations of the model due to empirical challenges estimating unbiased demand.

We note that while Cutler, Jessup, Kenkel, & Starr (135) and Jin, Kenkel, Liu, & Wang (254) perform their analyses on the cigarette market, these methodologies would be analytically similar to possible evaluations of dissuasion effects in the market for tobacco products. However, Levy, Norton, & Smith (250) note challenges with these approaches, explaining that characteristics like age and education may not properly capture differences in bias because they are related to other characteristics, like discount rates accounting for time-inconsistency, that likely affect smoking. These same challenges would apply to an analysis of dissuasion from consumption of tobacco products.

While Levy, Norton, & Smith (250) present theoretical demand curves, significant uncertainty remains regarding what unbiased demand curves for tobacco products might look like and how they could be estimated. The peer-reviewed literature provides a wide range of price elasticity estimates for market (biased) demand curves, and unbiased estimates are even more uncertain. For example, Massin & Miera (255) discuss an additional source of uncertainty with models like the ones suggested by Levy, Norton, & Smith (250).[92] Such models may tend to construct biased and unbiased demand curves using the same price elasticity of demand, or slope. This slope (i.e., how steep or flat the demand curve is) represents the rate of change in the quantity of tobacco products purchased in reaction to a change in price. Addicted and non-addicted consumers may not have the same reaction to a change in price; an unbiased demand curve for a tobacco product may have a much flatter slope than the biased demand curve, reflecting the behavior of the more price-conscious, non-addicted person who uses tobacco products. Thus, assuming the same elasticity of demand for addicted and non-addicted consumers is likely to overestimate consumer surplus (255). We request comment on this interpretation.

Peer-reviewed models of biased and unbiased demand for tobacco products, although an improvement on previous approaches, have yet to address such challenges. They also make simplifying assumptions that do not fully capture the complexity of tobacco demand and

[92] Massin and Miéra (254) appear to exclude Jin et al. (253) from the list of papers that suffer from the problems mentioned here. However, we request comment on this interpretation.

challenges specific to a nicotine product standard, including the continued availability of potential tobacco product substitutes.

Given these challenges and potential analytic approaches for modeling consumer surplus for tobacco products there is significant uncertainty regarding how consumer surplus impacts should be valued in tobacco product regulations. To conduct an analysis of biased versus unbiased demand for tobacco products, we would need, among other things, to estimate current unbiased market demand, the magnitude of internalities facing consumers, and the expected demand under this proposed nicotine product standard. This product standard would only impact one attribute of the product—the nicotine level—making it even more challenging to consider welfare effects. Section II.H.2.c (Utility Change for Consumers) of the main analysis describes this issue in more detail. We request comment on relevant data that could inform such an approach or an alternative approach.

3. Challenges with Estimating Consumer Surplus for Tobacco Products

Recent advances in behavioral economics are moving the field closer toward more reliable estimation of consumer surplus, recognizing significant challenges remain with modeling demand for tobacco products. The challenges relating to tobacco product demand and consumer surplus include: the addictive nature of tobacco products, initiation during adolescence when the brain is not yet fully developed, the developing nature of information about the health harms of smoking, tobacco product demand based on demand for other perceived benefits of smoking rather than tobacco product attributes themselves, the level of regret expressed by people who currently smoke cigarettes, desire to quit, and the availability of potential substitute tobacco products. Additionally, this proposed product standard restricts the nicotine level of the product but not other product attributes making it even more challenging to consider welfare effects. These challenges in modeling demand for tobacco products are described in more detail in section II.H.2.c (Utility Change for Consumers).

4. Conclusions

Given the concerns outlined in this appendix, including the complexity of modeling a hypothetical rational demand curve for a good with an internality and cognitive bias problems, this regulatory impact analysis does not estimate changes in consumer surplus stemming from this nicotine product standard. This applies to people who do not smoke cigarettes who are dissuaded from initiating the use of combusted tobacco products, to people who currently use combusted tobacco products who quit in response to the standard, and to people who currently use combusted tobacco products who switch to other tobacco products as a result of this product standard. Although consumer surplus loss among people who quit or switch may not be zero, there are a number of challenges and a lack of consensus surrounding the tools used to measure demand for tobacco products. As a result, we discuss consumer surplus qualitatively and request comment and/or data to assist in future application of potential modeling approaches.

Over the last ten years there has been a growing movement within peer-reviewed literature looking at approaches to modeling impacts of tobacco policy on consumer surplus. The literature has largely moved away from the utility offset method and instead has made significant strides towards directly modeling biased and unbiased demand curves. While we believe there will be an approach that can be used in regulatory impact analyses, there are currently still several technical issues that need to be solved, including:

- How do addiction, imperfect information, and internalities influence the magnitude of biased demand for these products?
- What role does the significant regret voiced by the majority of people who currently use tobacco products play in welfare analysis of addictive goods?
- How should we estimate an unbiased, non-addictive demand curve?
- How does the consumer utility and consumer surplus provided by substitute goods (both tobacco and non-tobacco) compare to consumer utility and consumer surplus provided by combusted tobacco products?
- If consumer welfare loss occurs, is it a temporary transition state that occurs during withdrawal, or does it last a lifetime?
- Given that estimating consumer surplus does not necessarily include a direct estimate of health benefits, how can an analysis of consumer surplus present health benefits clearly and transparently to the public?

FDA continues to encourage research and requests comment on this discussion; these questions raised; the application of consumer surplus analysis in the context of addictive products; the application of consumer surplus to a product standard that changes a product attribute; and potential methods for developing and comparing biased and unbiased demand curves for tobacco products.

D. Undiscounted Streams of Estimates and Estimates by Product Category

The following tables contain undiscounted annual streams of estimates for the 40-year time horizon from 2025 to 2064. In subsections 1, 2, and 3, undiscounted annual streams for costs, benefits, and transfers are presented for the low, primary, and high impact scenarios of the main analysis. Subsections 4, 5, and 6 present similar tables but for the unadjusted no Menthol, no Cigar Flavors baseline. Subsections 7 and 8 present undiscounted annual streams of estimates by tobacco product category for costs and transfers, respectively. The tables of benefits in the previous subsections present benefits both by tobacco product category and aggregated, whereas costs and transfers are presented aggregated annually.

1. Undiscounted Annual Costs of the Rule for the Main Analysis

Table 105. Undiscounted Annual Costs of the Rule, Main Analysis, Low Impact Scenario ($ Millions, 2023)

	Industry						Government		Consumer	
Year	Reading and Understanding	Economic Transition	Reformulation	Premarket Submission	Testing	Producer Surplus (loss)	Premarket Review	Enforcement	Search	Withdrawal*
2025	$112.1									
2026		$4,306.9	$8,968.0	$15.0			$15.6			
2027								$4.2	$482.1	$18.0
2028					$5.2	$11.5		$4.2		
2029					$4.7	$32.4		$3.5		
2030					$4.3	$58.7		$3.5		
2031					$3.9	$87.3		$3.5		
2032					$3.6	$115.7		$3.5		
2033					$3.3	$142.9		$3.5		
2034					$3.0	$167.2		$3.5		
2035					$2.8	$190.5		$3.5		
2036					$2.6	$211.9		$3.5		
2037					$2.4	$228.3		$3.5		
2038					$2.2	$241.5		$3.5		
2039					$2.1	$253.9		$3.5		
2040					$1.9	$263.8		$3.5		
2041					$1.8	$273.7		$3.5		
2042					$1.7	$279.1		$3.5		
2043					$1.6	$283.2		$3.5		
2044					$1.5	$286.5		$3.5		
2045					$1.4	$288.2		$3.5		
2046					$1.4	$287.5		$3.5		
2047					$1.3	$287.4		$3.5		
2048					$1.2	$286.8		$3.5		

2049					$1.2	$287.7		$3.5		
2050					$1.2	$286.4		$3.5		
2051					$1.1	$284.3		$3.5		
2052					$1.1	$282.0		$3.5		
2053					$1.1	$278.1		$3.5		
2054					$1.0	$275.0		$3.5		
2055					$1.0	$272.5		$3.5		
2056					$1.0	$269.1		$3.5		
2057					$1.0	$266.5		$3.5		
2058					$0.9	$263.3		$3.5		
2059					$0.9	$260.7		$3.5		
2060					$0.9	$257.8		$3.5		
2061					$0.9	$255.5		$3.5		
2062					$0.9	$252.6		$3.5		
2063					$0.9	$249.5		$3.5		
2064					$0.9	$246.9		$3.5		

*Withdrawal costs are calculated using a quality-adjusted life-year that uses a 2% discount rate

Table 106. Undiscounted Annual Costs of the Rule, Main Analysis, Primary Impact Scenario ($ Millions, 2023)

	Industry						Government		Consumer	
Year	Reading and Understanding	Economic Transition	Reformulation	Premarket Submission	Testing	Producer Surplus (loss)	Premarket Review	Enforcement	Search	Withdrawal*
2025	$373.5									
2026		$7,145.1	$610.4	$1.0			$1.1			
2027								$6.9	$1,446.4	$1,665.8
2028					$3.2	$2,109.2		$6.9		
2029					$1.5	$3,382.7		$5.4		
2030					$0.8	$3,770.6		$5.4		
2031					$0.4	$3,732.8		$5.4		

2032					$0.3	$3,527.4		$5.4		
2033					$0.2	$3,274.8		$5.4		
2034					$0.2	$3,019.8		$5.4		
2035					$0.1	$2,780.3		$5.4		
2036					$0.1	$2,562.3		$5.4		
2037					$0.1	$2,365.2		$5.4		
2038					$0.1	$2,187.9		$5.4		
2039					$0.1	$2,029.2		$5.4		
2040					$0.1	$1,888.7		$5.4		
2041					$0.1	$1,764.7		$5.4		
2042					$0.1	$1,655.1		$5.4		
2043					$0.1	$1,558.0		$5.4		
2044					$0.1	$1,471.7		$5.4		
2045					$0.1	$1,394.5		$5.4		
2046					$0.1	$1,325.3		$5.4		
2047					$0.1	$1,263.2		$5.4		
2048					$0.1	$1,207.4		$5.4		
2049					$0.1	$1,157.0		$5.4		
2050					$0.1	$1,111.4		$5.4		
2051					$0.1	$1,070.1		$5.4		
2052					$0.1	$1,032.6		$5.4		
2053					$0.1	$998.4		$5.4		
2054					$0.1	$967.2		$5.4		
2055					$0.1	$938.6		$5.4		
2056					$0.1	$912.4		$5.4		
2057					$0.1	$888.5		$5.4		
2058					$0.1	$866.4		$5.4		
2059					$0.1	$846.0		$5.4		
2060					$0.1	$827.2		$5.4		
2061					$0.1	$809.8		$5.4		
2062					$0.1	$793.7		$5.4		

2063					$0.1	$778.8		$5.4		
2064					$0.1	$765.1		$5.4		

*Withdrawal costs are calculated using a quality-adjusted life-year that uses a 2% discount rate

Table 107. Undiscounted Annual Costs of the Rule, Main Analysis, High Impact Scenario ($ Millions, 2023)

	Industry						Government		Consumer	
Year	Reading and Understanding	Economic Transition	Reformulation	Premarket Submission	Testing	Producer Surplus (loss)	Premarket Review	Enforcement	Search	Withdrawal*
2025	$700.4									
2026		$9,109.5	$35.2	$0.1			$0.1			
2027								$9.6	$2,892.8	$10,829.1
2028					$0.1	$5,707.5		$9.6		
2029					$0.1	$5,130.7		$7.4		
2030					$0.1	$4,621.1		$7.4		
2031					$0.1	$4,173.5		$7.4		
2032					$0.1	$3,782.2		$7.4		
2033					$0.1	$3,438.7		$7.4		
2034					$0.1	$3,137.8		$7.4		
2035					$0.1	$2,873.5		$7.4		
2036					$0.1	$2,640.3		$7.4		
2037					$0.1	$2,433.9		$7.4		
2038					$0.1	$2,250.8		$7.4		
2039					$0.1	$2,087.5		$7.4		
2040					$0.1	$1,943.8		$7.4		
2041					$0.1	$1,817.5		$7.4		
2042					$0.1	$1,706.3		$7.4		
2043					$0.1	$1,607.7		$7.4		
2044					$0.1	$1,520.0		$7.4		
2045					$0.1	$1,441.7		$7.4		

2046					$0.1	$1,371.5		$7.4		
2047					$0.1	$1,308.3		$7.4		
2048					$0.1	$1,251.5		$7.4		
2049					$0.1	$1,200.1		$7.4		
2050					$0.1	$1,153.7		$7.4		
2051					$0.1	$1,111.6		$7.4		
2052					$0.1	$1,073.2		$7.4		
2053					$0.1	$1,038.3		$7.4		
2054					$0.1	$1,006.4		$7.4		
2055					$0.1	$977.1		$7.4		
2056					$0.1	$950.3		$7.4		
2057					$0.1	$925.7		$7.4		
2058					$0.1	$903.0		$7.4		
2059					$0.1	$882.1		$7.4		
2060					$0.1	$862.8		$7.4		
2061					$0.1	$844.9		$7.4		
2062					$0.1	$828.3		$7.4		
2063					$0.1	$813.0		$7.4		
2064					$0.1	$798.8		$7.4		

*Withdrawal costs are calculated using a quality-adjusted life-year that uses a 2% discount rate

2. Undiscounted Annual Benefits of the Rule for the Main Analysis, By Product Category

Table 108: Undiscounted Annual Averted Deaths and Quality-Adjusted Life Years Gained From of the Rule, Main Analysis, 50th Percentile**

	Averted Deaths						QALYs Gained
Year	Tobacco Attributable*	Non-Premium Cigar	Pipe Tobacco	Secondhand Smoke	SIDS	Fire	Tobacco Attributable*

2025							
2026							
2027							
2028							
2029							
2030	13,578	247	34	1,281	12	18	838,330
2031	19,619	362	49	1,852	18	26	822,925
2032	25,115	464	63	2,370	23	34	797,748
2033	30,006	558	75	2,832	27	40	768,809
2034	34,361	647	86	3,243	31	46	738,814
2035	38,315	731	96	3,616	35	52	709,532
2036	41,864	812	105	3,951	38	56	681,844
2037	45,040	891	113	4,251	41	61	655,685
2038	47,861	969	120	4,518	44	65	631,123
2039	50,273	1,044	126	4,746	46	68	609,597
2040	52,390	1,119	131	4,947	48	71	589,999
2041	54,137	1,193	136	5,112	50	73	571,911
2042	55,363	1,257	139	5,230	51	75	555,466
2043	56,331	1,320	141	5,322	52	76	540,399
2044	57,120	1,383	143	5,399	52	77	526,556
2045	57,759	1,443	145	5,460	53	78	513,895
2046	58,299	1,505	146	5,513	53	79	502,770
2047	58,713	1,572	147	5,553	54	79	492,810
2048	59,025	1,643	148	5,587	54	80	483,823
2049	59,212	1,715	149	5,606	54	80	475,710
2050	59,427	1,793	149	5,629	54	80	468,451
2051	59,589	1,876	150	5,646	54	81	462,140
2052	59,375	1,952	149	5,628	54	80	456,504
2053	59,110	2,030	149	5,605	54	80	451,445
2054	58,838	2,107	148	5,581	54	80	446,891
2055	58,624	2,182	148	5,562	54	79	442,859

2056	58,341	2,259	147	5,537	53	79	439,315
2057	58,176	2,348	146	5,523	53	79	436,235
2058	58,070	2,446	146	5,514	53	79	433,581
2059	57,843	2,547	146	5,494	53	79	431,318
2060	57,725	2,653	146	5,485	53	78	429,402
2061	57,420	2,753	145	5,457	53	78	428,198
2062	56,425	2,818	142	5,364	52	77	427,214
2063	55,496	2,886	140	5,278	51	75	426,414
2064	54,660	2,958	138	5,201	50	74	425,758

*Note: "Tobacco Attributable" refers to only cigarettes and noncombusted products. Please see section II.G.1.a for additional detail

**Note: 50th percentile estimates are taken from each years' results over the range of model outputs, therefore summing across years may result in rounding differences and may not represent cumulative totals

Table 109. Undiscounted Annual Benefits of the Rule, Main Analysis, Low Impact Scenario by Product Category ($ Millions, 2023)

	Value of Avoided Mortality						Value of Avoided Morbidity	Total Benefits
Year	Tobacco Attributable*	Non-Premium Cigar	Pipe Tobacco	Secondhand Smoke	SIDS	Fire	Tobacco Attributable*	All Categories
2025								
2026								
2027								
2028								
2029								
2030	$4,809.9	$87.5	$12.0	$453.9	$4.4	$6.5	$68,734.5	$74,115.6
2031	$10,917.7	$201.5	$27.3	$1,030.4	$10.0	$14.7	$80,446.3	$92,663.2
2032	$20,007.8	$369.6	$50.1	$1,888.6	$18.3	$27.0	$91,023.3	$113,412.8
2033	$30,985.0	$576.9	$77.6	$2,925.7	$28.3	$41.8	$100,128.0	$134,806.8

2034	$43,099.9	$812.0	$108.0	$4,070.5	$39.4	$58.2	$108,608.0	$156,856.4
2035	$55,701.3	$1,063.9	$139.5	$5,260.2	$51.0	$75.2	$116,381.8	$178,751.0
2036	$68,733.6	$1,334.4	$172.2	$6,492.5	$62.9	$92.8	$122,707.8	$199,692.7
2037	$82,110.6	$1,626.2	$205.8	$7,760.0	$75.2	$110.9	$128,378.6	$220,382.5
2038	$95,138.6	$1,927.4	$238.5	$8,991.0	$87.1	$128.5	$133,496.7	$240,141.3
2039	$108,131.2	$2,248.2	$271.2	$10,223.4	$99.1	$146.1	$138,335.1	$259,606.2
2040	$120,915.2	$2,586.4	$303.4	$11,437.1	$110.8	$163.5	$142,839.6	$278,525.7
2041	$133,282.8	$2,942.7	$334.6	$12,613.0	$122.2	$180.3	$146,386.9	$296,049.7
2042	$144,653.9	$3,292.5	$363.4	$13,699.7	$132.7	$195.8	$150,145.9	$312,687.4
2043	$155,579.8	$3,657.0	$391.2	$14,747.8	$142.9	$210.8	$152,942.5	$327,891.1
2044	$166,134.0	$4,037.4	$418.2	$15,765.3	$152.8	$225.3	$155,634.9	$342,602.0
2045	$176,609.5	$4,434.7	$445.0	$16,775.6	$162.6	$239.8	$157,733.6	$356,649.8
2046	$186,769.2	$4,849.1	$471.0	$17,757.0	$172.1	$253.8	$160,310.5	$370,846.2
2047	$196,470.6	$5,294.4	$496.2	$18,706.9	$181.3	$267.4	$163,052.2	$384,746.7
2048	$205,895.5	$5,770.5	$520.6	$19,625.1	$190.2	$280.5	$165,587.8	$398,161.6
2049	$214,561.5	$6,265.3	$543.1	$20,474.8	$198.4	$292.6	$167,584.4	$410,224.1
2050	$223,222.5	$6,793.7	$565.6	$21,322.8	$206.6	$304.8	$169,817.9	$422,550.5
2051	$231,606.1	$7,360.9	$587.6	$22,150.2	$214.6	$316.6	$171,704.2	$434,269.1
2052	$238,501.8	$7,927.7	$606.2	$22,854.1	$221.5	$326.6	$173,307.5	$444,084.9
2053	$245,272.2	$8,510.6	$623.4	$23,501.2	$227.7	$335.9	$175,273.2	$454,093.3
2054	$251,992.7	$9,124.6	$641.1	$24,170.0	$234.2	$345.5	$177,174.6	$464,041.6
2055	$258,735.8	$9,753.4	$659.6	$24,865.5	$240.9	$355.4	$179,133.7	$474,113.5
2056	$265,332.8	$10,413.2	$677.0	$25,520.2	$247.3	$364.8	$181,202.6	$484,136.7
2057	$272,941.2	$11,142.6	$695.2	$26,208.8	$254.0	$374.6	$183,228.4	$495,234.0
2058	$280,981.1	$11,954.0	$714.8	$26,948.4	$261.1	$385.2	$185,245.2	$506,890.0
2059	$287,764.9	$12,807.6	$732.9	$27,630.9	$267.7	$394.9	$187,630.7	$517,639.9
2060	$294,553.7	$13,710.3	$752.1	$28,352.8	$274.7	$405.2	$189,793.1	$528,262.9
2061	$301,158.7	$14,644.2	$770.0	$29,028.3	$281.3	$414.9	$192,133.5	$538,861.9
2062	$305,740.3	$15,498.2	$782.7	$29,505.7	$285.9	$421.7	$194,615.5	$547,288.2
2063	$310,421.3	$16,377.3	$794.5	$29,952.7	$290.2	$428.1	$197,090.6	$555,799.5
2064	$314,982.7	$17,282.2	$806.2	$30,390.8	$294.5	$434.4	$199,774.3	$564,416.2

*Note: "Tobacco Attributable" refers to only cigarettes and noncombusted products. Please see section II.G.1.a for additional detail

Table 110. Undiscounted Annual Benefits of the Rule, Main Analysis, Primary Impact Scenario by Product Category ($ Millions, 2023)

	Value of Avoided Mortality						Value of Avoided Morbidity	Total Benefits
Year	Tobacco Attributable*	Non-Premium Cigar	Pipe Tobacco	Secondhand Smoke	SIDS	Fire	Tobacco Attributable*	All Categories
2025								
2026								
2027								
2028								
2029								
2030	$188,870.5	$3,437.7	$472.8	$17,824.8	$172.7	$254.8	$525,591.7	$736,889.7
2031	$275,621.7	$5,086.4	$690.0	$26,012.0	$252.1	$371.8	$521,092.6	$829,512.8
2032	$356,353.6	$6,581.3	$892.1	$33,631.6	$325.9	$480.7	$510,201.4	$908,966.1
2033	$430,019.0	$8,002.7	$1,076.6	$40,584.6	$393.3	$580.1	$496,610.6	$977,869.4
2034	$497,357.0	$9,364.0	$1,245.2	$46,940.8	$454.9	$670.9	$482,007.4	$1,038,737.2
2035	$560,125.5	$10,692.1	$1,402.3	$52,866.4	$512.3	$755.6	$467,533.2	$1,094,672.5
2036	$618,130.1	$11,991.9	$1,547.7	$58,344.9	$565.4	$833.9	$453,781.6	$1,146,061.8
2037	$671,684.6	$13,286.2	$1,681.8	$63,400.3	$614.3	$906.2	$440,735.6	$1,193,250.4
2038	$720,887.7	$14,587.9	$1,805.1	$68,049.0	$659.4	$972.6	$428,467.6	$1,236,439.9
2039	$764,786.0	$15,878.2	$1,915.3	$72,202.5	$699.6	$1,032.0	$417,992.4	$1,275,578.1
2040	$804,966.2	$17,187.4	$2,016.1	$76,003.3	$736.5	$1,086.3	$408,599.7	$1,311,724.1
2041	$840,123.3	$18,509.4	$2,104.4	$79,333.7	$768.7	$1,133.9	$400,034.3	$1,343,185.8
2042	$867,741.8	$19,699.0	$2,174.2	$81,966.1	$794.2	$1,171.5	$392,416.6	$1,367,180.6
2043	$891,745.2	$20,891.7	$2,234.8	$84,250.3	$816.4	$1,204.2	$385,590.2	$1,387,983.9
2044	$913,278.6	$22,105.7	$2,289.7	$86,317.9	$836.4	$1,233.7	$379,469.7	$1,406,813.5

2045	$932,727.8	$23,309.8	$2,339.0	$88,176.7	$854.4	$1,260.3	$374,048.7	$1,424,026.0
2046	$950,862.4	$24,553.9	$2,385.1	$89,915.1	$871.3	$1,285.1	$369,610.5	$1,440,818.7
2047	$967,195.0	$25,890.7	$2,426.6	$91,480.1	$886.4	$1,307.5	$365,911.4	$1,456,456.3
2048	$982,056.3	$27,330.4	$2,465.6	$92,948.5	$900.7	$1,328.5	$362,831.3	$1,471,241.5
2049	$995,006.7	$28,826.3	$2,498.9	$94,203.5	$912.8	$1,346.4	$360,314.6	$1,484,508.1
2050	$1,008,613.3	$30,438.2	$2,534.1	$95,533.6	$925.7	$1,365.4	$358,364.4	$1,499,193.5
2051	$1,021,481.1	$32,164.9	$2,567.5	$96,790.0	$937.9	$1,383.4	$357,071.9	$1,513,833.9
2052	$1,027,989.5	$33,801.7	$2,584.8	$97,444.3	$944.2	$1,392.7	$356,244.3	$1,521,848.5
2053	$1,033,627.5	$35,492.3	$2,599.8	$98,008.8	$949.7	$1,400.8	$355,819.2	$1,529,353.6
2054	$1,039,161.2	$37,211.0	$2,614.6	$98,567.8	$955.1	$1,408.8	$355,752.5	$1,537,134.7
2055	$1,045,745.0	$38,916.2	$2,631.8	$99,213.6	$961.4	$1,418.0	$356,068.1	$1,546,427.3
2056	$1,051,103.2	$40,701.1	$2,646.0	$99,748.8	$966.6	$1,425.7	$356,751.0	$1,554,823.6
2057	$1,058,603.1	$42,723.2	$2,665.6	$100,490.9	$973.7	$1,436.3	$357,792.6	$1,566,177.7
2058	$1,067,251.2	$44,954.7	$2,688.2	$101,343.1	$982.0	$1,448.5	$359,171.7	$1,579,344.3
2059	$1,073,695.0	$47,274.5	$2,705.4	$101,989.0	$988.3	$1,457.7	$360,869.6	$1,590,493.9
2060	$1,082,218.4	$49,730.3	$2,728.0	$102,841.9	$996.5	$1,469.9	$362,859.9	$1,604,372.1
2061	$1,087,270.9	$52,129.3	$2,741.0	$103,333.0	$1,001.3	$1,476.9	$365,460.5	$1,614,947.3
2062	$1,079,125.8	$53,885.6	$2,721.3	$102,588.5	$994.1	$1,466.3	$368,266.7	$1,610,571.6
2063	$1,071,969.0	$55,742.6	$2,704.3	$101,948.1	$987.9	$1,457.1	$371,252.9	$1,607,575.8
2064	$1,066,379.9	$57,700.4	$2,691.5	$101,466.5	$983.2	$1,450.2	$374,389.1	$1,606,567.6

*Note: "Tobacco Attributable" refers to only cigarettes and noncombusted products. Please see section II.G.1.a for additional detail

Table 111. Undiscounted Annual Benefits of the Rule, Main Analysis, High Impact Scenario by Product Category ($ Millions, 2023)

	Value of Avoided Mortality						Value of Avoided Morbidity	Total Benefits
Year	Tobacco Attributable*	Non-Premium Cigar	Pipe Tobacco	Secondhand Smoke	SIDS	Fire	Tobacco Attributable*	All Categories
2025								

2026								
2027								
2028								
2029								
2030	$323,871.1	$5,894.9	$810.8	$30,565.6	$296.2	$436.9	$567,423.4	$929,752.7
2031	$404,810.9	$7,470.6	$1,013.4	$38,204.4	$370.2	$546.0	$546,517.0	$999,499.8
2032	$479,297.0	$8,851.9	$1,199.9	$45,234.6	$438.3	$646.5	$527,157.8	$1,063,497.8
2033	$547,340.0	$10,186.1	$1,370.3	$51,657.1	$500.6	$738.3	$509,098.4	$1,121,657.9
2034	$610,077.8	$11,486.2	$1,527.4	$57,579.6	$557.9	$823.0	$492,140.2	$1,175,047.2
2035	$669,149.4	$12,773.2	$1,675.3	$63,156.6	$612.0	$902.7	$476,277.6	$1,225,484.6
2036	$724,043.4	$14,046.1	$1,812.8	$68,339.7	$662.2	$976.8	$461,678.3	$1,272,574.2
2037	$774,664.5	$15,323.2	$1,939.6	$73,120.9	$708.5	$1,045.1	$448,246.3	$1,316,134.0
2038	$820,728.8	$16,608.2	$2,055.1	$77,473.1	$750.7	$1,107.3	$435,660.6	$1,355,534.3
2039	$861,718.8	$17,890.1	$2,157.9	$81,351.0	$788.3	$1,162.7	$425,050.0	$1,391,326.9
2040	$899,934.1	$19,213.9	$2,253.8	$84,965.0	$823.3	$1,214.4	$415,672.4	$1,425,338.6
2041	$933,094.0	$20,556.4	$2,337.2	$88,107.4	$853.8	$1,259.3	$407,178.8	$1,454,695.0
2042	$958,154.3	$21,749.2	$2,400.5	$90,496.6	$876.9	$1,293.4	$399,627.2	$1,475,942.0
2043	$980,560.0	$22,967.4	$2,456.9	$92,621.3	$897.5	$1,323.8	$392,887.0	$1,495,089.3
2044	$999,320.5	$24,180.8	$2,504.6	$94,420.9	$914.9	$1,349.5	$386,850.3	$1,510,943.7
2045	$1,016,609.5	$25,400.9	$2,548.8	$96,087.1	$931.1	$1,373.3	$381,516.3	$1,525,894.0
2046	$1,033,482.8	$26,683.9	$2,592.0	$97,715.0	$946.9	$1,396.6	$377,163.0	$1,541,431.2
2047	$1,048,670.6	$28,069.9	$2,630.9	$99,179.9	$961.0	$1,417.5	$373,539.7	$1,555,942.3
2048	$1,062,725.6	$29,566.4	$2,667.3	$100,553.2	$974.4	$1,437.2	$370,544.6	$1,569,961.8
2049	$1,074,703.4	$31,125.0	$2,698.1	$101,715.5	$985.6	$1,453.8	$368,112.4	$1,582,304.3
2050	$1,087,461.2	$32,805.6	$2,731.2	$102,964.0	$997.7	$1,471.6	$366,246.6	$1,596,207.0
2051	$1,099,593.3	$34,609.7	$2,762.6	$104,146.9	$1,009.2	$1,488.5	$365,042.1	$1,610,198.9
2052	$1,105,263.0	$36,321.8	$2,777.5	$104,709.3	$1,014.6	$1,496.6	$364,303.6	$1,617,441.3
2053	$1,109,517.3	$38,079.1	$2,789.3	$105,152.1	$1,018.9	$1,502.9	$363,966.4	$1,623,587.5
2054	$1,113,836.7	$39,862.0	$2,800.9	$105,589.9	$1,023.2	$1,509.2	$363,986.4	$1,630,176.2
2055	$1,119,197.2	$41,628.0	$2,815.2	$106,127.3	$1,028.4	$1,516.8	$364,389.9	$1,638,278.8
2056	$1,122,748.0	$43,450.7	$2,824.7	$106,487.5	$1,031.9	$1,522.0	$365,162.9	$1,644,809.0

2057	$1,129,307.7	$45,553.8	$2,842.2	$107,148.8	$1,038.3	$1,531.4	$366,297.6	$1,655,311.0
2058	$1,137,600.7	$47,892.6	$2,863.9	$107,966.2	$1,046.2	$1,543.1	$367,773.9	$1,668,289.9
2059	$1,143,770.2	$50,338.8	$2,880.7	$108,599.9	$1,052.3	$1,552.2	$369,571.6	$1,679,378.4
2060	$1,152,484.5	$52,932.3	$2,903.6	$109,463.6	$1,060.7	$1,564.5	$371,662.8	$1,693,697.5
2061	$1,154,060.3	$55,316.6	$2,908.6	$109,650.9	$1,062.5	$1,567.2	$374,364.7	$1,700,559.0
2062	$1,142,041.7	$57,018.0	$2,879.5	$108,551.9	$1,051.9	$1,551.5	$377,273.2	$1,691,979.6
2063	$1,133,199.7	$58,917.6	$2,858.3	$107,755.0	$1,044.1	$1,540.1	$380,364.9	$1,687,280.0
2064	$1,127,068.6	$60,969.9	$2,844.0	$107,215.8	$1,038.9	$1,532.4	$383,611.6	$1,685,873.4

*Note: "Tobacco Attributable" refers to only cigarettes and noncombusted products. Please see section II.G.1.a for additional detail

3. Undiscounted Annual Transfers of the Rule for the Main Analysis

Table 112. Undiscounted Annual Transfers of the Rule, Main Analysis, Low Impact Scenario ($ Millions, 2023)

Year	Federal Tax to Consumers	State Tax to Consumers	Firm Revenue to Consumers	User Fees from Combusted to Noncombusted Firms
2025				
2026				
2027				
2028	$306.2	$645.7	-$4,395.6	$0.0
2029	$564.1	$1,176.3	-$2,485.1	$5.7
2030	$786.1	$1,632.3	-$781.4	$6.5
2031	$978.8	$2,027.3	$954.6	$7.5
2032	$1,140.9	$2,359.2	$2,896.3	$8.4
2033	$1,278.7	$2,640.6	$4,293.8	$9.4
2034	$1,391.3	$2,870.3	$5,399.5	$10.5
2035	$1,490.6	$3,072.8	$6,283.2	$11.8

2036	$1,576.2	$3,247.0	$7,001.9	$13.4
2037	$1,638.7	$3,373.8	$7,506.0	$15.2
2038	$1,687.4	$3,472.3	$7,904.1	$17.0
2039	$1,731.4	$3,561.1	$8,234.5	$18.9
2040	$1,765.9	$3,630.2	$8,528.6	$21.0
2041	$1,799.0	$3,696.7	$8,798.0	$23.2
2042	$1,817.0	$3,732.2	$8,974.1	$25.6
2043	$1,830.3	$3,758.2	$9,097.5	$27.8
2044	$1,840.6	$3,778.2	$9,214.2	$30.0
2045	$1,845.9	$3,787.8	$9,294.9	$32.3
2046	$1,843.0	$3,780.9	$9,320.1	$34.5
2047	$1,842.3	$3,778.7	$9,357.9	$36.6
2048	$1,840.0	$3,773.1	$9,381.2	$38.7
2049	$1,842.6	$3,777.7	$9,440.9	$40.8
2050	$1,837.6	$3,766.9	$9,438.5	$43.0
2051	$1,831.0	$3,752.7	$9,441.9	$45.0
2052	$1,823.5	$3,737.0	$9,440.5	$46.8
2053	$1,810.4	$3,709.7	$9,404.8	$48.5
2054	$1,800.7	$3,689.7	$9,390.8	$50.0
2055	$1,792.5	$3,672.5	$9,381.9	$51.5
2056	$1,781.4	$3,649.6	$9,366.5	$52.9
2057	$1,773.3	$3,633.0	$9,362.4	$54.2
2058	$1,762.9	$3,611.7	$9,336.1	$55.6
2059	$1,754.8	$3,595.2	$9,328.2	$56.7
2060	$1,745.5	$3,576.2	$9,315.6	$57.9
2061	$1,738.2	$3,561.3	$9,314.4	$58.9
2062	$1,728.8	$3,542.2	$9,304.6	$60.0
2063	$1,718.8	$3,522.2	$9,284.8	$60.9
2064	$1,710.8	$3,506.0	$9,282.6	$61.6

Table 113. Undiscounted Annual Transfers of the Rule, Main Analysis, Primary Impact Scenario ($ Millions, 2023)

Year	Federal Tax to Consumers	State Tax to Consumers	Firm Revenue to Consumers	User Fees from Combusted to Noncombusted Firms
2025				
2026				
2027				
2028	$4,910.6	$10,160.9	$13,681.2	$0.0
2029	$6,291.7	$12,998.7	$24,405.3	$51.2
2030	$6,678.2	$13,784.7	$29,162.5	$108.6
2031	$6,660.9	$13,740.5	$30,417.6	$185.7
2032	$6,483.6	$13,367.8	$32,206.3	$269.4
2033	$6,252.4	$12,884.9	$31,821.0	$338.0
2034	$6,007.4	$12,374.2	$30,907.3	$385.4
2035	$5,766.1	$11,872.0	$29,791.6	$413.9
2036	$5,536.1	$11,393.6	$28,635.4	$430.1
2037	$5,318.8	$10,941.8	$27,491.1	$439.4
2038	$5,114.6	$10,517.5	$26,388.8	$444.2
2039	$4,923.9	$10,121.4	$25,303.5	$445.8
2040	$4,748.5	$9,757.3	$24,373.7	$446.6
2041	$4,587.8	$9,423.8	$23,518.3	$446.0
2042	$4,440.7	$9,118.7	$22,721.2	$444.5
2043	$4,306.0	$8,839.5	$21,999.2	$442.5
2044	$4,182.6	$8,583.7	$21,335.5	$440.6
2045	$4,069.0	$8,348.4	$20,723.6	$438.9
2046	$3,964.5	$8,132.2	$20,164.7	$437.2
2047	$3,868.4	$7,933.4	$19,651.8	$435.7
2048	$3,779.9	$7,750.4	$19,164.4	$434.4
2049	$3,698.4	$7,582.1	$18,727.9	$433.2
2050	$3,623.3	$7,427.1	$18,325.4	$432.1

2051	$3,554.0	$7,284.3	$17,966.6	$431.1
2052	$3,490.0	$7,152.3	$17,628.5	$430.1
2053	$3,431.0	$7,030.9	$17,339.1	$429.3
2054	$3,376.4	$6,918.5	$17,077.1	$428.5
2055	$3,325.7	$6,814.5	$16,826.8	$427.9
2056	$3,278.9	$6,718.4	$16,603.0	$427.3
2057	$3,235.6	$6,629.5	$16,403.4	$426.8
2058	$3,195.4	$6,547.3	$16,220.6	$426.2
2059	$3,158.1	$6,471.0	$16,059.6	$425.8
2060	$3,123.4	$6,400.2	$15,913.6	$425.3
2061	$3,091.1	$6,334.5	$15,784.2	$425.0
2062	$3,061.1	$6,273.3	$15,668.8	$424.6
2063	$3,033.3	$6,216.8	$15,571.1	$424.3
2064	$3,007.4	$6,164.4	$15,486.4	$424.1

Table 114. Undiscounted Annual Transfers of the Rule, Main Analysis, High Impact Scenario ($ Millions, 2023)

Year	Federal Tax to Consumers	State Tax to Consumers	Firm Revenue to Consumers	User Fees from Combusted to Noncombusted Firms
2025				
2026				
2027				
2028	$8,120.1	$16,793.0	$26,520.3	$0.0
2029	$7,718.7	$15,953.1	$26,716.6	$558.6
2030	$7,335.0	$15,152.5	$26,066.5	$565.0
2031	$6,978.1	$14,408.3	$25,262.9	$565.9
2032	$6,648.8	$13,721.9	$26,701.3	$564.7
2033	$6,344.3	$13,087.2	$26,171.0	$562.6
2034	$6,063.7	$12,502.6	$25,335.1	$559.5

2035	$5,804.9	$11,963.6	$24,415.6	$556.5
2036	$5,565.6	$11,465.4	$23,489.4	$553.4
2037	$5,344.2	$11,004.4	$22,602.0	$550.5
2038	$5,138.9	$10,577.4	$21,757.5	$547.8
2039	$4,948.1	$10,180.5	$20,927.0	$545.2
2040	$4,773.6	$9,817.5	$20,226.4	$542.8
2041	$4,614.5	$9,486.9	$19,586.8	$539.9
2042	$4,469.5	$9,185.6	$19,010.4	$537.1
2043	$4,336.9	$8,910.3	$18,491.4	$534.4
2044	$4,215.2	$8,657.7	$18,001.1	$531.9
2045	$4,103.4	$8,425.7	$17,552.3	$529.6
2046	$4,000.5	$8,212.4	$17,145.9	$527.6
2047	$3,905.8	$8,016.1	$16,775.8	$525.7
2048	$3,818.5	$7,835.4	$16,422.8	$523.9
2049	$3,738.0	$7,668.9	$16,087.8	$522.3
2050	$3,663.8	$7,515.7	$15,789.7	$520.8
2051	$3,595.4	$7,374.4	$15,526.8	$519.3
2052	$3,532.3	$7,244.1	$15,296.3	$518.0
2053	$3,473.9	$7,123.7	$15,081.7	$516.8
2054	$3,419.8	$7,012.3	$14,892.3	$515.6
2055	$3,369.7	$6,909.2	$14,716.0	$514.5
2056	$3,323.3	$6,813.8	$14,554.1	$513.5
2057	$3,280.3	$6,725.6	$14,410.9	$512.6
2058	$3,240.5	$6,644.0	$14,283.7	$511.7
2059	$3,203.5	$6,568.2	$14,170.4	$510.9
2060	$3,169.0	$6,497.7	$14,069.4	$510.1
2061	$3,136.9	$6,432.3	$13,977.7	$509.4
2062	$3,107.0	$6,371.4	$13,901.1	$508.7
2063	$3,079.3	$6,315.0	$13,836.7	$508.1
2064	$3,053.5	$6,262.7	$13,781.5	$507.5

4. Undiscounted Annual Costs of the Rule for the No Menthol, No Cigar Flavors Baseline

Table 115. Undiscounted Annual Costs of the Rule, No Cigar Flavors, No Menthol Analysis, Low Impact Scenario ($ Millions, 2023)

	Industry						Government		Consumer	
Year	Reading and Understanding	Economic Transition	Reformulation	Premarket Submission	Testing	Producer Surplus (loss)	Premarket Review	Enforcement	Search	Withdrawal
2025	$112.1									
2026		$4,306.9	$8,968.0	$15.0			$15.6			
2027								$4.2	$517.7	$18.0
2028					$5.6	$11.7		$4.2		
2029					$5.2	$36.0		$3.5		
2030					$4.8	$69.4		$3.5		
2031					$4.5	$107.0		$3.5		
2032					$4.2	$149.4		$3.5		
2033					$3.9	$192.9		$3.5		
2034					$3.7	$235.9		$3.5		
2035					$3.4	$278.4		$3.5		
2036					$3.2	$318.1		$3.5		
2037					$3.0	$352.1		$3.5		
2038					$2.9	$384.2		$3.5		
2039					$2.7	$412.6		$3.5		
2040					$2.6	$438.7		$3.5		
2041					$2.4	$460.6		$3.5		
2042					$2.3	$483.3		$3.5		
2043					$2.2	$504.6		$3.5		
2044					$2.1	$524.1		$3.5		
2045					$2.0	$541.2		$3.5		
2046					$2.0	$554.1		$3.5		
2047					$1.9	$567.0		$3.5		

2048					$1.8	$576.2		$3.5		
2049					$1.8	$581.8		$3.5		
2050					$1.7	$589.0		$3.5		
2051					$1.7	$595.2		$3.5		
2052					$1.6	$600.4		$3.5		
2053					$1.6	$604.7		$3.5		
2054					$1.6	$608.5		$3.5		
2055					$1.5	$611.4		$3.5		
2056					$1.5	$614.4		$3.5		
2057					$1.5	$616.7		$3.5		
2058					$1.4	$618.0		$3.5		
2059					$1.4	$618.7		$3.5		
2060					$1.4	$619.6		$3.5		
2061					$1.4	$621.0		$3.5		
2062					$1.4	$619.6		$3.5		
2063					$1.4	$619.6		$3.5		
2064					$1.3	$619.0		$3.5		

Table 116. Undiscounted Annual Costs of the Rule, No Cigar Flavors, No Menthol Analysis, Primary Impact Scenario ($ Millions, 2023)

	Industry						Government		Consumer	
Year	Reading and Understanding	Economic Transition	Reformulation	Premarket Submission	Testing	Producer Surplus (loss)	Premarket Review	Enforcement	Search	Withdrawal
2025	$373.5									
2026		$7,145.1	$610.4	$1.0			$1.1			
2027								$6.9	$1,553.0	$1,665.8
2028					$4.3	$1,738.5		$6.9		
2029					$2.3	$3,294.2		$5.4		
2030					$1.3	$4,119.8		$5.4		

2031					$0.8	$4,431.5		$5.4		
2032					$0.5	$4,475.0		$5.4		
2033					$0.4	$4,382.1		$5.4		
2034					$0.3	$4,226.4		$5.4		
2035					$0.2	$4,046.7		$5.4		
2036					$0.2	$3,863.5		$5.4		
2037					$0.2	$3,683.0		$5.4		
2038					$0.2	$3,510.3		$5.4		
2039					$0.2	$3,347.6		$5.4		
2040					$0.2	$3,199.6		$5.4		
2041					$0.2	$3,066.1		$5.4		
2042					$0.2	$2,945.8		$5.4		
2043					$0.2	$2,836.5		$5.4		
2044					$0.2	$2,737.3		$5.4		
2045					$0.2	$2,646.7		$5.4		
2046					$0.2	$2,564.3		$5.4		
2047					$0.2	$2,488.8		$5.4		
2048					$0.2	$2,420.0		$5.4		
2049					$0.2	$2,356.8		$5.4		
2050					$0.2	$2,298.8		$5.4		
2051					$0.2	$2,245.5		$5.4		
2052					$0.2	$2,196.3		$5.4		
2053					$0.2	$2,151.1		$5.4		
2054					$0.2	$2,109.2		$5.4		
2055					$0.2	$2,070.5		$5.4		
2056					$0.2	$2,034.7		$5.4		
2057					$0.2	$2,001.7		$5.4		
2058					$0.2	$1,971.2		$5.4		
2059					$0.2	$1,942.8		$5.4		
2060					$0.2	$1,916.5		$5.4		
2061					$0.2	$1,892.0		$5.4		

2062					$0.2	$1,869.3		$5.4		
2063					$0.2	$1,848.3		$5.4		
2064					$0.2	$1,828.8		$5.4		

Table 117. Undiscounted Annual Costs of the Rule, No Cigar Flavors, No Menthol Analysis, High Impact Scenario ($ Millions, 2023)

	Industry						Government		Consumer	
Year	Reading and Understanding	Economic Transition	Reformulation	Premarket Submission	Testing	Producer Surplus (loss)	Premarket Review	Enforcement	Search	Withdrawal
2025	$700.4									
2026		$9,109.5	$35.2	$0.1			$0.1			
2027								$9.6	$3,106.0	$10,829.1
2028					$0.5	$6,353.6		$9.6		
2029					$0.2	$6,132.3		$7.4		
2030					$0.2	$5,769.8		$7.4		
2031					$0.1	$5,415.1		$7.4		
2032					$0.1	$5,088.0		$7.4		
2033					$0.1	$4,789.5		$7.4		
2034					$0.1	$4,518.3		$7.4		
2035					$0.1	$4,271.5		$7.4		
2036					$0.1	$4,046.0		$7.4		
2037					$0.1	$3,839.3		$7.4		
2038					$0.1	$3,649.6		$7.4		
2039					$0.1	$3,474.4		$7.4		
2040					$0.1	$3,319.1		$7.4		
2041					$0.1	$3,180.5		$7.4		
2042					$0.1	$3,056.1		$7.4		
2043					$0.1	$2,944.0		$7.4		
2044					$0.1	$2,842.5		$7.4		

2045					$0.1	$2,750.0		$7.4		
2046					$0.1	$2,665.7		$7.4		
2047					$0.1	$2,588.4		$7.4		
2048					$0.1	$2,517.8		$7.4		
2049					$0.1	$2,452.9		$7.4		
2050					$0.1	$2,393.4		$7.4		
2051					$0.1	$2,338.6		$7.4		
2052					$0.1	$2,288.1		$7.4		
2053					$0.1	$2,241.6		$7.4		
2054					$0.1	$2,198.5		$7.4		
2055					$0.1	$2,158.6		$7.4		
2056					$0.1	$2,121.8		$7.4		
2057					$0.1	$2,087.8		$7.4		
2058					$0.1	$2,056.3		$7.4		
2059					$0.1	$2,027.0		$7.4		
2060					$0.1	$1,999.8		$7.4		
2061					$0.1	$1,974.5		$7.4		
2062					$0.1	$1,951.0		$7.4		
2063					$0.1	$1,929.3		$7.4		
2064					$0.1	$1,909.2		$7.4		

5. Undiscounted Annual Benefits of the Rule for the No Menthol, No Cigar Flavors Baseline

Table 118. Undiscounted Annual Benefits of the Rule, No Cigar Flavors, No Menthol Analysis, Low Impact Scenario by Product Category ($ Millions, 2023)

	Avoided Mortality						Avoided Morbidity
Year	Tobacco Attributable*	Non-Premium Cigar	Pipe Tobacco	Secondhand Smoke	SIDS	Fire	Tobacco Attributable*

2025							
2026							
2027							
2028							
2029							
2030	$4,075.7	$73.8	$10.2	$384.7	$3.7	$5.5	$77,297.0
2031	$9,631.8	$176.4	$24.1	$909.0	$8.8	$13.0	$93,503.7
2032	$18,165.0	$332.5	$45.5	$1,714.9	$16.6	$24.5	$108,063.2
2033	$28,566.5	$526.1	$71.6	$2,697.7	$26.1	$38.6	$121,926.6
2034	$40,343.4	$750.6	$101.1	$3,811.6	$36.9	$54.5	$134,882.8
2035	$52,748.2	$992.8	$132.2	$4,983.0	$48.3	$71.2	$147,018.2
2036	$65,977.1	$1,259.8	$165.4	$6,234.8	$60.4	$89.1	$157,437.6
2037	$79,812.5	$1,551.6	$200.2	$7,548.3	$73.1	$107.9	$167,470.4
2038	$93,609.4	$1,857.3	$234.8	$8,853.0	$85.8	$126.5	$176,298.9
2039	$107,661.1	$2,186.5	$270.1	$10,184.1	$98.7	$145.6	$184,739.7
2040	$121,817.2	$2,540.8	$306.0	$11,537.2	$111.8	$164.9	$193,833.6
2041	$135,894.2	$2,918.7	$341.7	$12,880.6	$124.8	$184.1	$202,254.3
2042	$149,313.8	$3,298.3	$375.8	$14,168.0	$137.3	$202.5	$210,319.7
2043	$162,419.7	$3,700.1	$409.7	$15,446.8	$149.7	$220.8	$217,974.9
2044	$175,775.8	$4,126.1	$443.7	$16,726.9	$162.1	$239.1	$224,799.8
2045	$189,169.9	$4,577.6	$478.3	$18,031.1	$174.7	$257.7	$231,671.8
2046	$202,506.8	$5,058.9	$513.3	$19,350.1	$187.5	$276.6	$237,968.2
2047	$215,592.3	$5,569.7	$547.1	$20,623.0	$199.8	$294.8	$243,806.9
2048	$228,631.3	$6,134.7	$582.0	$21,939.3	$212.6	$313.6	$249,731.1
2049	$240,855.3	$6,707.1	$613.6	$23,131.9	$224.1	$330.6	$255,513.5
2050	$253,572.2	$7,334.4	$646.9	$24,388.5	$236.3	$348.6	$261,119.2
2051	$265,983.7	$8,010.6	$680.3	$25,644.6	$248.5	$366.5	$266,918.4
2052	$276,876.1	$8,668.8	$708.1	$26,695.8	$258.7	$381.6	$272,590.0
2053	$288,075.5	$9,374.5	$736.7	$27,772.3	$269.1	$396.9	$278,136.8
2054	$299,049.0	$10,110.2	$765.5	$28,858.0	$279.6	$412.5	$283,826.6
2055	$309,924.8	$10,875.6	$796.1	$30,011.3	$290.8	$428.9	$289,213.1

2056	$321,345.0	$11,688.8	$826.4	$31,153.2	$301.9	$445.3	$294,566.0
2057	$333,705.2	$12,568.0	$857.2	$32,317.1	$313.2	$461.9	$300,152.8
2058	$347,048.1	$13,562.5	$891.7	$33,614.8	$325.7	$480.4	$305,552.5
2059	$359,401.8	$14,605.9	$924.4	$34,850.2	$337.7	$498.1	$311,244.2
2060	$371,799.1	$15,676.3	$957.0	$36,079.4	$349.6	$515.7	$316,891.9
2061	$384,226.6	$16,834.0	$991.7	$37,383.9	$362.2	$534.3	$322,360.9
2062	$394,295.2	$17,888.1	$1,018.2	$38,383.9	$371.9	$548.6	$327,790.7
2063	$405,379.0	$19,030.5	$1,047.2	$39,479.1	$382.5	$564.3	$333,047.4
2064	$416,513.0	$20,150.1	$1,073.2	$40,457.9	$392.0	$578.3	$338,668.1

*Note: "Tobacco Attributable" refers to only cigarettes and noncombusted products. Please see section II.G.1.a for additional detail

Table 119. Undiscounted Annual Benefits of the Rule, No Cigar Flavors, No Menthol Analysis, Primary Impact Scenario by Product Category ($ Millions, 2023)

	Avoided Mortality, Monetized by VSL						Avoided Morbidity
Year	Tobacco Attributable*	Non-Premium Cigar	Pipe Tobacco	Secondhand Smoke	SIDS	Fire	Tobacco Attributable*
2025							
2026							
2027							
2028							
2029							
2030	$172,094.0	$3,114.6	$430.8	$16,241.5	$157.4	$232.1	$564,341.2
2031	$262,468.2	$4,808.0	$657.1	$24,770.7	$240.0	$354.0	$580,263.1
2032	$348,636.8	$6,380.2	$872.8	$32,903.6	$318.8	$470.3	$585,469.0
2033	$430,337.7	$7,921.2	$1,077.4	$40,616.1	$393.6	$580.5	$585,021.1
2034	$506,291.6	$9,409.8	$1,267.6	$47,785.7	$463.0	$683.0	$581,241.2
2035	$577,995.6	$10,869.6	$1,447.1	$54,554.7	$528.6	$779.7	$575,823.9
2036	$645,406.6	$12,309.9	$1,616.1	$60,924.1	$590.3	$870.8	$569,971.8
2037	$708,583.0	$13,749.8	$1,774.3	$66,890.4	$648.2	$956.0	$564,038.4

2038	$767,576.6	$15,202.2	$1,922.1	$72,461.8	$702.1	$1,035.7	$557,748.8
2039	$820,989.2	$16,642.6	$2,056.2	$77,515.4	$751.1	$1,107.9	$553,365.1
2040	$871,058.0	$18,114.1	$2,181.9	$82,253.4	$797.0	$1,175.6	$549,715.9
2041	$916,311.4	$19,613.9	$2,296.1	$86,558.4	$838.7	$1,237.1	$546,473.3
2042	$953,744.8	$20,978.2	$2,390.3	$90,112.9	$873.2	$1,288.0	$543,878.1
2043	$987,739.2	$22,363.2	$2,476.5	$93,360.4	$904.7	$1,334.4	$541,900.6
2044	$1,018,705.3	$23,760.8	$2,555.1	$96,325.1	$933.4	$1,376.7	$540,372.3
2045	$1,048,325.5	$25,170.9	$2,630.0	$99,148.5	$960.7	$1,417.1	$539,267.2
2046	$1,075,943.5	$26,620.6	$2,701.0	$101,823.3	$986.7	$1,455.3	$539,145.3
2047	$1,101,229.1	$28,165.6	$2,766.4	$104,289.0	$1,010.6	$1,490.6	$539,686.6
2048	$1,124,969.9	$29,804.1	$2,827.4	$106,588.1	$1,032.8	$1,523.4	$540,730.5
2049	$1,146,453.7	$31,510.6	$2,882.8	$108,676.2	$1,053.1	$1,553.3	$542,217.2
2050	$1,168,652.1	$33,335.9	$2,940.4	$110,848.6	$1,074.1	$1,584.3	$544,218.5
2051	$1,189,992.8	$35,283.3	$2,996.2	$112,952.9	$1,094.5	$1,614.4	$546,836.4
2052	$1,204,187.1	$37,139.0	$3,033.8	$114,370.1	$1,108.2	$1,634.7	$549,873.6
2053	$1,217,628.4	$39,056.0	$3,069.2	$115,704.8	$1,121.2	$1,653.7	$553,254.7
2054	$1,230,977.4	$41,001.0	$3,104.4	$117,031.1	$1,134.0	$1,672.7	$556,940.3
2055	$1,245,562.3	$42,926.8	$3,142.2	$118,456.7	$1,147.8	$1,693.1	$560,979.0
2056	$1,259,269.1	$44,950.9	$3,177.9	$119,803.6	$1,160.9	$1,712.3	$565,366.4
2057	$1,275,458.5	$47,208.0	$3,220.0	$121,389.6	$1,176.3	$1,735.0	$570,108.7
2058	$1,292,682.2	$49,671.8	$3,265.7	$123,112.4	$1,193.0	$1,759.6	$575,191.5
2059	$1,307,351.4	$52,208.0	$3,304.4	$124,570.0	$1,207.1	$1,780.4	$580,586.2
2060	$1,324,801.7	$54,877.2	$3,350.3	$126,301.3	$1,223.8	$1,805.2	$586,278.8
2061	$1,339,659.4	$57,531.8	$3,389.1	$127,763.3	$1,238.0	$1,826.1	$592,766.2
2062	$1,340,333.6	$59,602.8	$3,392.5	$127,894.0	$1,239.3	$1,827.9	$599,452.0
2063	$1,341,816.3	$61,754.2	$3,398.3	$128,110.5	$1,241.4	$1,831.0	$606,305.2
2064	$1,344,484.4	$63,968.0	$3,406.9	$128,436.8	$1,244.5	$1,835.7	$613,282.5

*Note: "Tobacco Attributable" refers to only cigarettes and noncombusted products. Please see section II.G.1.a for additional detail

Table 120. Undiscounted Annual Benefits of the Rule, No Cigar Flavors, No Menthol Analysis, High Impact Scenario by Product Category ($ Millions, 2023)

	Avoided Mortality, Monetized by VSL						Avoided Morbidity
Year	Tobacco Attributable*	Non-Premium Cigar	Pipe Tobacco	Secondhand Smoke	SIDS	Fire	Tobacco Attributable*
2025							
2026							
2027							
2028							
2029							
2030	$323,694.8	$5,858.4	$810.3	$30,549.0	$296.0	$436.6	$641,923.3
2031	$414,050.8	$7,584.7	$1,036.5	$39,076.4	$378.6	$558.5	$630,780.7
2032	$497,331.4	$9,101.2	$1,245.1	$46,936.7	$454.8	$670.8	$620,423.6
2033	$574,755.3	$10,579.3	$1,438.9	$54,245.3	$525.6	$775.3	$610,700.7
2034	$646,989.8	$12,024.7	$1,619.8	$61,064.7	$591.7	$872.8	$601,424.3
2035	$714,975.7	$13,445.6	$1,790.1	$67,483.9	$653.9	$964.5	$592,675.7
2036	$779,673.1	$14,869.7	$1,952.1	$73,593.3	$713.1	$1,051.8	$584,627.5
2037	$839,508.9	$16,290.0	$2,102.1	$79,248.1	$767.9	$1,132.7	$577,271.6
2038	$895,429.6	$17,735.7	$2,242.5	$84,538.0	$819.2	$1,208.3	$570,222.0
2039	$946,150.8	$19,179.7	$2,369.6	$89,332.2	$865.6	$1,276.8	$565,318.4
2040	$993,910.1	$20,667.9	$2,489.5	$93,850.0	$909.4	$1,341.4	$561,438.5
2041	$1,036,998.3	$22,193.6	$2,598.0	$97,942.7	$949.1	$1,399.9	$558,175.3
2042	$1,071,381.9	$23,562.7	$2,684.8	$101,214.5	$980.8	$1,446.6	$555,635.8
2043	$1,102,975.6	$24,963.3	$2,764.4	$104,215.3	$1,009.8	$1,489.5	$553,685.6
2044	$1,130,964.8	$26,369.6	$2,835.7	$106,900.9	$1,035.9	$1,527.9	$552,223.3
2045	$1,157,199.3	$27,785.1	$2,903.2	$109,445.8	$1,060.5	$1,564.3	$551,261.6
2046	$1,183,048.7	$29,268.3	$2,969.6	$111,950.6	$1,084.8	$1,600.1	$551,277.0
2047	$1,206,832.9	$30,859.0	$3,030.9	$114,261.7	$1,107.2	$1,633.1	$551,915.1
2048	$1,229,459.4	$32,565.0	$3,089.3	$116,461.8	$1,128.5	$1,664.5	$553,073.6
2049	$1,249,569.2	$34,344.3	$3,142.0	$118,449.1	$1,147.8	$1,692.9	$554,695.1

2050	$1,270,871.8	$36,247.6	$3,197.2	$120,530.5	$1,167.9	$1,722.7	$556,812.4
2051	$1,291,489.2	$38,281.1	$3,250.8	$122,550.0	$1,187.5	$1,751.6	$559,572.5
2052	$1,304,622.1	$40,219.4	$3,285.4	$123,856.0	$1,200.2	$1,770.2	$562,747.4
2053	$1,316,470.1	$42,208.2	$3,316.9	$125,043.2	$1,211.7	$1,787.2	$566,270.2
2054	$1,328,318.7	$44,220.5	$3,348.2	$126,220.7	$1,223.1	$1,804.0	$570,095.6
2055	$1,341,391.1	$46,212.9	$3,382.7	$127,524.8	$1,235.7	$1,822.7	$574,275.2
2056	$1,352,814.6	$48,273.5	$3,412.8	$128,659.1	$1,246.7	$1,838.9	$578,806.2
2057	$1,367,969.6	$50,616.9	$3,452.5	$130,155.1	$1,261.2	$1,860.3	$583,695.7
2058	$1,384,772.5	$53,184.4	$3,496.6	$131,818.4	$1,277.3	$1,884.0	$588,929.4
2059	$1,399,296.5	$55,859.6	$3,535.5	$133,282.9	$1,291.5	$1,905.0	$594,478.4
2060	$1,417,155.7	$58,669.4	$3,581.8	$135,029.2	$1,308.4	$1,929.9	$600,328.2
2061	$1,428,528.1	$61,316.4	$3,612.0	$136,168.0	$1,319.5	$1,946.2	$606,975.9
2062	$1,424,338.1	$63,315.7	$3,603.9	$135,861.1	$1,316.5	$1,941.8	$613,826.7
2063	$1,423,513.0	$65,489.1	$3,603.8	$135,858.4	$1,316.5	$1,941.8	$620,848.6
2064	$1,425,036.4	$67,781.1	$3,610.0	$136,092.9	$1,318.7	$1,945.1	$628,000.3

*Note: "Tobacco Attributable" refers to only cigarettes and noncombusted products. Please see section II.G.1.a for additional detail

6. Undiscounted Transfers of the Rule for the No Menthol, No Cigar Flavors Baseline

Table 121. Undiscounted Annual Transfers of the Rule, No Cigar Flavors, No Menthol Analysis, Low Impact Scenario ($ Millions, 2023)

Year	Federal Tax to Consumers	State Tax to Consumers	Firm Revenue to Consumers	User Fees from Combusted to Noncombusted Firms
2025				
2026				
2027				
2028	$315.0	$594.3	-$4,826.1	

2029	$600.7	$1,131.6	-$2,788.7	$5.6
2030	$850.1	$1,600.3	-$728.8	$6.4
2031	$1,059.0	$1,992.7	$1,317.5	$7.2
2032	$1,247.0	$2,345.6	$3,734.7	$7.9
2033	$1,406.7	$2,645.4	$5,602.6	$8.7
2034	$1,540.0	$2,895.5	$7,126.0	$9.6
2035	$1,654.0	$3,109.3	$8,432.5	$10.8
2036	$1,747.4	$3,284.4	$9,531.8	$12.1
2037	$1,816.4	$3,413.6	$10,417.4	$13.6
2038	$1,875.4	$3,524.1	$11,226.2	$15.1
2039	$1,921.0	$3,609.2	$11,879.4	$16.7
2040	$1,957.9	$3,678.1	$12,497.1	$18.3
2041	$1,984.0	$3,726.6	$13,055.9	$20.1
2042	$2,010.6	$3,776.1	$13,584.2	$21.8
2043	$2,033.2	$3,818.2	$14,062.8	$23.6
2044	$2,051.9	$3,852.8	$14,530.9	$25.5
2045	$2,065.6	$3,878.1	$14,935.5	$27.4
2046	$2,071.5	$3,888.9	$15,277.4	$29.3
2047	$2,077.8	$3,900.3	$15,609.5	$31.1
2048	$2,077.9	$3,900.2	$15,873.7	$32.9
2049	$2,071.8	$3,888.4	$16,080.8	$34.6
2050	$2,070.7	$3,886.0	$16,332.8	$36.1
2051	$2,067.6	$3,880.0	$16,538.5	$37.7
2052	$2,063.2	$3,871.3	$16,709.8	$39.3
2053	$2,058.4	$3,862.0	$16,886.6	$40.8
2054	$2,053.5	$3,852.6	$17,052.0	$42.3
2055	$2,048.0	$3,842.1	$17,200.1	$43.7
2056	$2,043.0	$3,832.4	$17,352.4	$45.0
2057	$2,037.3	$3,821.5	$17,492.3	$46.4
2058	$2,030.7	$3,809.0	$17,618.6	$47.6
2059	$2,024.0	$3,796.3	$17,745.3	$48.8

2060	$2,017.5	$3,783.9	$17,857.5	$49.9
2061	$2,012.1	$3,773.5	$17,976.2	$50.9
2062	$2,003.8	$3,757.7	$18,073.7	$52.0
2063	$1,997.4	$3,745.7	$18,172.6	$52.8
2064	$1,990.2	$3,732.0	$18,270.4	$53.6

Table 122. Undiscounted Annual Transfers of the Rule, No Cigar Flavors, No Menthol Analysis, Primary Impact Scenario ($ Millions, 2023)

Year	Federal Tax to Consumers	State Tax to Consumers	Firm Revenue to Consumers	User Fees from Combusted to Noncombusted Firms
2025				
2026				
2027				
2028	$4,590.7	$8,639.8	$10,272.8	
2029	$6,292.9	$11,839.5	$23,610.1	$37.4
2030	$6,955.4	$13,083.1	$31,169.2	$72.3
2031	$7,109.0	$13,369.6	$34,624.8	$119.9
2032	$7,034.1	$13,226.9	$37,976.4	$178.3
2033	$6,853.5	$12,885.4	$38,796.9	$239.6
2034	$6,628.8	$12,461.3	$38,805.5	$293.4
2035	$6,390.9	$12,012.6	$38,407.8	$334.6
2036	$6,155.7	$11,568.9	$37,825.0	$363.7
2037	$5,927.6	$11,138.9	$37,143.7	$384.3
2038	$5,710.4	$10,729.4	$36,415.6	$397.7
2039	$5,506.1	$10,344.5	$35,675.1	$406.3
2040	$5,315.6	$9,656.1	$34,455.3	$415.2
2041	$5,140.9	$9,354.8	$33,925.5	$416.7

2042	$4,981.0	$9,077.6	$33,424.3	$417.4
2043	$4,833.9	$8,822.8	$32,946.5	$417.5
2044	$4,698.8	$8,588.3	$32,511.2	$417.5
2045	$4,574.3	$8,372.7	$32,106.0	$417.4
2046	$4,459.9	$8,174.0	$31,726.2	$417.4
2047	$4,354.4	$7,991.4	$31,374.9	$417.5
2048	$4,257.5	$7,822.9	$31,047.1	$417.8
2049	$4,168.0	$7,667.4	$30,743.4	$418.0
2050	$4,085.5	$7,524.2	$30,486.4	$418.2
2051	$4,009.5	$7,391.7	$30,249.9	$418.4
2052	$3,939.2	$7,269.2	$30,038.4	$418.5
2053	$3,874.2	$7,155.7	$29,849.7	$418.8
2054	$3,813.9	$7,050.6	$29,676.0	$419.0
2055	$3,758.1	$6,953.2	$29,525.8	$419.2
2056	$3,706.4	$6,863.0	$29,393.4	$419.4
2057	$3,658.5	$6,779.2	$29,271.4	$419.6
2058	$3,614.0	$6,701.5	$29,177.0	$419.8
2059	$3,572.7	$6,629.0	$29,094.8	$420.0
2060	$3,534.3	$6,561.4	$29,017.2	$420.2
2061	$3,498.4	$6,498.5	$28,958.7	$420.4
2062	$3,465.0	$6,439.8	$28,906.5	$420.6
2063	$3,433.8	$6,385.4	$28,878.6	$420.8
2064	$3,405.0	$9,656.1	$34,455.3	$415.2

Table 123. Undiscounted Annual Transfers of the Rule, No Cigar Flavors, No Menthol Analysis, High Impact Scenario ($ Millions, 2023)

Year	Federal Tax to Consumers	State Tax to Consumers	Firm Revenue to Consumers	User Fees from Combusted to Noncombusted Firms
2025				
2026				
2027				
2028	$8,865.1	$16,682.1	$28,287.2	$0.0
2029	$8,575.8	$16,134.9	$30,809.3	$404.4
2030	$8,178.8	$15,385.7	$31,180.3	$512.6
2031	$7,792.1	$14,656.2	$31,173.5	$540.5
2032	$7,430.6	$13,974.3	$33,284.4	$548.5
2033	$7,095.1	$13,341.5	$33,326.1	$550.6
2034	$6,785.5	$12,757.5	$33,027.7	$550.4
2035	$6,499.6	$12,218.4	$32,570.8	$549.1
2036	$6,235.1	$11,719.8	$32,046.7	$547.7
2037	$5,990.2	$11,258.0	$31,505.8	$546.4
2038	$5,763.3	$10,830.4	$30,987.5	$545.1
2039	$5,552.5	$10,432.9	$30,437.8	$543.7
2040	$5,359.2	$10,068.7	$30,012.8	$542.6
2041	$5,183.2	$9,736.8	$29,621.4	$540.7
2042	$5,022.7	$9,434.2	$29,282.0	$538.9
2043	$4,875.9	$9,157.6	$28,976.1	$537.1
2044	$4,741.2	$8,903.6	$28,677.4	$535.5
2045	$4,617.2	$8,670.0	$28,397.0	$534.2
2046	$4,503.2	$8,455.0	$28,142.1	$533.1
2047	$4,398.1	$8,256.9	$27,906.4	$532.2
2048	$4,301.2	$8,074.3	$27,672.4	$531.3
2049	$4,212.0	$7,906.3	$27,477.0	$530.5

2050	$4,129.8	$7,751.3	$27,291.6	$529.8
2051	$4,053.7	$7,608.1	$27,129.2	$529.1
2052	$3,983.6	$7,475.8	$26,994.5	$528.5
2053	$3,918.5	$7,353.3	$26,862.0	$527.9
2054	$3,858.3	$7,239.8	$26,755.2	$527.4
2055	$3,802.5	$7,134.6	$26,655.3	$526.9
2056	$3,750.7	$7,037.0	$26,565.2	$526.5
2057	$3,702.8	$6,946.8	$26,500.4	$526.1
2058	$3,658.2	$6,862.8	$26,431.3	$525.7
2059	$3,616.7	$6,784.6	$26,371.7	$525.3
2060	$3,578.0	$6,711.7	$26,329.0	$524.9
2061	$3,542.0	$6,644.0	$26,297.2	$524.6
2062	$3,508.4	$6,580.7	$26,273.1	$524.3
2063	$3,477.2	$6,521.9	$26,263.6	$524.0
2064	$3,448.2	$6,467.1	$26,259.9	$523.7

7. Undiscounted Annual Costs of the Rule, Primary Estimate, By Tobacco Product Type

Table 124. Undiscounted Annual Costs of the Rule, Main Analysis, Primary Impact Scenario by Product Category ($ Millions, 2023)

Year	Cigarette & RYO	Cigar	Pipe Tobacco
2025	$349.0	$19.6	$4.9
2026	$6,783.0	$420.3	$139.2
2027	$2,460.4	$573.7	$11.2
2028	$1,948.2	$143.8	$27.3
2029	$3,094.7	$251.5	$43.4
2030	$3,423.7	$305.1	$48.0
2031	$3,363.8	$327.8	$47.2
2032	$3,154.1	$334.8	$44.3
2033	$2,904.9	$334.7	$40.8
2034	$2,657.0	$331.1	$37.3
2035	$2,426.1	$325.8	$34.0

2036	$2,217.0	$319.8	$31.1
2037	$2,029.1	$313.3	$28.5
2038	$1,860.9	$306.5	$26.1
2039	$1,711.0	$299.7	$24.0
2040	$1,579.3	$292.9	$22.2
2041	$1,463.7	$286.0	$20.5
2042	$1,362.4	$279.2	$19.1
2043	$1,273.3	$272.4	$17.9
2044	$1,194.6	$265.8	$16.8
2045	$1,124.9	$259.3	$15.8
2046	$1,063.0	$252.9	$14.9
2047	$1,008.0	$246.6	$14.1
2048	$959.0	$240.5	$13.5
2049	$915.3	$234.4	$12.8
2050	$876.3	$228.4	$12.3
2051	$841.3	$222.6	$11.8
2052	$809.9	$216.8	$11.4
2053	$781.8	$211.2	$11.0
2054	$756.5	$205.6	$10.6
2055	$733.7	$200.1	$10.3
2056	$713.2	$194.8	$10.0
2057	$694.8	$189.5	$9.7
2058	$678.2	$184.3	$9.5
2059	$663.1	$179.1	$9.3
2060	$649.5	$174.1	$9.1
2061	$637.3	$169.2	$8.9
2062	$626.2	$164.3	$8.8
2063	$616.2	$159.5	$8.6
2064	$607.3	$154.8	$8.5

8. Undiscounted Annual Transfers of the Rule, Primary Estimate, By Tobacco Product Type

Table 125. Undiscounted Annual Transfers of the Rule, Main Analysis, Primary Impact Scenario by Product Category ($ Millions, 2023)

Year	Cigarette	Cigar	Pipe Tobacco & RYO	Noncombusted
2025	$0.0	$0.0	$0.0	$0.0
2026	$0.0	$0.0	$0.0	$0.0
2027	$0.0	$0.0	$0.0	$0.0
2028	$13,783.4	$4,261.6	$1,690.5	-$16,163.1
2029	$17,396.1	$5,480.3	$2,152.3	-$13,611.1
2030	$18,300.9	$5,786.3	$2,285.7	-$11,368.2
2031	$18,140.6	$5,742.6	$2,285.5	-$10,253.1
2032	$17,565.6	$5,676.9	$2,258.4	-$9,324.3
2033	$16,856.5	$5,481.1	$2,190.9	-$8,877.4
2034	$16,119.6	$5,250.1	$2,112.0	-$8,484.7
2035	$15,401.9	$5,004.0	$2,031.0	-$8,135.9
2036	$14,721.7	$4,758.1	$1,952.0	-$7,811.6
2037	$14,082.5	$4,526.0	$1,876.2	-$7,516.8
2038	$13,484.5	$4,307.7	$1,804.3	-$7,242.2
2039	$12,928.7	$4,095.9	$1,736.0	-$7,004.9
2040	$12,419.2	$3,896.8	$1,676.4	-$6,791.2
2041	$11,954.7	$3,710.0	$1,621.9	-$6,597.6
2042	$11,531.9	$3,536.4	$1,572.3	-$6,438.0
2043	$11,146.7	$3,377.6	$1,527.1	-$6,289.0
2044	$10,795.5	$3,221.7	$1,485.9	-$6,149.5
2045	$10,474.3	$3,081.3	$1,448.3	-$6,031.5
2046	$10,180.7	$2,951.6	$1,413.8	-$5,923.9
2047	$9,912.4	$2,828.2	$1,382.4	-$5,825.3
2048	$9,667.2	$2,706.7	$1,353.8	-$5,749.4
2049	$9,443.0	$2,590.8	$1,327.7	-$5,670.6

2050	$9,238.1	$2,479.3	$1,304.1	-$5,602.1
2051	$9,050.9	$2,380.8	$1,282.6	-$5,540.1
2052	$8,879.5	$2,284.6	$1,263.2	-$5,494.6
2053	$8,722.9	$2,196.2	$1,245.7	-$5,440.6
2054	$8,579.6	$2,114.9	$1,230.0	-$5,396.1
2055	$8,448.4	$2,029.6	$1,215.8	-$5,362.9
2056	$8,328.7	$1,949.4	$1,203.1	-$5,332.7
2057	$8,219.5	$1,874.2	$1,191.8	-$5,306.0
2058	$8,119.7	$1,798.4	$1,181.6	-$5,283.5
2059	$8,028.5	$1,725.1	$1,172.7	-$5,262.0
2060	$7,945.2	$1,654.8	$1,164.8	-$5,247.6
2061	$7,869.3	$1,582.7	$1,158.0	-$5,232.2
2062	$7,800.0	$1,514.6	$1,152.1	-$5,223.0
2063	$7,737.2	$1,448.7	$1,147.0	-$5,213.7
2064	$7,680.4	$1,383.9	$1,142.8	-$5,206.7
Note: Negative values represent increases in tax revenues relative to baseline				