DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Product Standard For Menthol in Cigarettes

Docket No. FDA-2021-N-1349

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, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866. Thus, the Office of Information and Regulatory Affairs has reviewed this rule and its associated analysis.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a portion of business revenues may revert back to consumers who currently purchase menthol cigarettes, we find that the rule may have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule, if finalized, would result in expenditures that meet or exceed this amount.

B. Summary of Costs and Benefits

The summary of benefits and costs is presented in Table 1. The proposed rule, if finalized, would establish a tobacco product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. The quantified benefits of this proposed rule come from lower smoking-attributable mortality in the U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes. Qualitative benefits include: decreased illness and associated reductions in medical costs (both publicly and privately funded), decreased productivity loss, and improved health-related quality of life for menthol smokers and non-smokers; reductions in smoking-related fires; and reductions in cigarette butt litter and associated harms to the environment. We estimate that the present value of the monetized benefits over a 40-year time horizon ranges between $2,529 billion and $8,253 billion (primary estimate of $5,428 billion) at a 3% discount rate, and range between $1,369 billion and $4,470 billion (primary estimate of $2,941 billion) at a 7% discount rate. The primary annualized benefits equal $232 billion at a 3% discount rate and $220 billion at a 7% discount rate. Unquantified benefits are expected to provide additional benefits beyond those amounts and additional health and related benefits are expected to occur outside the time horizon used in this analysis.

The proposed rule, if finalized, would also create costs for firms, consumers and the Federal government. Firms face one-time costs to read and review the rule (undiscounted primary estimate of $186.6 million with a range of $56.0 million to $349.9 million), and may face one-time costs for reallocation, friction, and adjustment in the cigarette product market (undiscounted primary estimate of $235.9 million with a range of $0.2 million to $471.9 million). Firms may also face costs due to producer surplus loss over the 40 year time horizon (undiscounted primary estimate of $10,628 million with a range of $0 to $21,256). Consumers

may face one-time search costs of $359.3 million (undiscounted, range of $179.7 million to $539.0 million) to find substitute tobacco products as a replacement for menthol cigarettes. The FDA may face annual costs associated with enforcement of the proposed product standard (undiscounted range from $0 to $1.3 million, primary estimate $0.7 million per year). Qualitative costs may include changes in consumer surplus for some menthol cigarette product users, including potential utility changes for smokers of menthol cigarette products who switch from menthol to non-menthol cigarette products. We estimate that the present value of monetized costs over a 40-year time horizon ranges between $223.0 million and $13,421.6 million (primary estimate of $6,805.9 million) for a 3% discount rate, and between $208.0 million and $8,051.3 million (primary estimate of $4,113.2 million) at a 7% discount rate. The primary estimates for the annualized cost are $291 million at a 3% discount rate and $307 million at a 7% discount rate.

In addition to benefits and costs, this rule, if finalized, will create significant transfers from State Governments, Federal Government, and firms to consumers in the form of reduced revenue and tax revenue. The primary estimates for annualized transfers related to federal taxes are $2.0 billion at a 3% discount rate and $2.0 billion at a 7% discount rate. The primary estimates for the annualized transfers related to State taxes are $3.7 billion at a 3% discount rate and $3.7 billion at a 7% discount rate. The primary estimates for the annualized transfers between cigarette product manufacturers and consumers are $13.3 billion at a 3% discount rate and $13.0 billion at a 7% discount rate. Benefits, costs, and transfers are summarized in Table 1.

Table 1. Summary of Benefits, Costs, and Distributional Effects of Proposed Rule ($ Millions of 2020 Dollars over a 40 Year Time Horizon)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$220,000	$102,000	$334,000	2020	7%	40	
		$232,000	$108,000	$353,000	2020	3%	40	
	Annualized Quantified							
	Qualitative	Qualitative benefits include: decreased illness and associated reductions in medical costs (both publicly and privately funded), decreased productivity loss, and improved health-related quality of life for menthol smokers and non-smokers; reductions in smoking-related fires; and reductions in cigarette butt litter and associated harms to the environment.						
Costs	Annualized Monetized ($m/year)	$307	$16	$601	2020	7%	40	
		$291	$9	$573	2020	3%	40	
	Annualized Quantified							
	Qualitative	Changes in consumer surplus may occur for some menthol smokers.						
Transfers	Federal Annualized Monetized ($m/year)	$2,000	$1,000	$2,000	2020	7%	40	
		$2,000	$1,000	$2,000	2020	3%	40	
		From: Federal Government			To: Consumers			
	State Annualized Monetized ($m/year)	$4,000	$3,000	$4,000	2020	7%	40	
		$4,000	$3,000	$4,000	2020	3%	40	
		From: State Government			To: Consumers			
	Other Annualized Monetized ($m/year)	$13,000	$9,000	$15,000	2020	7%	40	
		$13,000	$9,000	$15,000	2020	3%	40	
		From: Cigarette Product Manufacturers			To: Consumers and Manufacturers of Other Tobacco Products			
Effects	State, Local, or Tribal Government: See transfers for estimated State excise tax impacts. See distributional effects for discussions of impacts to tribally-affiliated manufacturers and/or manufacturers operating on tribal lands. Small Business: Small menthol cigarette manufacturers are expected to face one-time costs for reading and understanding the rule and for planning and implementing reallocation procedures for menthol cigarette production lines. Small menthol cigarette manufacturers would also face revenue transfers as consumers cease purchasing menthol cigarette products. Wages: No effect Growth: No effect							

C. Terminology

In Table 2, we discuss several terms for we use in this preliminary regulatory impact analysis.

Table 2. Terms Used in the Regulatory Impact Analysis

Term	Description
We, our, us	We use these terms to refer to the United States Food and Drug Administration.
Deeming Rule	We use this term to refer to the 2016 final rule titled "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." The Deeming Rule deemed products meeting the statutory definition of "tobacco product," except accessories of the newly deemed tobacco products, to be subject to the tobacco product provisions of Chapter IX of the FD&C Act. Examples of deemed products include cigars, pipe tobacco, waterpipe tobacco, and ENDS.
ENDS	Electronic nicotine delivery systems deliver aerosolized e-liquid when inhaled. Generally, ENDS include e-cigarettes and e-liquids.
Cigarette	As defined in Section 900(3) of the FD&C Act (21 U.S.C. 387(3)) and as proposed in this proposed 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.
Cigarette Tobacco	As defined in Section 900(4) of the FD&C Act (21 U.S.C. 387(4)) and as proposed in this proposed 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. We have reiterated that definition in this proposal as it applies to cigarettes. Therefore, FDA proposes in this rule to define "component or part" in the context of part 1162 to mean any software or assembly of materials intended or reasonably expected: (1) To alter or affect the cigarette's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a cigarette. The term excludes anything that is an accessory of a cigarette. Examples of cigarette components or parts that would be subject to this proposed product standard include cigarette paper, filters, and flavor additives. With respect to these definitions, FDA notes that "component" and "part" are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this rule, FDA is using the terms "component" and "part" interchangeably and without emphasizing a distinction between the

Term	Description
	terms. FDA may clarify the distinctions between "component" and "part" in the future.
Roll – Your – Own Tobacco	As defined in Section 900(15) of the FD&C Act (21 U.S.C. 387(15)), and as proposed in this proposed 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	As defined in Section 201(rr) of the FD&C Act, and as proposed in this proposed rule, the term "tobacco product" is defined as 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); a device under Section 201(h); a combination product described in Section 503(g) (21 U.S.C. 353(g)); or a food under section 201(f) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.
Cigarettes that are Heated Tobacco Products	Heated tobacco products that meet the definition of a cigarette in the FD&C Act.
Cigarette Product(s)	For the purpose of this analysis, we define cigarette product(s) to include all products meeting the definition of "cigarette" in Section 900(3) of the FD&C Act (proposed § 1162.3 includes a definition of cigarette). This includes all types, sizes, nicotine strengths and formulations of cigarettes, cigarette tobacco and RYO tobacco, as well as HTPs that meet the definition of a cigarette in the FD&C Act (cigarettes that are HTPs).
Menthol Simulation	From Levy et al. 2021, this simulation is an extension of the Smoking and Vaping Model (SAVM), a compartmental model capable of simulating the population effects of cigarette smoking and ENDS use for specific birth cohorts (See Reference 88). For this study, the SAVM model was extended to evaluate non-menthol and menthol cigarettes separately, with the following use states captured in the model compartments: (1) Never users, (2) menthol smokers, (3) non-menthol smokers, (4) exclusive ENDS users, (5) former smokers using ENDS, (6) former smokers, and (7) former ENDS users.
T21 Laws	Federal, state, and local laws establishing 21 as the minimum age of sale for tobacco products. Federal law: Further Consolidated Appropriations Act, 2020 (Pub. L. No. 116-94, § 603 (2019)). In this impact analysis, we refer to these laws and their impacts on baseline cigarette smoking using the collective term "T21 Laws."

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

Abbreviation/Acronym	What It Means
ACES	U.S. Census Bureau, Annual Capital Expenditure Survey.
BLS	Bureau of Labor Statistics.
CBO	Congressional Budget Office.
CDC	Centers for Disease Control and Prevention.

Abbreviation/Acronym	What It Means
CPSC	U.S. Consumer Product Safety Commission.
CTP	U.S. FDA, Center for Tobacco Products.
EE	Expert Elicitation.
EIN	Employee Identification Numbers.
EMI	Euromonitor International.
ENDS	Electronic Nicotine Delivery Systems.
E.O.	Executive Order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FEMA	Federal Emergency Management Agency.
FR	The U.S. Federal Register.
GAO	U.S. Government Accountability Office.
GATS	Global Agricultural Trade System Online.
HHS	U.S. Department of Health and Human Services.
HTP	Heated Tobacco Product.
IRS	Internal Revenue Service.
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, Queer and Other Individuals.
MTF	Monitoring the Future.
NAICS	North American Industry Classification System.
NASEM	National Academies of Science Engineering and Medicine.
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.
NIQ - RMS	NielsenIQ Retail Measurement Services
NSDUH	U.S. SAMHSA, National Survey on Drug Use and Health.
NYTS	U.S. CDC, National Youth Tobacco Survey.
PATH	U.S. Population Assessment of Tobacco and Health.
PRAMS	U.S. CDC, Pregnancy Risk Assessment Monitoring System.
RYO	Roll-Your-Own Tobacco.
SAVM	Smoking and Vaping Model.
SBA	U.S. Small Business Administration.
SGR	Surgeon General's Report.
SIDS	Sudden Infant Death Syndrome.
SMI	Severe Mental Illness.
TCA	The Family Smoking Prevention and Tobacco Control Act. (Pub. L. 111-31; 123 Stat. 1776) (see also H.R. Rep. No. 111-58, pt. 1, at 37 (2009)).
TRLM	The Tobacco Registration and Listings Module (TRLM) in the FDA's Unified Registration and Listings System (FURLS).
TTB	Alcohol and Tobacco Tax and Trade Bureau.

Abbreviation/Acronym	What It Means
TUS-CPS	Tobacco Use Supplement to Current Population Survey.
UPC	Universal Product Code.
VSL	Value of a Statistical Life.

II. **Preliminary Regulatory Impact Analysis**

A. Background and Need for the Rule

Cigarettes are the most toxic consumer product when used as intended, and adding menthol as a characterizing flavor makes cigarettes more appealing and easier to smoke [1] [2]. Menthol as a characterizing flavor in tobacco products enhances product appeal, usability, and addictiveness and has played a role in creating and perpetuating tobacco-related health disparities. As described in the Preamble of this proposed rule, cigarette smoking is causally linked with increased risk of at least 12 cancers (e.g., oral, esophageal, and lung cancers), heart disease, and many other negative health outcomes [3]. Cigarette smoking is the leading cause of preventable death and disease in the United States and is responsible for more than 480,000 premature deaths per year [3]. It is estimated that individuals are living with a combined 14.0 million major smoking-related conditions in the United States [4], and the 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 [5].

FDA anticipates that prohibiting menthol as a characterizing flavor in cigarettes would reduce the initiation of and experimentation with cigarette smoking, decrease nicotine dependence and addiction to cigarettes, and increase the likelihood of cessation among current menthol cigarette smokers. Decreased cigarette initiation and experimentation, decreased progression to regular established cigarette smoking, and decreased cigarette consumption would lead to lower disease and death in the U.S. population due to diminished exposure to tobacco

smoke for both users and nonusers of cigarettes. Prohibiting menthol as a characterizing flavor in cigarettes is also anticipated to promote public health across population groups, reduce smoking related fires, and reduce environmental impacts from cigarette litter.

1. Market Failures Associated with Cigarette Smoking

Nicotine addiction can lead to cigarette smoking that does not accurately reflect individual preferences. There are several market failures associated with cigarette smoking, including asymmetric information; internalities such as time inconsistencies and the age-related inability to consider long-term health risks that result in user preferences that are misaligned with smoking behavior; and externalities such as secondhand smoke and fires, that result in negative impacts on non-smokers (both within and outside the smoker's household) and the environment. Additionally, despite significant declines in cigarette smoking since 1964, "very large disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country" [3]. We discuss nicotine addiction, internalities, externalities, and health disparities associated with cigarette smoking; how menthol as a characterizing flavor contributes to these market failures; and how the proposed rule would address market failures associated with cigarette smoking and improve social welfare.

a. Nicotine Addiction and Cigarette Smoking

Nicotine is the primary addictive chemical in tobacco [3] and numerous Surgeon General Reports from 1988 through 2020 have documented the many ways in which nicotine affects the brain and nicotine addiction drives smoking behavior. The 1988 Surgeon General's Report (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" [6]. 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." [5]. The role of nicotine addiction in driving cigarette use and cigarette sales is deliberate. After a nine-month trial, a Federal court ruled that the major United States 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(47) (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)).

b. Negative Internalities Associated with Cigarette Smoking

The psychology and economics literature 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 [7]. Many smokers have varying preferences, either over time or at the same time, making it difficult to determine the true or rational preference or choice. For example, Schelling (1984) 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 [8]. 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, smokers' decisions at early stages of use may impose significant costs on their future selves. Time inconsistencies stemming from consumers using lower discount rates for far future consequences of smoking as compared to near-present effects may also cause consumers to make current decisions that generate inefficiencies in the market.

Additional literature further explores internalities and other sources of market failure associated with tobacco product consumption [9] [10] [11].

Almost all tobacco product use starts in adolescence when the brain's critical areas for decision-making are not fully developed, creating an environment for impulsive behavior and time inconsistency. The 1994 and 2012 SGRs on smoking and health note that almost 90% of current adult regular smokers initiated smoking before age 18, and 99%initiated smoking before the age of 25, which is the approximate age at which the brain has completed development [12] [13]. Generally, those who begin smoking before the age of 18 are not aware of the degree of addictiveness and the full extent of the consequences of smoking [14]. The adolescent brain, which continues to develop until about age 25, is also more vulnerable to nicotine's effects than the adult brain. Exposure to nicotine during adolescence can disrupt brain development and have long-term consequences for executive cognitive function (such as task-switching and planning) and for the risk of developing a substance use disorder and various mental health problems (particularly affective disorders such as anxiety and depression) as an adult [15] [16]. Other long-term effects include decreased attention and increased impulsivity, which could promote the maintenance of nicotine use behavior [17]. Furthermore, the 2010 SGR noted that symptoms of dependence could result from even limited exposure to nicotine during adolescence [18]. 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 [19].

Although youth generally believe that they will be able to quit when they want, they actually have low success rates when making a quit attempt. For example, more than 60% of high school aged daily smokers have tried to quit, but less than 13% were successful at quitting

for 30 days or more [20]. Another survey revealed that "nearly 60 percent of adolescents believe that they could smoke for a few years and then quit" [21]. Because it is such a powerful addiction, addiction to nicotine is often lifelong [22]. The 2012 SGR notes that adolescence and young adulthood represents a time of "immaturity in consequential thinking, impulsivity, and decision-making skills" as brain development is continuing until around age 25 [13] [16]. This calls into question the ability of adolescent consumers to make fully informed, rational decisions regarding tobacco product use.

Tobacco product consumption behaviors are often misaligned with the user's preferences, further demonstrating time inconsistencies related to cigarette smoking. A study by Pechacek et al. (2018) finds that more than 82% of smokers reported high or very high discontent stemming from an "inability to quit, perceived addiction and regret about having started to smoke" [23]. The authors conclude that "the proportion of smokers who might be characterised 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" [23].

c. Externalities Associated with Cigarette Smoking

The use of combusted tobacco products also causes negative externalities, as an individual's cigarette smoking creates negative effects for others not captured in the price of the product [24]. Secondhand and thirdhand smoke are the most well-known examples of externalities from use of cigarettes. Other externalities stem from smoking-related fires and cigarette litter.

Exposure to cigarette smoke can cause harm to non-smokers. Data from the 2013-2014 National Health and Nutrition Examination Survey (NHANES) estimates that approximately 58 million American non-smokers (1 in 4) were exposed to secondhand smoke during that period,

including 14 million children [25]. The authors further conclude that "although secondhand smoke exposure among U.S. nonsmokers declined from 87.5% to 25.2% during 1988–2014, progress has stalled in recent years" [25]. Approximately half of all U.S. children aged 3 to 18 years are exposed to cigarette smoke regularly at home or other locations that still permit smoking [3]. In 2019, approximately one-quarter of middle and high school students reported breathing in secondhand smoke in their homes or in a vehicle [26]. It is well-established that exposure to secondhand tobacco smoke causes premature death and disease in children and in adults who do not smoke [27]. Secondhand smoke exposure is estimated to be responsible for over 41,000 deaths annually in the United States [3]. From 2005 to 2009, an estimated 7,330 lung cancer and 33,950 heart disease deaths annually were attributable to exposure to secondhand smoke [3].

Thirdhand smoke—the chemical residue from combusted tobacco smoke that can become imbedded in the environment (e.g., carpet, dust)—also results in exposure to harmful tobacco smoke constituents such as carcinogenic tobacco-specific nitrosamines [28] [29] [30] [31] [32]. In addition, research suggests that large quantities of thirdhand smoke (the amount of secondhand smoke produced by smoking 1 to 10 cigarettes) can also be introduced into indoor, nonsmoking environments by traveling on smoker's clothing and bodies [33]. Exposure to thirdhand smoke is of special concern for young children because of both their small size and their behaviors, such as crawling and frequently putting their hands in their mouths. [34]. For example, nicotine exposure from thirdhand smoke residue can be 6.8 times higher in toddlers than what would be inhaled by a passive (i.e., secondhand) smoker [35]. Thirdhand smoke can also harm overall health of pets through the presence of smoke residue [36] [37] [38].

The use of combusted tobacco products also results in fires causing injury, death, and property destruction. Even though all states have instituted laws requiring fire-safety-compliant cigarette paper (adoption began in 2003 with all states adopting these laws by 2012), smoking[1] remained the second leading cause of residential fire deaths in the United States in 2018 [39]. Cigarettes are the leading cause of smoking-related fires at 86.3% [40]. Between 2012 and 2016, there were an average of 18,100 home structure fires per year started by smoking materials, accounting for around 1 in 20 of all home fires (5%) [41]. The fatality rate for smoking-related residential building fires is seven times greater than for nonsmoking related fires [40]. Smokers themselves are not the only victims; one out of every four fatal victims of smoking-material fires were not the smoker whose cigarette initiated the fire [41] [42]. Accounting for 10% of fires (30,600 fires), smoking materials were the third largest cause (after intentional and outside or open fire for waste disposal) for local fire department responses to brush, grass, and forest fires from 2011 to 2015 [43].

Lastly, tobacco products, specifically cigarette butts, are one of the most frequently littered items [44] [45]. The cost of clean-up, if it occurs, is not a burden to manufacturers or users. Instead, it falls on local communities to deal with the pollution caused by the billions of cigarette butts improperly discarded every year. Cigarette butt abatement is estimated to cost the top 30 U.S. cities on average $264.5 million annually and an estimated annual mean of $6.46 per capita [46]. In addition, cigarette and cigar filters, which are made of plastic, remain in the environment for many years and leach toxic chemicals into the environment, potentially

[1] From FEMA's National Fire Administration data, "smoking" fires are those caused by "cigarettes, cigars, pipes, and heat from undetermined smoking materials."
https://www.usfa.fema.gov/downloads/xls/statistics/residential_nonresidential_fire_loss_estimates.xlsx

threatening human health and the environment, especially marine ecosystems [47] [48] [49] [50] [51] [52].

2. How Menthol Contributes to Market Failures Associated with Cigarette Smoking

Menthol is a flavor compound that is added to cigarettes, which produces a minty taste and cooling sensation when inhaled [53]. Menthol's role in enhancing nicotine addiction and the flavor and sensory properties of menthol contribute to continued use of menthol cigarettes. Nicotine's addictive properties are further reinforced by menthol [54] [55] [56] [57]. Menthol may also serve as an environmental cue (i.e., as a type of sensorimotor stimuli) associated with smoking, reinforcing the appeal of cigarettes for current menthol smokers and reducing the success of quit attempts [10].

Menthol in cigarettes makes it even more difficult to quit smoking [58] [59] [60] [61] [62] [63] [64] [65]. Evidence also shows that menthol in cigarettes contributes to reduced cessation success among smokers, particularly among Black smokers, who have higher rates of menthol use [59] [60] [61] [62] [63] [64] [66] [67] [68]. Data from 2003 and 2006-07 Tobacco Use Supplement to the Current Population Survey (TUS-CPS) found that overall, quit attempts in 2007 were 8.8% higher among menthol smokers compared to non-menthol smokers, but menthol smokers had 3.5% lower rates of quitting within the past year and 6% lower rates of quitting within the past 5 years compared to non-menthol smokers [63].

Menthol's contribution to continued use of cigarette products is also reflected in volume sales data for cigarettes. While volume sales of cigarettes decreased from 269.9 billion sticks in 2015 to 222.6 billion sticks in 2020 (-17.5%), volume sales of menthol cigarettes showed a smaller decrease over the same time (90.5 billion sticks in 2015 down to 77.8 billion sticks in

2020, a decrease of 14%). Accordingly, the market share of menthol cigarettes increased from 33.5% in 2015 to 35% in 2020 [69].

Menthol cigarettes also attract younger users because menthol cigarettes are perceived as less harsh and easier to smoke than non-menthol cigarettes [1] [2]. Menthol cigarette use is particularly high in younger populations. In the 2019 National Survey on Drug Use and Health (NSDUH) data, past-month menthol use among cigarette smokers was highest among young adults aged 18-25 years (51.0%), followed by youth aged 12-17 years (48.6%) and older adults age 26 and older (39.0%) [70].

3. Market Failure Addressed by the Proposed Rule

This product standard will address market failure associated with cigarette smoking. Prohibiting the use of menthol as a characterizing flavor in cigarettes would reduce the initiation and experimentation of cigarette smoking, decrease the likelihood of nicotine dependence and addiction, and increase the likelihood of cessation. The proposed standard would provide those who seek to quit smoking an improved chance of aligning their smoking behavior with their preferences and reduce negative internalities and externalities associated with smoking, leading to social welfare gains.

FDA also anticipates that this proposed standard prohibiting menthol as a characterizing flavor in cigarettes would improve health outcomes among vulnerable populations.[2] The proposed product standard would decrease the risk of tobacco-related death and disease among

[2] Throughout the regulatory impact analysis for this proposed rule, the term "vulnerable populations" refers to groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Examples of vulnerable populations include those with lower household income and educational attainment, certain racial or ethnic populations, underserved rural populations, individuals who identify as LGBTQ+, those pregnant or trying to become pregnant, those in the military or veterans, or those with mental health conditions or substance use disorders.

vulnerable populations, promoting public health, addressing tobacco-related health disparities, and advancing health equity.

4. Disparities in Cigarette Smoking and Resulting Health Outcomes

Cigarette smoking is associated with health disparities across population groups. As stated previously, "very large disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country," despite significant declines in cigarette smoking since 1964 [3]. A study examining disparities in tobacco-related cancer incidence and mortality found that tobacco-related mortality decreased between 2004 and 2013, however tobacco-related cancer incidence and mortality rates remain highest among African Americans,[3] accounting for more than 39,000 deaths annually between 2009 and 2013 [72].

Members of underserved communities such as African American and other racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower household income or educational attainment, and individuals with behavioral health disorders are more likely to report smoking menthol cigarettes than other population groups [70] [73] [74] [75] [76] [77] [78] [79] [80] [81] [82] [83] [84]. Out of all Non-Hispanic Black smokers, nearly 85% smoke menthol cigarettes, compared to 30% of Non-Hispanic White smokers who smoke menthol cigarettes [70]. Data from the 2005 National Health Interview Survey (NHIS) Cancer Control Supplement were used to examine racial and ethnic differences in menthol cigarette

[3] Throughout the regulatory impact analysis for this proposed rule, the FDA uses both the terms "Black" and "African American." The term "African American" is used to describe or refer to a person of African ancestral origins or who identifies as African American. "Black" is used to broadly describe or refer to a person who identifies with that term. Though both of these terms may overlap, they are distinct concepts (e.g., a Black person may not identify as African American). As a result, the FDA relies on the specific term used by researchers when citing to specific studies. The FDA uses the term "Black" when not citing to a specific study.

smoking and found that African American menthol smokers had a significantly decreased likelihood of quitting smoking compared to African American non-menthol smokers [60]. In addition, among youth, from 2011 to 2018, declines in menthol cigarette use were observed among non-Hispanic White youth but not among non-Hispanic Black or Hispanic youth [85]. The greater occurrence of tobacco-related disease and death and lower quitting rates among Black smokers may be partially attributed to the fact that Black smokers predominantly smoke mentholated cigarettes.

The burden of secondhand smoke exposure is also experienced disproportionately among members of some racial and ethnic groups and lower income groups. Among nonsmokers age 3 and older, findings from 2011-2018 NHANES data indicate that non-Hispanic Black persons and those living below the poverty level had the highest levels of secondhand smoke exposure compared to people of other races and those living above the poverty level, respectively; these disparities persisted across all years of the study analysis from 2011 to 2018 [86]. In 2011-2012, nearly 50% of non-Hispanic Black nonsmokers had detectable serum cotinine levels, compared with 22% of non-Hispanic White and 24% of Mexican American nonsmokers [87].

B. Baseline Conditions

1. Current Prevalence

In this section, we present estimates of cigarette product and menthol cigarette product prevalence from recent years, which serve as a reference throughout this analysis. Information from the National Health Interview Survey (NHIS) serves as a basis for *Status Quo* (baseline) and *Menthol Ban* scenario modeling performed by Levy et al. (2021) [88]; findings from the NSDUH data are used to estimate search costs later in Section II.D.3.a of the analysis.

a. Adult Prevalence

Among U.S. adults in 2019, cigarettes were the most commonly used tobacco product. Using 2019 data from the NHIS, the Centers for Disease Control and Prevention (CDC) reported that approximately 14.0% (34.1 million) of all U.S. adults were current cigarette smokers (which NHIS defined as having used ≥100 cigarettes during their lifetime and now smoking cigarettes "every day" or "some days") [89]. As part of their analysis, CDC estimated that cigarette prevalence was highest among adults ages 45-64 (17.0%), followed by those aged 25-44 (16.7%), those aged 65 and older (8.2%), and finally those aged 18-24 (8.0%) [89]. Results from previous CDC analysis of 2018 NHIS data indicated that around 13.7% (34.2 million) of all U.S. adults were current cigarette smokers, with cigarette prevalence highest among adults ages 25-44 (16.5%), followed by those ages 45-64 (16.3%), ages 65 and older (8.4%), and finally those aged 18-24 (7.8%) [90]. However, NHIS stopped assessing menthol cigarette smoking in 2015 and thus, does not provide data on menthol cigarette smoking for the years 2018 and 2019. NHIS data on overall cigarette smoking prevalence are summarized in Table 4.

Table 4. Prevalence of Current ("Every Day" or "Some Days") Cigarette Smoking among U.S. Adults by Age Group, 2018 and 2019 National Health Interview Survey Data

Group	2018	2019[1]
Young Adults ages 18-24	7.8%	8.0%
Adults ages 25-44	16.5%	16.7%
Adults ages 45-64	16.3%	17%
Adults ages 65+	8.4%	8.2%
Total U.S. Adults (18+)	13.7%	14.0%

[1]Although we present estimates from both Creamer et al. (2018 NHIS data) [90] and Cornelius et al. (2019 NHIS data) [89], we note that comparisons should be made with caution between the two sets of numbers. As Cornelius et al. note, "2019 NHIS documentation indicates that changes to the nonresponse adjustment approach and the calibration methods for the 2019 NHIS have the potential to affect comparisons of the weighted survey estimates over time. Because of the changes in weighting and design methodology, direct comparisons between estimates for 2019 and earlier years should be made with caution because the effect of these changes has not been fully evaluated at this time."

By contrast, NSDUH does gather data on menthol-cigarette use. A study that examined changes in menthol smoking prevalence among cigarette smokers using NSDUH data from 2004 to 2014 found that the prevalence of menthol smoking among current smokers (which NSDUH defines as past-month smoking) between 2008-2010 and 2012-2014 among adult smokers aged 26-34 went from 34.6% to 43.9%, among adult smokers aged 35-49 went from 30.3% to 32.3%, and among adult smokers aged 50 and older went from 30.6% to 32.9% [78]. In 2019 NSDUH data, past-month menthol use among adult cigarette smokers age 26 and older was 39.0% (15.4 million) of the 39.4 million adults aged 26 and older who were current cigarette smokers [70]. NSDUH data for smokers younger than age 26 are reported in the next section.

b. Youth and Young Adult Prevalence

Although menthol cigarette smoking is widespread in the United States, use of menthol cigarettes is especially common among youth and young adults who smoke cigarettes. In 2019, there were more than 18.5 million current smokers (defined in NSDUH as past-30-day use) of menthol cigarettes ages 12 and older in the United States [70]. Data from the 2019 NSDUH estimates that approximately 537,000 youth aged 12-17 years were current cigarette smokers, of

which 48.6% smoked menthol cigarettes (260,000 youth) [70]. For U.S. young adults aged 18-25 years, data from the 2019 NSDUH estimates that nearly 5.79 million were current smokers, of which 51% (2.96 million young adults) smoked menthol cigarettes [70]. Data from 2019 NSDUH are summarized across all age groups in Table 5.

Table 5. Prevalence of Current (Past 30-Day) Menthol Cigarette Smoking by Age Group, 2019 National Survey on Drug Use and Health

Age Group	Current Cigarette Smokers (Million)	Current Menthol Cigarette Smokers (2019, Million)	Percentage of Menthol Use among Current Cigarette Smokers (rounded)
U.S. youth aged 12-17	0.54	0.26	48.6%
U.S. young adults aged 18-25	5.79	2.96	51.0%
U.S. adults aged 26-34	9.45	4.79	50.7%
U.S. adults aged 35-49	13.09	5.00	38.2%
U.S. adults aged 50+	16.84	5.58	33.2%
Total U.S. adults (26+)	39.37	15.37	39.0%
Total U.S. current smokers (Aged 12+)	45.70	18.59	40.7%

Source: Reference 70.
Note: Estimates may not sum to totals due to rounding.

While data on trends of cigarette smoking from the National Youth Tobacco Survey (NYTS) show a decline in overall cigarette smoking and in menthol cigarette smoking among middle and high school student smokers from 2011 to 2018, nearly half (45.7%) reported smoking menthol cigarettes in 2018 [85]. Results from the 2019 NSDUH annual report show similar long-term declines, with past 30-day cigarette use among U.S. youth ages 12-17 falling from 13.0% (or 3.2 million people) in 2002 to 2.3% (or 572,000 people) in 2019 [196]. While the report concluded estimates of cigarette smoking in 2019 were similar to those in 2018 (2.7% or 672,000 people), there was a statistically significant difference ($p<0.05$) between past 30-day cigarette smoking in 2011 (7.8%) and 2019 (2.3%) [196].

With respect to daily cigarette smoking, an analysis of 2015 data from the Monitoring the Future (MTF) survey funded by the National Institutes of Health indicated that daily cigarette smoking decreased to 1.3% among 8th graders, compared to 2.9% in 2010; to 3.0% among 10th graders, compared to 6.6% in 2010; and to 5.5% among high school seniors, down from 6.7% in 2014 (the previous year of data) and 10.7% in 2010 [91]. More recently, a 2020 study examining MTF data over 1991-2019 found significant downward trends in daily cigarette smoking over 2015-2019 [92]. In particular, daily cigarette smoking prevalence among 8th graders declined at an annual rate of 15.1% over 2015-2019 (reaching 0.8% in 2019). Larger annual declines of 16.5% and 17.5% were witnessed over the same period among 10th and 12th graders, respectively, with daily cigarette smoking prevalence reaching a low of 1.3% for 10th graders and 2.4% for 12th graders in 2019 [92] [93]. These data are summarized in Table 6.

Table 6. Daily Cigarette Smoking Prevalence and Average Declines Among U.S. Youth by Grade Level

Grade	2015	2016	2017	2018	2019	Average Annual Decline in Prevalence During 2015-2019
8th graders	1.3%	0.9%	0.6%	0.8%	0.8%	15.1%
10th graders	3.0%	1.9%	2.2%	1.8%	1.3%	16.5%
12th graders	5.5%	4.8%	4.2%	3.6%	2.4%	17.5%

Source: Reporting of the Monitoring the Future Survey over 2010-2015 [91]; Meza et al. covering 2015-2019 [92]; Miech et al. providing yearly estimates over 2015-2019 [93].

While overall cigarette smoking has been declining across the population as a whole, this has not directly translated into equal long-term declines in use of menthol cigarettes among all groups. For example, a 2011 NSDUH report analyzing trends in menthol cigarette smoking over 2004-2010 found that, although the prevalence of past-30-day non-menthol cigarette smoking among youth and adults (ages 12 or older) had shown overall declines (from 17.1% to 14.1%),

past-30-day menthol cigarette smoking among this age group had increased (from 7.7% to 8.2%) [94]. The report also found prevalence estimates of menthol cigarette smoking had increased among young adults aged 18 to 25 (from 13.4% to 15.9%) and were stable among youth aged 12 to 17 (from 4.9% to 4.2%) and those aged 26 or older (from 7.0% to 7.4%) over the same period, while rates of non-menthol cigarette smoking decreased in each of these age groups [94]. Thus, while smoking prevalence has demonstrated overall decline, the rate of menthol cigarette smoking either increased (among young adults) or remained constant (among youth and adults). An additional study, which extended the 2011 NSDUH analysis through 2014 for menthol smoking among the population of cigarette smokers, shows the reported trend had persisted [78]. The prevalence of menthol cigarette smoking among past 30-day cigarette smokers over 2012-2014 had increased when compared to the period 2008-2010 (from 35% to 39%), despite declines in overall smoking prevalence [78].The disproportionate use of menthol cigarettes by youth and young adult smokers compared to older adults has remained consistent over time and across multiple studies with nationally representative populations (for additional discussion, see Section IV.B of the Preamble of this proposed rule).

More recent estimates verify that menthol cigarette smoking has remained prominent among youth and young adult cigarette smokers. Findings from 2018 NYTS data indicate that 1.4 million (5.4%) of high school and middle school youth reported smoking a cigarette in the past 30 days, of which around 640,000 (45.7%) report smoking with a menthol cigarette [85]. In 2019, the CDC estimated that approximately 1.15 million (4.3%) U.S. middle and high school students had smoked a cigarette in the past 30 days based on data from the NYTS, a nationally representative survey [95]. Among youth who had smoked a cigarette in the past 30 days, approximately 530,000 (46.7%) smoked a menthol cigarette [95]. Additionally, data from the

2019 NSDUH estimates that of the nearly 5.79 million U.S. young adults aged 18-25 years who were current (past 30-day) smokers, 51% smoked menthol cigarettes (2.96 million young adults) [70].

c. Menthol Cigarette Smoking Among Vulnerable Populations

Although menthol cigarette smoking is widespread in the United States, menthol cigarettes are used at a particularly high rate among members of vulnerable populations. Members of underserved communities such as African American and other racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower household income or educational attainment, and individuals with behavioral health disorders are more likely to report smoking menthol cigarettes than other population groups [70] [73] [74] [75] [76] [77] [78] [79] [80] [81] [82] [83] [84]. In fact, African American smokers, regardless of age, are disproportionately more likely to smoke menthol cigarettes than smokers of any other race [70] [77] [78] [81] [84] [85] [96] [97] [98] [99] .

Among all adults, data from the NHIS indicate that cigarette smoking decreased from 20.9% in 2005 to 15.1% in 2015 [82]. While there was a significant decrease in the prevalence of menthol smoking overall (5.3% in 2005 to 4.4% in 2015), the prevalence of menthol cigarette smoking did not decrease among male smokers, adult smokers aged 25-34, adult smokers aged 55 and older, non-Hispanic Asian smokers, Hispanic smokers, or smokers who had less than a high school education [82]. Additionally, this study highlights that while the prevalence of all cigarette smoking and of menthol smoking, specifically, have decreased over time (2005-2015), the prevalence of menthol smoking in 2015 remained highest among specific groups, such as non-Hispanic Black persons (11.9%) [82]. The prevalence of menthol cigarette smoking among minority youth remains particularly high. Findings from the 2018 NYTS show that, among

middle and high school students who were current cigarette smokers, 51.4% of non-Hispanic Black youth and 50.6% of Hispanic youth reported smoking menthol cigarettes, compared to 42.8% of non-Hispanic White youth [85]. These data are summarized in Table 7. Statistically significant differences in this proportion by race and ethnicity have been observed in the NYTS over the 2011-2018 period. While declines in menthol cigarette smoking from 2011-2018 have been observed among non-Hispanic White youth, declines were not observed among non-Hispanic Black youth or Hispanic youth [85].

Table 7. Proportion of Cigarette Smokers who Smoke Menthol Cigarettes Among Youth by Population—NYTS 2018

Population Group	Proportion of Cigarette Smokers who Smoke Menthol Cigarettes
Non-Hispanic Black Youth	51.4%
Hispanic Youth	50.6%
Non-Hispanic White Youth	42.8%

Adapted from Reference 85.

According to 2019 NHIS data, approximately 14.9% of non-Hispanic African American adults reported current cigarette use (having smoked ≥100 cigarettes during their lifetime and smoked every day or some days), compared to 14.0% of all U.S. adults and 15.5% of non-Hispanic White adults [89]. However, African American smokers have lower success with quitting cigarette smoking and bear a disproportionate burden of tobacco-related morbidity and mortality [100]. Additionally, African American smokers are also more likely than smokers from other racial and ethnic minority groups to try a menthol cigarette as their first cigarette, regardless of age [101] [102] [103] . When compared to adults of other racial and ethnic groups, the prevalence of menthol cigarette smoking is highest among non-Hispanic Black/African-American adults. According to 2019 NSDUH data, approximately 17.5% of non-Hispanic Black/African-American adults aged 18 and older reported past 30-day menthol cigarette

smoking, compared to 6.4% of Hispanic adults, 5.8% of non-Hispanic White adults, and 3.2% of non-Hispanic Asian population [70]. The same data indicate that, of the population of non-Hispanic Black/African-American smokers, nearly 85% smoke menthol cigarettes, compared to 48% of Hispanic smokers, 41% of non-Hispanic Asian smokers, and 30% of White smokers who smoke menthol cigarettes [70].

A systematic literature review of menthol smoking by gender found that female smokers are more likely to smoke menthol cigarettes compared to men [68]. Additionally, another study of trends in menthol smoking from 2004 to 2014 NSDUH data showed that women are significantly more likely to smoke menthol cigarettes than men [78]. This is consistent with data from the 2019 NSDUH, which indicated that a higher proportion and number of female adult cigarette smokers smoked menthol cigarettes (44.7%; 9.36 million) than among male adult cigarette smokers (37.0%; 8.96 million) [70]. High levels of menthol cigarette smoking have also been reported in pregnant smokers. An analysis of 2006 to 2015 participant data from two racially and ethnically diverse cohorts of pregnant smokers with lower educational attainment and lower household income indicated high prevalence of menthol use in both cohorts (85% and 87%) [83].

Study findings indicate that individuals who identify as lesbian, gay, or bisexual are more likely to report smoking menthol cigarettes compared to those who identify as heterosexual, as well as other disparities related to gender identity or sexual orientation.[4] A study examining menthol use by LGBT status found a higher prevalence and a higher likelihood of smoking menthol cigarettes among LGBT smokers compared to heterosexual smokers, and that these

[4] The relevant scientific studies cited herein do not provide data separated by sexual orientation and gender identity. Due to these study limitations, we discuss sexual orientation and gender identity in a combined manner, despite their important distinctions.

differences in use were even greater among LGBT female respondents compared to heterosexual women [80]. According to the study, an estimated 36.3% of LGBT smokers reported that they usually smoke menthol cigarettes, compared to 29.3% of heterosexual smokers [80]. The difference in menthol use was especially pronounced among LGBT women, with 42.9% of LGBT female smokers reporting menthol use as compared to 32.4% of heterosexual smokers [80]. Using more recent national data from the 2019 NSDUH, only 6.9% of those identifying as straight or heterosexual reported smoking menthol (15.95 million) compared to 14.0% of those identifying as lesbian, gay, or bisexual (2.04 million) [70]. An analysis of pooled data from the 2015-2019 NSDUH indicate that compared to heterosexual/straight respondents, respondents who identified as gay males, lesbian/gay females, or bisexual females reported higher prevalence of past 30-day smoking [104]. Additionally, compared to heterosexual/straight respondents, gay males, and bisexual males, findings indicated that lesbian/gay females and bisexual females had higher menthol preference (defined as past 30-day use of menthol cigarettes among those who smoked cigarettes in the past 30-days) [104]. These data are summarized in Table 8.

Table 8. Menthol Cigarette Smoking Among Adults (18+) by Population – 2019 National Survey on Drug Use and Health[1]

Population Group	Percent of Overall Population who Smoke Cigarettes	Percent of Overall Population who Smoke Menthol Cigarettes	Percent of Cigarette Smokers who Smoke Menthol Cigarettes
Non-Hispanic Black/African-American	20.8%	17.5%	85.0%
Hispanic	13.5%	6.4%	48.0%
Non-Hispanic Asian	8.1%	3.2%	41.0%
Non-Hispanic White	19.5%	5.8%	30.0%
Female	16.3%	7.2%	44.7%
Male	20.3%	7.4%	37.0%
LGBT	29.4%	14.0%	48.6%
Heterosexual	17.6%	6.9%	39.7%

[1]Estimates were derived using the Substance Abuse and Mental Health Services Administration public online data analysis system (SAMHSA PDAS) with respect to NSDUH 2019 data. Respondents who indicated "Yes" to using a cigarette in the past-30 days (cigmon) were classified as current cigarette smokers. Current menthol cigarette smoking status was assessed using the following question (cig30men): "Were the cigarettes you smoked during the past 30 days menthol?" Individuals who answered "Yes" to this question were classified as current menthol smokers. Data were weighted to account for the complex survey design and adjusted for nonresponse [70].

Study findings show social gradient effects (where higher levels of indicators such as household income are linked to better health outcomes and lower levels are linked to poorer health outcomes) for menthol cigarette use [70] [78] [84]. In 2019 NSDUH data, the prevalence of menthol smoking was 14.6% among those with a total family income less than $20,000, 9.1% among those with a family income between $20,000 and $49,999, 6.5% among those with a family income between $50,000 and $74,999, but only 3.8% among those with a family income above $75,000 [70]. In particular, among adult cigarette smokers, 48.6% of those with a total family income less than $20,000 smoked menthol cigarettes, compared to 42.1% of those with a family income between $20,000 and $49,999, 36.7% of those with a family income between $50,000 and $74,999, and 33.1% of those with a family income above $75,000 [70]. The 2019 NSDUH data also indicates that prevalence of non-menthol cigarette smoking was 15.3% among

those with a total family income less than $20,000, 12.4% among those with a family income between $20,000 and $49,999, 11.1% among those with a family income between $50,000 and $74,999, and 7.7% among those with a family income above $75,000 [70]. As a proportion of adult cigarette smokers, 51.3% of those with a total family income less than $20,000 smoked non-menthol cigarettes, compared to 57.8% of those with a family income between $20,000 and $49,999, 63.2% of those with a family income between $50,000 and $74,999, and 66.8% of those with a family income above $75,000 [70]. These data are summarized in Table 9.

Table 9. Prevalence of Menthol Cigarette Smoking Among Adults (18+) by Household Income Level—2019 National Survey on Drug Use and Health

	Menthol Cigarette Use		Non-Menthol Cigarette Use	
Reported Household Income	Menthol Cigarette Smoking Prevalence	Proportion of Cigarette Smokers Who Smoke Menthol Cigarettes	Non-menthol Cigarette Smoking Prevalence	Proportion of Cigarette Smokers Who Smoke Non-menthol Cigarettes
<$20,000	14.6%	48.7%	15.3%	51.3%
$20,00-$49,999	9.1%	42.2%	12.4%	57.8%
$50,000-$74,999	6.5%	36.8%	11.1%	63.2%
≥$75,000	3.8%	33.2%	7.7%	66.8%

Source: Reference 70.

In addition to overall cigarette use, menthol cigarette use is also higher among adults with mental health issues or illness [70] [79] [84] [105] [106]. In 2019, NSDUH data indicated that 17.4% of adults age 18 and older who reported past 30-day serious psychological stress reported past 30-day menthol smoking compared to only 6.6% of those who did not report past 30-day serious psychological stress, similar to rates of non-menthol smoking amongst these two populations (17.3% and 10.3%, respectively) [70]. According to the same data, 50.1% of adults age 18 and older who reported past 30-day serious psychological stress who smoke cigarettes reported smoking with a menthol cigarette compared to only 39.1% of those who did not report

past 30-day serious psychological stress [70]. Among adult cigarette smokers, 49.8% of adults age 18 and older who reported past 30-day serious psychological stress reported smoking with a non-menthol cigarette and 60.8% of those who did not report past 30-day serious psychological stress [70]. Lastly, an analysis of young adults (aged 18-30 years) receiving treatment for smoking cessation also found that of those with severe mental illness (SMI), more than half (58.0%) smoke menthol cigarettes [106]. These data are summarized in Table 10.

Table 10. Prevalence of Menthol Cigarette Smoking Among Individuals with Reported Mental Health Issues or Illness and Psychological Stress—2019 National Survey on Drug Use and Health

	Menthol Cigarette Use		Non-menthol Cigarette Use	
Population	Menthol Cigarette Smoking Prevalence	Proportion of Cigarette Smokers Who Smoke Menthol Cigarettes	Non-menthol Cigarette Smoking Prevalence	Proportion of Cigarette Smokers Who Smoke Non-menthol Cigarettes
Adults over age 18 with reported mental illness	17.4%	50.1%	17.3%	49.8%
Adults over age 18 without reported mental illness	6.6%	39.1%	10.3%	60.8%

Source: Reference 70.

d. Secondhand Smoke

Secondhand smoke exposure is harmful to the health of non-smokers. The 2006 SGR, "The Health Consequences of Involuntary Exposure to Secondhand Smoke," concluded that "secondhand smoke exposure causes premature death and disease in children and in adults who do not smoke" [27]. Exposure to secondhand smoke is a cause of cancer and respiratory and cardiovascular disease [3]. Children of parents who smoke, when compared with children of nonsmoking parents, have an increased frequency of respiratory infections like pneumonia and

bronchitis [107]. Children exposed to tobacco smoke in the home are also more likely to develop acute otitis media (middle ear infections) and persistent middle ear effusions (thick or sticky fluid behind the eardrum) [107]. Secondhand smoke exposure is currently estimated to be responsible for over 41,000 deaths annually in the U.S. [3].

From 2013-2014 an estimated 58 million U.S. non-smokers (25%) including 14 million children (aged 3-11), 9.1 million adolescents (aged 12-19), and 36.7 million adults were exposed to secondhand smoking [25]. In 2017, 55.1% of U.S. middle and high school students (14.3 million) reported being exposed to secondhand smoking in indoor and outdoor places [108]. Data from 2013-2016 shows that non-Hispanic Black youth have significantly higher exposure to secondhand smoke than other groups (61.8%) [109].

e. Maternal Smoking

Smoking during pregnancy is a leading preventable cause of infant morbidity and mortality [110]. It increases the risk of pregnancy complications, preterm-related deaths and sudden infant death syndrome (SIDS) [3]. Furthermore, postnatal exposure to secondhand smoke increases the likelihood an infant will develop SIDS [27]. Natality data from the U.S. Standard Certificate of Live Birth collected by the National Centers for Health Statistics (NCHS) estimate that 6.0% of women reported smoking at any point during pregnancy in 2019, down from 8.4% in 2014 [111] [112] . Data obtained from the CDC's 2019 Pregnancy Risk Assessment Monitoring System (PRAMS) suggest that 15.1% of pregnant women smoked during the three months before pregnancy, 6.8% smoked during the last three months of pregnancy, and 9.7% of women smoked postpartum at the time of survey administration [113].

f. Summary

As previously mentioned, estimates discussed within this section are presented in order to provide a more complete representation of baseline conditions prior to the implementation of this proposed product standard and to serve as a reference throughout this analysis. We specifically presented estimates from the NHIS since it provides a basis for modeling performed by Levy et al. (2021) [88] and data from NSDUH since estimates are utilized within later sections of this analysis.

2. Market Overview

a. Data Sources Considered

To estimate the impacts of the proposed rule on the tobacco industry and associated markets more broadly, we review a variety of data sources, including information submitted to FDA, information submitted to other Federal agencies, and third-party data for cigarettes, including cigarettes that are heated tobacco products; cigarette tobacco; and roll-your-own (RYO) tobacco. Recognizing that no single source reflects the complete scale of the tobacco market in terms of sales, entity counts, and product counts, we review multiple sources and assess each source's strengths and limitations for inclusion in this analysis. We note, as a limitation, that product definitions, market estimates, and methodology will differ across data sources. We solicit comments on how best to estimate the total number of affected entities and products, including any additional data sources that may be considered as part of this analysis.

i. FDA's Tobacco Registration and Product Listing Data

Owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product or products are required to register domestic manufacturing establishments with the FDA each year and submit biannually to the FDA a listing of those tobacco products manufactured at each establishment.

The Tobacco Registration and Listing Module (TRLM) in the FDA's Unified Registration and Listing System (FURLS) captures and maintains self-reported establishment registration information and associated product listings, including labels, advertising, and consumer information. We use data on product listings that have been added to the module as of June 2021.

There are several caveats associated with using the registration and product listing data. Under Section 905(i)(3)(b) of the Tobacco Control Act, entities that discontinue the manufacture, preparation, compounding, or processing for commercial distribution of a previously listed tobacco product are required to notify the FDA as part of biannual product listing updates. In practice, FDA has received some notifications of discontinuance. Entities may be miscategorized in the self-reported registration and product listing data in terms of the type of manufacturing they conduct or the category of product they produce. For example, FDA found that several registrants that appear to manufacture, prepare, compound, or process ENDS were likely miscategorized as cigarette manufacturers in the data reviewed for this analysis.

The product listing data likely overcount the number of domestic products impacted by this proposed product standard, as well. For example, multiple entities may list the same product as every registrant must submit a list of all tobacco products that are being manufactured,

prepared, compounded, or processed by the registrant for commercial distribution.[5] Although we strongly encourage owners to act as the agent for all operators within a given business structure, not all owners may choose to do so. 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. 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.[6] Technical difficulties and capacity restrictions with the TRLM 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 data may be resolved as companies provide updated product listing information on a biannual (twice per year) basis. FDA also continues to conduct inspections of establishments that manufacture tobacco products, which may result in the list of manufactured tobacco products fluctuating over time. However, FDA encourages registrants to address such issues in their own registration and product listing data.

[5] It is difficult to ascertain from the TRLM data whether such entities are under the same ownership structure or under separate ownership. For example, a contract manufacturer and a brand owner could have registered and listed the same products.

[6] Section 905(h) of the FD&C Act gives the FDA authority to require, by regulation, foreign establishments that are engaged in the manufacture, preparation, compounding, or processing of a tobacco product(s) to register their establishments and to list their products (21 U.S.C. 387e(h)). To date, the FDA has not promulgated a regulation requiring foreign manufacturers to register their establishments and list their products that are imported into the United States.

ii. Alcohol and Tobacco Tax and Trade Bureau Data

The Alcohol and Tobacco Tax and Trade Bureau (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"[7] —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.

TTB Permit Counts – From aggregate information provided by TTB, we can count the number of Employer Identification Numbers (EINs) associated with TTB permits for tobacco product manufacturers and importers. As manufacturers/importers often manufacture or import products in more than one tobacco product category, counts of EINs associated with TTB tobacco product manufacturing and importing permits in a specific category will, when totaled, overcount the number of entities potentially affected by this proposed product standard.

Summing TTB's counts of manufacturers and importers would generally result in an overestimate of the number of affected entities because an entity producing or importing products across multiple categories would be counted more than once. For the purposes of this

[7]From 26 U.S.C. 5702(c), cigarettes are defined as "(1) [a]ny roll of tobacco wrapped in paper or in any substance not containing tobacco, and (2) [a]ny roll of tobacco wrapped in any substance containing tobacco 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 described in paragraph (1) of this definition," and roll-your-own tobacco as "[a]ny tobacco 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 or cigars, or for use as wrappers of cigars or cigarettes." *id.*

analysis, however, we treat each count as unique, resulting in an over-count of such entities to better capture a range of compliance actions.

Monthly Tax Reports – To assess each entity's respective tax burden, TTB-permitted manufacturers and importers are each required to submit a monthly report to TTB on the amount of tobacco product manufactured or imported in the last month in each taxable tobacco product category.[8] Summary volume data from these reports, available through the TTB website, can provide insight on the total volume of tobacco products released for distribution in the U.S. market, but is not specific to any brand or market region and reflects no additional product characteristics other than those used to sort products into tax categories. Additionally, TTB tracks only the volume of tobacco product released for distribution, not consumer purchases.

iii. Retail Scanner Data

FDA receives sales data from NielsenIQ Retail Measurement Service (NIQ RMS) and Information Resources Incorporated (IRI) for tobacco products sold through food, drug, mass merchandise, and convenience stores across the United States. NIQ RMS and IRI track how often a Universal Product Code (UPC) is scanned at contracted retail outlets and collect pricing information from each contracted retailer. NIQ RMS and IRI then create and use weights to make their respective samples both regionally and nationally representative for their collective markets.[9]

Sales data provide information on the categories and brands of tobacco products available for sale at food, drug, mass merchandise, and convenience stores, including product attributes

[8]A description of taxed tobacco product categories can be found at the TTB website accessed at https://www.ttb.gov/tax-audit/tax-and-fee-rates.
[9] We note that product definitions, market estimates, and methodology differ across data sources.

and types of packaging. While information on brand owner is also available, these data do not cover all types of tobacco product retailers and, thus, cannot provide complete counts of manufacturers, importers, or retail locations.[10] We note that counts of UPCs generally provide a poor proxy for unique products, as new UPCs may be introduced by the manufacturer to offer special pricing or product discounts or as a means of tracking sales in different regions or outlets. We also recognize that retail scanner data primarily focuses on sales trends in market distribution and therefore prioritizes identification of those products with wider distribution networks through tracked retail outlets.

iv. Euromonitor International Data

Euromonitor International (EMI) tracks retail sales and volume data for detailed and summary-level tobacco product categories sold at brick-and-mortar stores and through online outlets. EMI provides information at the aggregate tobacco product category level and for some top brands and companies, but does not report on the number of manufacturers, importers, or products on the market. The sales and volume data provided by EMI cover tobacco products for sale in the United States, without differentiating between products produced domestically and those manufactured abroad and imported for sale within the United States. Of the categories EMI tracks, we expect that three categories—*Cigarettes, Fine Cut Tobacco, and Heated Tobacco Products*—most closely represent the tobacco product categories covered by this proposed product standard. Components and parts[11] containing menthol sold directly to consumers with the intention they be used as part of a cigarette product would also be affected by the proposed

[10] We note that retail scanner data does not include sales by online retailers and provides minimal coverage of tobacco specialty stores, such as tobacconists. However, retail scanner data is expected to provide better coverage of sales for cigarettes products as compared to other types of tobacco products.
[11] Examples of cigarette components and parts sold directly to consumers and affected by this proposed product standard includes mentholated rolling papers and filtered tubes.

product standard. Euromonitor does not report annual data for cigarette components and parts however, we expect the revenue sales from these products to be very small compared to the rest of the cigarette market.

b. Number of Affected Products

To understand the baseline state of the tobacco market, we first searched the active product listing information in TRLM 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 2,750 unique cigarette products. Filtering these yielded 950 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 for the category of RYO Tobacco, we found a total of 234 RYO tobacco products, 35 of which are menthol flavored and affected by this proposed product standard. Additionally, we searched TRLM for the product categories "Roll-Your-Own Filters" and "Roll-Your-Own Paper." Following this search, we identified 83 active RYO Paper products, 27 of which are mentholated and affected by this proposed product standard.

From TRLM data, there may be as many as 7 total authorized Heated Tobacco Products on the market, 3 of which appear to be menthol flavored. For the purposes of this analysis, we assume these 3 menthol flavored HTPs may be affected by this rule. As shown in Table 11, adding all cigarette (including cigarettes that are HTPs), RYO, and components and parts, we estimate 1,015 products would be affected by this proposed product standard.

Table 11. Count of Menthol Cigarette Products

	All Products	Products Identified as Menthol Flavored	Percent Menthol
Cigarettes	2,750	950	34.5%
RYO	234	35	15.0%
Components and Parts	83	27	32.5%
HTP	7	3	43.0%
Total	3,074	1,015	33.0%

For comparison, we also analyzed NIQ RMS and IRI data for a count of menthol cigarette products at the UPC level with non-zero volume sales in 2020, a criterion we use to identify whether a product is "active" in the U.S. market. We analyzed 53 weeks of sales data from NIQ RMS (weeks ending 1/04/2020 – 1/02/21, hereafter referred to as 2020 NIQ RMS data) for the cigarette and RYO categories [114].[12] Using the same identification criteria as used for the TRLM product listing data, we found 1,140 menthol cigarette products and 10 menthol RYO products with non-zero volume sales during 2020 [114].

We then analyzed data by the NIQ RMS variable "Brand High." Out of a total of 159 NIQ RMS identified cigarette brands and 9 RYO brands, 116 cigarette brands and 5 RYO brands recorded sales in 2020 with a menthol flavor [114]. Most of these brands also recorded sales of a non-menthol flavored product in the same category. There were only 10 cigarette brands and 1 RYO brand that had sales of menthol flavored products in 2020 but did not record sales for a

[12]The FDA's own analyses, calculations and conclusions informed in part by the NielsenIQ's Retail Measurement Service (NIQ RMS) data for the cigarette and RYO categories for the 53-week period ending 1/02/2021 (weeks ending 1/04/2020 – 1/02/21) for Total U.S. Expanded All Outlets Combined (xAOC) and convenience stores are those of the FDA and do not reflect the views of NielsenIQ. NielsenIQ is not responsible for, had no role in, and was not involved in analyzing and preparing the results reported herein, or in developing, reviewing or confirming the research approaches used in connection with this report. NielsenIQ RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See https://nielseniq.com/global/en/ for more information [114].

non-menthol flavor of the same product [114]. These brands had extremely low volume of sales and included names suggesting they may not be cigarette tobacco products [114].[13] Therefore, we make the simplifying assumption that all brands with a menthol product listed in NIQ RMS data also have a non-menthol version available on the market.

Table 12. NIQ RMS Brands and UPCs for Cigarette Products

	Total UPCs	Menthol UPCs	Menthol UPC Percent	Total Brands	Menthol Brands
Cigarettes	2,942	1,104	37.5%	159	116
RYO	39	10	25.6%	9	5
Total	2,981	1,114	37.4%	168	121

We analyzed 2020 IRI data (weeks ending 12/30/19 – 12/27/20, hereafter referred to as 2020 IRI data)[14] in a similar manner and found 3,822 total cigarette UPCs during the year 2020, 1,534 of which were classified by IRI as menthol cigarette UPCs [115]. Next, we analyzed the IRI variable "Brand Franchise Name." Out of a total of 151 IRI identified cigarette brands, 123 recorded sales in 2020 with a menthol flavor [115]. Again, we note that of these 123 menthol cigarette brands, 9 brands record no sales in a non-menthol flavor [115]. However, these brands also have very low volume of sales and have names that suggest they are not cigarette tobacco products. We followed the same process to analyze RYO tobacco and present the results in Table 13.

[13]For example, some brands had data suggesting low-digit cigarette pack sales during 2020 or include wording to suggest they may not be a cigarette tobacco product.

[14]Information Resources, Inc (IRI) data. Food and Drug Administration custom research definitions based on Information Resources, Inc. data, (weeks ending 12/30/19 – 12/27/20), Unit Sales, Total Multi-Outlet + Convenience, United States [115].

Table 13. IRI Brands and UPCs for Cigarette Products

	Total UPCs	Menthol UPCs	Menthol UPC Percent	Total Brands	Menthol Brands
Cigarettes	3,822	1,534	40.1%	151	123
RYO	159	33	20.8%	30	11
Total	3,981	1,567	39.4%	181	134

c. Number of Affected Entities

i. Domestic Manufacturers/Importers

Using TRLM data as of August 12th, 2021 and recognizing many of the previously discussed strengths and weaknesses of TRLM submission data, FDA has identified 68 domestic addresses for manufacturers of cigarettes, RYO tobacco, HTPs, and related components and parts. Of these registered establishments, 35 engage in the manufacture, preparation, compounding, or processing of menthol cigarettes and 12 establishments conduct similar operations for menthol RYO Tobacco. Seven menthol RYO establishments appear to be dual manufacturers of both menthol RYO tobacco and menthol cigarettes. Additionally, we identified 5 establishments which manufacture related components and parts to be sold directly to consumers, 3 of which manufacture menthol flavored components and parts. This suggests 43 (=35 + 12 + 3 - 7) as the count of domestic manufacturing establishments from TRLM potentially affected by the proposed product standard. This review of establishments in TRLM suggests manufacturers of currently marketed menthol cigarettes, RYO tobacco, cigarettes that are HTPs, and components and parts also manufacture non-menthol versions, often within the same brand.

As the proposed product standard applies to all tobacco products available for sale in the U.S. market that meet the definition of a cigarette, foreign manufacturers of menthol cigarettes and menthol RYO tobacco products intended for distribution in the U.S. market would also be affected. Currently, FDA does not require that foreign manufacturers of tobacco products or domestic importers of tobacco products intended for distribution in the U.S. market to register and list. Instead, we use the number of domestic importers of cigarettes and RYO tobacco from TTB to estimate the number of non-manufacturing establishments whose business of bringing menthol cigarettes or menthol RYO tobacco into the U.S. market would be affected.

ii. Domestic Wholesalers and Retailers

In addition to manufacturers and importers, wholesalers and retailers that sell menthol cigarette products may also face impacts from this proposed product standard. To estimate the number of wholesale and retail entities that sell tobacco products at baseline, we rely on data from the 2019 Statistics of U.S. Business (SUSB) for the number of total firms and establishments [116]. Although data for wholesalers of tobacco products are identified in a specific NAICS industry code in the 2019 SUSB data (424940, Tobacco and Tobacco Product Merchant Wholesalers), data for retailers include firms and establishments that both do and do not sell tobacco products.

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), as it is the most recent data available

[117] [118].[15] Multiplying these percentages by the count of establishments from the 2019 SUSB data, we estimate the number of tobacco-selling retail establishments in 2019. 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 2019. We note that, if firms that have multiple establishments are more or less likely to sell tobacco products than firms with only one establishment, this assumption could introduce some uncertainty to our estimates. Table 14 presents the NAICS codes and descriptions for wholesalers and retailers potentially affected by the proposed product standard, estimates of firms and establishments from the 2019 SUSB data, data from the 2017 Economic Census on establishments that sell tobacco products within each retail category, and our estimates of 2019 firms and establishments that sell tobacco products.

[15] We note that in 2017 there were additional NAICS codes that had negligible numbers of establishments selling tobacco products, such as 444190 Other building material dealers. We do not include these retailers in our estimates of those potentially affected by this proposed product standard.

Table 14. Affected Entities, Other than Tobacco Manufacturers and Importers

NAICS	NAICS Description	Firms (2019)[1]	Total Estab. (2019)[1]	Establishment Data by Products Sold (2017)			Estimated Entities Selling Tobacco	
				Estab. Selling Tobacco (2017)[2]	Total Estab. (2017)[3]	% Estab. Selling Tobacco (2017)	Firms (2019)	Estab. (2019)
42494	Tobacco and Tobacco Product Merchant Wholesalers[4]	1,308	1,493				1,308	1,493
44511	Supermarkets and Other Grocery (except Convenience) Stores	38,753	62,932	30,814	65,141	47.30%	18,332	29,769
44512	Convenience Stores	27,998	30,330	25,264	28,460	88.77%	24,854	26,924
44530	Beer, Wine, and Liquor Stores	30,531	34,618	18,700	34,440	54.30%	16,578	18,797
44611	Pharmacies and Drug Stores	19,486	44,902	19,247	45,358	42.43%	8,269	19,054
44711	Gasoline Stations with Convenience Stores	56,460	99,299	91,667	98,788	92.79%	52,390	92,141
44719	Other gasoline stations	9,525	13,331	3,725	16,581	22.47%	2,140	2,995
452311	Warehouse Clubs and Supercenters	34	8,307	6,735	8,202	82.11%	28	6,821
452319	All other general merchandise stores	7,720	43,640	31,194	41,241	75.64%	5,839	33,009
453991	Tobacco Stores	9,667	11,655	10,415	10,415	100.00%	9,667	11,655
	Total	201,482	350,507	237,761	348,626		139,404	242,657

[1]Reference 116.
[2]Reference 117.
[3] Referecen 118.
[4] By definition, all firms in NAICS 42494 sell tobacco products.

We are unable to assess if establishments that sell tobacco products sell menthol cigarette products and, therefore, assume all establishments that sell tobacco products sell menthol cigarette products. Given the complexities of growth and contraction in various industries, as well as the regularly changing landscape of jurisdictional 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 2019. Furthermore, given 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 2019. 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.

iii. Alcohol and Tobacco Tax and Trade Bureau (TTB)

We review aggregate data from the TTB which shows that there were 35 permitted manufacturers of tobacco products producing cigarettes and 10-12 permitted manufacturers of tobacco products producing RYO tobacco in 2020. Of the entities holding manufacturing permits for cigarettes, 26 of those entities also hold manufacturing permits for other categories of tobacco products. Of the entities holding manufacturing permits for RYO tobacco, 9 entities hold manufacturing permits for other tobacco product categories. For purposes of this analysis, we assume that none of the multi-category cigarette manufacturers produce RYO tobacco. This suggests that 47 domestic entities permitted by TTB may be affected by this proposed product standard.

Based on aggregate information from TTB,[16] in 2020 there were 14 importers that imported cigarettes and 19 importers that imported RYO tobacco. Of these, 10 importers reported handling of only cigarette products, and 4 importers of RYO tobacco reported handling of only RYO tobacco. It is possible that the importers of RYO tobacco who also import other

[16]TTB classifications of tobacco product categories do not necessarily match the FDA's classifications of tobacco product categories due to differences in definitions.

tobacco products may already be counted among the 4 importers of cigarette products who similarly import additional product categories. For this analysis, we use TTB data and assume 33 importers would be potentially impacted by the proposed rule, noting that these importers may also import other tobacco products outside the scope of the proposed product standard.

Additionally, available TTB data does not identify product characteristics beyond category, so we are unable to differentiate importers of menthol cigarettes and RYO tobacco separately from non-menthol cigarettes and RYO tobacco. For the purposes of this analysis, we assume any of these importers could handle menthol products and would be impacted by this proposed product standard. In addition, any business entity may act as both manufacturer and importer, however we are unable to identify such dual-role business entities without additional information. We therefore assume that the counts of manufacturers and importers represent mutually exclusive groups of entities. This approach likely leads to an overestimate of the number of entities impacted by the proposed product standard.

Given the close comparison between FDA's Establishment Registration data and TTB's permit holder counts, we use 43 as the count of affected domestic manufacturing establishments for this analysis. As FDA does not currently collect registration information for domestic importers, we will also use the TTB count of 33 domestic importers potentially affected by the proposed product standard.

iv. Foreign Manufacturers

To estimate the number of unique foreign manufacturers potentially affected by this proposed product standard, we review available tobacco product import data for fiscal year 2020

and find approximately 27 unique foreign manufacturers offering menthol cigarettes for sale in the United States.[17] We further consider impacts to these entities in Section II.F.3.

Table 15. Number of Manufacturers and Importers Potentially Affected by the Proposed Product Standard

Domestic Manufacturing Establishments (TRLM FURLS data)	Count
Cigarettes	35
RYO Loose Tobacco	12
Components and Parts	3
Total number of affected domestic manufacturing establishments	43
Importers (TTB data)	
Cigarettes	14
RYO Loose Tobacco	19
Total number of affected domestic importing entities	33
Total number of potentially affected domestic entities	76
Foreign Manufacturing Establishments	27

v. Small Tobacco Product Manufacturers

This proposed product standard is expected to prohibit the use of menthol as a characterizing flavor in all products meeting the definition of a cigarette product marketed in the U.S. The U.S. market for cigarettes and RYO tobacco is largely driven by three larger manufacturers (representing 91.1% of sales in the U.S. by volume), but some small tobacco product manufacturer entities would be affected by the proposed standard [69].

[17]The estimated imports of menthol cigarettes and the number of associated foreign facilities is derived from data on tobacco product shipments from FY 2020 prepared on July 22, 2021 and August 10, 2021 by U.S. Food & Drug Administration, Center for Tobacco Products, Office of Compliance and Enforcement.

Section 900 of the The Family Smoking Prevention and Tobacco Control Act (TCA) defines a tobacco product manufacturer as "any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States." The TCA further defines a 'small tobacco product manufacturer' as a tobacco product manufacturer that employs fewer than 350 employees, where the count of employees includes the employees of each entity that controls, is controlled by, or is under common control with the manufacturer.

Based on a review of industry submission and inspection data, Dun and Bradstreet data and publicly available information[18] regarding the 35 domestic manufacturers of menthol cigarettes registered with FDA, we estimate that 22 domestic manufacturers may meet the TCA definition of "small tobacco product manufacturer" [119]. We were unable to locate publicly available employment estimates for 5 registered cigarette establishments and, thus, assume these also meet the TCA definition of a "small tobacco product manufacturer."

Based on a similar review of publicly available employment estimates for establishments manufacturing RYO tobacco products, we estimate that 6 of these establishments may meet the TCA definition of "small tobacco product manufacturer." Additionally, we were unable to find publicly available employment estimates for 5 of the domestic manufacturers of RYO tobacco and, thus, assume these are small. We further assume that all 3 affected components and parts manufacturers are also small. We note that the assumptions here and in the previous paragraph may potentially lead to an overestimate of the number of tobacco product manufacturers that meet the TCA definition of a "small tobacco product manufacturer."

[18]Publicly available information includes review of company websites and press releases, news reports, and internet search results.

As the cited counts of domestic importers of cigarette and RYO tobacco products are based on a review of non-FDA, aggregate data, we are unable to estimate employment information to assess whether or not they may qualify as small under the TCA.

Overall, of the domestic manufacturers likely to be affected by the proposed product standard, 27 (77.1%) manufacturers of cigarettes, 11 (91.7%) manufacturers of RYO tobacco, and 3 (100%) manufacturers of components and parts may also meet the TCA definition of a "small tobacco product manufacturer." We request comment on these estimates.

Aside from the TCA, the Small Business Administration (SBA) also uses an employee count threshold to determine eligibility for small business assistance and flexibility. Under the SBA threshold, any tobacco product manufacturer with fewer than 1,500 employees would be considered eligible [120]. Using this alternative threshold and the same assumption regarding entities with unknown employee counts, we estimate that 29 (82.9%) domestic manufacturers of cigarettes, 12 (100%) domestic manufacturers of RYO tobacco, and 3 (100%) domestic manufacturers of components and parts may be considered small entities under the SBA threshold. We consider impacts and potential flexibility for these entities in Section III.

d. Sales Revenues and Volumes

We use NIQ RMS, and IRI, and EMI data to estimate the overall size of the menthol cigarette market by total sales revenue and volume during the year 2020.

i. Retail Scanner Data

a) Cigarette Market

NIQ RMS data shows that, in 2020, total cigarette dollar sales in retail outlets were $61.8 billion and total cigarette volume sales in retail outlets were 184.5 billion sticks [114]. Menthol

cigarettes account for $22.6 billion dollar sales and 66.7 billion sticks of volume sales (approximately 36.5 of total cigarette sales dollars and 36.2% of total cigarette volume).

We further analyze NIQ RMS data, categorizing cigarette products by their product flavor descriptions as either tobacco or menthol flavored, recognizing that all other characterizing flavors are prohibited in the cigarette market [114]. Using the NIQ product flavor attribute field that is based on labeling information, we assigned product UPCs to a menthol flavor category only if the product flavor attribute included the word "Menthol." All other product UPCs were categorized as tobacco flavored or unflavored, including cigarette product UPCs with a product flavor description of "Not Stated." Because of this, the volume and dollar sales we estimate for menthol cigarettes may be an underestimate if one or more menthol cigarette brands does not state their flavor on the label.

A review of 2020 IRI data analyzed in a similar method shows sales for menthol cigarette products at about $22.5 billion (34.1% of all cigarette products) [115].

b) RYO Tobacco Market

To analyze the RYO tobacco market, we use the NIQ RMS attribute field "common consumer name" built from labeling information and filter for "cigarette tobacco." We use a similar method for categorizing flavors of RYO tobacco as outlined for cigarettes. Volume sales of RYO tobacco are reported by NIQ in ounces, which we divide by 16 to convert to pounds. RYO tobacco sales are significantly smaller than cigarette sales with total RYO dollar sales of $36.2 million in 2020 and menthol sales of $1.0 million (2.7%) [114]. During 2020, total RYO volume sales were 301.5 thousand pounds, of which, 11.9 thousand were menthol.

A review of 2020 IRI data analyzed in a similar method shows sales for menthol RYO tobacco at about $4.6 million (7.7% of all RYO tobacco) [115]. We are unable to analyze sales

for components and parts sold directly to consumers in NIQ RMS or IRI data but, as stated earlier in this section, we expect their sales to be very small compared to the rest of the cigarette market.

c) Heated Tobacco Product Market

From the NIQ RMS data, we report sales of heated tobacco product sticks. However, the few products available in this category are new to the tobacco market, limited in retail distribution channels, and their sales may not be fully captured by retail scanner data due to their presence in specialty outlets. NIQ RMS data shows total HTP sales in 2020 to be less than $1.08 million [114]. We assume sales of heated tobacco product sticks with a menthol flavor are similar to proportion of sales for mentholated cigarettes as compared to the total cigarette market and estimate that 36.5% of the market for heated tobacco sticks is menthol flavored. A review of 2020 IRI data shows sales for menthol heated tobacco product sticks at about $1.2 million (57.1%) [115].

Table 16 presents cigarette, RYO, and HTP dollars sales from NIQ RMS and IRI data. Table 17 presents cigarette, RYO, and HTP volume sales from NIQ RMS data which we estimate as stick equivalents.

Table 16. 2020 NIQ RMS and IRI Dollar Sales

	IRI ($2020, Millions)			NIQ RMS ($2020, Millions)		
	Total	Menthol	Menthol (% of Total)	Total	Menthol	Menthol (% of Total)[1]
Cigarettes	$66,229.3	$22,572.1	34.1%	$61,832.5	$22,554.3	36.5%
RYO	$59.4	$4.6	7.7%	$36.2	$1.0	2.7%
HTPs	$2.1	$1.2	57.1%	$1.1	$.4	36.5%
Total	$66,290.8	$22,577.9	34.1%	$61,869.8	$22,555.7	36.5%

Source: Reference 115 and Reference 114.
[1]We assume menthol vs. non-menthol HTP sales follow the same break down as overall cigarette sales and estimate menthol HTP dollar sales as 36.5% of total HTP sales.

Table 17. 2020 NIQ RMS Volume Sales

	2020 Volume Sales, NIQ RMS (Millions of Sticks[1])		
	Total	Menthol	Menthol (% of Total)
Cigarettes	184,483.8	66,735.0	36.2%
RYO	195.4	7.7	3.9%
HTP	2.9	1.1	37.9%
Total	184,682.1	66,743.8	36.1%

Source: Reference 114.
[1]We assume 1 "stick equivalent" is equal to 0.7 grams of RYO tobacco.

ii. Euromonitor International Data

As presented in Table 18, EMI data reports that in 2020, out of 222.6 billion cigarette sticks sold in the United States, menthol cigarettes represented approximately 35% (77.8 billion sticks) [69].[19] In 2020 total U.S. cigarette dollar sales via all outlets[20] were $94.2 billion [69]. Euromonitor does not provide data for dollar sales of menthol flavored cigarettes. Assuming menthol and non-menthol cigarettes are sold at similar prices, we apply this percentage (approximately 35%) to total cigarette dollar sales and estimate that menthol cigarette sales were approximately $32.9 billion in 2020.

[19] Source: Euromonitor International Limited 2021 © All rights reserved.
[20] Euromonitor International (EMI) tracks retail sales and volume data for detailed and summary-level tobacco product categories sold at brick-and-mortar stores and through online outlets.

EMI data reports that total RYO tobacco dollar sales via all outlets were $333.1 million in 2020 and total volume sales were 5.9 million pounds [69]. However, EMI data do not provide information on dollar or volume sales specific to menthol RYO tobacco.

EMI reports total sales for "heated tobacco" products (excluding devices), at $21.6 million and 41.8 million sticks during 2020 [69]. [21] However, EMI does not report a menthol flavored specific breakout of for this category.

Table 18. 2020 EMI Revenue and Volume Sales for Total Cigarettes

	Revenues ($2020, Millions)			Volume Sales (Millions of Sticks[1])		
	Total	Menthol	Menthol (% of Total)	Total	Menthol	Menthol (% of Total)
Cigarettes	$94,173.3	$32,923.0	35.0%	222,562.4	77,808.9	35.0%
RYO	$333.1	-	-	1,861.7	-	-
Heated Tobacco	$21.6	-	-	41.8	-	-
Total	$94,528.0			224,465.9		

[1]According to EMI category definitions, RYO tobacco ("Fine Cut") converts into cigarettes, assuming a conversion rate of 0.7g of Fine Cut tobacco = 1 cigarette.

e. Summary of Sales and Product Counts

We consider the strengths, weaknesses, and coverage of each data source in determining the counts of products likely affected by this proposed rule. For this analysis, we use TRLM submission data for counts of affected products, EMI data for overall market trends by category and flavor, and retail scanner data for more product- and brand-specific analyses.

As an exception, we note that the NIQ RMS data analyzed earlier in this analysis suggests that menthol RYO tobacco sales account for approximately 3% of dollar sales of total

[21]From EMI, "Heated tobacco is the consumable element of tobacco vapour products and can come in the form of tobacco pods such as PloomTech capsules or in specially designed cigarettes, such as Philip Morris's Heets for use with iQOS or BAT's glo Neostiks." [69] Although EMI's "heated tobacco" category may include a wider range of products than the categorization of HTPs that meet the definition of a cigarette included in this proposed rule, we include sales for the entire category.

RYO tobacco [114]. However, IRI data suggests that menthol RYO tobacco sales account for approximately 7.7% of dollar sales [115]. As EMI data does not report menthol sales for RYO tobacco separately, we apply the 7.7% distribution of sales from IRI to the overall RYO market reported by EMI to estimate menthol-distribution for RYO tobacco during 2020. Also, as noted earlier, EMI does not report a menthol specific breakdown of HTP sales. However, because cigarettes that are HTPs are largely sold through online channels not captured by NIQ RMS and IRI retail scanner data, we assume the EMI reported 35% proportion of menthol cigarettes as compared to the overall market for total cigarettes applies to sales for cigarettes that are HTP.

From EMI 2020 volume sales data, menthol cigarettes represent 34.96% of total cigarette volume sales (presented in Table 18) [69]. We apply this percentage to RYO and cigarettes that meet the definition of an HTP total volume sales to estimate menthol volume sales for these categories in 2020. We present a summary of dollar sales, volume sales, and counts of products and brands in Table 19. We request comment on the assumptions and methodologies used to estimate these figures.

Table 19. Summary of Estimated Sales and Counts for Tobacco Products Affected by the Rule

Tobacco Product	Total Dollar Sales ($2020, million) [1]	Menthol Dollar Sales ($2020, million)	Total Volume Sales ($2020, million)	Menthol Volume Sales ($2020, million)[2]	Count of Affected Menthol Products (FDA 2021) [3]	Count of Affected Menthol Brands (2020) [4]
Cigarettes	$94,173.3	$32,923.0	222,562.4	77,808.9	950	116
RYO	$333.1	$25.6	1,861.7	650.9	35	5
Components and Parts	-	-	-	-	27	-
Cigarettes that are HTPs	$21.6	$7.6	41.8	14.6	3	1
Total	$94,528.0	$32,956.2	224,465.9	78,474.0	1,015	122

[1] From EMI data presented in Table 18.
[2] Menthol cigarette volume sales are 34.96% of total cigarette sales (see Table 18). We apply this percentage to RYO and cigarettes that meet the definition of an HTP total volume sales to estimate menthol volume sales in 2020.
[3] FDA count of affected products is determined by analysis of FDA TRLM data and marketing orders.
[4] From NIQ RMS data presented in Table 12.

f. Market Trends

i. Cigarettes

As smoking prevalence has decreased over time, the overall market for cigarettes continues to decrease as well. An analysis of EMI data shows that from 2015 to 2020, annual cigarette sales decreased by 47.3 billion sticks, from 269.9 billion sticks in 2015 to 222.6 billion sticks in 2020 (-17.5%) [69]. EMI projects this trend will continue and annual cigarette volume sales will decrease to 184.6 billion sticks in 2025, a decrease of 37.9 billion from 2021 (-17.0%). Annual nominal dollar sales have remained relatively constant due to frequent price increases. However, in terms of constant 2020 dollars (adjusted for inflation and benchmarked to the year 2020) EMI reports annual cigarette sales[22] decreased $7.8 billion (-7.6%), from $101.9 billion in

[22] EMI reports dollar sales for all years in constant 2020 dollars (adjusted for inflation) using inflation percentages for 2015 – 2025 that range from 0.12% to 2.44%.

2015 to $94.2 billion in 2020. Conversely, EMI projects that annual cigarette sales in terms of constant 2020 dollars will increase to $97.0 billion by 2025, an increase of $2.5 billion (2.7%) from 2020.

The overall decrease in the cigarette market applies to menthol cigarettes as well. EMI reports annual sales of menthol cigarette sticks decreased from 90.5 billion in 2015 to 77.8 billion in 2020 (-14.0%), less than the 17.5% decrease seen for cigarettes overall [69]. However, the menthol cigarette share of the overall cigarette market has increased from 33.5% to 35.0% over the same time frame, and menthol cigarette sales have declined at a slower rate when compared to non-menthol cigarette sales. EMI projects an estimated 10.0% volume decrease for menthol cigarettes from 2021-2025 in the absence of this proposed product standard. However, EMI also projects that the market share for menthol cigarettes by volume sales will increase to 36.3% in 2025 from 35.2% in 2021. These data and projections reflect evidence of the demand for menthol cigarette products, despite declining volume sales in the overall cigarette market.

ii. RYO Tobacco

EMI reports annual volume sales of RYO tobacco decreased from 3.4 billion stick equivalents in 2015 to 1.9 billion stick equivalents (-45.5%) in 2020 and annual dollar sales in constant 2020 dollars decreased from $631.1 million to $333.1 million (-47.2%) over the same time frame [69]. EMI projects annual RYO volume sales will decline further to 1.6 billion stick equivalents by 2025 but that annual dollar sales will increase to $335.8 million during the same time frame, suggesting that increased prices over time will offset declines in volume sales. Menthol-specific RYO tobacco sales trends are not available from EMI data.

iii. Heated Tobacco Products

Heated tobacco products are new to the market and, thus, EMI began reporting on heated tobacco sales data for 2019. From 2019 to 2020, EMI reports annual volume sales of heated tobacco increased from 12.3 million sticks to 41.8 million sticks and constant 2020 dollar sales increased from $6.1 million to $21.6 million [69]. EMI projects rapid growth for heated tobacco with volume sales reaching 6.6 billion sticks and constant 2020 dollar sales reaching $5.6 billion by the year 2025. However, given limited annual data and current uncertainty surrounding the market for HTPs in the United States, we use the 2020 estimate of $21.6 million dollar in sales for heated tobacco across all years of the time horizon. Menthol-specific heated tobacco sales trends are not available from EMI data.

iv. Projected Cigarette Product Sales, 40-year Time Horizon

In Section II.B.2.e (Table 19), we estimate that total cigarette product sales in 2020 were $94.5 billion, with approximately 35% of sales ($33.0 billion) attributable to menthol cigarette product sales. Using these sales along with market trends and sales projections, we estimate baseline sales and volume sales for cigarette products and menthol cigarette products over the 40-year time horizon that will be used in analyzing the impacts of this proposed product standard.

From EMI projections, we estimate an average annual increase in total cigarette product sales of $502 million each year between 2021-2025 (=$2,511 million projected increase for cigarettes and RYO tobacco / 5 years, holding sales of heated tobacco constant). Although EMI cigarette and RYO dollar sales projections from 2021 to 2025 reflect expected growth, we note that EMI's projected year over year growth marginally decreases to almost zero over the time

period. Therefore, to estimate baseline cigarette product dollar sales over 40 years, we first apply our estimated average annual increase each year through year 2025 (Year 2) and then use the 2025 estimate as a constant for the remaining years of the time horizon .

For cigarettes and RYO tobacco products, EMI projects that volume sales are likely to decline between 2021 and 2025; however, the rate of this decline varies year over year. We estimate an average annual decrease in total cigarette product sales of 7,643 million each year between 2021-2025 (=38,217 million projected decrease for cigarettes and RYO tobacco volume sales / 5 years, holding sales of heated tobacco constant). Therefore, to estimate baseline cigarette product volume sales over 40 years, we first apply our estimated average annual decrease each year through year 2025 (Year 2) and then use the 2025 estimate as a constant for the remaining years of the time horizon.

Although EMI projections suggest that the menthol portion of the cigarette product market may see small increases over the next five years (from 35% to roughly 36%), we use a simplifying baseline assumption that the menthol share of the cigarette product market will stay constant over the entire 40-year period at the same distributions noted in Table 19. We, therefore, estimate menthol cigarette product dollar and volume sales to be approximately 35% of projected total cigarette product sales in each year. Table 20 presents our baseline estimates of total cigarette product and menthol cigarette product sales and volume sales over the 40-year time horizon. We request comment, including additional data, on our projections and estimates of baseline cigarette product sales and volume sales over the 40 year time horizon.

Table 20. Baseline Sales and Volume Sales for Cigarette Products and Menthol Cigarette Products over 40-year Time Horizon

Year Count	Year	Sales ($2020, Billions)		Volume Sales (Millions of sticks)[1]	
		Cigarette Products	Menthol Cigarette Products	Cigarette Products	Menthol Cigarette Products
Year 0	2023	$96.04	$33.5	201,535.9	70,458
Year 1	2024	$96.54	$33.6	193,892.6	67,786
Year 2	2025	$97.04	$33.8	186,249.3	65,114
Year 3	2026	$97.04	$33.8	186,249.3	65,114
Year 4	2027	$97.04	$33.8	186,249.3	65,114
Year 5	2028	$97.04	$33.8	186,249.3	65,114
	…	…	…	…	…
Year 39	2062	$97.04	$33.8	186,249.3	65,114
Year 40	2063	$97.04	$33.8	186,249.3	65,114

[1] Menthol cigarette volume sales are 34.96% of total cigarette sales (see Table 18).

3. Federal and State Excise Taxes

According to IRS published data, Federal tobacco excise taxes are estimated to be $11.4 billion or approximately 14% of total Federal excise tax revenues for 2019 fiscal year [121]. Using total Federal government revenue of $3.6 trillion for 2019, the percentage of Federal tobacco excise taxes represents 0.3% of total Federal government revenue ($11.4 billion / $3,600 billion = 0.3%) [122]. From the Annual Survey of State Government Tax Collections, we calculate the proportion of tobacco tax revenues for States to be approximately $18.7 billion, or approximately 1.7% of total State revenues for 2019 ($18.7 / $1,093 billion = 1.7%) [123]. We assume that all of this estimate represents State excise tax revenue. We note, however, that not all taxed tobacco products are expected to be impacted by this proposed rule.

To understand the potential impacts of the proposed rule on excise taxes, we estimate current tobacco excise tax collections for menthol cigarette products and use these estimates to

project baseline tax revenues over the 40-year time horizon of analysis. Using estimated volume sales in stick equivalents from Table 19, we convert the total number of menthol cigarette stick equivalents into an estimate of equivalent packs, assuming 20 sticks per pack. We then multiply this estimate of pack equivalents by the $1.01 Federal excise tax per pack to estimate baseline Federal excise tax revenues from menthol cigarette products in 2020 [69] [124].

Each State has a unique excise tax rate and collection, along with different levels of cigarette production. We acknowledge that some States have high cigarette taxes while others have low cigarette taxes [124]. A national average, while not reflecting each State's unique tax effect, provides an approximation of the total change in excise tax collections by States. We therefore use the average estimated State excise tax rate for tobacco products ($1.91) and the same estimate of menthol cigarette product sales in terms of pack equivalents discussed in our estimate of Federal excise tax revenues to estimate State excise tax revenues from menthol cigarette products in 2020 [124].

Table 21 presents baseline Federal tax revenue, as well as State excise tax revenue using the average State excise tax rate, over the 40-year time horizon.

Table 21. Baseline Federal and State Excise Tax Revenues for Menthol Cigarette Products over 40-year Time Horizon

Year Count	Year	Baseline Volume Sales for Menthol Cigarette Products		Excise Tax Rates, Per Pack		Baseline Excise Tax Revenues	
		Millions of sticks[1]	Pack Equivalents (Millions)[2]	Federal (2020)[3]	State Average (2020)[3]	Federal (Billions)	State (Billions)
Year 0	2023	70,458	3,523	$1.01	$1.91	$3.6	$6.7
Year 1	2024	67,786	3,389	$1.01	$1.91	$3.4	$6.5
Year 2	2025	65,114	3,256	$1.01	$1.91	$3.3	$6.2
Year 3	2026	65,114	3,256	$1.01	$1.91	$3.3	$6.2
Year 4	2027	65,114	3,256	$1.01	$1.91	$3.3	$6.2
Year 5	2028	65,114	3,256	$1.01	$1.91	$3.3	$6.2
	…	…	…	…	…	…	…
Year 39	2062	65,114	3,256	$1.01	$1.91	$3.3	$6.2
Year 40	2063	65,114	3,256	$1.01	$1.91	$3.3	$6.2

[1]Baseline volume sales for menthol cigarette products from Table 20.
[2]Pack equivalents estimated by dividing menthol cigarette product sales in stick equivalents by 20.
[3]Reference 124.

4. COVID Impact

It is unclear to what extent the effects of Coronavirus disease 2019 (SARS-CoV-2, or COVID) and related mask mandates and stay-at-home orders affected menthol cigarette product sales, use, and prevalence. While we see a small spike in sales data for cigarette, RYO and cigarettes that are HTP products in early 2020 corresponding to the first months of stay-at-home orders, overall trends in yearly sales data appear similar to previous years [114]. We do not adjust baseline cigarette product sales to account for COVID impacts. We request comment on the extent to which COVID may impact future menthol cigarette sales and trends.

5. Jurisdictional Flavored Tobacco Product Sales Restrictions

In recent years, several jurisdictions have passed legislation restricting the sale of flavored tobacco products, including menthol cigarettes. Policy adoption is dynamic, jurisdictional flavor sales restrictions vary, and many of these policies include only specific product types or flavors, sales locations, or types of retailers [125].[23]

As of January 2022, at least 335 localities have passed restrictions on the sale of flavored tobacco products, with at least 145 of these localities explicitly restricting the sale of menthol cigarettes [126]. In addition, Massachusetts and California have passed legislation which prohibits the sale of menthol cigarettes; however, the California restriction is temporarily on hold.[24]

This complicated patchwork of flavored tobacco product legislation makes it difficult to estimate the potential impact of jurisdictional menthol cigarette restrictions on baseline prevalence and future trends. Additionally, jurisdictional flavored tobacco restrictions may be circumvented by consumer purchases made outside of the area. We request comment on how jurisdictional menthol flavor bans for cigarette products may impact future prevalence.

C. Analysis of Benefits

The proposed rule, if finalized, would establish a tobacco product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. FDA anticipates that prohibiting menthol as a characterizing flavor in cigarettes would reduce the initiation and experimentation

[23] "Sales locations" refers to the physical location of the sale. Some restrictions allow retailers located outside of specified "buffer" zones (e.g., areas within 500 feet of the property line of any public, private, or parochial secondary school) to sell flavored tobacco products.

[24] While legislation (SB 793) for California had proposed an effective date of January 1, 2021, the implementation date has been delayed until the November 2022 general election following a proposed referendum (https://www.sos.ca.gov/administration/news-releases-and-advisories/2021-news-releases-and-advisories/js21002). If voters approve the referendum, the new effective date would be 5 days after the Secretary of State certifies the election results (Cal. Const. art II § 10).

of cigarette smoking, decrease the likelihood of nicotine dependence and addiction, and increase the likelihood of cessation. Decreased cigarette experimentation, decreased progression to regular established cigarette smoking, and increased cessation would lead to lower disease and death in the U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes.

The benefits of this menthol product standard for current and potential menthol cigarette smokers stem from decreased initiation, increased cessation, and switching to tobacco products with potentially lower risks of health harms. From these impacts for smokers, FDA estimates a significant reduction in smoking-related premature death. We also estimate the impacts to nonsmokers of reductions in secondhand smoke exposure and infant exposure to maternal smoking. Reduced illness, medical cost savings, and increased productivity for smokers and nonsmokers, as well as reduced exposure to thirdhand smoke, smoking-related fires and cigarette litter, are discussed qualitatively as benefits of the proposed product standard.

1. Studies of Youth Initiation Following a Restriction on Sales of Menthol Cigarette Products

As discussed in the preamble for this proposed rule, FDA's expectation of a significant reduction in youth initiation and progression to regular cigarette smoking is supported by real-world experience of youth tobacco use prevalence decreasing following implementation of the Special Rule for Cigarettes (section 907(a)(1)(A) of the FD&C Act), which banned non-menthol flavored cigarettes. In recent years, several U.S. localities and some States have placed restrictions on the sale of menthol cigarettes in addition to restrictions on the sale of other flavored tobacco products. Results from evaluations of these policies also provide evidence of

decreases in use and sales of tobacco products after policy implementation [127] [128] [129] [130].

- In 2018, Minneapolis and St. Paul, Minnesota expanded their sales restrictions on flavored tobacco products (including e-cigarettes) to include menthol, mint, and wintergreen tobacco products. An evaluation of this sales restriction found decreases in youth cigarette (3.8% to 2.3%), cigar (2.7%to 1.6%), smokeless tobacco (1.6% to 1.2%), and hookah (2.4% to 1.3%) product use after policy implementation in the Twin Cities metro area, which includes Minneapolis and St. Paul [129]. An increase in youth e-cigarette prevalence from 10.5% to 15.7% occurred after the policy in the Twin Cities, but this increase was lower than the rest of the State of Minnesota where e-cigarette prevalence increased from 10.0% to 18.8% [129]. Although prevalence of youth overall tobacco use increased after the policy in the Twin Cities from 12.2% to 16.5% and increased in the rest of the state from 13.9% to 20.1%, these increases were driven by youth e-cigarette use and align with national youth tobacco use trends [129]. Increases in youth overall tobacco use after the policy were lower in the Twin Cities than in the rest of the state, suggesting that the policy mitigated increases in overall tobacco use.
- In July 2018, San Francisco, California implemented a sales restriction on all flavored tobacco products, including menthol cigarettes. The San Francisco Department of Public Health announced that enforcement would begin January 2019 and enforcement with routine retailer compliance inspections began April 2019 [131].

- An evaluation of the impact of the San Francisco policy on tobacco product sales, a proxy for consumption, found that total tobacco sales decreased by a statistically significant 25% from before policy implementation (July 2015-July 2018) to a post-policy enforcement period (January-December 2019) [127]. This study also found a statistically significant decrease in the overall sales of flavored tobacco products (from 39,350 average weekly unit sales to 1,546 average weekly unit sales), including menthol cigarettes (from 21,463 average weekly unit sales to 860 average weekly unit sales), to low levels after policy enforcement [127].
- Changes in sales of tobacco products in San Francisco after policy enforcement were also reflected in young adult tobacco use patterns. A retrospective study of a convenience sample of young adult ever tobacco users in San Francisco found a statistically significant lower prevalence of overall tobacco use among 18-to 24-year-olds (from 100% to 82.3%) and 25-to 34-year-olds (from 100% to 92.4%) about 11 months after policy enforcement (November 2019) [128].
- As with Yang et al. (2020), another study on San Francisco's flavored tobacco policy, this one using Youth Risk Behavior Survey (YRBS) data reported that San Francisco's flavor restriction was associated with increased odds of cigarette smoking among high school students relative to other school districts [132]. However, another study reported a methodological mistake with these findings: data collection for the 2019

YRBS in San Francisco occurred in Fall 2018, prior to when the San Francisco flavor restriction was enforced in April 2019 [133].

- In June 2020, Massachusetts implemented a statewide sales restriction on flavored tobacco products (including menthol cigarettes) [130]. An evaluation of retail sales data assessed state-level cigarette sales per 1000 people in Massachusetts and comparison states without statewide flavor sales restrictions [130]. After the flavor sales restriction, the adjusted sales of cigarettes in Massachusetts versus the comparison states decreased by 372.27 packs per 1000 people for menthol cigarettes and by 282.65 packs per 1000 people for all cigarettes [130].

Outside the United States, an evaluation of provincial menthol sales restrictions in Canada on youth (Nova Scotia, New Brunswick, Alberta, Quebec, and Ontario) and adult (Nova Scotia, New Brunswick, Alberta, Quebec, Ontario, Prince Edward Island, and Newfoundland & Labrador) cigarette use found that menthol sales restrictions were associated with decreases in menthol cigarette smoking [134]. While this study found that provincial menthol sales restrictions were not associated with an overall change in youth and adult past 30-day cigarette use, this finding is inconsistent with the authors' supplemental analysis that found decreases in menthol cigarette sales and no effect on non-menthol cigarette sales post-implementation [134]. The study also found an increase in adult self-reported purchasing of cigarettes from First Nations reserves, which were exempt from the sales restriction [134]. This purchasing behavior was not assessed among youth. In the United States, however, the proposed menthol product standard would apply nationwide, including on Tribal lands.

Although there are limitations in attributing public health outcomes to the evaluations described in this section, such evaluations are useful to inform our discussion of the anticipated

effect of the proposed menthol product standard. Findings from these evaluations generally suggest that youth use of cigarettes would decrease following implementation of the proposed product standard. FDA requests comments and data on the impact of these menthol cigarette sales restrictions on nonusers and users of tobacco products

Additionally, evaluations of provincial, state, and local policies likely underestimate the potential impact of a national policy. Depending on availability of tobacco products in jurisdictions neighboring those where local policies were passed, users and nonusers may easily be able to access tobacco products from these locations. FDA anticipates that a nationwide standard that prohibits the manufacture and sale of menthol cigarettes would likely have a greater impact in decreasing youth cigarette use compared to that observed from policies from limited jurisdictions, because a nationwide product standard would eliminate the manufacture of these products as well as the opportunity for youth to easily travel to neighboring jurisdictions that do not have a menthol sales restriction or use online retailers to purchase menthol cigarettes.

FDA acknowledges there may be limitations to relying on aggregate tobacco sales information as a proxy for consumption. In addition, overall sales data are more likely to be driven by adult than adolescent use, given the larger size of the adult population as well as the tendency for youth to acquire tobacco via social sources [135]. However, studies have shown that sales and consumption tend to be highly correlated [136] [137] [138]. Additionally, sales data provide information on purchases of tobacco products in a defined area, which could include neighboring jurisdictions [139] [140] and can serve as a proxy for consumption of tobacco products after policy implementation.

2. Studies of Quit Attempts and Smoking Cessation Following Restrictions on Sales of Menthol Cigarette Products

In addition to the long-term public health benefits that would accrue from the prevention or reduction of menthol cigarette smoking among youth and young adults, FDA anticipates that the proposed standard would increase the likelihood that many existing menthol cigarette smokers would stop smoking cigarettes altogether, yielding health benefits from smoking cessation. FDA expects that the proposed rule prohibiting menthol as a characterizing flavor in cigarettes would result in substantial changes in tobacco use patterns among current tobacco users. Current menthol smokers would either: (1) Quit smoking or tobacco use altogether, (2) transition to non-menthol cigarettes or other combusted tobacco products, or (3) switch to other tobacco products, including potentially less harmful tobacco products. Given the large proportion of menthol cigarette use among smokers, the role of menthol in reducing cessation success among cigarette smokers, and the empirical evidence published through 2021 from policies restricting the sales of flavored tobacco products in the United States and Canada, FDA expects that the proposed product standard would lead many menthol cigarette smokers to stop using cigarettes.

As discussed in the preamble for this proposed rule, real-world experience from Canada's laws prohibiting the sale of menthol tobacco products provides information on the potential behavioral impacts the menthol product standard could have on cigarette use in the United States. Studies evaluating the impact of these laws have found increased reports of quit attempts and quitting smoking following policy implementation [141] [142] [143] [144].

- In a study of Ontario one year after policy implementation, a statistically significant 56% of study participants who were smokers before the sales

restriction reported making a quit attempt and 19% reported quitting smoking [142].

- In a study of smokers from the Canadian provinces of Quebec, Ontario, Prince Edward Island, Newfoundland and Labrador, and a nationwide restriction covering British Columbia, Saskatchewan, and Manitoba, 21.5% of pre-ban menthol smokers reported quitting smoking (defined as those who had currently quit or cut down to smoking less than monthly) after policy implementation [144].
- Another study of adult smokers from Canadian provinces that implemented menthol sales restrictions found a small non-significant increase in the likelihood of ever trying to quit following policy implementation [134].

While the percent of smokers who reported quitting post-policy in these studies varies based on the length of time after policy implementation, geographic location, and definition of quitting, the percent of quitting post-policy was higher than the percent of current smokers from Ontario who reported quitting smoking 30 days or longer pre-policy in 2014, 7.9% [145].

Further supporting FDA's expectation that a prohibition on menthol cigarettes would increase quitting by menthol cigarette smokers is evidence from Canada that, following prohibitions on menthol cigarettes, menthol smokers there reported higher rates of quit attempts and quitting smoking than non-menthol smokers [142] [143] [144]. Studies from Ontario one year and two years after policy implementation found a higher likelihood of quit attempts and quitting smoking among those who reported smoking menthol cigarettes daily before the sales restriction (baseline) when compared with smokers who reported smoking non-menthol cigarettes daily [142] [143]. Similarly, in a study looking across seven Canadian provinces that had implemented menthol sales restrictions, menthol smokers were more likely than non-

menthol smokers to make a quit attempt and remain quit [144]. In addition, there is evidence that previous menthol smoking is not associated with relapse [143] [144]. This suggests that menthol sales restrictions help those who quit smoking menthol cigarettes to stay quit.

Analysis of tobacco manufacturer wholesale data found a significant decline in the overall cigarette sales in Ontario in the month following Ontario's menthol sales restriction. This was followed by a statistically significant increase in the sales of overall cigarettes driven by an increase in non-menthol cigarettes in Ontario, suggesting a slight rebound effect; however, overall cigarette sales approximately 8 months following the menthol sales restriction were lower than study baseline (October 2012) [146]. Similarly, an analysis of retail sales data found a small increase (0.4%) in sales of non-menthol cigarettes in the 6 months following policy implementation [147]. However, tobacco manufacturer wholesale sales and retail sales data do not completely reflect individual-level tobacco use behaviors. For example, some individual smokers may have obtained menthol cigarettes through channels not included in the Ontario sales data (e.g., other provinces) or switched to non-restricted products, which may result in an overestimation of the impacts. In spite of this limitation, comparing sales data with the self-report data suggests increased smoking cessation occurred as a result of the sales restriction.

Several U.S. localities have placed restrictions on the sale of menthol cigarettes in addition to restrictions on the sale of flavored tobacco products. FDA is aware of two studies that report on the impact of the policy in San Francisco on cessation. The first, a retrospective study with a relatively small convenience sample of young adult ever tobacco users in San Francisco found of the 20 participants who were exclusive menthol cigarette smokers before the policy, 5% (n=1) quit any tobacco use after the policy and, among 61 participants menthol cigarette and other tobacco users before the policy, 3.3% (n=2) quit after the policy [128]. A second study

examining the impact of the same policy among clients enrolled in a San Francisco residential substance use disorder treatment facility found that participants surveyed about 5 months after the policy (n=102) were statistically significantly less likely to report menthol as the usual cigarette smoked compared to participants surveyed before the policy [148]. This study found no evidence that the policy was associated with decreased number of cigarettes per day or increased readiness to quit among current smokers [148]. The marginal effects observed in this study are not entirely unanticipated. This population with substance use disorder may have been less sensitive to the regional menthol ban compared to the general population due to their unique risk factors and pervasive patterns of tobacco use.

Taken together, these two San Francisco studies provide limited evidence of the impact of a menthol cigarette sales restriction on cessation in the United States [128] [148]. Both studies rely on convenience samples and do not include a control group, limiting their generalizability to people other than study participants [128] [148]. In addition, the study conducted by Yang et al. (2020) only collects data after the policy was implemented [128]. Given this, FDA relies more on the evidence from Canada which includes multiple longitudinal cohort studies of the general population at different time points following policy implementation and in various locations that have implemented menthol sales restrictions to inform expectations on the impact of the proposed product standard on cessation.

While the 2020 Surgeon General's Report *Smoking Cessation* concluded that "the evidence is suggestive but not sufficient to infer that restricting the sale of certain types of tobacco products…increases smoking cessation…," this assessment was based on empirical evidence published through 2019 [5]. Numerous studies have been published since the 2020 Surgeon General's Report and were considered in FDA's assessment of the impact of a proposed

product standard on cessation. The recently published evaluation studies have examined the impact of menthol sales restrictions in multiple Canadian provinces [134] [143] [144] [146] [147] [149] and State and local jurisdictions in the United States [127] [128] [130] [148]. When these studies are considered with the evaluation evidence published before 2020, tFDA concludes that there is substantial evidence of increases in quit attempts and quitting by adult smokers after a menthol cigarette sales restriction [130] [134] [150]. Further, recent longitudinal data from the U.S. Population Assessment of Tobacco and Health (PATH) study and a systematic review of the literature all indicate that menthol cigarette smoking is associated with reduced cessation success compared to non-menthol smokers [64] [65] [68]. Thus, by banning menthol cigarettes, FDA expects to increase smoking cessation across the population. This is further evidenced by expert elicitation and simulation studies, which assessed and modeled menthol restrictions in the US, resulting in substantial estimated public health benefits (see additional discussion in Section II.C.3) [88] [152]. These findings, all more recent than the 2020 Surgeon General's report, suggest that a menthol ban is appropriate for the protection of the public health.

The sum of the available evidence, the continued use of menthol cigarettes by millions of Americans, the additional challenges for menthol smokers to quit smoking, and the empirical evidence from policies restricting the sales of menthol cigarettes in Canada in at least seven individual provinces, as well as policies restricting the sales of flavored tobacco products in the United States, suggest that the proposed standard would lead many menthol cigarette smokers to stop using cigarettes, yielding considerable health benefits.

3. Modeling the Effects of a Menthol Cigarette Sales Restriction

The population health benefit of prohibiting menthol cigarettes has been examined in several simulation studies conducted in the past decade [88] [151] [152] [153].

A 2011 study by Levy et al. simulated the future benefit of a U.S. menthol cigarette ban, estimating potential impacts on future smoking prevalence and smoking attributable mortality for the total population, and for African Americans specifically [151]. The model used data from the 2003 TUS-CPS to characterize current smoking status, initiation and cessation rates by cigarette type, various other sources to characterize smoking relapse rates, and the Cancer Prevention Study II (CPS II) to characterize mortality risks, which were treated as equivalent for menthol and non-menthol smokers. The analysis simulated the 2010-2050 period, with a menthol ban going into effect in 2011. The study compared three menthol ban scenarios against a status quo scenario with no menthol ban:

1. 10% of menthol smokers quit permanently and 10% who would have initiated as menthol smokers do not take up smoking,
2. 20% quit, and 20% never initiate, and
3. 30% quit, and 30% never initiate.

The study estimated that by 2050, under these menthol ban scenarios, 324,000 (scenario 1) to 634,000 (scenario 3) smoking attributable deaths would have been averted in the United States overall, while relative declines in smoking prevalence were expected to range from 4.8% to 9.7%, under scenarios 1 and 3, respectively. Among African Americans, by 2050, an estimated 92,000 to 238,000 smoking attributable deaths would have been prevented, while relative declines in smoking prevalence ranged from 9.1% to 24.8% [151].

To estimate the anticipated benefits of this proposed menthol product standard, we utilize results from the more current 2021 study by Levy et al., which is informed by an expert elicitation and simulates the future benefits of a menthol cigarette ban on the U.S. population over a 40-year time horizon from 2021-2060 [88] [152].[25] As discussed in the Preamble of this proposed rule (Section V.C.5), this model compares a *Status Quo Scenario,* in which no menthol ban was implemented, to a simulated *Menthol Ban Scenario,* in which a complete ban on menthol flavor in both cigarettes and cigars was implemented in 2021.[26] It also incorporates current use of electronic nicotine delivery system (ENDS) products, referred to as "nicotine vaping products" (NVP) by the authors, in order to allow for transitions between cigarette smoking and use of ENDS in reaction to a menthol ban [88].

The Levy et al. (2021) menthol simulation (hereafter – Menthol Simulation) uses the Smoking and Vaping Model (SAVM), a compartmental model capable of simulating the population health effects of cigarette smoking and ENDS use for specific birth cohorts.[27] For the

[25] Levy et al. (2021) provide discussion of expert elicitation in their paper, noting: "To better gauge the potential impact of a menthol cigarette ban in the United States, we conducted an expert elicitation (EE). In this process, the judgment of a group of experts is systematically collected and synthesized to develop point estimates and credible bounds for an unknown parameter. EEs have been used by the US Environmental Protection Agency and other Federal agencies, as well as the Intergovernmental Panel on Climate Change. In the field of tobacco control, EEs have been used to estimate the health risks and behavior regarding low-nitrosamine smokeless tobacco and the effects of requiring low-nicotine content cigarettes." Please see [152] for a full list of refences cited by the authors in their discussion of expert elicitation. Further, HHS supports the use of EEs in addressing uncertainty in RIAs and provides a list of key considerations when conducting EEs [154].

[26] The *Menthol Ban Scenario* models a ban of menthol in cigarettes and cigars, but includes only the benefits attributed to the menthol cigarette smoking ban. Cigars are covered in the model because it is assumed that menthol cigarette smokers could simply switch to menthol cigars if a menthol cigarette ban was put in place and if menthol cigars were still available. The FDA's expectation is that, even if menthol was not prohibited as a characterizing flavor in cigars, this rule would still reduce initiation and experimentation of cigarette smoking, decrease nicotine dependence and addiction, and increase cessation among current menthol cigarette smokers. However, since the FDA is concurrently pursuing a proposed rule, published elsewhere in this issue of the *Federal Register*, that would prohibit characterizing flavors (other than tobacco) in cigars, the *Menthol Ban Scenario* is directly applicable.

[27] As Tolles & Luong (2020) describe in their Journal of the American Medical Association, Guide to Statistics and Methods paper, "[i]n compartmental models, individuals within a closed population are separated into mutually exclusive groups, or compartments, based on their disease status. Each individual is considered to be in 1 compartment at a given time, but can move from one compartment to another based on the parameters of the model" [155]. In the modeling used for this analysis, compartments are based on type of tobacco product and use status.

Menthol Simulation, the SAVM model was extended to evaluate non-menthol and menthol cigarettes separately, with the following use states captured in the model compartments: (1) never users, (2) menthol smokers, (3) non-menthol smokers, (4) exclusive ENDS users, (5) former smokers using ENDS, (6) former smokers, and (7) former ENDS users.[28]

The Menthol Simulation utilized historical data from the National Health Interview Survey (1965-2013) for estimates of smoking prevalence (specific model inputs can be found in the manuscript) [88] [152]. With historical data, the SAVM model projected prevalence estimates of never, current, and former smoking by age and gender beginning in 2013. The Menthol Simulation then recalibrated the SAVM model using 2013-2018 NHIS data to improve model estimates of smoking prevalence after ENDS products became more widely available around 2013. Supplements 1 and 2 for the Menthol Simulation provide information on smoking prevalence and nicotine vaping product prevalence through 2040 and 2060 under the *Status Quo* scenario [88].

Population Assessment of Tobacco and Health (PATH) study data were used to model age- and gender-specific rates of smoking initiation (i.e., any initiation of regular cigarette smoking by age 40) and cessation (i.e., cessation of regular cigarette smoking for two years, including those who temporarily use ENDS but ultimately quit all tobacco use), cigarettes-to-ENDS switching (i.e., cessation of regular cigarette smoking with initiation of regular ENDS smoking), and initiation of ENDS use (i.e., initiation of regular ENDS use without regular cigarette smoking). The Menthol Simulation incorporates separate rates of initiation, cessation and switching for menthol and non-menthol smokers.

[28] Note that the model estimates the effects for users and potential users of tobacco products only; it does not independently estimate the effects on others, such as reduced mortality among nonsmokers due to disease and reduced infant deaths due to sudden death infant syndrome (SIDS). Such benefits are assessed separately in Section II.C.5 below ("Valuing Benefits from Reduced Externalities").

The Menthol Simulation incorporates the following assumptions:

1. Dual users of cigarettes and ENDS were modeled to have the same risks as current smokers.
2. Smokers who switched completely to ENDS before age 35 were treated the same as exclusive ENDS users, while smokers who switched to ENDS age 35 or later were considered separately as former smokers using ENDS.
3. The ratio of menthol to non-menthol cessation was modeled as 0.8, in effect modeling menthol cigarette smokers as 20% less likely to quit smoking.
4. The ratio of menthol to non-menthol ENDS switching was modeled as 0.9, in effect modeling menthol cigarette smokers as 10% less likely to switch to ENDS.
5. Annual rate of cigarettes-to-ENDS switching was modeled to decline 10% annually from 2018.
6. The excess relative risk of mortality for ENDS products compared to cigarettes was set at 0.15, in effect modeling the mortality risk of ENDS use as 15% of the mortality risk of cigarette smoking over the same period.
7. Transitions from cigarettes to heated tobacco products (HTPs) were modeled to have the same risk as transitions to ENDS, transitions from menthol cigarettes to non-menthol cigars were modeled to have the same risk as transitions to non-menthol cigarettes, and transitions from cigarettes to smokeless tobacco were modeled to have the same risk as transitions to non-menthol cigarettes.
8. A ban on menthol cigarettes was assumed to have no effects on non-menthol smokers.

9. Current smokers become former smokers after having quit for 2 years to reflect cessation net of relapse.

To estimate the specific effects of a "menthol ban" on current and future tobacco use, an expert elicitation (EE) was conducted [152]. The EE used a systematic approach to identify 11 leading academic experts on topics related to the impacts of menthol flavor bans in tobacco products. Experts estimated a number of behaviors under a menthol ban, such as continued (illicit) menthol product use, menthol to non-menthol product switching, switching to other nicotine products (e.g., ENDS, smokeless tobacco products), and tobacco cessation. Experts estimated the effects of a menthol ban for youth and young adults ages 12-24 who would otherwise have initiated smoking by age 24 (i.e., future menthol smokers), which were used to calculate the ongoing initiation rates beginning with the simulated ban in 2021 in the *Menthol Ban Scenario*. Among menthol smokers in both the *Status Quo Scenario* and *Menthol Ban Scenario*, experts estimated transitions over a two-year period for ages 18-24 and 35-54, which were modeled as mean net differences applied to menthol smokers up to age 30 and over age 30, respectively. Levy et al. (2021) rely on mean transition estimates from the EE to "ensure that all transitions sum to 100%," but the authors also report the minimum and maximum expert responses to provide context [152].

In modeling the *Menthol Ban Scenario*, Levy et al. (2021) assume the following direct transitions for never smokers to other tobacco product use and status compartments:

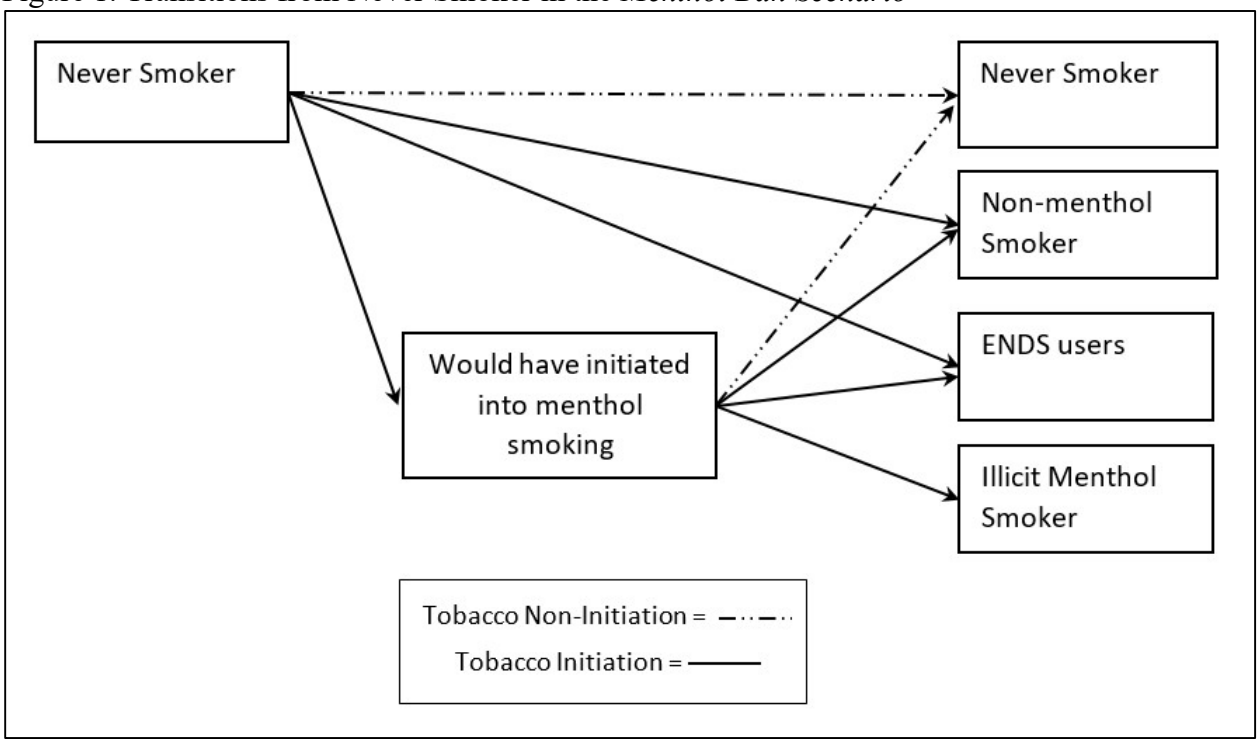
1. do not initiate tobacco product use and re-enter the group of never smokers,
2. initiate non-menthol smoking and enter the group of non-menthol smokers, or
3. initiate into ENDS use and enter the group of ENDS users.

Outside of these direct transitions, a final portion of never smokers, designated as the group who would have initiated into menthol smoking under the *Status Quo Scenario* (referred to as “would-be menthol smokers”), are subject to an additional set of transitions. Rather than directly entering the group of menthol smokers—as would be possible under the Status Quo Scenario—"would-be menthol smokers” are redistributed under the following possible transitions:

1. do not initiate into any tobacco use and transfer back to the group of never smokers,
2. initiate into non-menthol smoking and enter the group of non-menthol smokers,
3. initiate into ENDS use and enter the group of ENDS users, or
4. initiate into illicit menthol cigarette use and enter the group of illicit menthol cigarette smokers.

Figure 1 summarizes all possible transitions from the group of never smokers under the *Menthol Ban Scenario*, with initiation transitions indicated by solid arrows and transitions associated with non-initiation indicated by dashed arrows.

Figure 1. Transitions from Never Smoker in the *Menthol Ban Scenario*



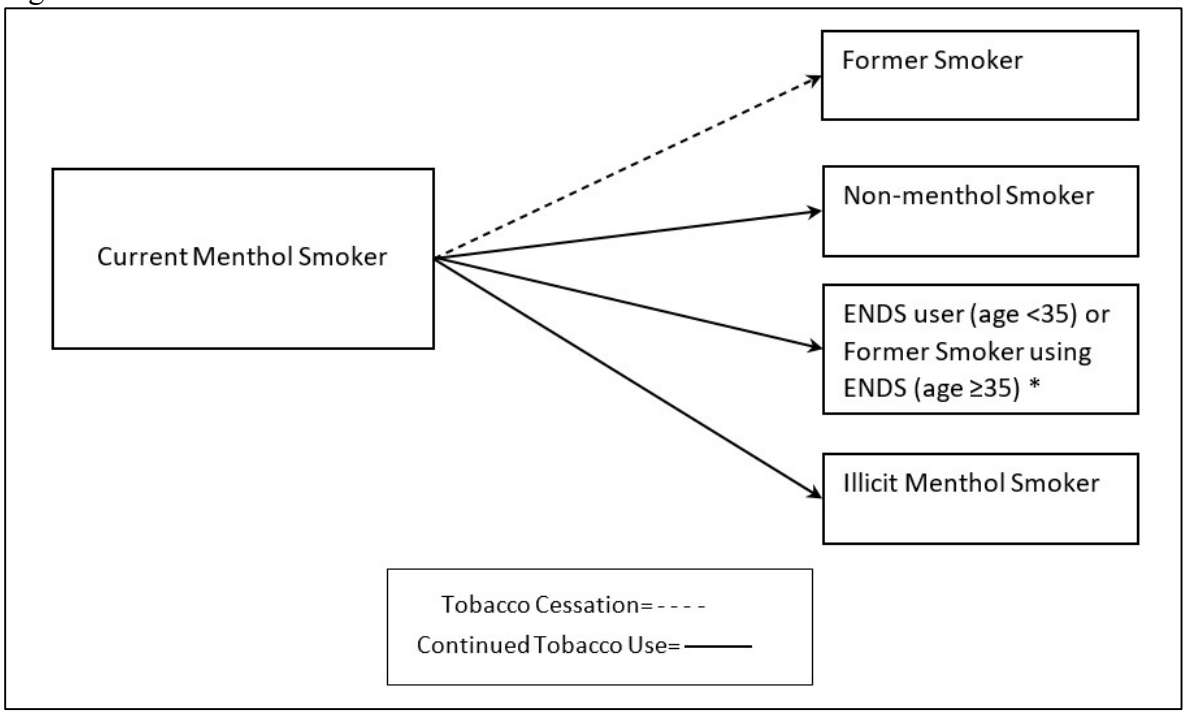
Adapted from Reference 88, Figure S.3.1 in Supplement 3.

Current menthol smokers are subject to four possible transitions under the *Menthol Ban Scenario*:

1. cease tobacco product use and enter the compartment of former smoker,
2. switch to non-menthol smoking and enter the compartment of non-menthol smoker,
3. switch to ENDS use and enter the compartment of ENDS user or former smoker using ENDS, or
4. continue with illicit menthol cigarette use and enter the compartment of illicit menthol smoker.

We display these transitions and the impacted groups in Figure 2, with transitions associated with continued tobacco use indicated by solid arrows and transitions associated with cessation indicated by dashed arrows.

Figure 2. Transitions from Current Menthol Smoker in the *Menthol Ban Scenario*



Adapted from Reference 88, Figure S.3.2 in Supplement 3.

As Figure 1 and Figure 2 demonstrate, each compartment of the Menthol Simulation is heavily influenced by the rate of initiation, continued tobacco use, and cessation during each period. For example, never smokers may initiate into non-menthol cigarette use in one period and then cease tobacco use at some future period. Similarly, the population of current menthol smokers may continue as tobacco users during the first period of the policy, but then cease all tobacco use and become a former smoker during some future period under the *Menthol Ban Scenario*. Thus, initiation and cessation are considered within the results of the model as a dual process that drives projected prevalence under both the *Status Quo* and *Menthol Ban* scenarios. While the differences between the *Status Quo* and *Menthol Ban* scenarios are directly related to these transitions, health impacts from initiation/non-initiation, cessation, and switching between tobacco products are not separately estimated.

The simulations in Levy et al. (2021) and its online supplements provide estimated reductions in mortality in two different formats—avoided premature deaths and avoided life-years lost—under the *Menthol Ban Scenario* by 2021, 2026, and 2060, with 2060 estimates representing cumulative results over the entire 40-year period of analysis (2021-2060) [88]. Table 22 presents the results of the Menthol Simulation in terms of smoking and vaping attributable premature deaths, with an estimate of the overall avoided premature deaths under the *Menthol Ban Scenario* as compared to the *Status Quo Scenario*, i.e., no prohibition of menthol cigarettes. Table 23 presents the results of the Menthol Simulation in terms of smoking and vaping attributable life-years lost, with an estimate of the overall avoided life-years lost under the *Menthol Ban Scenario* as compared to the *Status Quo Scenario*. Cumulatively, the Menthol Simulation estimates 654,221 fewer premature deaths (an average of approximately 16,250 per year), or 11,311,077 avoided life-years lost (an average of approximately 300,000 per year), by 2060 under the *Menthol Ban Scenario* as compared to the *Status Quo Scenario* [88].

Table 22. Menthol Simulation Smoking and Vaping Attributable Deaths under *Status Quo* and *Menthol Ban* Scenarios

Scenario	Category/Year	2021	2026	2060	Cumulative Total [1]
Status Quo Scenario	Menthol smoker	77,455	74,136	39,418	2,402,279
	Non-menthol smoker	122,242	106,124	37,923	2,909,245
	Former smoker	175,798	189,490	192,368	8,500,851
	ENDS user [3]	5,031	7,296	11,032	392,107
	Former ENDS user	0	0	1,717	12,811
	Total	380,525	377,046	282,457	14,217,294
Menthol Ban Scenario	Menthol smoker	77,455	6,792	2,557	271,469
	Non-menthol smoker	122,242	151,299	55,379	4,157,520
	Former smoker	175,798	191,098	195,744	8,620,599
	ENDS user [3]	5,031	10,768	12,859	499,475
	Former ENDS user	0	0	1,895	14,010
	Total	380,525	359,958	268,435	13,563,073
Menthol Ban vs Status Quo [2]	Number of Avoided Premature Deaths	-	17,088	14,022	654,221

Adapted from Reference 88, Table 1, page 4.

[1] The cumulative impact is measured in terms of the sum of the smoking and vaping attributable deaths over the years 2021 through 2060.

[2] The Menthol Ban vs Status Quo represents the absolute difference in premature deaths between the *Menthol Ban Scenario* and the *Status Quo Scenario.*

[3] Current use of electronic nicotine delivery system (ENDS) products is referred to as "nicotine vaping products" (NVP) by the authors. "ENDS user" in this table includes new exclusive NVP users and former smokers now using NVPs from the modeling.

Table 23. Menthol Simulation Smoking and Vaping Attributable Life-Years Lost under *Status Quo* and *Menthol Ban* Scenarios

Scenario	Category/Year	2021	2026	2060	Cumulative Total[1]
Status Quo Scenario	Menthol smoker	1,335,250	1,242,012	556,131	37,846,630
	Non-menthol smoker	1,949,502	1,655,744	581,810	45,122,020
	Former smoker	1,323,247	1,404,460	1,050,414	53,496,563
	ENDS user [3]	86,635	122,874	181,241	6,494,346
	Former ENDS user	0	2	32,110	278,716
	Total	4,694,635	4,425,092	2,401,706	143,238,275
Menthol Ban Scenario	Menthol smoker	1,335,250	111,678	30,555	4,174,157
	Non-menthol smoker	1,949,502	2,403,756	841,520	64,926,659
	Former smoker	1,323,247	1,424,993	1,065,194	54,531,402
	ENDS user [3]	86,635	122,874	181,241	6,494,346
	Former ENDS user	0	2	35,817	306,840
	Total	4,694,635	4,113,651	2,182,890	131,927,198
Menthol Ban vs Status Quo [2]	Number of Avoided Life-Years Lost	-	311,441	218,817	11,311,077

Adapted from Reference 88, Table 1, page 4.

[1] The cumulative impact is measured in terms of the sum of the smoking and vaping attributable life years lost over the years 2021 through 2060.

[2] The Menthol Ban vs Status Quo represents the absolute difference in premature life years lost between the *Menthol Ban Scenario* and the *Status Quo Scenario.*

[3] Current use of electronic nicotine delivery system (ENDS) products is referred to as "nicotine vaping products" (NVP) by the authors. "ENDS user" in this table includes new exclusive NVP users and former smoker now using NVPs from the modeling.

Table 24. Menthol Simulation Smoking and Vaping Prevalence under *Status Quo* and *Menthol Ban* Scenarios

Scenario	Category/Year	2021	2026	2060	Cumulative Total[1]
Status Quo Scenario	Menthol smoker	5.4%	4.5%	2.4%	-55.7%
	Non-menthol smoker	7.1%	5.7%	2.7%	-62.6%
	Former smoker	19.4%	18.4%	9.2%	-52.7%
	Exclusive NVP user [2,3]	3.5%	4.7%	5.8%	64.4%
	Former NVP user [3]	0.2%	0.6%	4.6%	1972.5%
Menthol Ban Scenario	Menthol smoker	5.4%	0.3%	0.1%	-98.5%
	Non-menthol smoker	7.1%	8.4%	4.2%	-40.9%
	Former smoker	19.4%	19.1%	9.2%	-52.4%
	Exclusive NVP user [2,3]	3.5%	5.7%	7.4%	108.0%
	Former NVP user [3]	0.2%	0.6%	5.6%	2418.0%

Adapted from Reference 88, Table 1, page 4.
[1] The cumulative impact is measured in terms of the relative change from 2021 to 2060 for prevalence rates (ie, (2060–2021)/2021).
[2] Current use of electronic nicotine delivery system (ENDS) products is referred to as "nicotine vaping products" (NVP) by the authors.
[3] Exclusive NVP users includes new exclusive NVP users and former smoker now using NVPs.

Compared to the *Status Quo Scenario*, in which no menthol ban was implemented, under the *Menthol Ban Scenario* the estimated overall smoking prevalence declined 14.7% by 2026 and 15.1% by 2060.

4. Estimating Benefits from Mortality Risk Reductions

From the Menthol Simulation, we use the difference in premature deaths under the *Status Quo* and *Menthol Ban* scenarios to estimate the impacts of the proposed product standard, adjusting for the impacts of Federal, State, and local laws establishing 21 as the minimum age of

sale for tobacco products (T21 Laws) and updating to the timeline of the proposed menthol product standard.

a. Adjustment 1: Using Sensitivity Analyses from the Menthol Simulation to Adjust for the Impacts of T21 Laws

In December 2019, the Further Consolidated Appropriations Act, 2020, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and established a new Federal minimum age for the sale of tobacco products, prohibiting sale to any individual below the age of 21 (Public Law. 116-94). As part of their EE, Levy et al. (2021) asked the experts to report the expected impact of raising the minimum age to 21 on their estimates. Expert opinion was ultimately mixed, with half of respondents indicating T21 Laws would have no impact on their estimates while other respondents indicated potentially important impacts on smoking initiation [152]. Due to this lack of consensus, Levy et al. (2021) proceeded with a base model which did not incorporate the impacts of T21 Laws separately from their potential baseline effects (that is, their contribution, even in the absence of a menthol ban, to overall downward trends in smoking prevalence) [88].

However, within their analysis, Levy et al. acknowledge that while increased enforcement of T21 Laws would reinforce the impacts of a "menthol ban," these policies may also reduce their projected results due to decreased smoking initiation not captured within the baseline of their model [88]. In order to account for the possible impacts of these additional tobacco control policies, Levy et al. (2021) performed sensitivity analyses on the baseline level of smoking initiation and cessation. We incorporate the Menthol Simulation sensitivity results regarding reduced initiation in the *Status Quo Scenario* as a proxy for reduced initiation in the baseline resulting from T21 Laws. Table 25 presents the results of this sensitivity analysis.

Table 25. Cumulative Avoided Mortality Under a *Menthol Ban* Scenario*,* Incorporating Reduced Baseline Initiation to Account for T21 Laws (2021-2060)

	Cumulative Avoided Premature Deaths		Cumulative Avoided Life-Years Lost	
Description	Estimate	Relative Difference from Base Modeling	Estimate	Relative Difference from Base Modeling
Base Menthol Simulation	654,221	-	11,311,077	-
Decrease Overall Smoking Initiation Rate in the Status Quo scenario by 10%	647,128	-1.1%	11,083,049	-2.0%

Adapted from Reference 88, Table 2, page 5.

Using the Levy et al. sensitivity analysis that decreases initiation immediately by 10% in the *Status Quo* scenario to account for the effects of T21 Laws results in fewer avoided premature deaths and fewer avoided life-years lost under this proposed product standard. As noted in Table 25, if T21 Laws resulted in an *immediate and ongoing* 10% reduction in baseline initiation, this would reduce Menthol Simulation estimates to 647,128 avoided smoking-attributable premature deaths (a 1.1% reduction) and 11,083,049 avoided life-years lost (a 2.0% reduction) by 2060.

While the Menthol Simulation is focused on health gains over the 40-year period (2021-2060), Levy et al. (2021) note that "much of the impact [under the *Menthol Ban Scenario*] is on initiation and related health effects that occur after 40 years" [88].[29] Similarly, we expect the reduction in initiation from T21 Laws to accumulate over time and note that much of the impact from these policies may also occur after 40 years. We request comment on this approach, including about how to refine it to incorporate emerging literature as it is peer-reviewed and

[29] Levy et al. (2021) calculated year-by-year projections, and also projected avoided premature deaths out to 60 years. Although the full range of estimates for this time horizon are not available from the publication, Levy, et al. (2021) note in the paper that "[w]hen the analysis is extended to consider a 60-year period, life-years gained increase from 11.3 to 14.7 million [88]. If such data become available, the FDA may include them in its regulatory impact analysis of a final product standard.

published [30] and on how to further incorporate the effects of T21 Laws in the baseline prevalence trends and adjustments to estimates of avoided premature deaths and avoided life-years lost estimated in this regulatory impact analysis.

b. Adjustment 2: Distributing Reductions in Mortality Risk Over Time and Updating to Product Standard Timelines

As noted in the Department of Health and Human Service's *Guidelines for Regulatory Impact Analysis* (2016), an estimate of the change in risk for the average affected individual serves as the starting point for valuing benefits associated with any policy addressing health risks [158].[31] To present the estimate of mortality risk reduction, we need to estimate when the risk reduction occurs. As noted by Levy et al. (2021), "smoking-attributable deaths are estimated as the excess mortality risk at each age for current and former smokers multiplied by their respective populations," creating an estimate of population-weighted mortality risk reduction in each year [88]. Methodology from the underlying SAVM model provides the following description of calculations for premature deaths:

> Total premature deaths are calculated by multiplying the excess risks of smoking or vaping by the number of current and former smokers and vapers. The excess risk for current (former) smokers is calculated by subtracting the death rate of never smokers from the death rate of current (former) smokers at the same age and year [156, page 89].

Therefore, the Menthol Simulation estimates "averted deaths" from reductions in population-level mortality risk in each year—avoided premature deaths at the time that the

[30] For example, emerging literature such as Bryan, Calvin, et al. "Do State Tobacco 21 Laws Work?" NBER Working Paper No. 28173, https://www.nber.org/system/files/working_papers/w28173/revisions/w28173.rev0.pdf.
[31] See U.S. Department of Health and Human Services Regulatory Impact Analysis Guidance [158, pages 13-18] for further discussion on valuing mortality risk reductions. See also [157].

mortality risk is reduced under the *Status Quo* and *Menthol Ban* scenarios for the population within each smoking status, with respect to age and year. In this way, the Menthol Simulation appears to treat "averted deaths" and mortality risk reductions synonymously. In analyzing the proposed product standard, we use the cumulative total and available point estimates of avoided premature deaths from the Menthol Simulation, adjusted for T21 Laws, and incorporate the average estimate of avoided premature deaths in each year as an estimate of the reduced mortality risk ("averted deaths") in each year.

We are proposing a one-year effective date for the proposed menthol product standard. For this reason, we assume that the policy will take effect in 2024, rather than in 2021 as assumed in the Menthol Simulation. Incorporating this two-year lag to align with the proposed product standard, we set 2024 as Year 1 and estimate impacts of the proposed product standard over the period 2025-2063 (Years 2-40) rather than 2022-2060.[32] Levy et al. (2021) estimate avoided premature deaths on average each year of the Menthol Simulation's 40-year time horizon (approximately 650,000 avoided premature deaths/40 years of modeling = approximately 16,250 avoided premature deaths each year). We note that this average is in the range of the two point estimates provided in modeling years 2026 (17,088 avoided premature deaths) and 2060 (14,022 avoided premature deaths). As the authors did not estimate premature avoided deaths in 2021, the year in which a *Menthol Ban Scenario* takes effect in the Menthol Simulation, we estimate mortality risk reductions beginning in Year 2 (2025) and average the cumulative avoided premature deaths under the proposed product standard over the following 39 years through 2063. This results in an estimated 16,593 mortality risk reductions in each year 2025-2063 (647,128 avoided premature deaths/39 years = 16,593 avoided premature deaths each

[32] The simulation results in Levy et al. (2021) reflect no difference in the *Status Quo* and *Menthol Ban* scenarios for the initial year (2021) in which the simulation assumes implementation of a menthol ban.

year 2025-2063). We request comment, including data, to assist with distributing these mortality risk reductions (i.e., "averted deaths" under the Menthol Simulation) over time.[33]

In Table 26, we present the estimated mortality risk reductions ("averted deaths") in 2025 (Year 2, the first year after the product standard becomes effective), in 2029 (Year 6), in 2063 (Year 40), and cumulative over the entire time horizon.

Table 26. Estimated Average Annual Mortality Risk Reductions ("Averted Deaths"), All Adjustments Incorporated

Year Count	Year	Estimated Average Annual Mortality Risk Reductions ("Averted Deaths")
Year 1	2024	--
Year 2	2025	16,593
Year 3	2026	16,593
Year 4	2027	16,593
Year 5	2028	16,593
Year 6	2029	16,593
…	…	…
Year 39	2062	16,593
Year 40	2063	16,593
Total		647,128

Note: These estimates include effects for users and potential users of tobacco products only, and do not include effects to nonusers.

As the Menthol Simulation does not include confidence intervals or ranges around its results, Table 26 only includes point estimates. Changes in the baseline assumptions are incorporated by the authors as sensitivity analyses, the results of which are modeled independently. We incorporate the Levy et al. (2021) sensitivity analysis regarding a 10%

[33] This uncertainty regarding the distribution over time of the avoided premature deaths across the 40 year time horizon impacts the model estimates. In sections II.C.8.b and II.C.8.c, we conduct two sensitivity analyses incorporating alternative assumptions.

reduction in baseline initiation rates as a proxy for the impacts of T21 laws. We discuss the impact of the remaining sensitivity analyses from Levy et al. (2021) on the Menthol Simulation base modeling results (without our adjustments) in Section II.C.8. We request comment, including additional studies and data, on the estimated impact of this proposed product standard in terms of annual averted premature deaths (including ranges) and methods for estimating health impacts from avoided initiation, cessation, and switching to other tobacco products in isolation.

c. Valuing Avoided Premature Deaths from the Proposed Product Standard

To value the estimated reduction in mortality risk expected to accrue from this proposed menthol product standard, we follow U.S. Department of Health and Human Services *Regulatory Impact Analysis Guidance* (HHS 2016) and incorporate a value per statistical life (VSL) approach [158]. This approach uses a range of VSL estimates to measure the value of reduced mortality. VSL estimates do not represent the dollar value of a person's life, but instead are calculations based upon the amount individuals are willing to pay for small reductions in mortality risk. We use annual VSL estimates recommended by the Department of Health and Human Services, which are based on a review of published studies [159].[34] Table 27 presents VSL values for the 2023-2063 period.

[34] We extrapolate VSL estimates, only provided through 2049, out through 2063 using the methodology outlined in the U.S. Department of Health and Human Services *Regulatory Impact Analysis Guidance* [158] and HHS updated Appendix D [159].

Table 27. Value of Statistical Life (VSL) Estimates Over Time Horizon

Year Count	Year	VSL Estimates ($2020, Million Rounded)		
		Low Estimate	Central Estimate	High Estimate
Year 1	2024	$5.5	$11.8	$17.9
Year 2	2025	$5.5	$11.9	$18.1
Year 3	2026	$5.6	$12.0	$18.2
Year 4	2027	$5.6	$12.1	$18.4
Year 5	2028	$5.7	$12.2	$18.5
Year 6	2029	$5.7	$12.3	$18.7
…	…	…	…	…
Year 39	2062	$7.4	$15.9	$24.3
Year 40	2063	$7.5	$16.1	$24.5

We then multiply the estimated avoided premature deaths in each year by the corresponding VSL estimates (low, central, high). As a result of these calculations, we present the stream of undiscounted benefits attributable to this proposed rule in Table 28.

Table 28. Estimated Value of Average Annual Avoided Premature Deaths (Undiscounted)

Year Count	Year	Estimated Average Annual Avoided Premature Deaths	Undiscounted Value of Avoided Premature Deaths ($2020, Billion Rounded)		
			Low Estimate	Primary Estimate	High Estimate
Year 1	2024	-	-	-	-
Year 2	2025	16,593	$91.26	$197.46	$300.33
Year 3	2026	16,593	$92.92	$199.12	$301.99
Year 4	2027	16,593	$92.92	$200.78	$305.31
Year 5	2028	16,593	$94.58	$202.43	$306.97
Year 6	2029	16,593	$94.58	$204.09	$310.29
…	…	…	…	…	…
Year 39	2062	16,593	$122.79	$263.83	$403.21
Year 40	2063	16,593	$124.45	$267.15	$406.53
TOTAL		647,128	$4,188.08	$8,983.46	$13,666.02

Note: These estimates include effects for users and potential users of tobacco products only, and do not include effects to nonusers.

We then discount the stream of benefits presented in Table 28 using 3% and 7% discount rates. The primary present value of total avoided premature deaths from this proposed product standard is approximately $4,955 billion at a 3% discount rate (low $2,309 billion; high $7,535 billion), and approximately $2,685 billion at a 7% discount rate (low $1,250 billion; high $4,081 billion). The primary annualized value of avoided premature deaths from this proposed product standard, for users and potential users of tobacco products only, is approximately $212 billion at a 3% discount rate (low $99 billion; high $322 billion), and approximately $200 billion at a 7% discount rate (low $93 billion; high $305 billion). These estimates of present and annualized value for avoided premature deaths from this proposed product standard are summarized in Table 29. For the full stream of undiscounted benefits over time, see Appendix B.

Table 29. Present and Annualized Values of Avoided Premature Deaths from the Proposed Product Standard (3% and 7% Discounting)

Category	Discount Rate	Benefits ($2020, Billion)		
		Low	Primary	High
Undiscounted Value of Avoided Premature Deaths	N/A	$4,188	$8,983	$13,666
Present Value of Avoided Premature Deaths	3%	$2,309	$4,955	$7,535
	7%	$1,250	$2,685	$4,081
Annualized Value of Avoided Premature Deaths	3%	$99	$212	$322
	7%	$93	$200	$305

Note: These estimates include effects for users and potential users of tobacco products only, and do not include effects to nonusers.

d. Limitations of these estimates

We note several limitations in the Menthol Simulation and the adjustments we make in our analysis of mortality risk reduction from the proposed product standard. First, transitions in the Levy et al. (2021) simulations were modeled only in one direction—relapse after two years

(i.e., reinitiating regular cigarette smoking or ENDS use after entering any group containing former smokers/users) was not considered, leading to potential overestimates in benefits [88]. Second, we note that estimated transitions from menthol cigarette smoking to smokeless tobacco product use were transferred to non-menthol cigarette use, thereby incorporating an assumption that smokeless tobacco product use carries similar risks as non-menthol cigarette smoking, leading to potential underestimates in benefits. Third, the *Menthol Ban Scenario* considered by Levy et al. (2021) assumes that HTPs would remain on the market, while our proposed product standard would prohibit menthol flavored cigarettes that are HTPs, potentially leading to a negligible overestimate in benefits (current sales of these products represent less than 0.1% of the market for menthol cigarette products). Last, although age- and gender-specific effects were modeled, other sources of population heterogeneity, such as race, ethnicity, socioeconomic status, and geographical location, were not simulated. Taken in total, it is unclear what impact these limitations would have on the results estimated in the Levy et al. (2021) Menthol Simulation. Despite these limitations, FDA believes that the results estimated in the Levy et al. (2021) Menthol Simulation present realistic estimates of the impacts of a nationwide menthol cigarette product standard. In Section II.B.1.c. of this analysis, we present prevalence estimates for populations of particular interest and we further discuss potential impacts of the proposed menthol product standard for such populations in the distributional analyses included in Section II.F.1.

We also note that the preceding quantified estimates do not include impacts in terms of avoided illness (morbidity), leading to an overall underestimate of the impact of the proposed product standard. In Section II.C.6, we qualitatively discuss other benefits of this proposed product standard, such as avoided morbidity and associated reductions in medical costs.

5. Valuing Benefits from Reduced Externalities

The present and annualized value from mortality risk reductions ("averted deaths") for current and potential users of cigarette products estimated in Table 29 represent the benefits expected to accrue directly to current menthol smokers and those who do not initiate cigarette smoking under the proposed menthol cigarette product standard. However, cigarette smoking creates externalities that affect non-smokers both within and outside the smoker's household, as well. To assess the impact of the proposed product standard for non-smokers, we analyze benefits from expected reductions in secondhand smoke exposure and reduced maternal smoking impacts on infants. These benefits are then added to the quantified benefits from avoided premature deaths expected to accrue directly to current menthol smokers and those that do not initiate cigarette smoking under the proposed menthol cigarette product standard.

a. Benefits from Reduced Exposure to Secondhand Smoke

As discussed in Section II.B.1.d., secondhand smoke exposure is harmful to the health of non-smokers. The 2006 SGR titled *The Health Consequences of Involuntary Exposure to Secondhand Smoke* concluded that "secondhand smoke exposure causes premature death and disease in children and in adults who do not smoke" [27]. Exposure to secondhand smoke is a cause of cancer and respiratory and cardiovascular disease [3].

According to the 2014 SGR, more than 437,000 premature deaths per year are caused by active cigarette smoking, and an additional 41,280 premature deaths among adults aged 35 years and older are due to secondhand smoke [3]. Specifically, secondhand smoke causes approximately 7,330 deaths from lung cancer and 33,950 deaths from coronary heart diseases in non-smokers annually [3].

Secondhand smoke is particularly harmful to children. Children of parents who smoke, when compared with children of nonsmoking parents, have an increased frequency of respiratory infections like pneumonia and bronchitis [107]. Children exposed to tobacco smoke in the home are also more likely to develop acute otitis media (middle ear infections) and persistent middle ear effusions (thick or sticky fluid behind the eardrum) [107]. According to the 2006 Surgeon General's Report, the evidence is sufficient to conclude that secondhand smoke exposure from parental smoking causes negative health effects, including: lower respiratory illness in infants and children; middle ear disease in children; cough, phlegm, wheeze, and breathlessness among children of school age, and ever having asthma among children of school age; the onset of wheeze illnesses in early childhood; persistent adverse effects on lung function across childhood; and a lower level of lung function during childhood [27]. Secondhand smoke is associated with 150,000 to 300,000 lower respiratory tract infections in infants and children under 18 months of age per year, 790,000 doctor's office visits related to ear infections per year, and 202,000 asthma cases each year [27] [160]. The 2014 SGR reported 400 sudden infant death syndrome (SIDS) deaths related to perinatal smoking or secondhand smoking [3]. The benefits of reduced maternal smoking on infant health are further discussed in Section II.C.5.b.

The burden of secondhand smoke exposure is experienced disproportionately among nonsmokers from some racial and ethnic minority groups and people with lower income. Among nonsmokers age 3 and older, findings from 2011-2018 NHANES data indicate that non-Hispanic Black persons and those living below the poverty level had the highest levels of secondhand smoke exposure as compared to people of other races and those living above the poverty level, respectively; these disparities persisted across all years of the study analysis from 2011 to 2018 [86]. From 1999 to 2012, the percentage of the nonsmoking population age 3 and older exposed

to secondhand smoke (defined in the study as levels 0.05-10 ng/mL to indicate secondhand smoke exposure) declined across all racial and ethnic groups [87]. However, a significantly higher proportion of non-Hispanic Black nonsmokers continued to have detectable serum cotinine levels, compared to Mexican American and non-Hispanic White nonsmokers. For example, in 2011-2012, nearly 50% of non-Hispanic Black nonsmokers had detectable serum cotinine levels, compared with 22% of non-Hispanic White and 24% of Mexican American nonsmokers [87]. Due to the disparities in secondhand smoke exposure discussed here and further in the preamble for this proposed rule (Section V.C.4), the proposed menthol product standard is anticipated to reduce smoking-related morbidity and mortality for vulnerable populations, especially youth.

The proposed product standard is estimated to reduce cigarette smoking in current smokers, resulting in reduced secondhand smoke exposure. Furthermore, reduced secondhand smoke would be associated with reduced premature morbidity and mortality in infants, children, adolescents and adult nonsmokers. We estimate the impacts of reduced secondhand smoke exposure on mortality, but do not estimate the benefits that accrue from reductions in productivity losses or medical costs associated with treatment prior to death, or other costs associated with secondhand smoke-related illness.

The 2014 SGR estimates total smoking-attributable mortality for adult active smokers at 437,400 per year with an additional 41,280 deaths from secondhand smoke (counting 33,950 coronary heart disease and 7,330 lung cancer-associated deaths only, and therefore not counting deaths from other diseases attributable to secondhand smoke) [3]. The additional smoking-attributable mortality due to secondhand smoke is 7.76% of active smoker mortality (33,950/437,400) for coronary heart disease and 1.68% (7,330/437,400) for lung cancer.

We account for mortality averted due to reduced exposure to secondhand smoke as a result of the proposed product standard by multiplying our estimated number of avoided premature deaths from Table 26 and the ratios calculated above for secondhand smoke exposure for heart disease and lung cancer.[35] Thus, by 2063, we estimate he cumulative number of avoided premature deaths due to reductions in secondhand smoke exposure would be 50,217 (= 647,128*0.0776) with respect to heart disease and 10,872 (= 647,128*0.0168) with respect to lung cancer. This implies a total of 61,089 (=50,217 + 10,872) avoided premature deaths would accrue by 2063 as a result of reduced second hand smoke exposure under the proposed product standard. We summarize the results of these calculations within Table 30.

Table 30. Cumulative Avoided Premature Deaths from Reductions in Secondhand Smoke Due to Cigarette Smoking (2023-2063)

Category	Percentage of Total Cumulative Avoided Premature Death	Cumulative Avoided Premature Deaths
Attributable to Heart Disease	7.76%	50,217
Attributable to Lung Cancer	1.68%	10,872
Attributable to both Heart Disease and Lung Cancer	9.44%	61,089

Since we estimate additional reductions in smoking-attributable mortality due to secondhand smoke exposure for both coronary heart disease and lung cancer to be 9.44% of the cumulative avoided premature death, this would represent a similar proportional increase within of the stream of expected mortality reductions presented within Table 26. That is, for every 100 mortality risk reductions presented in Table 26, we would include about 9 additional reductions

[35] Applying a proportion to two values and then taking the difference between those values is equivalent to applying the proportion directly to the difference. In this case, avoided premature deaths under the proposed product standard represents a difference of values (see *Status Quo* and *Menthol Ban* scenarios in Table 22). Therefore, we may apply the secondhand smoke related proportions of mortality for coronary heart disease and lung cancer directly to our estimated annual number of avoided premature deaths in Table 26.

in smoking-attributable mortality due to secondhand smoke exposure. We note that this analysis likely provides an underestimate, as it does not include all cancers or other health impacts caused by secondhand smoke exposure. Since mortality risk reductions were monetized by multiplying the estimated number of mortality risk reductions and the associated VSL value for that particular year, calculations used to estimate the total benefits of this rule would carry an additional 9.44% representing increased reductions in smoking-attributable mortality due to secondhand smoke exposure.[36] Thus, we estimate the additional benefits due to reduced exposure to secondhand smoke by multiplying our total estimated benefits presented in Table 29 by the proportion of cumulative avoided mortality risk reductions ("averted deaths") attributable to reduced second hand smoke exposure. We present the summary of quantified benefits from reduced second hand smoke exposure under the proposed product standard in Table 31.

Table 31. Present and Annualized Values of Avoided Premature Deaths Due to Reduced Secondhand Smoke Exposure under this Proposed Product Standard

Category	Discount Rate	Secondhand Smoke – Benefits[1] ($2020, Billion)		
		Low	Primary	High
Undiscounted Value of Avoided Premature Deaths	N/A	$395.4	$848.0	$1,290.1
Present Discounted Value of Avoided Premature Deaths	3%	$217.9	$467.8	$711.3
	7%	$118.0	$253.5	$385.3
Annualized Value of Avoided Premature Deaths	3%	$9.3	$20.0	$30.4
	7%	$8.8	$18.9	$28.8

[1]Benefits from avoided mortality due to secondhand smoke exposure is calculated by applying the 9.44% value to the total estimated benefits for users and potential users of cigarette products due to this proposed product standard—see Table 29.

[36] Since we have estimated additional avoided smoking-attributable mortality due to secondhand smoke exposure to be 9.44% of the cumulative avoided premature deaths estimated by Levy et al. (2021), we would increase the total number cumulative avoided premature deaths by multiplying our previously estimated cumulative avoided premature deaths by 1.0944, or 1+0.0944. Thus, a 9.44% increase in avoided premature deaths would represent an equivalent 9.44% increase in total benefits estimated within of the main analysis.

Thus, as a result of this product standard, we estimate the primary present value of avoided premature death due to reduced secondhand smoke exposure is approximately $467.8 billion at a 3% discount rate (low $217.9 billion; high $711.3 billion), and approximately $253.5 billion at a 7% discount rate (low $118.0 billion; high $385.3 billion). The primary annualized value of avoided premature death due to reduced secondhand smoke exposure is estimated to be $20.0 billion at a 3% discount rate (low $9.3 billion; high $30.4 billion), and approximately $18.9 billion at a 7% discount rate (low $8.8 billion; high $28.8 billion).

This analysis assumes that mortality risk reductions ("averted deaths") from reduced secondhand smoke exposure are distributed similarly over time as mortality risk reductions ("averted deaths") from reduced cigarette smoking. Additionally, these estimates do not include other cancers or health effects associated with secondhand smoke or account for specific impacts on populations. We also do not separately estimate medical costs or reduced health-related quality of life and productivity associated with disease and death from secondhand smoke. We request comment on this analysis, other methods that may more fully incorporate the impacts of reductions in secondhand smoke exposure, and additional data regarding changes to secondhand smoke-attributable mortality over time.

b. Benefits from Reduced Maternal Smoking on Infant Health

As discussed in Section II.B.1.e, smoking during pregnancy is a leading preventable cause of infant morbidity and mortality [110]. It increases the risk of pregnancy complications, preterm-related deaths and SIDS [3]. Furthermore, postnatal exposure to secondhand smoke increases the likelihood an infant will develop SIDS, a causal link established in the 2004 SGR [27] [161].

FDA anticipates the proposed rule would result in lower smoking prevalence and cigarette consumption in the U.S., thus reducing the more than 1,000 annual smoking-attributable infant deaths reported by the 2014 SGR [3]. To estimate the averted mortality due to reduced perinatal tobacco exposure, we scale the benefits estimated for tobacco-attributable mortality.

The 2014 SGR reports 437,400 U.S. deaths each year are attributable to active cigarette smoking, with the major causes of excess mortality among smokers being cancer, cardiovascular and metabolic diseases, and respiratory disease [3]. The same report estimates 613 prenatal deaths and 400 SIDS cases annually due to smoking during or after pregnancy, based on a smoking-attributable fraction of mortality of 5.79% for prenatal conditions and 17.26% for SIDS [3]. Hence, SIDS deaths due to maternal smoking represent at least an additional 0.09% (= (400)/437,400) deaths attributed to direct cigarette smoking.[37] In order to estimate avoided SIDS deaths, we then apply the value of 0.09% to our estimate of the number of avoided premature deaths due to the product standard from Table 26.[38] Thus, the proposed product standard is expected to result in approximately 592 (=647,128*0.09%) avoided SIDS deaths by 2063. We present a summary of these estimates within Table 32.

[37]The FDA's discussion of baseline prevalence in Section II.4.1.c highlights that women are more likely to smoke menthol cigarettes. Therefore, this calculation likely underestimates the benefits of reduced maternal smoking as the denominator includes cigarette smoking-attributable deaths across all populations.

[38] We note that applying a proportion to two values and then taking the difference between those values is equivalent to applying the proportion directly to the difference. In this case, avoided premature deaths under the proposed product standard represents a difference of values (see *Status Quo* and *Menthol Ban* scenarios in Table 22). Therefore, we apply the proportion of infant mortality directly to our estimated annual number of avoided premature deaths in Table 26.

Table 32. Cumulative Avoided Premature Deaths from Infant Mortality under the Proposed Menthol Cigarette Product Standard

	Estimate
Cumulative Avoided Premature Deaths, 2023-2063	647,128
Additional SIDS deaths as a Proportion of Cumulative Avoided Premature Deaths	0.09%
Cumulative Avoided Infant Deaths due to SIDS, 2023-2063	592

Since cumulative infant deaths due to SIDS represent 0.09% of the total estimated cumulative avoided premature deaths for smokers and potential smokers, they would represent a similar proportional increase to mortality reductions presented in Table 26. That is, for every 1,000 mortality risk reductions ("averted deaths") presented in Table 26, we would include about 1 additional mortality risk reduction ("averted death") to account for avoided SIDS mortality. Since mortality risk reductions were monetized by multiplying the estimated number of mortality risk reductions and the associated VSL value for that particular year, this proportional increase would be carried through each of the calculations used to estimate the total benefits of this rule.[39] Thus, we estimate the benefits for avoided SIDS deaths by applying the proportion of cumulative premature deaths attributable to SIDS (0.09%) directly to the total estimated benefits presented in Table 29. We present the summary of benefits within

Table 33.

[39] Since we have estimated additional smoking-attributable mortality due to premature infant death to be 0.09% of the cumulative avoided premature deaths estimated by Levy et al. (2021), cumulative avoided premature deaths with the addition of avoided premature infant mortality is equal to our previously estimated total cumulative avoided premature deaths multiplied by 1+0.0009.

Table 33. Present and Annualized Values of Avoided SIDS Deaths Under the Proposed Product Standard

Category	Discount Rate	Reduced SIDS Mortality – Benefits[1] ($2020, Billion)		
		Low	Primary	High
Undiscounted Value	N/A	$3.8	$8.2	$12.5
Present Discounted Value	3%	$2.1	$4.5	$6.9
	7%	$1.1	$2.5	$3.7
Annualized Value	3%	$0.1	$0.2	$0.3
	7%	$0.1	$0.2	$0.3

[1]Benefits from avoided SIDS deaths are calculated by applying the 0.09% value to the total estimated benefits due to this proposed product standard—see Table 29.

Thus, the primary present value of avoided premature infant death is approximately $4.5 billion at a 3% discount rate (low $2.1 billion; high $6.9 billion), and approximately $2.5 billion at a 7% discount rate (low $1.1 billion; high $3.7 billion). The primary annualized value of avoided premature infant death from this proposed product standard is approximately $0.2 billion at a 3% discount rate (low $0.1 billion; high $0.3 billion), and approximately $0.2 billion at a 7% discount rate (low $0.1 billion; high $0.3 billion).[40]

In addition to reducing infant mortality caused by cigarette smoke exposure, the proposed rule is also likely to lower infant morbidity. By reducing smoking during pregnancy and after delivery, the proposed standard likely would result in fewer pregnancy complications and fewer adverse infant outcomes, including preterm delivery and restricted fetal growth (low birth weight). The 2004 SGR found sufficient evidence to infer causal relationships between smoking and fetal growth restriction and between smoking and decreased gestation/increased preterm

[40] Note that by calculating the value of reduced SIDS mortality by using the standard VSL, we may not be including certain benefits specific to avoiding the deaths of children, such as "the value of reducing the risk that parents will be responsible for the deaths of or serious injury to their own children." See 79 Fed. Reg. 19,177, 19,236 (Apr. 7, 2014) (discussing unquantified considerations involving deaths or injuries to children).

delivery [161]. Dietz et al. (2010) estimated that 5.3-7.7% of preterm deliveries and 13.1-19.0% of term low-birth-weight deliveries were attributable to maternal smoking, based on 11.5% of non-multiple live-born infants exposed to cigarette smoking in utero [18] [162].

In the following, we provide approximate morbidity estimates of smoking-attributable preterm delivery and low birth weight based on vital statistics data collected by NCHS and estimates of smoking prevalence in the U.S. In 2019, there were 3,747,540 births reported in the U.S. [111]. Of these births, 10.23% (n=383,061) were preterm deliveries and 8.31% (n=311,245) were low birth weight. Using the estimates of smoking-attributable preterm birth and low-birth-weight deliveries from Dietz et al. (2010), we can approximate smoking-attributable preterm birth and low-birth-weight deliveries for the 2019 NCHS birth estimates [111] [162]. Using the low values of the smoking-attributable ranges from Dietz et al. (2010) (preterm deliveries: 5.3%; low birth weight: 13.1%), there were approximately 16,496 (311,245*0.053) low-birth-weight deliveries and 50,181 (383,061*0.131) preterm deliveries attributable to smoking in 2019 [162]. The proposed product standard is expected to reduce morbidity associated with smoking-attributable preterm delivery and low birth weight.

We request comment on our estimates of maternal and infant health effects from reductions in cigarette smoking, including additional studies, data, and methods to consider health disparities in the analysis.

6. Further Qualitative Discussion of Benefits

While our quantified estimates of the potential impacts to smokers and non-smokers from a menthol product standard suggest a significant public health benefit to the United States resulting from substantial reductions in smoking prevalence, these analyses do not address other

additional benefits. We provide a qualitative discussion of other benefits that are expected to accrue to both smokers and non-smokers from the proposed product standard in this section.

a. Avoided Illness and Improved Health-Related Quality of Life

The SAVM simulation and our associated estimates of mortality risk reduction do not separately account for increased quality of life from decreased tobacco-related disease and illness (morbidity). As discussed in the preamble for this proposed rule (Section V.C.2), quitting cigarette smoking, including menthol cigarettes, 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."[5] 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]. The 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 [5].

A study using 2006-2012 data from the NHIS estimated that 6.9 million U.S. adults had a combined 10.9 million self-reported smoking-attributable medical conditions, highlighting that smoking cigarettes often causes co-morbid diseases [4]. The study estimated that individuals are living with 14.0 million major smoking-related conditions in the United States, including more

than 7.4 million cases of chronic obstructive pulmonary disease, nearly 2.3 million heart attacks, 1.8 million cases of diabetes, nearly 1.2 million stroke events, more than 300,000 cases of lung cancer, and nearly 1 million cases of other smoking-attributable cancers (bladder, cervix, colon/rectum, kidney, larynx, mouth, tongue, lip, throat, pharynx, stomach) [4]. The authors noted that the morbidity estimates are likely underestimates due to underreporting of diseases in surveys and the absence of several major medical conditions.

Another study, which examined disparities in tobacco-related cancer incidence and mortality, found that tobacco-related mortality decreased between 2004 and 2013, however tobacco-related cancer incidence and mortality rates remain highest among African Americans, accounting for more than 39,000 deaths annually between 2009 and 2013 [72]. Cigarette smoking, in addition to causing disease, can diminish overall health status, leading to higher risks for surgical complications, including wound healing and respiratory complications, increased absenteeism from work, and greater use of health care services [3]. Increased smoking cessation, reduced cigarette consumption, and decreased progression to regular cigarette smoking due to this proposed product standard would reduce not only the mortality from smoking, but it also would reduce the enormous burden of cigarette-attributable disease in the United States and improve health-related quality of life for smokers and non-smokers.

We expect that the proposed product standard would reduce some of the morbidity attributable to smoking and that these benefits would accrue to smokers who quit or reduced their cigarette product use, those that do not initiate, as well as those impacted by secondhand smoke exposure. However, many smokers may suffer from more than one tobacco-related morbidity condition. As quantifying benefits from reduced morbidity would require additional yearly data on the impacts of smoking on health-related quality of life, we discuss these impacts

qualitatively and request comment and additional data that would assist with estimating the impacts of reduced morbidity, separate from estimates of mortality impacts.

b. Medical Cost Savings and Avoided Productivity Loss

Smokers use more medical services during their lifetimes than comparable non-smokers. Cigarette smoking cessation and associated decreases in tobacco-related morbidity (illness) due to this product standard are expected to reduce medical costs and productivity losses. We outline the overall costs of cigarette smoking in terms of medical costs and productivity losses, noting the expected impacts from this proposed product standard.

A 2012 Congressional Budget Office (CBO) report on the effects of raising the excise tax on cigarettes applies regression analysis to two large national surveys to estimate that smoking-attributable health care costs in the U.S. between 2000 and 2008 accounted for 7% of total annual health care spending [163]. The CBO further estimates that current and former smokers have higher annual health care spending per capita than similar people who have never smoked. The CBO estimates that current and former smokers have higher annual health care spending per capita than similar people who have never smoked: about $1,425 for 45–64-year-olds; about $1,568 for 65–74-year-olds; and about $1,853 for ages 75 and older. The difference in annual spending is around $285 for 18- to 24-year-olds, and around $570 for 25- to 44-year-olds.[41] The CBO finds that former smokers have higher medical costs than current smokers immediately after quitting; poor health may motivate smokers to quit with the effects of such illnesses raising health care costs immediately following. Like the CBO, we assume that former smokers' annual

[41] The CBO costs were updated from 2008 dollars to 2020 dollars using the most recent medical care Consumer Price Index data from the Bureau of Labor Statistics (http://www.bls.gov/cpi/cpid1312.pdf).

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 $176 billion annually for direct medical care for adults [3]. Smoking-attributable costs included nearly $156 billion in lost productivity due to premature death and exposure to secondhand smoke [3]. More specifically, productivity losses due to secondhand smoke-attributable deaths are estimated to cost the United States $5.6 billion each year [3]. 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 [3].

Xu et al. (2021) 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 [164]. Their results suggest that, during 2010 to 2014, 11.7% of U.S. healthcare spending each year was attributable to adult cigarette smoking, with health care spending by current smokers accounting for 6.0% and former smokers accounting for 5.7% (1.3% quit in the last five years + 4.4% quit more than 5 years = 5.7%). 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. Private insurance and out-of-pocket costs accounted for only $63.8 billion (12.3%) of these costs during 2010 to 2014 [164].

Bolnick et al. (2020) 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 $130 billion dollars in 2016 in the U.S. [165]. Tobacco smoke ranked fifth highest in terms of all

U.S. healthcare spending that could be attributed to modifiable risk factors, i.e., risk factors that may be mitigated through behavior. Cardiovascular disease (32.6%) and musculoskeletal disorders (21.4%) accounted for the largest portions of healthcare costs attributable to tobacco smoke [165].

Similar to the previous section on avoided illness, quantifying benefits from reduced medical costs would require additional annual data specific to the impacts of cigarette product use and associated medical costs. While we do not separately estimate reductions in smoking-attributable medical costs and avoided productivity losses due to this product standard, we expect that benefits would accrue to smokers who quit or reduced their cigarette use, those that do not initiate, as well as those impacted by secondhand smoke exposure. We request comment, including data and research, that would assist in quantifying such reductions.

c. Reduction in Cigarette Smoking Related Fires

The analysis of benefits for the menthol product standard does not quantify potential benefits for reductions in harms caused by smoking-related fires due to expected reductions in cigarette smoking. Even though all states have instituted laws requiring fire-safety-compliant cigarette paper (adoption began in 2003 with all states adopting these laws by 2012), smoking[42] remained the second leading cause of residential fire deaths in the United States in 2018 [39]. Cigarettes are the leading cause of smoking-related fires at 86.3% [40]. The proposed product standard would lower the prevalence of cigarette smoking, which is likely to decrease the occurrence of smoking-related fires.

[42] From FEMA's National Fire Administration data, "smoking" fires are those caused by "cigarettes, cigars, pipes, and heat from undetermined smoking materials."
https://www.usfa.fema.gov/downloads/xls/statistics/residential_nonresidential_fire_loss_estimates.xlsx

Estimates from two different sources – the U.S. Fire Administration and the National Fire Protection Association – both show the impact of smoking-related fires. The National Fire Protection Association estimates that there were 16,500 home smoking material[43] fires in 2016, which resulted in 660 home smoking material fire deaths [41]. The U.S. Fire Administration, using different calculation methods,[44] estimates that smoking was the cause of 7,000 residential building fires in 2019 that accounted for 320 deaths, 750 injuries, and more than $314.4 million in estimated losses [166]. Although residential building smoking fires decreased 10% between 2010-2019 [166], the U.S. Fire Administration ranked smoking as the second leading cause of residential fire deaths in 2018 [39].

Smoking-related residential fires result in higher death rates and injuries than non-smoking-related residential fires. From 2008 to 2010, there were an estimated 24.2 deaths per 1000 smoking-related fires versus 3.1 deaths for non-smoking-related fires, and the rate of fire injuries from smoking in residential buildings was more than triple that of residential non-smoking fires [40]. Most deaths in home smoking material fires begin in the bedroom (40%) [1671]. Smoking material fires also kill people around the smoker; one out of four fatal victims of smoking material fires is not the smoker whose cigarette started the fire [42].

These numbers are likely underestimates of the actual number of fires caused by smoking materials since the majority of unwanted fires in residential buildings are not attended by or reported to fire departments [168]. In a 2004-2005 study, the U.S. Consumer Product Safety

[43] Where "smoking materials" include "cigarettes, pipes, cigars, and undetermined smoking material. While the contents are not specified, most are presumably lit tobacco products." (Ahrens, 2010).
[44] For the U.S. Fire Administration methodology, please see https://www.usfa.fema.gov/downloads/pdf/statistics/national_estimate_methodology.pdf. For the National Fire Protection Association's methodology please see https://www.nfpa.org/-/media/Files/News-and-Research/Fire-statistics-and-reports/NFPA-estimates-and-methodology/HowNationalEstimatesAreCalculatedForHomeStructureFires.pdf.

Commission estimated 14 unreported cigarette fires for every reported home cigarette fire identified in the study, or 155,000 unreported home cigarette fires per year [168].

Smoking materials cause fires and damage outside the home as well. Smoking was listed as the cause of 2,400 nonresidential building fires in 2019, leading to approximately $27 million in losses [169]. Accounting for 10% of fires (30,600 fires), smoking materials were the third largest cause (after intentional and outside or open fires for waste disposal) for local fire department responses to brush, grass, and forest fires from 2011 to 2015 [43]. These fires can spread quickly to buildings or vehicles on the property, causing significant property damage.

As the prevalence of cigarette smoking is expected to decline due to this proposed menthol product standard, we also expect that the number of smoking-related fires would decline. As recent data on smoking-related fires are not available by type of smoking product,we do not quantify these decreases as part of this analysis. We request comment, including additional data and studies, to estimate reductions in smoking-attributable fires and related savings.

d. Reduced Exposure to Thirdhand Smoke

Thirdhand smoke—the chemical residue of combustible 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 [28] [29] [30] [31] [32]. 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 smoker's clothing and bodies [33]. 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 [34]. For example, nicotine exposure from thirdhand smoke residue can be 6.8 times higher in toddlers than what would be inhaled by a passive (i.e., secondhand) smoker [35].

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 [36] [37] [38]. 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 do not quantify the reduction in thirdhand smoke exposure separately.

e. Reductions in Cigarette Butt Litter

Tobacco products, specifically cigarette butts, are one of the most frequently littered items [44] [45]. For example, in 2019, the Ocean Conservancy found that cigarette butts were the most collected piece of litter throughout the U.S., reaching over 900,000 items collected and over three times the amount of the next most littered item (food wrappers). 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 $264.5 million annually and an estimated annual mean of $6.46 per capita [46]. 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 threatening human health and the environment, especially marine ecosystems [47] [48] [49] [50] [51] [52].

We do not estimate the impact of reduced cigarette butt litter due to reductions in cigarette smoking prevalence but note that this proposed product standard would also reduce one of the most frequently littered items. We request comment, including additional data and studies, on estimating reductions in cigarette butt litter associated with reductions in cigarette smoking.

7. Uncertainty

The projections based on the Menthol Simulation are subject to potential uncertainties. We discuss the main sources of uncertainty here, noting that assumptions around some of these uncertainties are explored further in the sensitivity analyses in Section II.C.8.

a. Jurisdictional Restrictions on the Sale of Menthol Cigarettes

In recent years, several jurisdictions have restricted the sale of flavored tobacco products, including menthol cigarettes. If more jurisdictions enact restrictions on the sale of menthol cigarettes, in absence of a federal menthol cigarette product standard, regional policy changes may have an impact on future trends in status quo menthol cigarette smoking prevalence.

As we outline in Section II.B.5, as of January 2022, at least 335 localities have passed restrictions on the sale of flavored tobacco products, with at least 145 of these localities explicitly restricting the sale of menthol cigarettes [126]. In addition, two States have passed legislation which prohibits the sale of menthol cigarettes (Massachusetts and California).[45] The comprehensiveness of jurisdictional flavor sales restrictions varies considerably, however, and many of these policies include only specific product types or flavors, sales locations, or types of retailers [125].[46]

This complicated patchwork of flavored tobacco product legislation makes it difficult to estimate the potential impact of jurisdictional menthol cigarette restrictions on baseline

[45] While legislation (SB 793) for California had proposed an effective date of January 1, 2021, the implementation date has been delayed until the November 2022 general election following a proposed referendum (https://www.sos.ca.gov/administration/news-releases-and-advisories/2021-news-releases-and-advisories/js21002). If voters approve the referendum, the new effective date would be 5 days after the Secretary of State certifies the election results (Cal. Const. art II § 10).

[46] "Sales locations" refers to the physical location of the sale. Some restrictions allow retailers located outside of specified "buffer" zones (e.g., areas within 500 feet of the property line of any public, private, or parochial secondary school) to sell flavored tobacco products.

prevalence and future trends. Additionally, jurisdictional flavored tobacco restrictions may be circumvented by consumer purchases made outside of the area. A national product standard prohibiting menthol as a characterizing flavor in cigarette products is expected to provide more uniform coverage and reduce the likelihood of cross-border purchases that circumvent regional tobacco product sales restrictions. We request comment on how jurisdictional menthol flavor bans for cigarette products may impact future prevalence.

b. Health Impacts of ENDS products

The lifetime health impacts of ENDS use are still uncertain. Health impacts of ENDS use on nonusers, including potential secondhand smoke exposure and impacts on maternal/infant health, are also uncertain. Simulations in the Levy et al. (2021) modeling assume an excess relative risk of mortality for ENDS products compared to cigarettes of 0.15, in effect modeling the mortality risk of ENDS use as 15% of the mortality risk of cigarette smoking over the same period. If additional research shows that ENDS use is more harmful than the assumptions made in these simulations, then we have overstated the benefits of the proposed product standard. Conversely, if future research shows that ENDS use is less harmful, the benefits of the proposed product standard may be underestimated. In Section II.C.8 we discuss alternative assumptions in the Menthol Simulation by Levy et al. (2021) regarding the health harms of ENDS use and the resulting impact on estimates of avoided premature deaths and avoided life years lost under a potential *Menthol Ban Scenario*.

c. Switching to Other Tobacco Products

The *Menthol Ban Scenario* models a ban of menthol in cigarettes and cigars, but includes only the benefits attributed to the menthol cigarette smoking ban. Cigars are covered in the

model because it is assumed that menthol cigarette smokers could simply switch to menthol cigars if a menthol cigarette ban was put in place and if menthol cigars were still available. FDA's expectation is that, even if menthol was not prohibited as a characterizing flavor in cigars, this rule would still reduce initiation and experimentation of cigarette smoking, decrease nicotine dependence and addiction, and increase cessation among current menthol cigarette smokers. However, since FDA is concurrently pursuing a proposed rule, published elsewhere in this issue of the *Federal Register*, that would prohibit characterizing flavors (other than tobacco) in cigars, the *Menthol Ban Scenario* is directly applicable.

8. Sensitivity Analyses

a. Menthol Simulation Sensitivity Analyses

Levy et al. (2021) conducted several sensitivity analyses in which the authors altered the assumptions in the baseline used for the Menthol Simulation, resulting in changes under both the *Status Quo* and *Menthol Ban* scenarios [88].[47] Increasing the ratio of menthol to non-menthol cessation from 0.8 to 1.0, in effect making menthol cigarettes no harder to quit than non-menthol cigarettes, had the greatest impact on the model estimates, resulting in decreasing avoided premature deaths averted by 29.5% and avoided life-years lost by 24.2%. Eliminating the 10% annual decline in cigarette-to-ENDS switching from the model, in effect increasing the appeal of ENDS beyond 'early adopter' birth cohorts, reduces deaths averted by 20.5% and life-years lost averted by 21.9%. Other sensitivity analyses include: increasing the overall smoking initiation rate by 10%; 10% absolute increases and decreases in the excess relative risk of ENDS products compared to cigarettes; and 10% relative changes in smoking cessation, ENDS initiation, and

[47] Each of these sensitivity analyses represent separate modeling runs by Levy et al. (2021) under different assumptions/conditions. The results should be considered independently.

ENDS cessation. These other sensitivity analyses resulted in modest (under 10%) changes to model-predicted avoided premature deaths and avoided life-years lost. Table 34 presents a comparison of these sensitivity analyses in terms of the relative difference from the base modeling results for the *Menthol Ban Scenario*.

Table 34. Avoided Premature Death and Avoided Life-Years Lost under Several Sensitivity Analyses

Description		Avoided Premature Deaths - Relative Difference from Base Modeling	Avoided Life-Years Lost - Relative Difference from Base Modeling
Assume the baseline menthol cigarette cessation rate is the same as non-menthol cigarette cessation rate		-29.50%	-24.20%
Reduce the baseline assumption of 10% reduction in ENDS switching rate each year to an assumption 0% decline in switching rate each year		-20.50%	-21.90%
Increase baseline overall smoking initiation rates by 10%		1.1%	2.0%
Assumed Baseline Health Harms of ENDS products	ENDS risk at 5% of cigarette-attributable excess mortality risk	5.00%	5.40%
	ENDS risk at 25% of cigarette-attributable excess mortality risk	-4.90%	-5.30%
Assumed Baseline Switching Rate to ENDS products	Reduce overall switching rate by 10%	2.40%	2.70%
	Increase overall switching rate by 10%	-2.40%	-2.60%
Assumed Baseline Smoking Cessation Rates	Reduce baseline overall smoking cessation rates by 10%	7.4%	5.9%
	Increase baseline overall smoking cessation rates by 10%	-6.80%	-5.60%
Assumed Baseline	Reduce baseline ENDS initiation rate by 10%	0.03%	0.1%

Description		Avoided Premature Deaths - Relative Difference from Base Modeling	Avoided Life-Years Lost - Relative Difference from Base Modeling
ENDS Initiation Rates	Increase baseline ENDS initiation rate by 10%	-0.03%	-0.1%
Assumed Baseline ENDS Cessation Rates	Reduce baseline ENDS cessation rate by 10%	-0.6%	-0.5%
	Increase baseline ENDS cessation rate by 10%	0.5%	0.5%

Adapted from Reference 88, p. 19.

b. Linear Interpolation of Menthol Simulation Results

As discussed in Section II.C.4.b, the main analysis adopts the two point estimates and the total, cumulative avoided premature deaths (647,128) provided by the Menthol Simulation and assumes a uniform distribution, with an average of 16,593 avoided premature deaths per year expected to occur over 2025-2063. However, as a sensitivity analysis, we only consider the number of "averted deaths" reported during 2026 and 2060 as endpoints (16,900 averted deaths in 2029 and 13,868 averted deaths in 2063, accounting for T21 Laws and the later effective date of the policy) and perform a linear interpolation to estimate benefits over intervening years.[48] We note that incorporating a simple linear interpolation between these two point estimates alone results in an estimate of averted deaths during the 40-year time horizon (538,436) that differs significantly from cumulative estimates presented in the Menthol Simulation. We present the results of the linear interpolation within Table 35.

[48] We note that Levy et al. (2021) present results from 2026 and 2060 in order "to display illustrative short-term and long-term status" [88].

Table 35. Estimated Annual Mortality Risk Reductions ("Averted Deaths") under Sensitivity Analysis, All Adjustments Incorporated

Year Count	Year	Estimated Annual Mortality Risk Reductions ("Averted Deaths," Linearly Interpolated)
Year 6	2029	16,900
Year 7	2030	16,811
Year 8	2031	16,722
Year 9	2032	16,632
Year 10	2033	16,543
Year 11	2034	16,454
…	…	…
Year 39	2062	13,957
Year 40	2063	13,868
Total (2023-2063)		538,436

Note: These estimates include effects for users and potential users of tobacco products only, and do not include effects to nonusers. Additionally, we assume that the policy will take effect in 2024 rather than 2021, as assumed by the Menthol Simulation (for example, impacts during 2026 will translate to 2029).

In order to monetize the estimated number of mortality risk reductions ("averted deaths") due to the assumptions of this section, we perform similar calculations as in Section II.C.4.b and apply VSL estimates to each respective year of reduced mortality risk within Table 35. We present a summarized comparison between the estimated monetized benefits for users and potential users of tobacco products under the main analysis and this sensitivity analysis in Table 36. These estimates do not include effects to nonusers.

Table 36. Comparison of Benefits, Sensitivity Analysis and Main Analysis ($2020, Billion)

Value of Mortality Risk Reductions		Discount Rate	Benefits ($2020, Billion)		
			Low	Primary	High
Present Value	Main Analysis	3%	$2,309	$4,955	$7,535
		7%	$1,250	$2,685	$4,081
	Sensitivity	3%	$1,853	$3,975	$6,046
		7%	$916	$1,966	$2,989
	Difference	*3%*	*($456)*	*($980)*	*($1,489)*
		7%	*($334)*	*($719)*	*($1,093)*
Annualized	Main Analysis	3%	$99	$212	$322
		7%	$93	$200	$305
	Sensitivity	3%	$79	$170	$258
		7%	$68	$147	$223
	Difference	*3%*	*($19)*	*($42)*	*($64)*
		7%	*($25)*	*($54)*	*($82)*

In addition to differing significantly from the cumulative results presented in the Menthol Simulation, we note that the linear interpolation in this sensitivity analysis implies mortality risk reductions ("averted deaths") do not occur before Year 6 (the first year explicit changes in estimates are reported by the Menthol Simulation results—see Table 22). However, the 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 [5]. For example, results from the Nurses' Health Study find reductions in heart disease and stroke mortality risk of 46% within 5 years, 61% in 5-10 years, and 58% for 10-15 years compared to reductions in lung cancer mortality risk of 34%, 53%, and 29% during these periods [170, Table 3]. The evidence is also sufficient to infer that the risk of stroke decreases after smoking cessation, and approaches that of never smokers over time [5]. We request comment on this sensitivity analysis, including annual data that would assist in refining the distribution of mortality risk reductions over time.

c. Monetizing Benefits at Year 40

In addition to the main analysis and the previous sensitivity analysis, we further explore the sensitivity of the assumptions in the main benefits analysis regarding the uncertainty of the timing of benefits monetization using an extreme example. To do so, we consider only the cumulative results (647,128 "averted deaths," adjusted for T21 Laws and updating to the timeline of the proposed menthol product standard) and monetize the total "averted deaths" over the 40-year time horizon in Year 40.

However, it is clear from the Menthol Simulation and scientific evidence that changes in mortality risk and avoided premature deaths will occur far earlier than Year 40. We note that the Menthol Simulation estimates averted deaths earlier in the time-horizon and spread out over the entire 40-year period, as indicated by the two available point estimates (17,088 "averted deaths" in 2026 and 14,022 "averted deaths" in 2060). As previously noted in Section II.C.8.b, the 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 [5]. The evidence is also sufficient to infer that the risk of stroke decreases after smoking cessation, and approaches that of never smokers over time [5]. Thus, this sensitivity analysis is only meant to explore the timing of the monetization of benefits.

We perform similar calculations as in Section II.C.4.c and apply VSL estimates (low, central, and high) presented in Table 27 during Year 40. A summarized comparison between the estimated monetized benefits for users and potential users of tobacco products under the main analysis and this sensitivity analysis is presented in Table 37. These estimates also do not include effects to nonusers. We request comment on this sensitivity analysis, including the timing of monetization of benefits.

Table 37. Comparison of Benefits, Sensitivity Analysis under Alternative Timing of Benefits Monetization and Main Analysis ($2020, Billion)

Value of Mortality Risk Reductions		Discount Rate	Benefits ($2020, Billion)		
			Low	Primary	High
Present Value	Main Analysis	3%	$2,309	$4,955	$7,535
		7%	$1,250	$2,685	$4,081
	Sensitivity	3%	$1,488	$3,194	$4,860
		7%	$324	$696	$1,059
	Difference	*3%*	*($821)*	*($1,761)*	*($2,674)*
		7%	*($926)*	*($1,990)*	*($3,022)*
Annualized	Main Analysis	3%	$99	$212	$322
		7%	$93	$200	$305
	Sensitivity	3%	$64	$136	$208
		7%	$24	$52	$79
	Difference	*3%*	*($35)*	*($75)*	*($114)*
		7%	*($69)*	*($149)*	*($226)*

9. Summary of Benefits

The primary present value quantified benefits of the proposed rule are approximately $5,428 billion with a 3% discount rate (lower bound $2,529 billion; upper bound $8,253 billion) and $2,941 billion with a 7% discount rate (lower bound $1,369 billion; upper bound $4,470 billion).

The primary annualized quantified benefits of the proposed rule are approximately $231.8 billion with a 3% discount rate (lower bound $108.0 billion; upper bound $352.5 billion) and $219.6 billion with a 7% discount rate (lower bound $102.2 billion; upper bound $333.7 billion). Table 38 and Table 39 summarize the quantified benefits of the proposed rule. The tables also present the unquantified benefits of the proposed rule.

Table 38. Summary of Present Value Quantified and Unquantified Benefits ($2020, Billion)

	Discount Rate	Present Value Lower Bound	Present Value Primary	Present Value Upper Bound
Value of Avoided Premature Deaths	3%	$2,309	$4,955	$7,535
	7%	$1,250	$2,685	$4,081
Reduction in Secondhand Smoke Associated Mortality from Lung Cancer & Cardiovascular effects	3%	$218	$468	$711
	7%	$118	$254	$385
Reduction in Infant Mortality	3%	$2	$5	$7
	7%	$1	$2	$4
Other Population Health Benefits from Reduced Cigarette Smoking	The reduction in cigarette smoking from this proposed product standard is also expected to result in decreased tobacco-related disease and illness and associated reductions in medical costs, reductions in productivity loss, and improvements in health-related quality of life.			
Reduction in Smoking Related Fires and Fire Damage	As the prevalence of cigarette smoking declines, we expect that the number of smoking-related fires would also decline.			
Reduction in Smoking Related Environmental Impacts	Reduction in prevalence would lead to less cigarette litter and associated harms to the environment.			
Total Quantified PV Benefits	*3%*	*$2,529*	*$5,428*	*$8,253*
	7%	*$1,369*	*$2,941*	*$4,470*

Table 39. Summary of Annualized Quantified and Unquantified Benefits ($2020, Billion)

	Discount Rate	Annualized Lower Bound	Annualized Primary	Annualized Upper Bound
Value of Mortality Risk Reduction from Avoided Premature Deaths	3%	$98.6	$211.7	$321.8
	7%	$93.3	$200.5	$304.7
Reduction in Secondhand Smoke Associated Mortality From Lung Cancer & Cardiovascular effects	3%	$9.3	$20.0	$30.4
	7%	$8.8	$18.9	$28.8
Reduction in Infant Mortality	3%	$0.1	$0.2	$0.3
	7%	$0.1	$0.2	$0.3
Other Population Health Benefits from Reduced Cigarette Smoking	The reduction in cigarette smoking from this proposed product standard is also expected to result in decreased tobacco-related disease and illness and associated reductions in medical costs, reductions in productivity loss, and improvements in health-related quality of life.			
Reduction in Smoking Related Fires and Fire Damage	As the prevalence of cigarette smoking declines, we expect that the number of smoking-related fires would also decline.			
Reduction in Smoking Related Environmental Impacts	Reduction in prevalence would lead to less cigarette litter and associated harms to the environment.			
Total Quantified Annualized Benefits	3%	$108.0	$231.8	$352.5
	7%	$102.2	$219.6	$333.7

D. Analysis of Costs

The proposed product standard prohibiting menthol as a characterizing flavor in cigarettes (including cigarettes that are HTPs), cigarette tobacco, RYO tobacco, and cigarette components and parts would create new costs for domestic manufacturers, wholesalers, and retailers of these tobacco products, as well as for foreign manufacturers or importers. Manufacturers,importers, wholesalers, and retailers are expected to read and review the proposed product standard to understand the requirements it includes. FDA expects manufacturers may face one-time costs associated with reallocation, friction, and adjustment in the market for

cigarette products, and may face on-going costs due to producer surplus loss over the 40 year time horizon under the proposed product standard. Consumers of affected tobacco products may face some search costs as they switch to other tobacco products when their usual product is removed from the market. FDA may face annual costs associated with enforcement of the proposed product standard. Qualitative costs may include changes in consumer surplus for some menthol cigarette product users, including potential utility changes for smokers of menthol cigarette products who switch from menthol to non-menthol cigarette products. We discuss these costs in further detail within the sections below.

1. Costs to Industry

a. Costs to Read and Understand the Rule

If finalized, all entities affected by this proposed rule would need to devote time to read and understand the rule, which would result in a one-time cost. The current preamble and codified of this proposed rule contain approximately 42,000 words combined. Consistent with HHS guidance, we assume that industry reviewers read at the average adult reading speed of approximately 200 words to 250 words per minute [158]. For the purposes of this analysis, we estimate 200 words per minute as our lower-bound, 250 words per minute as our upper-bound, and take the midpoint of this range (225) as our primary estimate. Thus, the time to read and understand the regulation would range from 2.80 to 3.50 hours and our primary estimate would be approximately 3.11 (=42,000/[225*60]) hours per person. We further assume that one to five people would read the proposed rule at each entity manufacturing, importing, or selling affected products – one person for our lower bound estimate, 3 for our primary estimate, and 5 people for our upper bound estimate.

To value the time associated with reading and understanding this proposed rule, we use composite wages calculated from the 2020 Bureau of Labor Statistics' (BLS) national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry and for the beverage and tobacco product manufacturing [171] [172].[49] We use a mix of 50% management occupations (occupation code 11-0000) and 50% legal occupations (occupation code 23-0000) [171] [172]. This mix yields a composite wage of $71.67 per hour.[50] We double this value to account for benefits and other indirect costs, yielding an hourly labor cost of $143.33 per hour [173].

We estimate the cost for one reviewer to read the proposed rule would be approximately $445.92 (=3.11*$143.33) on average. For our primary estimate associated with reading and understanding the proposed rule, we assume an average of three people from each affected entity would read the proposed rule and calculate approximately $1,337.75 (=3*$445.92) in costs for each affected entity. As previously discussed in Section II.B.2.c, we estimate that the proposed rule would affect 76 entities manufacturing or importing menthol cigarette products. Using Table 14 from our discussion of affected entities, we estimate that there are a total of 1,308 wholesalers and 138,096 (=139,404-1,308) retailers that sell tobacco products and would also be affected. Thus, we estimate 139,480 affected domestic entities (manufacturers, importers, wholesalers, and retailers) would experience approximately $186.6 million (lower bound $56.0 million ; upper bound $349.9 million) in total costs for reading and understanding the proposed rule. Table 40 includes a summary of these costs.

[49] The BLS did not publish wage estimates for legal occupations within the tobacco manufacturing industry in 2020. We use, instead, the legal occupation wage reported for the beverage and tobacco manufacturing industry (NAICS 312000).

[50] The management occupation average wage is listed at $64.99 per hour, and the legal occupation average wage is listed at $78.34 per hour. The calculation is 0.5*($64.99) + 0.5*($78.34) = $71.67 per hour.

Table 40. One-time Costs for Reading and Understanding the Proposed Rule (Year 0, $2020)

Inputs	Lower-Bound Estimated Value	Primary Estimated Value	Upper-Bound Estimated Value
Reading Time (Hours)	2.80	3.11	3.50
Composite Wage ($ per hour)	$143.33	$143.33	$143.33
Number of People Reading Per Entity	1	3	5
Cost per Entity	$401	$1,338	$2,508
Number of Affected Domestic Manufacturers & Importers	76	76	76
Number of Affected Domestic Wholesalers	1,308	1,308	1,308
Number of Affected Domestic Retailers	138,096	138,096	138,096
Total Affected Domestic Entities	139,480	139,480	139,480
Total Cost	$55,976,672	$186,588,905	$349,854,197

b. Reallocation, Friction, and Adjustment Costs for Manufacturers

To estimate the potential changes in manufacturing processes due to the proposed product standard, we first combine information from industry documents along with FDA subject matter expertise and experience from tobacco product manufacturer inspections to establish a baseline understanding of production processes for menthol cigarette products.

According to tobacco industry documents and FDA subject matter expertise, cigarette manufacturers obtain whole leaf tobacco bales from tobacco farmers [174]. As it is unlikely that the tobacco leaf suppliers (tobacco farmers) add menthol to cured tobacco leaves, we consider that menthol is generally added to cigarettes in one of several ways:

- During the tobacco filler blend manufacturing process, sprayed as a casing or a topping;
- Sprayed on at the end of the production process but before packing; or

- Added to a component (e.g., cigarette paper or filter) or as a component (menthol bead) within the cigarette.

Menthol may be added during tobacco filler blending, which generally requires several steps including leaf casing and cut filler topping. It is more likely that menthol is applied to the cut filler during tobacco blending, rather than applied to the un-cut tobacco as casing. For example, manufacturers may add menthol to cut filler as the top-dressing (or topping) in top-dressing drums [175].

Menthol can also be applied to cigarettes at the end of production, but before packing, using a menthol/ethanol spray that may also include additives such as propylene glycol. This spray solution can be applied to the cut tobacco filler while on a duct or conduit using a moving menthol stream [176]. The mentholated cut filler is then fed into cigarette machines approximately 12-24 hours after the top-dressing is applied [176].

Cigarette manufacturers may also apply menthol to non-tobacco components of cigarettes. Application may be done by spraying the menthol solution onto the inner foil of the packaging material of cigarette boxes [174]. Menthol can be applied to other components of cigarettes—such as the cigarette paper and filter [174]—or added to the filter component through use of mentholated tipping papers or plug wraps. Techniques used by cigarette manufacturers for incorporating menthol into cigarettes have involved the use of microencapsulated menthol, capsulized menthol, and mentholated filaments, some of which provide smokers themselves a way of releasing menthol into the cigarette [176]. Manufacturers may also use menthol derivatives as ingredients in cigarettes which, upon heating, decompose and release menthol into the smoke stream [176].

Based on our review of available documents, inspection reports, and industry submitted materials, we also find similar processes for adding menthol to other cigarette products, such as cigarettes that are HTPs and RYO tobacco. Menthol may be added to the filters as a menthol thread, cigarette paper, and/or reconstituted tobacco sheet during production, or a menthol solution may be added to other components or parts for cigarettes that are HTPs. The production of RYO follows processes like that for cigarette tobacco filler, with menthol added during the topping step of production, sprayed on prior to packaging, or from mentholated non-tobacco materials. We do not expect RYO tobacco to be flavored by capsules, decomposing rods, filaments, or other novel techniques for introducing menthol, as RYO tobacco is sold in loose form for incorporation in cigarettes rolled by consumers. Some small cigarette tobacco product manufacturers also purchase cut tobacco or cigarette components that are already mentholated. We request comment on baseline production processes for cigarette products with menthol as a characterizing flavor, including techniques for adding menthol to tobacco blends and cigarette components.

Information gathered from FDA manufacturer inspections reflects that most manufacturers use the same equipment for both menthol and non-menthol cigarette production, with line operators required to clean equipment between production runs. In response to the proposed product standard prohibiting menthol as a characterizing flavor in cigarette products, we expect manufacturers to transition their business towards non-menthol cigarettes and other tobacco products. Any such changes would be characterized by both costs and cost savings.

Costs may take the form of time needed to plan and implement cleaning and reallocation procedures for cigarette production lines, while cost savings may be generated from reduced ingredient and component purchases and fewer hours spent on cleaning menthol-related

contaminants. Using assumptions and available data, we estimate costs for manufacturers and discuss cost savings qualitatively.

As we note in Section II.B.2.c.i, our analysis of TRLM data suggests that manufacturers of currently marketed menthol cigarettes (including cigarettes that are HTPs), RYO tobacco, and components and parts also manufacture non-menthol versions, often within the same brand. Therefore, we expect affected manufacturers may incur some one-time adjustment costs as they spend time reallocating resources to produce non-menthol cigarettes and other tobacco products or reduce production capacity in response to the overall reduction in cigarette product demand. We assume that all entities affected by this proposed rule would face one-time reallocation costs in Year 0 (2023).

Information from FDA subject matter experts suggests that production line cleaning between menthol and non-menthol cigarette products may take approximately 2-4 hours (including, for example, rinsing with an alcohol-water solution and drying). Using this information, we estimate that, at minimum, planning and performing production line reallocation and cleaning activities would take 40 hours. From Section II. B.2.c, there are 43 domestic manufacturing establishments of menthol cigarette products and related cigarette components and parts that may face these one-time costs.

To value the time to plan and implement reallocation procedures for those cigarette product lines affected by the proposed rule, we use composite wages calculated from the 2020 Bureau of Labor Statistics' national industry-specific occupational employment and mean wage estimates for the tobacco manufacturing industry [171]. We assume a mix of 20% upper management occupations (occupation code 11-1000), 70% middle management occupations (occupation code 11-1021), and 10% administrative occupations (occupation code 43-0000).

This mix yields a composite wage of $53.59 (0.2*($64.96) + 0.7*($54.82) + 0.1*($22.19) = $53.59). We double this to account for benefits and other indirect costs, yielding an hourly labor cost of $107.17.

Multiplying the hourly labor cost by the assumed number of hours, we estimate that, at minimum, each cigarette tobacco product manufacturer could incur one-time costs of approximately $4,287. As shown in Table 41, the lower bound cost we estimate for affected entities to adjust production of cigarette products is approximately $184,332. We request comment on these assumptions and calculations, as well as the time it may take manufacturers to plan and perform cigarette production line reallocation and cleaning activities.

Table 41. Lower Bound, One-time Costs for Altering Cigarette Production, (Year 0, $2020)

	Lower-Bound Estimate Value
Hours	40
Wage ($ per hour)	$107.17
Cost per entity	$4,286.80
Number of domestic manufacturing entities	43
Total cost	$184,332

Affected entities may also respond to the proposed rule by planning and implementing procedures for one-time costs related to disposition of capital equipment. We assume these costs represent a percentage of current menthol cigarette product manufacturer revenues. To estimate this percentage, we look to data from the U.S. Census Bureau's 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 [177]. ACES reports that capital expenditures during 2010-2019 in the overall tobacco manufacturing industry ranged from $325 million to $511 million, with a 10-year average of $402 million. As outlined in Table 42, we compare the annual estimates of total capital expenditures in each year to total dollar sales in the tobacco industry to estimate annual

capital expenditures as a percent of annual dollar sales. This percentage ranges from 0.28% to 0.47%, with a 10-year average of 0.36%.

Table 42. Capital Expenditures in the Tobacco Manufacturing Industry (NAICS 3122, $Million)

Year	Capital Expenditures ($Millions)			Tobacco Industry Dollar Sales, Excluding ENDS (EMI, $Million)[2]	Capital Expenditures as a Percent of Dollar Sales
	Structures	Equipment	Total[1]		
2010	$94	$330	$424	$105,546	0.40%
2011	$91	$295	$387	$107,318	0.36%
2012	$52	$290	$342	$109,038	0.31%
2013	$62	$328	$390	$108,886	0.36%
2014	$65	$445	$511	$108,798	0.47%
2015	$176	$284	$460	$112,515	0.41%
2016	$86	$240	$325	$114,650	0.28%
2017	$105	$275	$381	$116,785	0.33%
2018	$101	$230	$331	$117,785	0.28%
2019	$77	$389	$466	$117,309	0.40%
10-Year Average	$91	$311	$402	$111,863	0.36%

Source: Reference 177 and Reference 69

[1] Totals do not add due to rounding.

[2] We exclude ENDS dollar sales from total EMI tobacco industry dollar sales for consistency in calculations. Capital expenditures under NAICS code 3122 do not include expenditures by firms manufacturing electronic cigarettes or associated refills.

As we are unable to estimate what portion of the capital expenditures reported by ACES are solely related to cigarette manufacturing, or specifically to menthol cigarette product manufacturing, we assume that annual capital expenditures by menthol cigarette product manufacturers are similar to those of the overall tobacco market. In Section II.E.3 (Transfers), we estimate menthol cigarette product-specific dollar sales (revenues) over the 40-year time horizon used for analysis of this proposed product standard. Using the highest ratio of capital expenditures for the tobacco manufacturing industry from Table 42 (0.47%) and menthol cigarette product sales in Year 0 (2023) from Table 20 ($33,465 million), we estimate baseline, maximum annual capital expenditures associated with the production of menthol cigarette products in Year 0 in Table 43 ($157.3 million).

Table 43. Maximum, Annual Capital Expenditures for Menthol Cigarette Products

	Estimate
Tobacco Manufacturing Capital Expenditures as a Percent of Dollar Sales (max)	0.47%
Year 0 (2023) Menthol Cigarette Product Dollar Sales ($2020, Millions)	$33,465.8
Estimated, Maximum Capital Expenditures for Menthol Cigarette Products (2020$, millions)	$157.3

We note the uncertainty associated with one-time costs to adjust production, such as potentially requiring additional labor, disposing of current equipment, or purchasing new equipment for the manufacture of tobacco products other than menthol cigarette products. To account for this uncertainty, we assume that manufacturers may either need to dispose of or acquire equipment and estimate primary and upper bound costs for reallocation, friction, and adjustments based on maximum annual acquisition of equipment and structures by cigarette product manufacturers. As a primary estimate, we multiply our estimate of maximum annual capital expenditures for menthol cigarette products ($157.3 million, Table 43) by 150%. As an upper bound, we multiply this same estimate of maximum annual capital expenditures for menthol cigarette products by three. Table 44 presents the full range of one-time adjustment costs, using hours associated with planning and performing cigarette production line reallocation and cleaning activities as the lower bound and three times maximum annual capital expenditures for menthol cigarette products as the upper bound.

Table 44. Summary of One-Time Reallocation, Friction, and Adjustment Costs, (Year 0, $2020)

	Lower-Bound Estimate Value	Primary Estimate Value[1]	Upper-Bound Estimate Value[2]
Total cost	$184,332	$235,933,594	$471,867,189

However, we note that firms may be able to repurpose or reallocate capital to manufacture other tobacco products or continue to domestically manufacture menthol cigarette products for export to foreign countries. We request comment and data on the extent to which menthol cigarette manufacturers may shutdown production lines, rather than repurpose them, requiring potential disposition of equipment including through resale.

For some manufacturers, the proposed product standard may result in reduced production costs instead. Costs related to cleaning equipment between production cycles and associated downtime may be reduced for manufacturers that currently produce menthol and non-menthol cigarette products using the same production lines. We request comment and data on time for cleaning production equipment and other associated tasks that may be reduced under this proposed product standard.

Concurrently with this proposed rule, FDA is proposing a product standard rule restricting the use of characterizing flavors, other than tobacco flavor, in cigars. Qualitative analysis of the interaction between the two proposed rules suggests that some efficiencies in compliance would be realized for those entities who manufacture flavored cigars in addition to menthol cigarette products.

c. Wholesalers and Retailers of Menthol Cigarette Products

The proposed product standard prohibiting menthol as a characterizing flavor in cigarette products may also have impacts on wholesalers and retailers of menthol cigarette products. We do not estimate a friction cost to wholesalers or retailers as this product standard will not impact the use of their productive resources. Prior to the effective date of the proposed standard, wholesalers, retailers and related entities may continue to sell available stock of menthol cigarette products. With many retailers under contract to provide dedicated shelf space for

tobacco products, we expect that retailers will be stocked by wholesalers and distributors with other tobacco products to fill the shelf space previously reserved for menthol cigarette products.[51]

In Section II.E, we analyze the amount of cigarette product revenues that transfer back to consumers who would have otherwise purchased menthol cigarette products in absence of the rule. These revenue transfers include retailer margins that would have accrued to retailers of menthol cigarette products in the absence of the proposed rule. Some consumers are expected to use the transferred value to purchase non-menthol cigarette products and other tobacco products. These transfers may result in tobacco product purchases from the same retailers that previously sold menthol cigarettes products. Consumers who quit use of tobacco products (or do not initiate) under this proposed product standard are expected to use the transferred value to purchase other non-tobacco goods. These purchases of other, non-tobacco goods may result in revenues for the same wholesalers and retailers that previously sold menthol cigarette products or may create new revenues for different wholesalers and retailers.

For these reasons, and to avoid double counting in our analysis of transfers, we do not separately estimate the impacts of changes in wholesale and retail sales and associated wholesale and retail margins under this proposed product standard. We request comment and data on the extent to which retailers would need to renegotiate contracts with tobacco product manufacturers; how often such contracts are renewed at baseline; the portion of the current retail price of menthol cigarettes that is attributable to wholesale and retail margin (i.e., wholesale or

[51] "These tobacco company incentive programs require retailers to follow specific product placement and advertising placement for the manufacturer's specific brands." United States District Court for the District of Columbia, *Plaintiffs' 2018 Supplemental Brief On Retail Point Of Sale Remedy, United States v. Philip Morris USA, Inc.*, in *Civil Action No. 99-CV-2496* 2018, United States District Court For The District Of Columbia; District Of Columbia.

retail mark-up); information on how these margins compares to margins for non-menthol cigarettes, other tobacco products, and non-tobacco goods sold by wholesalers and retailers that currently sell menthol cigarette products; and potential changes in net wholesale and retail trade margins attributable to the proposed rule.

d. Changes in Producer Surplus

Menthol cigarette product manufacturers may experience a change in producer surplus as a result of this proposed product standard. In Section II.E.3, we estimate the amount of revenue that will transfer from producers and importers of cigarette products back to consumers who previously purchased menthol cigarette products. Although such transfers of revenue generally encompass producer surplus, we separately estimate changes in producer surplus for suppliers of cigarette products in this section in isolation.

Producer surplus is the difference between the market price a producer receives for its product and the minimum price it would accept. In this analysis, we seek to estimate the amount of producer surplus associated with a projected decline in cigarette consumption. Utilizing estimates from the Section II.B.3 (Baseline) and the Section II.E.3 (Transfers), we base our calculations of changes in producer surplus on firm revenue (less excise taxes), the elasticity of supply, and the percent change in quantity of cigarette products sold in the market.

Depending on how the market is defined, the cigarette industry could be considered concentrated. Previous empirical research has estimated the supply elasticity of tobacco at 7.0 [178]. We adopt this supply elasticity of 7.0 to calculate the change in producer surplus associated with the decrease in consumption expected to result from the proposed rule. Price elasticity of supply measures the responsiveness of an industry to changes in demand for its product and is based on the relationship between quantity produced and the minimum price

producers accept for that quantity, with quantity and price typically moving in the same direction. For example, an increase in quantity demanded is typically associated with an increase in the minimum price accepted and an associated increase in the market price.

However, 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 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 [179]. 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 government policies [13] [180] [181].[52,53,54] This evidence suggests that cigarette product manufacturers may respond to the proposed product standard by retaining or increasing market prices, regardless of changes in their minimum price accepted.

As a primary estimate of the producer surplus change in the market for cigarette products under this proposed rule, we calculate the portion of producer surplus bounded by the change in quantity demanded and the elasticity of supply. Together the change in quantity demanded and

[52] See SGR 2012 [13], 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/.

[53] "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)." [180, page 31]

[54] "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)." [181, page 702]

the elasticity of supply determine the change in minimum price accepted. We treat this estimated value as producer surplus loss for cigarette product manufacturers under the proposed rule. However, this calculation does not account for potential changes in the market price of cigarette products.

Let Q* and P* denote the baseline quantity for cigarette products and market price for cigarette products, respectively, and Q` denotes the new quantity of cigarette products sold under the proposed rule. We let P` represent the new minimum price a producer would accept at production level Q`. We calculate the loss associated with producer surplus in the cigarette product market as:

$$Producer\ Surplus\ Loss_{Cigarette\ mark} = \left(\frac{1}{2}\right) \times \Delta P \times \Delta Q$$

where ΔQ represents the change in quantity sold, in response to the proposed product standard, and ΔP represents the difference between the current market price for cigarette products and the minimum price producers would accept at production level Q`.

Let $\%\Delta Q$ represent the percentage reduction in the quantity of cigarette products supplied to the market following the proposed product standard. Thus, the new quantity of cigarette products supplied is given by:

$$Q` = (1 - \%\Delta Q) \times Q^*$$

Similarly, we let $\%\Delta P$ represent the percentage difference between the current market price and the new minimum accepted price for producers. Therefore, the new minimum accepted price for cigarette products is given by:

$$P` = (1 - \%\Delta P) \times P^*$$

Hence, we find $\Delta P\ and\ \Delta Q$ are:

$$\Delta P = P^* - P` = P^* - (1 - \%\Delta P) \times P^* = (\%\Delta P) \times P^*$$

$$\Delta Q = Q^* - Q` = Q^* - (1 - \%\Delta Q) \times Q^* = (\%\Delta Q) \times Q^*$$

The price elasticity of supply is given by the following formula:

$$\varepsilon_S = \frac{\%\ Change\ in\ Quantity\ Produced}{\%\ Change\ in\ Minimum\ Price\ Accepted} = \frac{\%\Delta Q}{\%\Delta P}$$

Under the proposed rule, some previous consumers of menthol cigarette products are expected to switch to non-menthol cigarette products. These purchases, along with their associated revenues and producer surplus, would stay within the market for cigarette products. Instead, we estimate the remaining amount of producer surplus in the current menthol cigarette product market that would be lost by cigarette product producers and importers. As discussed in Section II.E.3 (Transfers), we assume a maximum of 67.0% of current menthol cigarette product users would transition away from the cigarette product market. Menthol cigarette product volume sales represent approximately 35% of overall product cigarette volume sales (from Table 19). Using these percentages, we estimate that the percentage reduction in quantity of cigarette products demanded in the market as:

$$\%\Delta Q = (\text{Menthol \% of Cigarette Product Volume Sales}) \times (\text{\% of Menthol Smokers Leaving Cigarette Product Market})$$

$$\%\Delta Q = 35\% \times 67.0\% = 23.4\%$$

Thus, since we assume the price elasticity of supply is 7, we find that:

$$\%\Delta P = \frac{\%\Delta Q}{7} = \frac{23.4\%}{7} = 3.3\%$$

Therefore, the primary estimate of producer surplus loss is given by:

$$Producer\ Surplus\ Loss_{Cigarette\ market} = \left(\frac{1}{2}\right) \times \Delta P \times \Delta Q$$
$$= \left(\frac{1}{2}\right) \times [(\%\Delta P) \times P^*] \times [(\%\Delta Q) \times Q^*]$$
$$= \left(\frac{1}{2}\right) \times [(\%\Delta P) \times (\%\Delta Q)] \times [P^* \times Q^*]$$
$$= \left(\frac{1}{2}\right) \times [(\%\Delta P) \times (\%\Delta Q)] \times [\text{ Cigarette Product Revenue}_{\text{without rule}}]$$
$$= \left(\frac{1}{2}\right) \times [(3.4\%) \times (23.5\%)] \times [\text{Cigarette Product Revenue}_{\text{without rule}}]$$

In Section II.B.2.f.iv (Projected Cigarette Product Sales, 40-Year Time Horizon), we estimate baseline sales (revenues) in the cigarette product and menthol cigarette product market over the 40-year time horizon used in analysis of this proposed rule. Similarly, we estimate baseline Federal and State excise tax revenues from menthol cigarette products over the 40-year time horizon in Section II.B.3. From these sections, we use the estimates in Table 20 (baseline revenues) and Table 21 (baseline excise taxes) and subtract baseline total Federal and State excise tax revenues from baseline menthol cigarette product revenues in each year to generate annual estimates of menthol cigarette product revenues, exclusive of Federal and State excise taxes. We summarize this adjustment in Table 45.

Table 45. Baseline Industry Revenue Projections for Menthol Cigarette Products, With and Without Excise Taxes ($2020 Billion, undiscounted)

Year Count	Year	Total Cigarette Product Revenue (Billion)[1]	Menthol Cigarette Product Revenue (Billion)[1]	Total Menthol Cigarette Product Excise Tax Revenue (Billion)[2]	Total Menthol Cigarette Product Revenue, Exclusive of Excise Taxes (Billion)[3]
Year 0	2023	$96.0	$33.5	$10.3	$23.2
Year 1	2024	$96.5	$33.6	$9.9	$23.7
Year 2	2025	$97.0	$33.8	$9.5	$24.3
Year 3	2026	$97.0	$33.8	$9.5	$24.3
Year	2027	$97.0	$33.8	$9.5	$24.3
Year 5	2028	$97.0	$33.8	$9.5	$24.3
	…	…	…	…	…
Year 39	2062	$97.0	$33.8	$9.5	$24.3
Year 40	2063	$97.0	$33.8	$9.5	$24.3

[1] Total Cigarette Product and Menthol Cigarette Product Revenues (Sales) from Table 20.
[2] Total menthol cigarette product excise tax revenues calculated as annual baseline Federal excise tax revenue + annual baseline State excise tax revenue from Table 21.
[3] Total menthol cigarette product revenues, exclusive of excise taxes, are calculated by subtracting total menthol cigarette product excise tax revenues from menthol cigarette product revenues.

This estimate of market revenue excluding excise taxes may be further split between manufacturers, distributors, and retailers; however, we expect that manufacturers capture the largest portion of this revenue and assume menthol cigarette product revenues, exclusive of excise taxes, represent manufacturer revenues. We use these revenue estimates as cigarette product revenues in absence of the proposed product standard. Since the proportion of baseline cigarette dollar sales attributable to menthol cigarette products in Table 19 is approximately 35%, we calculate:

$$\text{Cigarette Product Revenue}_{\text{without rule}} = \frac{\text{Menthol Cigarette Product Revenue}_{\text{without rule}}}{35.0\%}$$

We use total cigarette product revenue over the 40-year period and calculate producer surplus loss corresponding to each year of projected cigarette product revenue. We summarize the results of these calculations in Table 46.

Table 46. Primary Estimation of Producer Surplus Loss for Menthol Cigarette Products ($2020 Million, Undiscounted)

Year Count	Year	Menthol Cigarette Manufacturer Revenue (excluding excise tax)	Producer Surplus Loss[1] (Primary)
Year 0	2023	$23,178.90	$0.00
Year 1	2024	$23,744.08	$0.00
Year 2	2025	$24,309.27	$272.51
Year 3	2026	$24,309.27	$272.51
Year 4	2027	$24,309.27	$272.51
Year 5	2028	$24,309.27	$272.51
...	…	…	…
Year 39	2062	$24,309.27	$272.51
Year 40	2063	$24,309.27	$272.51

[1]Primary Producer Surplus Loss = Total Manufacturer Revenue (Menthol, no excise tax) * (1/2) * (3.4 %) * (23.4% / 35%). We note estimates presented within this table are based on exact values and may differ slightly from rounded calculations.

As a lower bound, we adopt the simplifying assumption used in some recent economics literature [182] that supply is perfectly elastic at the current market price. A perfectly elastic supply curve implies that the quantity of cigarettes supplied to the market will adjust to any quantity demanded at the observed market price (i.e. market price remains constant). Because the supply curve overlaps the pre-tax market price, the baseline producer surplus equals zero when the supply curve is perfectly elastic. Under these assumptions, the lower bound for producer surplus loss for each year would be zero.

As previously discussed, it is uncertain how producers of cigarette products would respond to the proposed product standard. If we assume the market price for cigarette products decreases under the proposed product standard, as in a typical market, the producer surplus loss would be larger than our primary estimate. Although we note that this assumption is not in-keeping with evidence regarding market prices in the cigarette market, we double our primary estimate of producer surplus loss as an upper bound. We present the full range of undiscounted estimates within Table 47.

Table 47. Estimation of Producer Surplus Loss for Menthol Cigarette Products ($2020 Million, Undiscounted)

Year Count	Year	Lower	Primary	Upper[1]
Year 0	2023	$0.00	$0.00	$0.00
Year 1	2024	$0.00	$0.00	$0.00
Year 2	2025	$0.00	$272.51	$545.01
Year 3	2026	$0.00	$272.51	$545.01
Year 4	2027	$0.00	$272.51	$545.01
Year 5	2028	$0.00	$272.51	$545.01
...	…	…	…	…
Year 39	2062	$0.00	$272.51	$545.01
Year 40	2063	$0.00	$272.51	$545.01
Total		$0.00	$10,627.75	$21,255.50

[1]The upper bound estimate for producer surplus loss is taken as double the primary estimate for each year.

We then discount the stream of lost producer surplus presented within Table 47 using 3% and 7% discount rates. The primary present value of total producer surplus loss from this proposed product standard is approximately $6.0 billion at a 3% discount rate (low $0; high $12.1 billion), and approximately $3.4 billion at a 7% discount rate (low $0; high $6.8 billion). The primary annualized value of lost producer surplus from this proposed product standard is approximately $0.3 billion at a 3% discount rate (low $0; high $0.5 billion), and approximately $0.3 billion at a 7% discount rate (low $0 billion; high $0.5 billion). These estimates of present and annualized value for lost producer surplus from this proposed product standard are summarized in Table 48. For the full stream of undiscounted producer surplus loss over time, see Appendix 0.

Table 48. Present and Annualized Values of Producer Surplus Loss ($2020, Million)

Category	Discount Rate	Low	Primary	Upper
Undiscounted Value of Producer Surplus Loss	N/A	$0.00	$10,627.75	$21,255.50
Present Value of Producer Surplus Loss	3%	$0.00	$6,034.36	$12,068.71
	7%	$0.00	$3,378.30	$6,756.60
Annualized Value of Producer Surplus Loss	3%	$0.00	$257.74	$515.48
	7%	$0.00	$252.22	$504.44

This analysis relies 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 only assesses one point in the supply chain. There may be additional changes in producer surplus at other points in the supply chain. The degree to which intermediaries in the market experience changes in surplus depends on market structure and integration.

For this analysis, we assume a maximum of 67.0% of current menthol cigarette smokers would transition away from the cigarette product market. We explore other scenarios of transitions away from the cigarette product market (41% and 59% transfer) under this proposed rule in Section II.E.3 (Transfers) and note that these alternative transition scenarios would result in lower producer surplus loss. Our analysis of changes in producer surplus also focuses solely on the market for cigarette products, presenting a partial analysis from the perspective of cigarette product manufacturers instead of a more general analysis that considers impacts across the entire economy. We note that the estimates of lost producer surplus in the preceding tables do not include adjustments to account for consumers who switch to other tobacco products (ENDS,

for example) made by the same firms that currently manufacture menthol cigarette products. Given the high level of concentration in the tobacco market, portions of lost producer surplus in the market for menthol cigarette products may return to the same producers through the purchase of other tobacco products. Further, consumers who cease tobacco product use are expected to purchase other goods and services, resulting in transfers of revenue from cigarette producers back to consumers and then on to other sectors of the economy. This shift would result in reduced producer surplus for cigarette manufacturers and importers, but increased revenues and associated producer surplus for other industries. We request comment on assumptions used in this analysis of producer surplus, including detailed data on the elasticity of supply in the cigarette product market, market structure and vertical integration, and the resulting price impacts of this of this proposed standard. We also request comment on overall revenue transfers estimated in Section II.E.3.

2. Costs for Premarket Review of New Tobacco Products

As we note in Section II.B.2.c.i, our analysis of TRLM data suggests that manufacturers of currently marketed menthol cigarettes (including cigarettes that are HTPs), RYO tobacco, and components and parts also manufacture non-menthol versions, often within the same brand. Therefore, we do not expect that manufacturers would modify their currently-marketed menthol cigarette products rather than remove them from the market and do not estimate additional costs for premarket review of such modified products under this proposed rule. Although demand for other, currently marketed tobacco products may increase as a result of this proposed product standard, we do not estimate a marginal change in the number of new tobacco products seeking premarket reviews under this proposed product standard. However, we request comment on the extent to which manufacturers would modify current menthol cigarette products to remove the

characterizing flavor and seek to reintroduce such products to the market. We also request comment on the extent to which other tobacco products may seek premarket review for new products introduced solely in response to the proposed product standard.

3. Consumer Costs

a. Cost of Searching for Other Tobacco Products

While some current menthol tobacco product users are expected to stop using tobacco products following the effective date of the proposed standard, and some youth and young adults are projected to avoid initiation of tobacco product use altogether (see Section II.C.3), others may switch to use of other tobacco products. These other tobacco products may include non-menthol versions of the previously purchased product (non-menthol cigarettes from the same brand), or non-cigarette tobacco products such as smokeless tobacco or electronic nicotine delivery systems (ENDS). As they seek other tobacco products, we assume these consumers may face search costs during the first two years (transition period from Menthol Simulation) following the effective date of the proposed standard [88]. Search costs may include the time it takes a former menthol cigarette smoker to research substitute products, including talking to other tobacco product users, searching for reviews on the internet and social media, and reviewing tobacco product packages in the store.

As a consequence of this proposed product standard, we assume the entire population of current menthol smokers will engage in search for replacement tobacco products. In order to account for T21 Laws, we further restrict the population of searchers to individuals ages 21 and older. Using 2019 NSDUH data, we estimate that there were 17,485,568 current menthol

smokers (past 30-day use) aged 21 and older [71].[55] Transitions from menthol cigarette smoking to use of other tobacco products are expected to occur in the first two years following the implementation of a *Menthol Ban* [152]. We, therefore, assume that the number of current menthol cigarette smokers aged 21 and older searching for other tobacco products would be distributed evenly between the first two years following the effective date of the proposed product standard (i.e., 9.0 million current menthol smokers aged 21 and older may search each year over Years 2 and 3).

The amount of time a consumer may spend searching when switching from one tobacco product category to another depends on several factors, including the availability and visibility of other tobacco products in local tobacco retail markets and online websites. Although tobacco products users may search for other tobacco products at any time and for any reason, we estimate that this search process may take between 30 minutes and 90 minutes per current menthol smoker and occur one additional time following the proposed product standard.

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 ASPE report on "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices" [173]. We start with a measurement of the usual weekly earnings of wage and salary workers of $990. We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.75. We adjust this hourly rate downwards by an effective tax rate of about 17%, resulting in a post-tax hourly wage rate of $20.55. By multiplying our annual estimate of current menthol smokers aged 21 and older by the estimated

[55] In order to account for complex survey design, analytical weights are used to create national estimates from NSDUH data. The unweighted count of current (past 30-day) menthol smokers aged 21 and older was n=3,528.

range for search time (range of 30 minutes to 90 minutes, 60 minutes primary) and a $20.55 per hour wage rate, we estimate that the proposed rule may result in approximately $359.3 million (primary, undiscounted) in consumer search costs, spread evenly over the first two years following the effective date of the proposed rule. [56] These estimates are presented in Table 49.

Table 49. Undiscounted Consumer Search Costs Over Time ($2020, Millions)

Year Count	Year	Searching Population[1]	Search Costs ($2020, Million)		
			Lower Bound (30 minutes)	Primary (60 minutes)	Upper Bound (90 minutes)
Year 1	2024	-	-	-	-
Year 2	2025	8,742,784	$89.8	$179.7	$269.5
Year 3	2026	8,742,784	$89.8	$179.7	$269.5
Year 4	2027	-	-	-	-
Year 5	2028	-	-	-	-
Year 6	2029	-	-	-	-
…	…	…	…	…	…
Year 39	2062	-	-	-	-
Year 40	2063	-	-	-	-
Total		17,485,568	$179.7	$359.3	$539.0

[1] Searching population includes former menthol cigarette product users aged 21 and older who may search for new tobacco products as a result of the proposed rule.
Note: Estimates may not add, due to rounding.

The primary present value of search costs is approximately $314.6 million at 3% discount (lower bound $157.3 million; upper bound $471.9 million) and $265.6 million at 7% discount (lower bound $132.6 million; upper bound $397.7 million). The primary annualized value of search costs is approximately $13.3 million at 3% discount (lower bound $6.6 million; upper bound $19.9 million) and $19.7 at 7% discount (lower bound $9.9 million; upper bound $29.6 million). Table 50 presents these estimates.

[56] As a sensitivity analysis, we assess the search cost with the augmented post-tax wage rate to account for non-wage benefits by doubling the wage. Using this wage rate of $25.10, the search costs would be $438.9 million with a lower bound of $219.4 million and an upper bound of $658.3 million (undiscounted).

Table 50. Present and Annualized Value of Consumer Search Costs at 3% and 7% (2023-2063, $2020 Million)

Category	Discount Rate	Total Search Costs ($2020, Million)		
		Lower Bound	Primary	Upper Bound
Undiscounted Search Costs	N/A	$179.7	$359.3	$539.0
Present Discounted Value of Search Costs	3%	$157.3	$314.6	$471.9
	7%	$132.6	$265.2	$397.7
Annualized Value of Search Costs	3%	$6.6	$13.3	$19.9
	7%	$9.9	$19.7	$29.6

While we estimate search costs for all current menthol smokers, menthol smokers, across several surveys, have said that if menthol cigarettes were no longer available, they would consider quitting smoking altogether [183] [184] [185] [186] [187] [188] [210]. Some studies evaluating the impact of Canada's laws prohibiting the sale of menthol tobacco products have found increased reports of quit attempts and quitting smoking following policy implementation [141] [142] [143] [144]. Consumers that cease use of tobacco products are also likely to replace tobacco product purchases with savings or purchases of other goods they already consume.

As part of the expert elicitation, Levy et al. (2021) asked "experts to consider dual users of cigarettes with other products as exclusive cigarette users" [152]. Thus, current dual users (menthol cigarettes + other tobacco products) may already be familiar with other tobacco products. Additionally, current menthol cigarette smokers may switch to non-menthol cigarette products marketed under the same brand names, reducing search costs. We request comment on search costs, wage rate assumptions, and related calculations.

b. Utility Changes for Consumers

Regulations that reduce the demand for a product or that raise its market price may lead to reductions 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 his or her 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 [189]. 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 cigarette smokers, the concept of consumer surplus, or consumer utility, is premised on the assumptions that smokers are rational in their decision-making about smoking, fully informed about the associated risks associated with smoking, and derive benefit from smoking above the price they pay. 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.

In general, economic research has recognized significant challenges with modeling demand for tobacco products and associated changes in utility. These challenges are compounded in the context of menthol-flavored tobacco products because menthol in cigarettes enhances nicotine addiction through a combination of its flavor, sensory effects, and interaction with nicotine in the brain, facilitating repeated experimentation with cigarettes and progression to regular smoking, which repeatedly exposes the brain to nicotine [1] [190]. These potential challenges include:

- the addictive nature of tobacco products and the role of menthol plays in enhancing the effects of nicotine;

- cigarette smoking initiation during adolescence, when the brain is not yet fully developed, and how menthol as a characterizing flavor affects youth appeal;
- the developing nature of public awareness 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 current smokers, desire to quit, and menthol's impact on quitting.

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

i. Addictive Nature of Tobacco Products

Tobacco use is the leading preventable cause of disease and death in the United States [3]. Cigarettes, like other tobacco products, contain the highly addictive substance nicotine, and menthol has been shown to enhance the effects of nicotine (See Section IV.D of the Preamble of this proposed rule). Summarizing years of research and analysis in the field of smoking and tobacco product use, numerous SGRs from 1988 through 2020 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."[57] 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" [6]. Speaking specifically to behavior and patterns of use, the report notes that "[p]atterns of tobacco use are regular and compulsive, and a withdrawal syndrome usually accompanies tobacco abstinence" [6]. Most recently, 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" [5]. As discussed in the Preamble of this proposed rule, menthol's flavor, sensory effects, and interaction with nicotine in the brain plays a role in making it easier to experiment, progress to regular smoking and dependence, and harder to quit smoking.

The National Institute on Drug Abuse (NIDA) includes tobacco and nicotine among commonly used drugs, stating that "nicotine acts in the brain by stimulating the adrenal glands to release the hormone epinephrine (adrenaline) and by increasing levels of the chemical messenger dopamine," and that "for many who use tobacco, brain changes brought on by continued nicotine exposure result in addiction" [191] [192]. As DiFranza et al. (2002) discuss, the onset of nicotine dependence is "the point of experiencing loss of autonomy over tobacco use" [193]. Multiple studies have shown that symptoms of nicotine dependence can arise early after youth start smoking cigarettes, even among infrequent users [19] [194] [195] .[58]

[57] 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" [6 at p.7-8].

[58] The 1988 SGR 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.

The research presented above shows that cigarette 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 demand, meaning that determining the point at which addiction overtakes the choice to continue to smoke cigarettes poses a significant challenge. Additional uncertainty stems from menthol's enhancing effect on nicotine addiction in the brain and menthol's ability to mask the harshness of tobacco smoke, particularly for those initiating tobacco use.

ii. Cigarette smoking initiation during adolescence when the brain is not yet fully developed and how menthol as a characterizing flavor affects youth appeal

Based on over 50 years of published and peer-reviewed scientific evidence and data, the 2014 SGR concluded that 87% of adult smokers start smoking before age 18, [3]. Previous SGRs indicate that the percentage of smokers initiating tobacco products before the age of 18 has remained mostly constant. The 1994 and 2012 SGRs on smoking and health note that almost 90% of current adult regular smokers initiated smoking before age 18, and 99% initiated smoking before the age of 25, which is the approximate age at which the brain has completed development [12] [13]. As nearly all smokers begin before age 25, the approximate age at which the brain has completed development, such users are more vulnerable to developing nicotine dependence [3] [5] [12] [13]. The report further notes that adolescence and young adulthood represents a time of "immaturity in consequential thinking, impulsivity, and decision-making skills" [13]. Current data reflect continued initiation by youth—the 2019 National Survey on Drug Use and Health (NSDUH) found that 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 each day [196].

As discussed further in the Preamble of this proposed rule, due to the combined effects of nicotine and menthol in the developing brain, youth who smoke menthol cigarettes are particularly vulnerable to the effects of menthol on progression to regular use and nicotine dependence.

In the literature that discusses consumer welfare loss for individuals prevented from initiation, there is strong support for the position that consumer welfare losses for individuals prevented from initiating tobacco product use should not be considered within a welfare analysis [197] [198] [199]. 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." [197] 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" [199].

Youth smokers 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" [200]. 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..." [200].

iii. Developing nature of public awareness 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, 29 additional reports have been released in the 45 years between 1964-2010 documenting the "overwhelming and conclusive biologic, epidemiologic, behavioral, and pharmacologic evidence that tobacco use is deadly" [18]. 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 assessing awareness of available information. As more information about the health harms of smoking enters public awareness, individuals are expected to be more informed. However, research has shown that being a member of a group with lower socioeconomic status is associated with having lower knowledge of the negative health consequences of smoking (see 85 FR 15638 - Tobacco Products; Required Warnings for Cigarette Packages and Advertisements for a more detailed discussion). How such ongoing information development is assimilated by different individuals and incorporated into modeling results presents additional challenges and sources of uncertainty.

iv. 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 [201] [202] [203].

Over time, the original derived demand rationale for tobacco product use (such as peer acceptance) may no longer be relevant, but users may be unable to stop due to the development of addiction. This suggests an additional explanation of derived demand: nicotine. In this case, smoking a cigarette is the fastest way to deliver nicotine to the brain. In addition to the tobacco user's 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 [204]. 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 [205]. These stimuli often act as secondary or conditioned reinforcers that contribute to the smoking "reward" and dependence [204] [206], and may also serve as another source of derived demand. Thus, it is difficult to disentangle the demand for cigarettes 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.

v. Regret expressed by current smokers, desire to quit, and menthol's impact on quitting

The significant level of regret experienced by the vast majority of smokers also plays a role in welfare analysis. It is difficult to estimate unbiased demand, and in particular consumer surplus, for menthol cigarettes when most smokers state that they regret having ever started smoking and wish to quit. In an analysis of 2015 National Health Interview Survey data, Babb et al. (2017) find that the majority of smokers stated that they wanted to quit smoking (68%) and 56% of smokers made a serious attempt to quit, but only about 7% of smokers reported that they had recently quit [207]. More recently, Pechacek et al. (2018) find that "more than 80% of current smokers report high (22.5%) or very high (59.8%) discontent due to inability to quit, perceived addiction and regret about having started to smoke" [23]. The authors conclude that "the proportion of smokers who might be characterised 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" [23]. These smokers "could have a substantial net welfare gain if new regulations helped them escape their concerns about the health effects from continuing smoking" [23]. These surveys of smokers consistently reflect that smoking preference and smoking behavior do not align, meaning empirical evidence shows that the decision utility of smokers 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.[59]

A number of nationally representative studies among young adult and adult smokers also show that menthol in cigarettes contributes to reduced cessation success [59] [60] [61] [62] [63] [64] [65] [66]. Additionally, quit attempts were higher among menthol smokers compared to non-menthol smokers, but menthol smokers had 3.5% lower rates of quitting within the past year and 6% lower rates of quitting within the past 5 years compared to non-menthol smokers [63]. The role menthol plays in youth appeal, nicotine addiction in the brain, and rates of successful quit attempts suggest that menthol adds an additional challenge and source of uncertainty in modeling rational demand for menthol cigarettes.

vi. What role does menthol play in discussions of consumer surplus for cigarettes?

As addressed by the potential challenges above, it is difficult to disentangle the consumption driven by addiction from that which may be driven by demand for menthol in cigarette products. Thus, modeling consumers' willingness to pay for addictive products and, in particular, isolating the value consumers place on a key characteristic of an addictive product, such as menthol in cigarette products, is a source of uncertainty.

To the extent that the demand for menthol cigarettes stems from the demand for nicotine, substitutes for cigarette products are readily available. Former smokers of menthol cigarette products who switch to non-menthol cigarette products would not experience the health benefits associated with reduced consumption. However, substitute products could potentially provide the

[59] 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.

same or more consumer surplus for some people who, due to a *status quo bias,* continued using menthol cigarettes because menthol cigarettes were the tobacco product with which they initiated [208].

A recent literature review by Cadham et al. (2020) examined surveys asking menthol cigarette smokers what they would do in response to a hypothetical menthol ban and, based on responses from U.S. menthol smokers, concluded that banning menthol cigarettes would increase quit attempts and switching to potentially less harmful tobacco products [209].[60] As discussed in Cutler et al. (2015), an implicit price increase (higher search or acquisition costs) is one potential approach to estimating the amount consumers would need to spend to realize the same utility they acquired from smoking menthol cigarette products [197]. See Section II.D.3.a for an analysis of search costs.

Bernheim and Rangel (2004) argue that any regulation that helps eliminate cues that help sustain biased demand could also be welfare improving [10]. The Bernheim and Rangel (2004) model proposes that the consumption of addictive goods is often a mistake triggered by environmental cues. They consider that any government actions that eliminate environmental cues would "unambiguously increase welfare" for individuals dissuaded from smoking [10]. For example, if menthol serves as an environmental cue (i.e., as a type of sensorimotor stimuli), eliminating menthol as a characterizing flavor in cigarettes will increase welfare (upon smoking dissuasion) by first reducing the reinforcing appeal of cigarettes for current menthol smokers and encouraging current menthol smokers to quit smoking. Further, Bernheim and Rangel (2004)

[60] For hypothetical menthol bans, Cadham et al. (2020) found that 11% to 46% of individuals intended to switch and 24% to 64% would try to quit. We note that all but one of the studies Cadham et al. (2020) examined in compiling these ranges for hypothetical menthol bans were U.S.-based [209].

note that "though individuals may have some ability to avoid problematic cues and create their own counter-cues, the government is arguably better positioned to do this" [10].

Following the removal of menthol as a characterizing flavor, current menthol cigarette consumers can choose to cease all tobacco product use or switch to another product. For instance, they could seek menthol flavors from other addictive or non-addictive products and/or continue obtaining nicotine from non-mentholated cigarettes. As suggested by Bernheim and Rangel (2004), cessation that occurs due to a regulation that eliminates a cue (such as the characterizing flavor menthol) will likely be welfare improving for individuals dissuaded from smoking [10].

vii. Summary

FDA does not believe that any reasonable consideration of consumer utility change, even if such a change were negative, would change our E.O. 12866 determination that benefits associated with this rule justify the costs.[61] While FDA believes that consumer utility change is an appropriate impact to consider qualitatively for the proposed product standard, we decline to 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 smoking is driven primarily by nicotine addiction, including menthol's enhancing effect on nicotine addiction; b)

[61] FDA reiterates that the benefits of this rule are expected to be very large. For example, the value of avoided premature deaths due to secondhand smoke exposure alone, for which consumer surplus would not apply under any scenario, is $467.8 billion (at a 3% discount rate) or $253.5 billion (at a 7% discount rate), while the total costs are $6.8 billion (at a 3% discount rate) or $4.1 billion (at a 7% discount rate). This is in addition to the value of all prevented premature deaths arising from firsthand smoking and all qualitative benefits to users and potential users of menthol products combined. 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 determination that benefits associated with this rule justify the costs.

the vast majority of adult smokers 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 smoking, and many still do not fully understand this information today; d) a smoker's 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; e) evidence of regret shows that the decision utility of smokers is not aligned with their experience utility, particularly in light of the reduced success that menthol smokers have in quit attempts; and f) the role of menthol flavoring specifically, including the possibility that switching products could increase utility for some due to status quo bias, and the existence of readily available substitute products.

Given the challenges outlined above and the breadth of literature and approaches discussed in Appendix A, this regulatory impact analysis qualitatively discusses but does not estimate changes in consumer surplus stemming from the proposed menthol product standard. We request comment and/or data to assist in future application of potential modeling approaches.

4. Government Costs

Although the amount of tobacco product user fees available to FDA would not change under this proposed product standard, FDA enforcement costs may potentially decrease in the short and long term due to fewer products to review during cigarette inspections, fewer cigarettes being imported, and a reduced number of product listing submissions in TRLM. Conversely, FDA enforcement costs may potentially increase in the short term due to one-time tasks such as updating inspector training materials and websites regarding the new product standard. Ongoing enforcement tasks may include lengthier inspections should menthol products be identified

during review and possible additional complaints handling, including follow-up actions such as for-cause inspections. The enforcement of the proposed rule, if finalized, would also include investigating, drafting, and processing warning letters, and taking other enforcement actions as necessary, including, but not limited to, civil money penalties, criminal prosecution, seizure, and injunction.

We currently undertake these inspection and monitoring activities while enforcing the Tobacco Control Act and this work is expected to be conducted by existing staff. We assume that, at most, the work of 5 current full-time equivalent (FTE) employees may be associated with enforcement of this proposed rule, if finalized. We, therefore, use a range of zero to 5 FTEs, with 2.5 FTEs as a primary estimate, to estimate the portion of user fees that are expected to be associated with performing the necessary tasks due to this proposed rule. We use an annual wage based on an agency-wide estimate of the average cost for FTE employees to value this effort. [62] The fully-loaded (inclusive of benefits and other indirect costs) cost per FTE in 2020 equals $263,646. Therefore, the annual cost of enforcement is estimated to range from $0 to $1,318,230, with $659,115 as a primary estimate.

We note that these costs would not affect the total amount of user fees or the size of the Federal budget. The TCA requires that industry user fees fully fund our regulation of tobacco products. Therefore, these costs represent an opportunity cost for agency resources. These government costs represent an opportunity cost, but this rule will not result in changes to overall FDA accounting costs, the size of the Federal budget, or the amount of tobacco industry user

[62] We note that the average, agency-wide cost for an FTE is between a General Schedule 13 and 14. See the General Schedule Payscale Table, Washington-Baltimore-Arlington, DC-MD-VA-WV-PA region available at https://www.federalpay.org/gs/locality/washington-dc.

fees. We estimated annual government enforcement costs in Table 51 and the present and annualized values over the full 40-year time horizon in

Table 52.

Table 51. Annual Government Enforcement Costs ($2020, Million)

Year Count	Year	Government Enforcement Costs ($2020, Million)		
		Low	Primary	High
Year 1	2024	$0.0	$0.7	$1.3
Year 2	2025	$0.0	$0.7	$1.3
Year 3	2026	$0.0	$0.7	$1.3
Year 4	2027	$0.0	$0.7	$1.3
Year 5	2028	$0.0	$0.7	$1.3
Year 6	2029	$0.0	$0.7	$1.3
…	…	…	…	…
Year 39	2062	$0.0	$0.7	$1.3
Year 40	2063	$0.0	$0.7	$1.3
	Total	$0.0	$26.4	$52.7

Table 52. Present and Annualized Values of Government Costs Over a 40-Year Time Horizon ($2020, Million)

Category	Discount Rate	Government Costs ($2020, Million)		
		Low	Primary	High
Undiscounted	N/A	$0.0	$26.4	$52.7
Present Discounted Values	3%	$0.0	$15.2	$30.5
	7%	$0.0	$8.8	$17.6
Annualized Values	3%	$0.0	$0.7	$1.3
	7%	$0.0	$0.7	$1.3

5. Sensitivity Analysis - Cost of Searching for Other Tobacco Products

While some current menthol tobacco product users are expected to stop using tobacco products following the effective date of the proposed standard, and some youth and young adults are projected to avoid initiation of tobacco product use altogether (seeSection II.C.3), others may switch to use of other tobacco products. These other tobacco products may include non-menthol versions of the previously purchased product (non-menthol cigarettes from the same brand), or

non-cigarette tobacco products such as smokeless tobacco or electronic nicotine delivery systems (ENDS). As they seek other tobacco products, we assume these consumers may face search costs during the first two years (transition period from Menthol Simulation) following the effective date of the proposed standard [88]. Search costs may include the time it takes a former menthol cigarette smoker to research substitute products, including talking to other tobacco product users, searching for reviews on the internet and social media, and reviewing tobacco product packages in the store.

To estimate the population of current menthol cigarette smokers that may search for substitute tobacco products including non-menthol cigarette products, smokeless tobacco products, and ENDS, we rely on estimates from the expert elicitation used in modeling a potential ban on menthol cigarettes [152]. Experts on average estimated 51.4% more switching to non-menthol combustible tobacco products, smokeless tobacco products, and ENDS products among current menthol smokers aged 18-24 and 52.2% more switching to these products among current menthol smokers aged 35-54 under the *Menthol Ban* scenario as compared to the *Status Quo* scenario.[63] Table 53 presents estimates from the expert elicitation by category of tobacco product, as well as the calculated net percent switching overall.

[63] Among menthol smokers in both the *Status Quo Scenario* and *Menthol Ban Scenario*, experts estimated transitions over a two-year period for ages 18-24 and 35-54 [152], which were modeled as mean net differences applied to menthol smokers up to age 30 and over age 30, respectively [88].

Table 53. Percent Switching between Tobacco Product Categories

Transition	Percent Transitions of Menthol Smokers Aged 18-24			Transitions of Menthol Smokers Aged 35-54		
	Status Quo	Menthol Ban	Net Change	Status Quo	Menthol Ban	Net Change
Switched from Menthol Cigarettes to Non-Menthol Combustible Products[1]	10.4%	44.0%	33.6%	7.3%	49.4%	42.1%
Switched to Smokeless Products	1.5%	3.7%	2.2%	2.6%	2.4%	-0.2%
Switched to ENDS Products[2]	8.5%	24.1%	15.6%	9.7%	20.0%	10.3%
Total			51.4%			52.2%

Source: Reference 152, Tables 3 and 4.
[1]These estimates represent transitions from menthol cigarettes to non-menthol combustible tobacco products, including switching to non-menthol cigarettes and non-menthol cigars.
[2]The expert elicitation refers to Nicotine Vaping Products (NVP), which we have renamed to Electronic Nicotine Delivery Systems (ENDS) here.

Using 2019 NSDUH data, we estimate that there were 2,957,621 current menthol smokers (past 30-day use) aged 18-25 and 4,997,203 current menthol smokers (past 30-day use) aged 35-49 in 2019, the populations that most closely match the populations described in the expert elicitation [70] [152]. We use the total population of current menthol cigarette smokers aged 18-25 and 35-49 in 2019 (7,954,824 smokers) to create weighted averages for quitting and continuing tobacco product use [70].

To estimate the weighted percent of additional switching for young adults, we first estimate the ratio of menthol cigarette smokers aged 18-25 from 2019 NSDUH data (2,957,621)

as compared to the entire combined population of menthol cigarette smokers aged 18-25 and 35-49 (7,954,824), which results in a weight of 37.2% (2,957,621 / 7,954,824 = 37.2%) [70]. Then, we multiply the percent of current menthol smokers aged 18-24 that may switch to other tobacco products as a result of a menthol ban (51.4%) by this population weight ratio (37.2%) to create a weighted estimate of additional switching to other tobacco products for the young adult population of 19.1% (51.4% * 37.2% = 19.1%).

To estimate the weighted percent of additional switching for adults, we first estimate the ratio of menthol cigarette smokers aged 35-49 (4,997,203 NSDUH 2019) as compared to the entire combined population of menthol cigarette smokers aged 18-25 and 35-49 (7,954,824 NSDUH 2019), which results in a weight of 62.8% (4,997,203 / 7,954,824 = 62.8%). Then, we multiply the percent of current menthol smokers aged 35-54 that may switch to other tobacco products as a result of a menthol ban (52.2%) by this population weight ratio to create a weighted estimate of additional switching to other tobacco products for the adult population of 32.8% (52.2% * 62.8% = 32.8%).

From these percentages and population estimates, we create a weighted average of 51.9% (19.1% + 32.8% = 51.9%) more menthol cigarette smokers may switch to non-menthol combustible tobacco products, smokeless tobacco products, and ENDS under the proposed product standard, as compared to the *Status Quo Scenario*. We multiply 51.9% by the total population of current menthol cigarette smokers from 2019 NSDUH data aged 21 and older (17,485,568 smokers), to account for T21 Laws, and estimate that approximately 9.0 million current menthol cigarette smokers within this age range may additionally search for other tobacco products under the proposed product standard [71]. Transitions from menthol cigarette smoking to use of other tobacco products are expected to occur in the first two years following

the implementation of a *Menthol Ban* [152]. We, therefore, assume that the number of current menthol cigarette smokers aged 21 and older searching for other tobacco products would be distributed evenly between the first two years following the effective date of the proposed product standard (i.e., 4.5 million current menthol smokers aged 21 and older may search each year over Years 2 and 3).[64]

The amount of time a consumer may spend searching when switching from one tobacco product category to another depends on several factors, including the availability and visibility of other tobacco products in local tobacco retail markets and online websites. Although tobacco products users may search for other tobacco products at any time and for any reason, we estimate that this search process may take between 30 minutes and 90 minutes per current menthol smoker and occur one additional time following the proposed product standard.

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 ASPE report on *Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices* [173]. We start with a measurement of the usual weekly earnings of wage and salary workers of $990. We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.75. We adjust this hourly rate downwards by an effective tax rate of about 17%, resulting in a post-tax hourly wage rate of $20.55. By multiplying our annual estimate of current menthol smokers aged 21 and older expected to additionally switch to other tobacco products (4.5 million) by the estimated range for search time

[64] In simulations under the *Menthol Ban Scenario*, Levy et al. (2021) note that "for those already menthol smokers, experts considered transitions over a two-year period under the status quo and under a menthol ban. We model the experts' estimates of mean net transitions (the difference in two-year transitions under the status quo and a menthol ban)." [88, page 3]

(range of 30 minutes to 90 minutes, 60 minutes primary) and a $20.55 per hour wage rate, we estimate that the proposed rule may result in approximately $186.5 million in consumer search costs, spread evenly over the first two years following the effective date of the proposed rule. [65] These estimates are presented in Table 54.

Table 54. Undiscounted Consumer Search Costs Over Time ($2020, Millions)

Year Count	Year	Searching Population[1]	Search Costs ($2020, Million)		
			Lower Bound (30 minutes)	Primary (60 minutes)	Upper Bound (90 minutes)
Year 1	2024	-	-	-	-
Year 2	2025	4,537,729	$46.6	$93.3	$139.9
Year 3	2026	4,537,729	$46.6	$93.3	$139.9
Year 4	2027	-	-	-	-
Year 5	2028	-	-	-	-
Year 6	2029	-	-	-	-
…	…	…	…	…	…
Year 39	2062	-	-	-	-
Year 40	2063	-	-	-	-
Total		9,075,457	$93.3	$186.5	$279.8

[1] Searching population includes former menthol cigarette product users aged 21 and older who may search for new tobacco products as a result of the proposed rule.
Note: Estimates may not add, due to rounding.

The primary present value of search costs is approximately $173.2 million at 3% discount (lower bound $86.6 million; upper bound $259.9 million) and $157.6 million at 7% discount (lower bound $78.8 million; upper bound $236.4 million). The primary annualized value of search costs is approximately $7.4 million at 3% discount (lower bound $3.7 million; upper bound $11.1 million) and $11.8 at 7% discount (lower bound $5.9 million; upper bound $17.6 million). Table 55 presents these estimates.

[65] As a sensitivity analysis, we assess the search cost with the augmented post-tax wage rate to account for non-wage benefits by doubling the wage. Using this wage rate of $25.10, the search costs would be $227.8 million with a lower bound of $113.9 million and an upper bound of $341.7 million (undiscounted).

Table 55. Present and Annualized Value of Consumer Search Costs at 3% and 7% (2023-2063, $2020 Million)

Category	Discount Rate	Total Search Costs ($2020, Million)		
		Lower Bound	Primary	Upper Bound
Undiscounted Value of Search Costs	N/A	$93.3	$186.5	$279.8
Present Discounted Value of Search Costs	3%	$86.6	$173.2	$259.9
	7%	$78.8	$157.6	$236.4
Annualized Value of Search Costs	3%	$3.7	$7.4	$11.1
	7%	$5.9	$11.8	$17.6

We do not estimate search costs for current menthol smokers that cease use of tobacco products. Across several surveys, menthol smokers have said that if menthol cigarettes were no longer available, they would consider quitting smoking altogether [183] [184] [185] [186] [187] [188] [210]. Studies evaluating the impact of Canada's laws prohibiting the sale of menthol tobacco products have found increased reports of quit attempts and quitting smoking following policy implementation [141] [142] [143] [144]. Consumers that cease use of tobacco products are also likely to replace tobacco product purchases with savings or purchases of other goods they already consume.

As part of the expert elicitation, Levy et al. (2021) asked "experts to consider dual users of cigarettes with other products as exclusive cigarette users" [152]. Thus, current dual users (menthol cigarettes + other tobacco products) may already be familiar with other tobacco products. Additionally, current menthol cigarette smokers may switch to non-menthol cigarette products marketed under the same brand names, reducing search costs. We request comment on search cost assumptions and calculations.

6. Summary of Costs

The present value quantified costs of the proposed rule are approximately $6,805.9

million (lower bound $223.0 million; upper bound $13,421.6 million) with a 3% discount rate and $4,113.2 million (lower bound $208.0 million; upper bound $8,051.3 million) with a 7% discount rate. The annualized quantified costs of the proposed rule are approximately $290.6 million (lower bound $9.5 million; upper bound $573.1 million) with a 3% discount rate and $307.0 million (lower bound $15.5 million; upper bound $601.0 million) with a 7% discount rate. Table 56 and

Table 57 summarize the quantified and unquantified costs of the proposed rule (in present and annualized values, 2020 dollars to show specificity).

Table 56. Summary of Present Value Quantified and Unquantified Costs ($2020, Rounded)

Cost Category		Discount Rate	Present Value Costs		
			Lower Bound	Primary	Upper Bound
Industry	Read and Understand	3%	$55,977,000	$186,589,000	$349,854,000
		7%	$55,977,000	$186,589,000	$349,854,000
	Reallocation, Friction, and Adjustment Costs	3%	$184,000	$235,934,000	$471,867,000
		7%	$184,000	$235,934,000	$471,867,000
	Producer Surplus	3%	$0	$6,034,355,000	$12,068,711,000
		7%	$0	$3,378,298,000	$6,756,596,000
Consumer	Search Costs	3%	$166,884,000	$333,769,000	$500,653,000
		7%	$151,793,000	$303,585,000	$455,378,000
	Consumer Surplus	Changes in consumer surplus may occur for some menthol smokers. See Appendix A for complete qualitative discussion.			
Government Enforcement Costs		3%	$0	$15,235,000	$30,471,000
		7%	$0	$8,787,000	$17,574,000
Total Quantified Costs in Present Value		*3%*	*$223,045,000*	*$6,805,882,000*	*$13,421,556,000*
		7%	*$207,954,000*	*$4,113,193,000*	*$8,051,269,000*

Note: Totals may not represent the sum of other estimates due to rounding.

Table 57. Summary of Annualized Quantified and Unquantified Costs ($2020, Rounded)

Cost Category		Discount Rate	Annualized Costs		
			Lower Bound	Primary	Upper Bound
Industry	Read and Understand the Rule	3%	$2,362,000	$7,872,000	$14,761,000
		7%	$4,161,000	$13,870,000	$26,007,000
	Friction/Adjustment Costs	3%	$8,000	$10,077,000	$20,155,000
		7%	$14,000	$17,615,000	$35,229,000
	Producer Surplus	3%	$0	$257,742,000	$515,484,000
		7%	$0	$252,222,000	$504,445,000
Consumer	Search Costs	3%	$7,128,000	$14,256,000	$21,384,000
		7%	$11,333,000	$22,666,000	$33,998,000
	Consumer Surplus	Changes in consumer surplus may occur for some menthol smokers. See Appendix A. for complete qualitative discussion.			
Government Costs		3%	$0	$651,000	$1,301,000
		7%	$0	$656,000	$1,312,000
Total Quantified Annualized Costs		*3%*	*$9,498,000*	*$290,598,000*	*$573,085,000*
		7%	*$15,508,000*	*$307,029,000*	*$600,991,000*

Note: Totals may not represent the sum of other estimates due to rounding.

E. Transfers

We analyze the amount of excise taxes and cigarette product revenues that transfer, under this proposed product standard, from Federal and State governments and producers/importers of menthol cigarette products back to consumers who would have purchased menthol cigarette products. Some consumers would use the transferred value to purchase non-menthol cigarette products manufactured by the same entities that previously manufactured menthol cigarettes. These purchases, along with their associated excise taxes and revenues, would stay within the market for cigarette products. We estimate the remaining amount of excise taxes and revenue that would transfer back to consumers who do not initiate, quit use of tobacco products, or switch to tobacco products other than cigarettes under this proposed product standard.

An expert elicitation conducted by Levy et al. (2021) of the potential impacts of a ban on menthol cigarettes suggests that approximately 33% of current menthol cigarette users aged 18-24 and approximately 41% of current menthol cigarette users aged 35-54 may additionally transition to non-menthol cigarettes in response to a potential menthol ban for a roughly 15 percent overall reduction in smoking [152].[66] A study of menthol sales restrictions in Quebec, Ontario, Prince Edward Island, Newfoundland and Labrador, and a nationwide ban covering British Columbia, Saskatchewan, and Manitoba, Canada found that approximately 59% of pre-restriction menthol smokers (including those who reported smoking "tobacco and menthol" cigarettes) reported using non-menthol cigarettes following policy implementation [144].To develop a range of estimated transfers *away* from cigarette products, we use these estimates of switching between menthol and non-menthol cigarette products and create three separate scenarios: 41% (=100-59, low estimate), 59% (=100-41, primary estimate), and 67% (=100–33, high estimate) of menthol cigarette product purchases transfer away from the cigarette product market. We assume these transfers occur over the same years (2025-2063) that the Levy et al. (2021) Menthol Simulation projects health impacts.

1. Discussion of Federal and State Excise and Sales Tax Revenues

The proposed rule would prohibit menthol as a characterizing flavor in cigarettes and is estimated to reduce overall cigarette consumption. This reduction in consumption would lead to less tax revenue for governments that tax tobacco products.

[66] To determine the 'attributable' portion of switching, we reviewed the Levy et al. (2021) Expert Elicitation paper. We found the mean estimates for switching proportions under the *Status Quo* and *Menthol Ban* scenarios. By taking the difference between these transition probabilities, we estimate the additional switching which may occur following the effective date of a potential menthol ban.

Modeling by Levy et al. (2021) of the potential impacts of a menthol ban on cigarettes suggests that some current users of menthol cigarette products would cease smoking entirely, while others would switch to other tobacco products such as non-menthol cigarettes and ENDS [88] [152].

As consumers would no longer be purchasing menthol cigarettes, and cigarette manufacturers would no longer produce menthol cigarettes, we assume that 100% of the annual excise tax collection from menthol cigarette products would transfer away from Federal and State governments. Excise taxes would no longer be collected from cigarette manufacturers for the production of menthol cigarettes. We assume that excise taxes are passed on to consumers through retail and wholesale price increases[67] and we, therefore, consider potential decreases in excise tax collections to be net transfers from Federal and State governments to consumers.

We expect that some consumers would use some of the transferred value to purchase non-menthol cigarette products manufactured by the same entities that previously manufactured menthol cigarettes. As cigarette manufacturers increase production of non-menthol cigarettes to meet this increased consumer demand, we estimate Federal and State excise taxes would be assessed and collected on the additional production of non-menthol cigarettes. For this analysis, we do not consider consumer purchases of non-menthol cigarettes by former menthol cigarette product users to result in a transfer of excise taxes. Instead, we analyze the transfer of annual cigarette excise tax revenue away from Federal and State governments and back to consumers (i.e., transfer of excise tax revenues back to consumers, without replacement).

[67] See, for example, Federal Trade Commission, *Competition and the Financial Impact of the Proposed Tobacco Industry Settlement,* September 1997 at page 25, where it states: "research shows that the [tobacco] industry has commonly, in effect, 'passed through' to consumers 100 percent or more of tax increases by raising price" [179]. See also [211] and [212].

In addition to excise taxes, most jurisdictions also collect sales taxes on tobacco transactions. Reductions in sales tax collections are likely to be offset as consumers would increase purchases and consumption of other taxable products, including non-menthol cigarettes. Therefore, to the extent that consumers purchase other products subject to a sales tax, we do not expect State sales tax revenue collections to be affected by this proposed rule. We also do not estimate changes in other transfers between smokers and Federal and State governments that may occur under the baseline, such as medical costs and other financial effects of smoking, in this section (see discussion in sections II.C.6.a and II.C.6.b.). We request comment on other financial spillovers due to this standard that may impact net transfers, including ways in which non-smokers may subsidize smokers.

2. Estimation of Federal and State Excise Tax Revenue Transfers

In Section II.B.3, we estimate baseline Federal excise tax revenues over our 40-year time horizon. Using estimates from Table 21 and applying our 3-scenario range of transfers, we estimate a total undiscounted value of approximately $52.6 billion in transfers in the 41% scenario (low), $75.7 billion in transfers in the 59% scenario (primary), and $85.9 billion in transfers in the 67% scenario (high) from the Federal government (in the form of reduced exise tax collections) to consumers. Table 58 presents baseline estimates of menthol cigarette product sales and Federal excise tax revenues, as well as estimates of Federal excise tax transfers under the three scenarios, over a 40-year time horizon.

Table 58. Transfer of Federal Excise Tax Revenues Under the Proposed Product Standard (Change in Overall Cigarette Excise Tax Revenues)

Year Count	Year	Volume Sales of Menthol Cigarette Products (Millions of Sticks)[1]	Menthol Cigarette Product Volume Sales in Pack Equivalents (Millions)[2]	Federal Excise Tax Rate ($2020)[3]	Baseline Federal Excise Tax Revenue for Menthol Cigarette Poducts ($2020, Billion)	Transfer of Federal Excise Tax Revenues ($2020, Billion, Undiscounted)		
						41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Year 0	2023	70,458	3,523	$1.01	$3.6	-	-	-
Year 1	2024	67,786	3,389	$1.01	$3.4	$1.3	$1.9	$2.2
Year 2	2025	65,114	3,256	$1.01	$3.3	$1.3	$1.9	$2.2
Year 3	2026	65,114	3,256	$1.01	$3.3	$1.3	$1.9	$2.2
Year 4	2027	65,114	3,256	$1.01	$3.3	$1.3	$1.9	$2.2
Year 5	2028	65,114	3,256	$1.01	$3.3	$1.3	$1.9	$2.2
…	…	…	…	…	…	…	…	…
Year 39	2062	65,114	3,256	$1.01	$3.3	$1.3	$1.9	$2.2
Year 40	2063	65,114	3,256	$1.01	$3.3	$1.3	$1.9	$2.2
Total		2,677,677	133,884	-	$135.2	$52.6	$75.7	$85.9

[1] Baseline menthol cigarette product volume sales from Table 20.
[2] Pack equivalent volume sales are estimated by dividing volume sales in stick equivalents by 20.
[3] Source: Reference 124.

Using the same methodology used for estimation of Federal tax transfers, we multiply baseline State excise tax revenue from menthol cigarette products in each year from Table 21 by the assumed percentage of State excise tax revenue that transfers back to consumers. As shown in Table 59, by applying the same 3-scenario range of transfers, we estimate an undiscounted value of approximately $99.4 billion in transfers in the 41% scenario (low), $143.1 billion in transfers in the 59% scenario (primary), and $162.5 billion in transfers in the 67% scenario (high) from States (in the form of reduced excise tax collections) to consumers in total, over the 40-year period. We assume these transfers occur over the same years (2025-2063) that the Levy et al. (2021) Menthol Simulation projects health impacts.

These estimates of changes in State collections of excise taxes are presented on average. Each State has a unique excise tax rate and collection, along with different levels of cigarette production [124]. We acknowledge that some States have high cigarette taxes while others have low cigarette taxes. A national average, while not reflecting each State's unique tax effect, provides an approximation of the total change in excise tax collections by States.

Table 59. Transfers of State Excise Tax Under the Proposed Product Standard (Change in Overall Cigarette Excise Tax Revenues)

Year Count	Year	Volume Sales of Menthol Cigarette Products (Millions of sticks)[1]	Menthol Cigarette Product Volume Sales in Pack Equivalents (Millions)[2]	State Average Excise Tax Rate (2020)[3]	Baseline State Excise Tax Revenue for Menthol Cigarette Products ($2020, Billion)	Transfers of State Excise Tax Revenue ($2020, Billion, Undiscounted)		
						41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Year 0	2023	70,458	3,523	$1.91	$6.7	-	-	-
Year 1	2024	67,786	3,389	$1.91	$6.5	-	-	-
Year 2	2025	65,114	3,256	$1.91	$6.2	$2.5	$3.7	$4.2
Year 3	2026	65,114	3,256	$1.91	$6.2	$2.5	$3.7	$4.2
Year 4	2027	65,114	3,256	$1.91	$6.2	$2.5	$3.7	$4.2
Year 5	2028	65,114	3,256	$1.91	$6.2	$2.5	$3.7	$4.2
…	…	…	…	…	…	…	…	…
Year 39	2062	65,114	3,256	$1.91	$6.2	$2.5	$3.7	$4.2
Year 40	2063	65,114	3,256	$1.91	$6.2	$2.5	$3.7	$4.2
Total		2,677,677	133,884	-	$255.7	$99.4	$143.1	$162.5

[1] Baseline menthol cigarette product volume sales from Table 20.
[2] Pack equivalent volume sales are estimated by dividing volume sales in stick equivalents by 20.
[3] Source: Reference 124.

We then discount the stream of Federal and State excise tax revenue transfers presented within Table 58 and Table 59, using 3% and 7% discount rates. The primary present value of total Federal and State excise tax revenue transfers from this proposed product standard is approximately $124.20 billion at a 3% discount rate (low $86.31 billion; high $141.04 billion),

and approximately $69.53 billion at a 7% discount rate (low $48.32 billion; high $78.96 billion).[68] The primary annualized value of total Federal and State excise tax revenue transfers from this proposed product standard is approximately $5.30 billion at a 3% discount rate (low $3.69 billion; high $6.02 billion), and approximately $5.19 billion at a 7% discount rate (low $3.61 billion; high $5.90 billion). These estimates of present and annualized value for revenue transfer from this proposed product standard are summarized in Table 60 and

Table 61.

Table 60. Present and Annualized Value of Federal and State Excise Tax Revenue Transfers

Category	Discount Rate	Transfers of Federal Excise Tax Revenue ($2020, Billion)			Transfers of State Excise Tax Revenue ($2020, Billion)		
		Low	Primary	High	Low	Primary	High
Undiscounted Value	N/A	$52.6	$75.7	$85.9	$99.4	$143.1	$162.5
Present Discounted Value	3%	$29.9	$43.0	$48.8	$56.5	$81.2	$92.3
	7%	$16.7	$24.1	$27.3	$31.6	$45.5	$51.7
Annualized Value	3%	$1.3	$1.8	$2.1	$2.4	$3.5	$3.9
	7%	$1.2	$1.8	$2.0	$2.4	$3.4	$3.9

Table 61. Present and Annualized Value of Total Excise Tax Revenue Transfers

Category	Discount Rate	Total Transfers of Excise Tax Revenue* ($2020, Billion)		
		Low	Primary	High
Undiscounted Value	N/A	$152.01	$218.75	$248.41
Present Discounted Value	3%	$86.31	$124.20	$141.04
	7%	$48.32	$69.53	$78.96
Annualized Value	3%	$3.69	$5.30	$6.02
	7%	$3.61	$5.19	$5.90

*The present and annualized values of total excise tax revenue transfers is the sum of Federal and State excise tax revenues, at 3% and 7%.

[68] The present and annualized values of total excise tax revenue transfers is the sum of Federal and State excise tax revenues, at 3% and 7%.

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.

3. Transfer of Revenue from Cigarette Market to Consumers and Markets for other Tobacco Products

Under the proposed product standard, menthol cigarette product manufacturer revenues, exclusive of excise taxes, would transfer from the production of menthol cigarette products back to consumers.[69] We expect that some consumers would use the transferred value to purchase non-menthol cigarette products manufactured by the same entities that previously manufactured menthol cigarettes. For this analysis, we do not consider consumer purchases of non-menthol cigarettes to result in a net transfer of revenues, as these purchases would stay within the market for cigarette products. We estimate transfers from the cigarette market to consumers who purchase other tobacco products authorized for market or other non-tobacco goods and services.

In Section II.B.2.f.iv, we estimate baseline sales (revenues) in the cigarette product and menthol cigarette product market over the 40-year time horizon used in analysis of this proposed rule. Similarly, we estimate baseline Federal and State excise tax revenues from menthol cigarette products over the 40-year time horizon in Section II.B.3. From these sections, we use the estimates in Table 20 (baseline revenues) and Table 21 (baseline excise taxes) and subtract baseline total Federal and State excise tax revenues from baseline menthol cigarette product revenues in each year to generate annual estimate of menthol cigarette product revenues, exclusive of excise taxes. We summarize this adjustment in Table 62.

[69] We note that estimated revenue transfers encompass economic profit, or the revenue minus explicit costs and implicit (opportunity) costs, which is equal to producer surplus.

Table 62. Baseline Industry Revenue Projections for Menthol Cigarette Products, With and Without Excise Taxes ($2020 Billion, undiscounted)

Year Count	Year	Total Cigarette Product Revenue (Billion)[1]	Menthol Cigarette Product Revenue (Billion)[1]	Total Menthol Cigarette Product Excise Tax Revenue (Billion)[2]	Total Menthol Cigarette Product Revenue, Exclusive of Excise Taxes (Billion)[3]
Year 0	2023	$96.0	$33.5	$10.3	$23.2
Year 1	2024	$96.5	$33.6	$9.9	$23.7
Year 2	2025	$97.0	$33.8	$9.5	$24.3
Year 3	2026	$97.0	$33.8	$9.5	$24.3
Year 4	2027	$97.0	$33.8	$9.5	$24.3
Year 5	2028	$97.0	$33.8	$9.5	$24.3
…	…	…	…	…	…
Year 39	2062	$97.0	$33.8	$9.5	$24.3
Year 40	2063	$97.0	$33.8	$9.5	$24.3

[1] Total Cigarette Product and Menthol Cigarette Product Revenues (Sales) from Table 20.
[2] Total menthol cigarette product excise tax revenues calculated as annual baseline Federal excise tax revenue ($4.0 billion) + annual baseline State excise tax revenue ($7.5 billion) from Table 21.
[3] Total menthol cigarette product revenues, exclusive of excise taxes, are calculated by subtracting total menthol cigarette product excise tax revenues from menthol cigarette product revenues.

This estimate of market revenue excluding excise taxes may be further split between manufacturers, distributors, and retailers; however, we expect that manufacturers capture the largest portion of this revenue and assume menthol cigarette product revenues, exclusive of excise taxes, represent manufacturer revenues. We then apply our 3-scenario range of transfers *away* from the cigarette product manufacturers and *to* consumers (and potentially manufacturers of other tobacco products) over the entire 40-year period. We estimate the undiscounted present value of this transfer to be approximately $389.7 billion in transfers in the low scenario (41%), $560.8 billion in transfers in the primary scenario (59%), and $636.9 billion in transfers in the high scenario (67%) from manufacturers of cigarette products to consumers. We assume these transfers occur over the same years (2024-2062) that the Levy et al. (2021) Menthol Simulation projects health impacts and present these estimates in Table 63.

Table 63. Transfer of Revenue from Cigarette Product Manufacturers to Consumers Over 40-year Time Horizon ($2020 Billion, Undiscounted)

Year Count	Year	Total Menthol Cigarette Product Revenue, Exclusive of Excise Taxes ($2020, Billion)	Transfer of Revenue from Menthol Cigarette Product Manufacturers ($2020, Billion)		
			41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Year 0	2023	$23.2	-	-	-
Year 1	2024	$23.7	-	-	-
Year 2	2025	$24.3	$10.0	$14.3	$16.3
Year 3	2026	$24.3	$10.0	$14.3	$16.3
Year 4	2027	$24.3	$10.0	$14.3	$16.3
Year 5	2028	$24.3	$10.0	$14.3	$16.3
…	…	…	…	…	…
Year 39	2062	$24.3	$10.0	$14.3	$16.3
Year 40	2063	$24.3	$10.0	$14.3	$16.3
Total		$994.98	$388.71	$559.36	$635.20

We then discount the stream of revenue transfers presented within Table 63 using 3% and 7% discount rates. The primary present value of total revenue transfer from this proposed product standard is approximately $317.6 billion at a 3% discount rate (low $220.7 billion; high $360.7 billion), and approximately $177.8 billion at a 7% discount rate (low $123.6 billion; high $201.9 billion). The primary annualized value of revenue transfer from this proposed product standard is approximately $13.6 billion at a 3% discount rate (low $9.4 billion; high $15.4 billion), and approximately $13.3 billion at a 7% discount rate (low $9.2 billion; high $15.1 billion). These estimates of present and annualized value for revenue transfer from this proposed product standard are summarized in Table 64.

We request comment on this analysis, including estimates of the portion of transfers back to consumers that may be spent on tobacco products other than cigarettes.

Table 64. Present and Annualized Values of Revenue Transfers *from* Cigarette Product Manufacturers *to* Consumers under the Proposed Product Standard ($2020, Billion)

Category	Discount Rate	Revenue ($2020, Billion)		
		41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Undiscounted Value of Revenue Transfer	N/A	$388.7	$559.4	$635.2
Present Value of Revenue Transfer	3%	$220.7	$317.6	$360.7
	7%	$123.6	$177.8	$201.9
Annualized Value of Revenue Transfer	3%	$9.4	$13.6	$15.4
	7%	$9.2	$13.3	$15.1

As discussed in Section II.D.1.d., menthol cigarette product manufacturers may experience a change in producer surplus as a result of this proposed product standard. In this section, we estimate the amount of revenue that transfers from producers and importers of menthol cigarette products back to consumers who previously purchased menthol cigarette products. As noted previously, such transfers of revenue generally encompass producer surplus. However, we separately estimate lost producer surplus for suppliers of menthol cigarettes (see Section II.D.1.d) in order to estimate impacts for the cigarette market in isolation and, to avoid double counting, we subtract lost producer surplus from the present and annualized values of transfers. Table 65 and Table 66 present the results of these calculations.

Table 65. Summary of Present Value of Quantified Transfers, Less Producer Surplus Loss ($2020, Billion)

Category	Present Value of Transfers (3%)			Present Value of Transfers (7%)		
	Low Estimate	Primary Estimate	High Estimate	Low Estimate	Primary Estimate	High Estimate
Transfers from Cigarette Product Manufacturers to Consumers or Manufacturers of Other Tobacco Products	$220.70	$317.60	$360.66	$123.56	$177.81	$201.91
Lost Producer Surplus	$0.00	$6.03	$12.07	$0.00	$3.38	$6.76
Transfers from Cigarette Product Manufacturers, Less Producer Surplus Loss	$220.70	$311.56	$348.59	$123.56	$174.43	$195.16

Table 66. Summary of Annualized Quantified Transfers, Less Producer Surplus Loss ($2020, Billion)

Category	Annualized Transfers (3%)			Annualized Transfers (7%)		
	Low Estimate	Primary Estimate	High Estimate	Low Estimate	Primary Estimate	High Estimate
Transfers from Cigarette Product Manufacturers to Consumers or Manufacturers of Other Tobacco Products	$9.43	$13.57	$15.40	$9.22	$13.27	$15.07
Lost Producer Surplus	$0.00	$0.26	$0.52	$0.00	$0.25	$0.50
Transfers from Cigarette Product Manufacturers, Less Producer Surplus	$9.43	$13.31	$14.89	$9.22	$13.02	$14.57

4. FDA User Fees

Chapter IX of the FD&C Act provides for the collection of quarterly user fees from each manufacturer and importer of cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, or RYO tobacco.[70] 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 as a result of this rule. The total amount of user fees collected in 2019 and each year that follows remain constant under the statute at $712 million. For fiscal year 2021, approximately 85.2% of total tobacco user fees were allocated to the cigarette tobacco product class and 0.04% to the RYO tobacco product class.[71] The amount of user fees paid by each tobacco product class is dependent upon Federal excise taxes associated with the gross removal of tobacco products into 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.[72]

Changes in tobacco product user fees are not a social cost; instead, reallocation of user fees between tobacco product classes represent a transfer between tobacco companies. Any decrease in market share and, thus, user fees collected from one tobacco product class results in a corresponding reallocation of user fees to manufacturers and importers of other tobacco product classes subject to user fees. As some smoking cessation and switching to tobacco products other than cigarettes is expected under the proposed product standard, the amount of user fees paid by

[70] See Section 919.
[71] https://wayback.archive-it.org/7993/20201221035726/https://www.fda.gov/tobacco-products/manufacturing/tobacco-user-fee-assessment-formulation-product-class
[72] Taxation of tobacco products, as defined by the Internal Revenue Code, falls under the jurisdiction of the U.S. Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB). Under the Internal Revenue Code, TTB permits and regulates both manufacturers and importers of tobacco products. Although the FDA assesses user fees on manufacturers and importers of certain tobacco products pursuant to Section 919 of the FD&C Act, neither the FDA's act of ''deeming'' nor any other FDA regulations directly affect the taxation of any tobacco product, nor do FDA regulations affect which businesses are subject to TTB jurisdiction under the Internal Revenue Code.

the cigarette class is expected to be reduced while the amount of user fees paid by other tobacco product classes may increase. Changes in taxable product volumes and the related distribution of market share among tobacco product classes subject to user fees under the proposed product standard are uncertain. A single manufacturer may also 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 that are additionally uncertain. For these reasons, we do not quantitatively estimate reallocation of user fees. We request comment on the amount of user fees that may transfer between tobacco product classes under the proposed product standard and overall net changes in user fee allocation.

F. Distributional Effects

1. Vulnerable Populations

The overall quantified benefits of the proposed product standards across all populations are discussed in Section II.C.4. FDA expects the public health benefits of this rule to be particularly pronounced among vulnerable populations, such as youth and young adults, African American and other racial and ethnic minority populations, individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+), pregnant persons, those with lower household income and educational attainment, and individuals with behavioral health disorders. These populations have the highest prevalence of menthol cigarette smoking and suffer a disproportionate burden of the related harms.

As previously discussed, Black smokers, regardless of age, have the highest rate of menthol cigarette use than smokers of any other race or ethnicity. According to 2019 NHIS data, approximately 14.9% of non-Hispanic African American adults reported current cigarette use

(having smoked ≥100 cigarettes during their lifetime and smoked every day or some days), compared to 15.5% of non-Hispanic White adults [89]. According to 2019 NSDUH data, approximately 17.5% of non-Hispanic Black/African-American adults reported past 30-day menthol cigarette smoking, compared to compared to 6.4% of Hispanic adults, 5.8% of non-Hispanic White adults, and 3.2% of non-Hispanic Asian population [70]. The same data indicate that, of the population of non-Hispanic Black/African-American smokers, nearly 85% smoke menthol cigarettes, compared to 48% of Hispanic smokers, 41% of non-Hispanic Asian smokers, and 30% of White smokers who smoke menthol cigarettes [70].

The prevalence of menthol cigarette smoking among Black youth smokers is high as well. Findings from 2018 NYTS data show that, among middle and high school students who were current cigarette smokers, 51.4% of non-Hispanic Black youth and 50.6% of Hispanic youth reported smoking menthol cigarettes, compared to 42.8% of non-Hispanic White youth [85]. Statistically significant differences in this proportion by race and ethnicity have been observed in the NYTS over the 2011-2018 period. While declines in menthol cigarette use from 2011-2018 have been observed among non-Hispanic White youth, declines were not observed among non-Hispanic Black youth or Hispanic youth [85].

FDA expects the proposed menthol product standard would result in lower smoking prevalence and cigarette consumption in the United States, especially among Black smokers. To estimate reductions in mortality risk for Black menthol cigarette smokers under the proposed product standard, we scale the benefits estimated for tobacco-attributable mortality by the percentage of tobacco-attributable mortality specific to Black smokers. 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 (437,400/2,326,810 = 18.8%) [3]. Applying

the smoking-attributable fraction (18.8%) to 2019 death estimates from CDC WONDER, there were a total of 324,620 Black/African-American deaths and approximately 61,029 (=324,620*0.188) smoking-attributable Black/African-American deaths [213]. However, because smoking prevalence is nearly 1% higher among Black adults than for the general population, this estimate of smoking-attributable deaths is likely an underestimation for this population.

At baseline, the Levy et al. (2021) model projects that in 2021 there were 380,525 total smoking and vaping-attributable deaths [88]. As previously estimated, there were 61,029 smoking-attributable Black/African-American adult deaths in 2019 [213]. Thus, we estimate that Black smoking-attributable deaths accounted for 16.04% (=61,029/380,525) of U.S. total smoking-attributable deaths in 2021. We assume this proportion of Black smoking-attributable deaths will remain constant over the period 2024-2063 and apply this proportion to our estimate of the number of avoided premature deaths due to the product standard from Table 26.[73] Thus, we estimate 103,799 (=647,128*0.1604) Black/African-American premature deaths would be avoided under the proposed standard in association with reduced exposure over the period 2024-2063. We present a summary of these estimates within Table 67. We note, however, that these estimates represent a subset of overall estimated benefits across all populations.

[73] We note that applying a proportion to two values and then taking the difference between those values is equivalent to applying the proportion directly to the difference. In this case, total cumulative avoided premature deaths under the proposed product standard represents a difference of values (see *Status Quo* and *Menthol Ban* scenarios in Table 22Table 22). Therefore, we apply the proportion of Black smoking-attributable deaths within the U.S. population directly to the number of avoided premature deaths under the product standard in Table 26.

Table 67. Cumulative Avoided Premature Deaths Under the Proposed Product Standard, Black Adult Population

	U.S. Total Population	Black Adult Population
Cumulative Avoided Premature Deaths, 2023-2063	647,128	103,799
Percentage of All U.S. Cumulative Avoided Premature Deaths	-	16.04%

This analysis presents an underestimate of cumulative avoided premature deaths under the proposed product standard for the Black adult population, as it assumes that avoided premature deaths under the proposed rule for this population would be proportional to the current smoking-attributable premature death rate by population group. However, Levy et al. (2021) note that "[u]nder a menthol ban, experts estimated 48% of African-Americans who would otherwise initiate menthol smoking would not initiate smoking or vaping compared with 39% for the overall population, and African-American menthol smokers aged 35–54 would be more likely to quit all tobacco use (27% vs 22%). With African-Americans having disproportionately high rates of menthol smoking, a menthol ban would reduce downstream health disparities in smoking-related morbidity and mortality" [88].

As previously discussed, LGBTQ+ smokers exhibit significantly higher rates of menthol cigarette use compared to other population groups of adult smokers. A study of menthol cigarette use by sexual orientation found a higher prevalence and a higher likelihood of smoking menthol cigarettes among LGBT smokers compared to heterosexual/straight smokers [80]. According to the study, an estimated 36.3% of LGBT smokers reported that they usually smoke menthol cigarettes, compared to 29.3% of heterosexual/straight smokers [80]. The difference in menthol use was especially pronounced among LGBT women, with 42.9% of LGBT female smokers

reporting menthol use as compared to 32.4% of heterosexual smokers [80]. Using more recent national data from the 2019 NSDUH, 6.9% of those identifying as heterosexual reported smoking menthol (15.95 million) compared to 14.0% of those identifying as lesbian, gay, or bisexual (2.04 million) [70].

Study findings show social gradient effects (where higher levels of indicators such as household income are linked to better health outcomes and lower levels are linked to poorer health outcomes) for menthol cigarette use [70] [78] [84]. In 2019 NSDUH data, the prevalence of menthol smoking was 14.6% among those adults aged 18 and older with a total family income less than $20,000, 9.1% among those with a family income between $20,000 and $49,999, 6.5% among those with a family income between $50,000 and $74,999, and 3.8% among those with a family income above $75,000 [70]. For additional discussion, see Section IV.B of the Preamble of this proposed rule.

In addition, menthol cigarette use is also higher among adults with behavioral health conditions or illness [70] [79] [84] [105] [106]. In 2019, NSDUH data indicated that 17.4% of adults age 18 and older who reported past month serious psychological stress reported past month menthol smoking compared to only 6.6% of those who did not report past month serious psychological stress [70]. A study utilizing 2008/2009 NSDUH data also found that cigarette smokers with mental health symptoms are more likely to smoke menthol cigarettes than smokers who report mild or no mental health symptoms [79]. An additional analysis of young adults (aged 18-30 years) receiving treatment for smoking cessation also found that of those with severe mental illness (SMI), more than half (58.0%) smoke menthol cigarettes [106].

Members of underserved communities such as African American and other racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower

household income or educational attainment, and individuals with behavioral health disorders are more likely to report smoking menthol cigarettes than other population groups [70] [73] [74] [75] [76] [77] [78] [79] [80] [81] [82] [83] [84]. Prohibiting menthol as a characterizing flavor in cigarettes is expected to confer larger benefits among these populations.

Given these existing population trends in menthol cigarette product smoking, these populations may also experience a disproportionate level of consumer costs associated with this proposed rule. We request comment on these assumptions and estimates.

2. Impacts to Tribally-Affiliated Manufacturers and/or Manufacturers Operating on Tribal Lands

The proposed rule would prohibit the use of menthol as a characterizing flavor in cigarette products and cigarette components and parts, including those that are sold separately to consumers. Any "person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product[,] or imports a finished tobacco product for sale or distribution in the United States" is a tobacco product manufacturer under §900(20) of the FD&C Act and must comply with all applicable requirements under the FD&C Act and the FDA's implementing regulations, including the proposed menthol product standard, if finalized. 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 the FDA and to list their products. Under Section 704 of the FD&C Act, FDA inspects such establishments registered under Section 905 of the FD&C Act, to evaluate whether a manufacturer, including those that are tribally-affiliated and/or operating on Tribal land, is in compliance with the FD&C Act and the FDA's implementing regulations.

Of the count of domestic manufacturers potentially affected by the proposed menthol product standard, FDA estimates that there are 13 tobacco product manufacturers that are tribally-affiliated and/or operate on Tribal land, all of which manufacture products affected by the proposed product standard. As persons submitting registration and listing data to the 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.[74] 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.

Information about the manufacturing volume of these establishments is not known. However, the 13 establishments referenced above as tribally affiliated and/or operating on Tribal land appear to be small entities, based on 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.

As the product standard would apply to manufacturers of menthol cigarettes, any retailers engaged in the manufacture of menthol cigarettes would also fall under the definition of manufacturer under the FD&C Act and be required to register and list. Thus, such entities would be covered by the discussions in the previous cost sections.

[74] The 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 the 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 registered establishments not engaged in the manufacture, preparation, compounding, or processing of tobacco products, such as certain warehouses, due to confusion.

We estimate the impacts of the proposed product standard across all manufacturers in Sections II.D and II.E of this analysis. More detailed analysis of the potential impacts to small businesses, including small tobacco product manufacturers that may operate on Tribal land and/or be tribally affiliated, are discussed in Section III. We request comment on our estimates of the potential impacts of the proposed product standard on manufacturers, including those that are tribally-affiliated and/or operating on Tribal land.

3. U.S. Agriculture and International Effects

The proposed menthol product standard is expected to impact demand for menthol cigarette products. In this section, we discuss the types of tobacco used in cigarette manufacturing, trends in domestic raw tobacco production, and we analyze the impacts on U.S. tobacco leaf growers and international trade of raw tobacco due to an expected reduction in demand for menthol cigarette products.

The three primary types of tobacco used in manufacturing all cigarettes and RYO are bright (also known as flue-cured), burley, and oriental. Bright and burley types of tobacco are grown in the United States, while oriental tobacco type is imported, mostly from Turkey [214]. Over the past five years, tobacco leaf production in the United States has decreased from 630 million pounds in 2016 to about 390 million pounds in 2020—a reduction of almost 40% (see Table 68) [215]. Additionally, in 2020, bright and burley tobacco production represented about 83% of total U.S. tobacco leaf production. (see

Table 69).

Table 68. U.S. Tobacco Leaf Production, 2016-2020, (1,000 lbs)

States	2016	2017	2018	2019	2020	5-year average
Georgia	28,350	26,250	23,750	18,900	19,276	22,805
Kentucky	136,280	183,300	134,370	123,390	107,235	127,129
North Carolina	331,800	360,040	251,925	234,700	184,127	250,895
Pennsylvania	20,460	18,990	17,400	14,300	13,440	16,600
South Carolina	24,700	25,200	22,140	15,770	8,400	18,630
Tennessee	35,690	43,000	39,610	30,490	29,380	34,956
Virginia	51,440	53,381	44,046	30,406	27,555	39,499
United States	628,720	710,161	533,241	467,956	389,413	510,514

Source: Reference 215.

Table 69. U.S. and State Bright and Burley Tobacco Production, 2016-2020 (1,000 lbs)

	2016	2017	2018	2019	2020	5-year average
Class 1, Flue-cured (Bright)						
Georgia	28,350	26,250	23,750	8,900	19,276	21,305
North Carolina	330,000	358,600	250,800	234,000	183,600	271,400
South Carolina	24,700	25,200	22,140	15,770	8,400	19,242
Virginia	48,400	50,600	42,000	28,500	26,400	39,180
United States	431,450	460,650	338,690	297,170	237,676	353,127
Class 3A, Light air-cured, Types 31 and 32 (Burley)						
Kentucky	106,750	129,150	80,000	77,900	72,150	93,190
North Carolina	1,800	1,440	1,125	700	527	1,118
Pennsylvania	16,620	14,670	11,880	8,800	7,920	11,978
Tennessee	16,200	18,000	9,010	6,400	4,340	10,790
Virginia	2,520	2,200	1,500	1,330	680	1,646
United States	143,890	165,460	103,515	95,130	85,617	118,722
Total U.S. Production of Bright and Burley Tobacco	575,340	626,110	442,205	392,300	323,293	471,850
Total Bright and Burley Production as a Share of Total U.S. Tobacco Production	92%	88%	83%	84%	83%	86%

Source: FDA analysis of USDA Annual Crop Production Summary reports [215].
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.

The number of U.S. farms growing tobacco has decreased over the past few decades. In 2017, owners and employees of approximately 6,000 farms were growing tobacco—a dramatic

drop from approximately 93,000 tobacco farms in 1997 [216]. 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.[75] 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 were expected to 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 [217].[76] 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 [218]. Analysis of total U.S. production and trade data of raw tobacco shows cigarettes manufactured in the United States use domestically-produced and imported bright and burley tobacco. To analyze the impact of the proposed menthol product standard on U.S. growers and international trade, we estimate the reduction in the use of tobacco for domestic manufacturing of cigarettes for domestic distribution under various scenarios of reduced prevalence, assuming menthol cigarettes represent 35% of the U.S. market. Before we can analyze the impact of changes in prevalence on

[75] P.L. 108-357, Title VI, the Fair and Equitable Tobacco Reform Act of 2004
[76] For more information, see the United States Department of Agriculture, Farm Service Agency's website on the Tobacco Transition Payment Program at https://www.fsa.usda.gov/FSA/webapp?area=home&subject=toba&topic=landing.

reduction in demand for bright and burley tobacco, we first estimate the amount of bright and burley tobacco available for use in the United States that is used in the manufacture of cigarettes.

In Table 70, we convert the number of sticks of cigarettes produced domestically for distribution in the U.S. market into an estimated weight of the tobacco used to manufacture these cigarettes, assuming that tobacco filler represents 65%-75% of the weight of a cigarette, or about 0.7 grams per stick [69] [219]. Based on internal subject matter expertise, we then assume that the majority (80%) of the total weight of cigarette tobacco filler is comprised of bright and burley tobacco. To determine how much of net domestic supply of bright and burley tobacco is used in manufacturing cigarettes for the U.S. market, we calculate the net bright and burley tobacco supply available for U.S. tobacco product manufacturing (U.S. Production + U.S. Imports - Exports = Net Supply Available for U.S. Manufacturing). To convert between tobacco weights and measurements provided in terms of cigarette sticks, we divide the number of cigarette sticks available for sale in the U.S. market by 317,514.4 (= 0.7g tobacco filler per stick * 453.592 grams per lb * 1,000). During the five years between 2016 and 2020, between 47% and 69% of net bright and burley supplies were used to manufacture cigarettes. The rest of the bright and burley tobacco supplies may have been used in the manufacture of RYO, little cigars and cigarillos, and pipe tobacco for sale in the U.S. market or for export. We request any data and comment regarding these estimates and assumptions.

Table 70. Estimating Weight of Tobacco in Cigarettes Manufactured Domestically for the Sale in the U.S. Market

	2016	2017	2018	2019	2020	5-year average
Cigarettes Removed For Taxable Distribution in the U.S. market, including Imported Cigarettes (billion sticks)	249.8	239.3	226.9	213.4	215.6	229.0
Imported Cigarettes (billion sticks)	7.6	7.9	8.4	10.0	12.7	9.3
Cigarettes Manufactured in the U.S. for Export (billion sticks)	18.2	4.1	2.2	2.3	2.1	5.8
Number of Cigarettes Manufactured and Distributed in the U.S. market (billion sticks)	242.2	231.4	218.5	203.4	203.2	219.7
Total Weight of Cigarette Filler Manufactured and Distributed in the U.S. (weight in 1,000 lbs)[1]	373,759	357,145	337,213	313,842	313,507	339,093
Estimated Total Weight of Bright and Burley Tobacco in Cigarettes Manufactured and Distributed in the U.S. (80% of cigarette filler weight)	299,007	285,716	269,770	251,073	250,805	271,274
Net Bright and Burley Tobacco Supply available for Domestic Tobacco Product Manufacturing (Table 71)	589,949	622,815	393,517	454,210	375,757	487,250
Percentage of Net Supply of Bright and Burley Tobacco Used in Domestic Manufacturing of Cigarettes for Sale in the U.S. Market	51%	46%	69%	55%	67%	56%

Source: FDA analysis of TTB and USDA reports [214] [215] [220].

[1] To convert number of sticks to 1,000 lbs, we divide the number of distributed sticks by 317,514.4 (= 0.7g tobacco filler per stick * 453.592 grams per lb * 1,000); totals may not add due to rounding.

Table 71. Estimating Net U.S. Supply of Bright and Burley Tobacco (weight in 1,000 lbs)

	2016	2017	2018	2019	2020	5-year Average
Domestic Production	575,340	626,110	442,205	392,300	323,293	471,850
Imports	251,559	202,099	174,167	198,358	153,378	195,912
Subtotal: Domestic Production plus Imports	826,899	828,209	616,372	590,658	476,671	667,762
Exports	236,950	205,394	222,856	136,448	100,914	180,512
Total U.S. Supply: Subtotal minus Exports	589,949	622,815	393,517	454,210	375,757	487,250
Imports of Bright and Burley as Share of Total U.S. Supply	43%	32%	44%	44%	41%	40%

Source: Reference 215.

To consider the distributed impact of the proposed rule on the industry demand for raw tobacco, we recognize that during the five years ending in 2020 about 40% of the total U.S. supply of bright and burley tobacco was imported. We also estimated in Section II.B.2.d (baseline) that menthol cigarettes represent about 35% of total U.S. sales for cigarettes. We consider overall declines in the demand for raw tobacco for cigarettes to follow the 3 scenarios described previously and present these reductions at the bottom of Table 72.

We recognize that despite large decreases in domestic production of raw tobacco over the past 5 years, imported tobacco volumes have consistently remained about 40% of the total tobacco leaf supply for use. We expect that this relationship would continue, with approximately 40% of the reduced demand for raw tobacco attributable to reduced import totals. Because U.S. exports of menthol cigarettes would not be affected (see Section VII.A of the Preamble of this proposed rule) by this product standard rule, some of the available supply of bright and burley tobacco may be used to manufacture additional tobacco products for export.

Table 72. Reduction in Bright and Burley Tobacco Use Resulting from the Menthol Product Standard (1,000 lbs)

	2020	5-year Average
Total Bright and Burley Tobacco Supply available for U.S. Tobacco Product Manufacturing (1,000 lbs)	375,757	487,250
Total Weight of Menthol Cigarettes Manufactured and Distributed in the U.S. (weight in 1,000 lbs)	109,727	118,683
Weight of Bright and Burley Tobacco no longer used for Cigarettes under 67% scenario	73,517	79,517
Weight of Bright and Burley Tobacco no longer used for Cigarettes under 59% scenario	64,739	70,023
Weight of Bright and Burley Tobacco no longer used for Cigarettes under 41% scenario	44,988	48,660
Bright and Burley Tobacco no longer used for cigarettes as Share of Net U.S. Tobacco Supply (%)		
Percent of Total Bright and Burley Tobacco no longer used for Cigarettes under 67% scenario	20%	16%
Percent of Total Bright and Burley Tobacco no longer used for Cigarettes 59% scenario	17%	14%
Percent of Total Bright and Burley Tobacco no longer used for Cigarettes 41% scenario	12%	10%

Any imports of menthol cigarettes and cigars manufactured by foreign firms would stop as manufacturers, importers, wholesalers, and retailers would stop offering these products for sale in the United States. Based on internal data providing a count of unique addresses for foreign manufacturers of tobacco products with exports of tobacco products to the United States, we estimate 27 foreign manufacturers of menthol cigarettes would be affected by this proposed product standard.[77] In dollar terms, for fiscal year 2020, the value declared for United States customs of imported menthol cigarettes was approximately $17.7 million. Imports from Canada

[77] The estimated imports of menthol cigarettes and the number of associated foreign facilities is derived from data on tobacco product shipments from FY 2020 prepared on July 22, 2021 and August 10, 2021 by U.S. Food & Drug Administration, Center for Tobacco Products, Office of Compliance and Enforcement.

amounted to 53% of this declared value total, the most of any manufacturer country exporting such products to the United States, followed by Turkey with 44%. Based on internal data on import lines, this total of $17.7 million represents approximately 0.89% of the declared value for all imported tobacco products over fiscal year 2020, which totaled $1.99 billion.

With the establishment of this tobacco product standard, menthol cigarettes may no longer be introduced into domestic commerce. Because this product standard does not affect cigarettes and RYO products with menthol as a characterizing flavor manufactured for export, it is uncertain if domestic entities would continue to manufacture such products for export at a higher, lower, or same rate. We request comment and additional data on the potential effects of the proposed rule on both domestic and foreign entities and international trade.

Eliminating the use of menthol as a characterizing flavor in cigarettes may have impacts on the regions and industries that are associated with the supply chain of mint growing and menthol manufacturing. The extent to which these supply chain components are imported is uncertain. We request comments on the implications for international trade and affected entities of the mint and menthol manufacturing industries.

G. Illicit Trade

The benefits of the proposed product standard would be reduced if smokers were still able to obtain a consistent supply of menthol cigarettes. FDA does not anticipate that a significant and consistently large supply of illicit menthol cigarettes would be available following rule implementation. However, we discuss uncertainty around the potential for illicit trade in menthol cigarettes and illicit product use, exploring a range of research and available data regarding current markets for illicit trade and outlining the how illicit product use is factored into the Menthol Simulation from Levy et al. (2021) [88].

The term "illicit trade" is defined as "any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity" [21 U.S.C. § 387(8)]. This broad definition encapsulates a wide variety of actions that could be undertaken to attempt to subvert laws regulating the manufacture, distribution and sales of tobacco products or of other products used to evade FDA regulations. These laws include tax rates, import and export requirements, minimum age of sale and other age-based restrictions, tobacco product standards, and other FDA regulations.

Illicit markets for contraband and nonconforming tobacco products each carry their own set of incentives and disincentives, thus it is difficult to compare one set of circumstances to another, or to effectively predict the illicit activities that might arise following any particular tobacco regulation (particularly when much depends on inherently unpredictable human behavior). It is similarly difficult to capture an accurate picture of any existing illicit market due to data-gathering challenges regarding illegal activities, though some anecdotal information is available through publicized enforcement efforts.[78, 79]

Data have been collected in an attempt to determine the extent of illicit trade in tobacco products, primarily cigarettes. However, much of the data collection has been focused on tax-evading cigarette purchases, the most common type of illicit trade in tobacco products in the United States. As described below, these data likely overestimate the potential for future illicit

[78] In addition to data-gathering challenges, it is often unclear what assumptions are being made and the specifics of the analysis that goes into estimating illicit trade rates. For examples and discussion, see [221] [222].
[79] For example, see FDA enforcement announcements at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/august-30-2017-two-charged-federal-court-smuggling-counterfeit-cigarettes;https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/march-30-2018-counterfeit-cigarette-smuggler-sentenced-prison; and https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/man-pleads-guilty-selling-counterfeit-vapes; and https://www.fda.gov/news-events/press-announcements/cbp-fda-seize-counterfeit-unauthorized-e-cigarettes.

trade markets that may arise as the result of this proposed product standard. More recent studies of regional and international menthol restrictions in cigarettes offer additional data and information on the potential presence of illicit activities that may follow an FDA menthol product standard.

1. Existing research in illicit trade markets

The ease of transport across State lines and the significant cigarette tax disparities between States results in significant, but localized, tax-evading illicit trade [223]. The localized nature of the activity presents difficulties when trying to estimate the overall percentage of cigarette sales in the United States that are illicit. For example, the results of a 2009-2010 survey of smokers found that although approximately one in five cigarette packs collected did not contain the tax stamp of the jurisdiction where it was purchased, for those smokers residing in New York State, the rate was much higher [224]. Another survey, analyzing the presence of tax stamps on discarded cigarette packs in five northeastern U.S. cities (New York, Boston, Providence, Philadelphia, and Washington, D.C.), found that although 41.3% of the packs had the proper tax stamp across all cities, it ranged from a low of 18.6% (Washington, D.C.) to a high of 73.1% (Philadelphia) [225]. The survey attributed between 30.5% and 42.1% of the packs to interstate illicit trade across the cities [225].

Further complicating efforts to measure illicit trade are the local shifts over time, reflecting changes in jurisdictional taxation, and other regulatory measures. For example, when New York State imposed a cigarette tax increase and restricted the ability of Native American tribes to sell to non-native consumers, the volume of untaxed cigarettes purchased by Tribes for resale dropped from 23.3 million in 2010 to 16,000 in 2012 [226]. During a similar time period (2011-2013), the proportion of cigarette packs discarded in New York City bearing the tax

stamps of Southern States (i.e., likely illegal tax-evading cigarettes) increased from 9.7% to 58.6% [226].

Ease of cigarette transport across State lines is one of the factors allowing tax-evading illicit trade to flourish in certain parts of the United States. This, however, would not be the case under the proposed product standard; because the proposed standard would apply nationwide, there would be no legal domestic sales of nonconforming products to consumers. This suggests that absent other factors, the rates of existing tax-evading illicit trade in cigarettes will be higher than any illicit trade that could arise as a result of implementing this product standard.

2. Data and Reports on the Current State of Illicit Trade in Tobacco Products

Very few data sources offer estimates of the size of the illicit trade due to data-gathering challenges regarding illegal activities. EMI International offers estimates of illicit trade in cigarettes in the United States in its tobacco products data, comparing the amount of duty-paid cigarettes to the total amount of cigarettes consumed. A recent national estimate (which does not account for interstate illicit trade) ranges from 3.6% in 2015 to a high of 4.2% in 2020 [69]. Euromonitor predicts an increase in illicit U.S. sales from 2020 through 2025 (4.2% up to 4.7%), not accounting for additional regulatory actions.

In 2015, the FDA commissioned a report by the National Academies of Science Engineering and Medicine (NASEM) to examine international illicit tobacco markets, how those markets are impacted by policy changes, and lessons that could apply to the United States [227]. The committee examined the impact of tougher anti-smuggling laws, track and trace systems, public education efforts, and effective enforcement interventions. As a part of this research, the Committee estimated the overall percentage of the U.S. cigarette market represented by illicit trade. The report explores a number of methods for calculation (noting the flaws of each),

including measuring the trade gap, comparing tax-paid sales and self-reported consumption, econometric modeling, population survey methods, empty pack collections and pack observation studies, and expert opinions [227, Table 4-1].

Ultimately, the Committee chose to compare tax-paid sales and self-reported consumption measures, and using the data available, estimated a national illicit trade rate (of tax-evading cigarettes) of 8.5% in 2011, a growth from 3.2% in 1993 [227, page 97 and Table 4-3]. The Committee used other data sources to estimate an overall potential range from 8.5% to 21%. The high-end estimate reflects the methodology of the pack return survey by Fix et al. (2013) [224].

In March 2018, the FDA announced the availability of a draft concept paper that described aspects of the tobacco product market and consumer behavior that may be relevant to the development of future illicit markets and sought public comment (83 FR 11754, March 16, 2018). The draft paper breaks down the mechanics of an illicit trade market into their various components and examines factors that might support or hinder the establishment of a persistent illicit trade market in the face of an FDA tobacco product standard [228]. The paper primarily focused on a hypothetical product standard limiting the amount of nicotine in cigarettes, but also considered one that would limit harmful constituents in cigarettes and smokeless tobacco.

Because the paper examines hypothetical illicit trade markets where there is no appropriate existing comparison, specific illicit trade rates were not estimated or predicted. Rather, the paper identifies the elements required to establish illicit trade markets, and how those elements might weigh in favor of or against the establishment of persistent illicit trade markets.

The public was invited to submit comments on the draft concept paper (83 FR 11754, March 16, 2018). While additional analyses and resources were provided, there were no data

submitted indicating that estimating illicit trade rates (either current tax-evading illicit trade in cigarettes or potential future illicit trade markets) requires a different approach.

3. Analysis of Potential Illicit Product Use under a *Menthol Ban* Scenario

As discussed in the in Section II.C.3, the Menthol Simulation by Levy et al. (2021) simulated the future benefit of a menthol cigarette ban on the U.S. population as a whole over the 2021-2060 period [88]. This model compared a *Status Quo Scenario,* in which no menthol ban was implemented, to a simulated *Menthol Ban Scenario* in which a complete ban on menthol cigarettes and cigars was implemented in 2021. To estimate the specific effects of a menthol ban on current and future tobacco use, an expert elicitation was conducted [152]. Experts estimated a number of behaviors under a menthol ban, such as continued (illicit) menthol product use. Rather than supplying a definition of "illicit" as part of the questionnaire, experts were asked to provide their interpretation of what constituted "illicit products." Responses included sales from "Indian reservations," non-conforming foreign imports, domestically-produced counterfeit products, "do-it-yourself, post-market products" such as flavorings that would allow smokers to add menthol cigarettes and cigars after purchase, and, infrequently, internet sales [152].

Experts estimated the percentage of the total population, aged 12-24, that would have initiated menthol cigarette smoking under the *Status Quo Scenario* but instead may initiate with an illicit product under the *Menthol Ban Scenario*. For current smokers, experts also estimated the percentage of the smoking population that would transition to use of illicit products under a *Menthol Ban Scenario* during the initial two years following implementation. Table 73 presents these estimates by age group.

Table 73. Expert Elicitation Estimates of Transitions to Illicit Product Use under a *Menthol Ban* Scenario (n=11)

Description of Population		Total Population (Mean)
Percent of the population, aged 12-24, that would have initiated menthol cigarette smoking under the *Status Quo Scenario* that may, instead, initiate with an illicit product under a *Menthol Ban Scenario*		2.6%
Percent of current smokers that would potentially transition to illicit products under a *Menthol Ban Scenario*	Menthol Smokers, Age 18-24	6.5%
	Menthol Smokers, Age 35-54	5.7%
	Non-Menthol Smokers, Age 35-54	0%

Adapted from Reference 152, pages 25-32.
Note: Among menthol smokers in both the Status Quo Scenario and Menthol Ban Scenario, experts estimated transitions over a two-year period for ages 18-24 and 35-54 [152], which were modeled as mean net differences applied to menthol smokers up to age 30 and over age 30, respectively [88].

Estimates for the total population were adapted to fit the simpler structure of the SAVM. For example, transitions from menthol cigarettes to illicit products were treated as a transition to non-menthol cigarettes for purposes of estimating relative risk, smoking-attributable deaths and life-years lost over the 2021-2060 period under a *Menthol Ban Scenario* [88]. We estimate benefits using these assumptions of illicit product use in Section II.C.4.

While the potential for additional illicit product use could diminish the expected population health benefits of the proposed standard, FDA expects that such effects would be minimal. As discussed in Section V of the Preamble of this proposed rule, evidence from Canada and San Francisco further suggest that the impact of the proposed rule on the illicit market would not be significant [128] [134] [141] [142] [144] [229]. Nationwide implementation of this proposed menthol cigarette product standard would minimize the opportunities for development

of an illicit market. Unlike with regional flavor restrictions for tobacco products, cross-border sales of menthol cigarettes between U.S. jurisdictions would not be available.

If an illicit market develops after this proposed menthol standard is finalized, FDA has the authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, including those imported illegally or purchased online (see section VII.C of preamble for this proposed product standard for additional information about FDA's enforcement authorities). FDA conducts routine surveillance of sales, distribution, marketing, and advertising related to tobacco products and takes corrective actions when violations occur. After this proposed menthol standard is finalized, it would be illegal to import menthol cigarettes and such products would be subject to import examination and refusal of admission under the FD&C Act. Similarly, it would be illegal to sell or distribute menthol cigarettes, including those sold online, and doing so may result in FDA's initiating enforcement or regulatory actions. We note that the Prevent All Cigarette Trafficking Act of 2009 (PACT Act) establishes restrictions that make cigarettes generally nonmailable through the U.S. Postal Service, subject to certain exceptions (18 U.S.C. 1716E). Outside of these exceptions, the U.S. Postal Service cannot accept or transmit any package that it knows, or has reasonable cause to believe, contains nonmailable cigarettes, smokeless tobacco, or ENDS. FDA can take enforcement action against manufacturers, distributors, and importers who manufacture or distribute contraband and illicit tobacco products in interstate commerce, and retailers who fail to comply with applicable Federal laws and regulations, including those found in the FD&C Act and FDA's rules and regulations, covering these products. We note that FDA's enforcement would only address manufacturers, distributors, wholesalers, importers, and retailers. FDA cannot and will not enforce against individual consumer possession or use of menthol cigarettes. We request

comment, including data and additional studies, on this discussion of illicit trade, the expert elicitation estimates regarding "illicit trade" that are incorporated in the Menthol Simulation, and how potential illicit product use could further impact public health.

We note that this proposed product standard would also cover menthol flavoring that is separate from the cigarette. For example, menthol can be added to non-menthol cigarettes via drops, capsules, filter tips for RYO tobacco, or cards that can be inserted into a cigarette pack or pouch of rolling tobacco [230] [231]. Such menthol flavorings would be considered components or parts of cigarettes under proposed § 1162.3, if they are intended or reasonably expected to: (1) alter or affect the cigarette's performance, composition, constituents, or characteristics; or (2) be used with or for the human consumption of a cigarette, and they would not be accessories of cigarettes. Therefore, the manufacture, distribution, sale, or offer for distribution or sale of such products would be prohibited should this proposed rule be finalized.

H. Analysis of Regulatory Alternatives

We analyze several alternatives to the proposed rule: extending the effective date, prohibiting menthol as an intentional additive in all cigarette products, and allow exemption requests for cigarette products.

1. Extend the Effective Date of the Product Standard from 1 year to 2 years

The effective date included in this proposed product standard allows manufacturers a year after the publication of the rule to comply with the prohibition on menthol as a characterizing flavor in cigarettes (including cigarettes that are HTPs), cigarette tobacco, and RYO tobacco. Under this alternative, we analyze the impacts on the benefits and costs of the proposed product

standard of extending the effective date to two years following publication.[80] This alternative results in delayed onset of benefits but is also expected to reduce costs and transfers.

Additional delay, past the proposed 1-year effective date, would increase the numbers of youth and young adults who experiment with menthol cigarettes and become regular smokers, delay cessation by current smokers, and exacerbate health disparities. Overall, the delayed onset of benefits would mean an additional year of unchanged mortality risk from the baseline as current users of menthol cigarette products continue using these products for another year and another cohort of youth and young adults initiate tobacco use with menthol cigarettes.

Under this regulatory alternative, we would expect that consumers would not begin switching to other tobacco products until the proposed standard becomes effective, resulting in a 1-year delay of search costs. We also expect that manufacturing establishments, with an additional year to plan and implement reallocation procedures, would be able to spread these costs across the two years. However, we expect the cost estimates for reading and understanding the rule for manufacturing, wholesaling, and retailing firms would still occur in the first year (2024) and be unaffected by this alternative.

In addition to the delay in benefits and costs, the one-year delay in consumers ceasing tobacco product use or switching to non-menthol cigarette products or other tobacco products would result in a delay in revenue transfers. We summarize the primary value of these impacts on the total costs, benefits, and transfers in Table 74.

[80] For the purpose of this analysis we assume that if the menthol cigarette product standard effective date is extended to 24 months then the cigar flavors product standard would also be extended to 24 months.

Table 74. Summary of Benefits with a 1-year Delay in the Proposed Product Standard compared to the Main Analysis ($2020, Billion)

Value of Mortality Risk Reductions		Discount Rate	Benefits ($2020, Billion)		
			Low	Primary	High
Present Value	Main Analysis	3%	$2,309	$4,955	$7,535
		7%	$1,250	$2,685	$4,081
	Alternative	3%	$2,223	$4,769	$7,252
		7%	$1,171	$2,513	$3,819
	Difference	*3%*	*($86)*	*($186)*	*($283)*
		7%	*($80)*	*($172)*	*($262)*
Annualized Value	Main Analysis	3%	$99	$212	$322
		7%	$93	$200	$305
	Alternative	3%	$95	$204	$310
		7%	$87	$188	$285
	Difference	*3%*	*($4)*	*($8)*	*($12)*
		7%	*($6)*	*($13)*	*($20)*

Although benefits are presented in billions of dollars, costs are presented in terms of dollars, rounded to the nearest thousand, to provide an estimate of the differences in costs that would occur under this alternative. Table 75 presents a comparison of the costs under this alternative.

Table 75. Summary of Costs with a 1-year Delay in the Proposed Product Standard compared to the Main Analysis (Present and Annualized Values, $2020)

Value of Mortality Risk Reductions		Discount Rate	Costs ($2020)		
			Low	Primary	High
Present Value	Main Analysis	3%	$223,045,000	$6,805,882,000	$13,421,556,000
		7%	$207,954,000	$4,113,193,000	$8,051,269,000
	Alternative	3%	$218,182,000	$6,366,945,000	$12,548,543,000
		7%	$198,017,000	$3,641,542,000	$7,117,898,000
	Difference	*3%*	*($4,863,000)*	*($438,937,000)*	*($873,013,000)*
		7%	*($9,937,000)*	*($471,651,000)*	*($933,371,000)*
Annualized	Main Analysis	3%	$9,498,000	$290,598,000	$573,085,000
		7%	$15,508,000	$307,029,000	$600,991,000
	Alternative	3%	$9,319,000	$269,027,000	$530,137,000
		7%	$14,784,000	$270,926,000	$529,519,000
	Difference	*3%*	*($179,000)*	*($21,571,000)*	*($42,948,000)*
		7%	*($724,000)*	*($36,103,000)*	*($71,472,000)*

2. Prohibit Menthol as an Intentional Additive

Studies suggest that menthol may currently be present in cigarettes not labeled as menthol cigarettes [175] [219] [232] [233] [234]. More recently, Schneller et al. (2020) measured the amount of menthol in cigarettes across 12 cigarette brands, noting that products marketed as "non-mentholated" cigarettes contained menthol [235]. This alternative considers a prohibition on the use of menthol as an intentional additive in a cigarette product production process. This alternative contrasts with the current proposed product standard which would prohibit menthol as a characterizing flavor in cigarettes, but does not restrict the use of menthol as an additive. Under this alternative, a manufacturer of cigarettes would be prohibited from intentionally adding menthol or causing menthol to be added, of any quantity, during a cigarette product's production or packaging process.

This regulatory alternative would more strictly direct cigarette product manufacturing such that menthol could not be intentionally added to cigarette products at any stage of production or packaging. If FDA pursued this regulatory option, the rule could potentially impact more manufacturers of cigarette products. FDA expects that the costs to industry of adjusting production procedures under this alternative would be similar to those estimated under the proposed rule. Manufacturers would be required to develop and maintain purchase control records and production records to demonstrate that menthol was not added at any stage, such that any detected level of menthol in a commercial product would be unintentional. These records may create additional recordkeeping costs for those manufacturers that do not already create and maintain similar information. Additionally, any change in a cigarette additive that results in a new tobacco product would require a firm to submit for premarket review, creating additional costs.

The health benefits of this alternative are uncertain. As discussed in the Preamble of this proposed rule, menthol in cigarettes enhances nicotine addiction through a combination of its flavor, sensory effects, and interaction with nicotine in the brain, facilitating repeated experimentation with cigarettes and progression to regular smoking, which repeatedly exposes the brain to nicotine [1] [190]. It is unknown to what extent non-characterizing menthol additives influence cigarette smoking and, thus, we cannot estimate what additional effect prohibiting menthol as an intentional additive in cigarette products would have on initiation and experimentation, nicotine dependence and addiction for cigarettes, and the likelihood of cessation among current cigarette smokers.

This alternative may also reduce some government costs in comparison to the proposed product standard, as inspectors may be able to determine compliance by only reviewing existing production and purchase control records. In addition to information reviewed during inspection, ingredient listing submissions required under Section 904(a)(1) of the FD&C Act could also be used to confirm that menthol is not intentionally being added to cigarette products.

We request comment and data on the comparative costs and benefits associated with prohibiting menthol not only as a characterizing flavor in cigarette products, but as an intentional additive.

3. Allow Exemption Requests for Cigarette Products

We are proposing that this product standard would cover all products meeting the definition of "cigarette" in section 900(3) of the FD&C Act (proposed § 1162.3 includes a definition of cigarette). This includes all types, sizes, nicotine strengths and formulations of cigarettes, cigarette tobacco and RYO tobacco, as well as HTPs that meet the definition of a cigarette in the FD&C Act (cigarettes that are HTPs).

In general, as discussed in the preamble for this proposed rule, menthol as a characterizing flavor in tobacco products enhances product appeal, usability, and addictiveness and has played a role in creating and perpetuating tobacco-related health disparities. While these effects raise concerns in the context of any tobacco product—none of which is without risk—FDA recognizes that certain products that meet the definition of cigarette in the FD&C Act may present different considerations with respect to this proposed product standard. For example, certain cigarettes may produce significantly fewer or lower levels of toxicants or have significantly reduced potential for creating or sustaining addiction. Recognizing that tobacco products exist on a continuum of risk, with combustible cigarettes being the deadliest, FDA recognizes that certain, specific products meeting the definition of a cigarette (e.g., some that are not combustible or are minimally addictive) may pose less risk to individual users or to population health than other products meeting the definition of a cigarette. FDA also notes that there is wide variability even within certain types of cigarettes, such as variability in toxicants or youth appeal among HTPs or minimally addictive cigarettes. Accordingly, FDA is considering options that would allow certain products that present different considerations to seek exemptions from the product standard on a case-by-case basis.

Section 910 of the FD&C Act provides that those seeking to market new tobacco products via a premarket tobacco application may justify a deviation from a product standard to which it does not conform. However, no similar provision exists for pre-existing products or products that already are authorized under, or that seek authorization under, other pathways, i.e., the substantial equivalence pathway or exemption from substantial equivalence. FDA is considering whether a final product standard rule should include a provision for requesting an exemption from the standard for certain products within particular categories, on a case-by-case

basis, consistent with the potential for differential public health impacts among products meetings the definition of "cigarette", as discussed above.

Accordingly, the Preamble for this proposed rule requests comments on exemptions, including:

1. whether the final rule should include a provision that allows for firms to request an exemption from the standard for specific products of certain types (e.g., noncombusted, reduced nicotine), on a case-by-case basis;
2. for what types of products should firms be eligible to request an exemption;
3. for an exemption provision, how should the agency evaluate exemption requests, and what data and information should firms be required to submit for this; and
4. if an exemption provision should apply to products currently on the market at the time of the final rule's effective date, how the exemption process should work (e.g., require that any exemption request be received within 180 days of publication so the agency has time to make a determination before the effective date).

We note that the benefits and costs of this alternative are uncertain. We assume that firms would only submit an exemption request when the potential net profits from such a request are expected to be positive and outweigh the costs of submission. We request comment on the potential impact of this rule alternative on industry costs, the Agency's use of resources, and the public health.

III. **Initial Small Entity Analysis**

FDA has examined the economic impacts 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 rule on small entities. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this document, serves as the Initial Regulatory Flexibility Analysis (IRFA), as required under the Regulatory Flexibility Act.

Initial Regulatory Flexibility Analysis Elements:

1. Reasons action is being considered and object of the rule (see Section II.A) and legal basis for the rule (see Section I.C of the preamble to this proposed rule)
2. Estimate of the small entities impacted (in this section)
3. Compliance requirements (see Section II.D)
4. Significant alternatives considered (see Section II.H and this section)
5. Duplicative overlapping and conflicting rules (see Section II.B.5)

A. Description and Number of Affected Small Entities

The Small Business Administration (SBA) uses an employee count threshold to determine when firms qualify as small tobacco product manufacturers or small tobacco and tobacco product merchant wholesalers and annual sales to determine who may be a small retailer [120]. The SBA thresholds for manufacturers and wholesalers only account for employment and does not take into revenue into consideration as is the case with other types of small business

thresholds. Conversely, the SBA thresholds for retailers considers only annual sales and does not take counts of employees into consideration. The SBA notes that when determining a business size, all domestic and foreign affiliates need to be considered.[81] SBA employment threshold for tobacco manufacturing (NAICS code 312230) is currently 1,500 employees and for tobacco and tobacco product merchant wholesalers (NAICS 424940) is 250 employes [120]. SBA thresholds for retailers range from $8 Million to $35 Million in annual sales, depending on the specific NAICS category.

The TCA defines a "small tobacco product manufacturer"[82] as a tobacco product manufacturer that employs fewer than 350 employees, where the count of employees includes the employees of each entity that controls, is controlled by, or is under common control with the manufacturer. However, for the purposes of this IRFA analysis, we use the SBA threshold to determine the count of small tobacco manufacturers affected by the proposed product standard.

FDA's estimates are based on review of Dun and Bradstreet data and publicly available information[83] for establishments manufacturing menthol cigarettes and menthol RYO tobacco products (See Section II.B.2.c). We estimate 29 menthol cigarette manufacturers and 12 RYO tobacco manufacturers may fall below the SBA employee threshold for tobacco manufacturing. Of these, approximately seven menthol cigarette manufacturers also produce menthol RYO products, but we do not adjust for this dual manufacturing in our analysis. We also identified

[81] SBA determines whether an entity qualifies as a small business concern by counting its receipts or employees plus the receipts or employees of all its domestic and foreign affiliates, regardless whether the affiliates are organized for profit. (13 C.F.R. § 121.103(a)(6)) [236].
[82] Section 900 of the TCA defines a tobacco product manufacturer as "any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States."
[83] Publicly available information includes review of company websites and press releases, news reports, and internet search results.

three manufacturers of menthol flavored cigarette rolling paper and estimate that these are all small tobacco manufacturers. There are currently no small manufacturers of HTPs.

Table 76. Number of Small Tobacco Manufacturing Entities Impacted by the Proposed Rule

Category	Total count	Number that are Small	Small Entities as a% of Total
Menthol Cigarettes	34	29	85%
Menthol RYO Tobacco	12	12	100%
Menthol Rolling Paper	3	3	100%
Menthol HTP	2	0	0%

In addition to these menthol cigarette and RYO tobacco manufacturers and importers, we also estimate the number of wholesaler and retailer firms that sell tobacco products (1,308 wholesale firms and 138,096 retail firms; see analysis and tables in Section II.B.2.c.ii *Domestic Wholesalers and Retailers*). To identify which potentially affected tobacco product wholesalers and retailers may qualify as small entities, we utilize data from the 2017 SUSB [237] for wholesalers and the 2017 Economic Census [238] for retailers to compare whether their annual sales may fall below the SBA threshold for their respective NAICS code. By comparing the counts of firms whose annual sales in 2017 fall below the SBA threshold to the total number of firms in the category, we estimate the percentage of tobacco product wholesaler and retailers potentially qualifying as small entities. We present these thresholds and calculations in Table 77.

Table 77. Estimated Percentage of Small Wholesale and Retail Firms by Category

NAICS	Description of NAICS Category	SBA Size Standard (employees or $million)	Nearest Census Size Category, without Exceeding (employees or $million, rounded)	Total Number of Firms	Number of Firms Below Census Size Standard	Percentage of Small Firms (%)
Wholesalers[1]						
424940	Tobacco and Tobacco Product Merchant Wholesalers	250	200	1,285	1,240	96.5%
Retailers[2]						
445110	Supermarkets and Other Grocery (except Convenience) Stores	$35.0	$25.0	40,981	30,123	73.5%
445120	Convenience Stores	$32.0	$25.0	25,844	18,095	70.0%
445300	Beer, Wine, and Liquor Stores	$8.0	$5.0	30,313	25,380	83.7%
446110	Pharmacies and Drug Stores	$30.0	$25.0	19,259	17,939	93.1%
447110	Gasoline Stations with Convenience Stores	$32.0	$25.0	56,926	52,553	92.3%
447190	Other gasoline stations	$16.5	$10.0	10,084	8,521	84.5%
452311	Warehouse Clubs and Supercenters	$32.0	$25.0	9	0	0.0%
452319	All other general merchandise stores	$35.0	$25.0	7,857	6,596	84.0%
453991	Tobacco Stores	$8.0	$5.0	8,286	6,143	74.1%

[1] Estimates of total wholesalers and number of firms likely below closest Census employee count threshold sourced from 2017 SUSB [237].
[2] Estimates of total retail firms and number of firms likely falling below the Census sales threshold sourced from 2017 Economic Census [238]

Using the most current data on tobacco-selling firms, we apply the 2017 percentage of small wholesale and retail firms by NAICS code to the total number of firms selling tobacco products in 2019 and estimate the number of small wholesale and retail firms under each SBA threshold. We present the results of these calculations in Table 78.

Table 78. Percentage and Estimate of Small Wholesale and Retail Firms with Tobacco Sales

NAICS	NAICS Description	Count of Firms with Tobacco Sales, 2019 data[1]	Estimated Percentage of Small Firms (%), 2017 data[2]	Estimated Count of Small Firms with Tobacco Sales
42494	Tobacco and Tobacco Product Merchant Wholesalers	1,308	96.5%	1,262
44511	Supermarkets and Other Grocery (except Convenience) Stores	18,332	73.5%	13,475
44512	Convenience Stores	24,854	70.0%	17,402
44530	Beer, Wine, and Liquor Stores	16,578	83.7%	13,880
44611	Pharmacies and Drug Stores	8,269	93.1%	7,702
44711	Gasoline Stations with Convenience Stores	52,390	92.3%	48,366
44719	Other gasoline stations	2,140	84.5%	1,808
452311	Warehouse Clubs and Supercenters	28	0.0%	0
452319	All other general merchandise stores	5,839	84.0%	4,902
453991	Tobacco Stores	9,667	74.1%	7,167
	Total	139,404		115,963

[1] From Table 14.
[2] From Table 77.

We request comment on these assumptions, calculations, and data sources relating to the estimation of tobacco-selling firms that may fall below SBA thresholds.

B. Economic Effect on Small Entities

Small entities would be subject to the costs to firms as described in the cost section (See Section II.D). This includes the cost of reading and understanding the proposed rule and the one-time cost to reallocate productive resources to other tobacco products. Using Table 40, we estimate the one-time cost to read and understand the proposed rule to range from $401 to $2,508 per entity. Using Table 41, we estimate the one-time cost for planning and implementing reallocation procedures to range from $4,287 (=$184,332 / 43 entities, assuming 40 hours of labor) to $8,574 (assuming 80 hours of labor) per small entity. Thus, we estimate the total one-time costs for menthol cigarette and RYO tobacco manufacturers to be $4,688 to $11,082 per small entity.

We also expect that tobacco-selling wholesale and retail firms would experience one-time costs to read and understand the proposed rule ($401 to $2,508 per entity). We do not estimate a friction cost to wholesalers or retailers as this product standard will not impact the use of their productive resources. Prior to the effective date of the proposed standard, wholesalers, retailers and related entities may continue to sell available stock of menthol cigarette products. Therefore, we do not estimate any additional costs for inventory disposition for small retailers. As discussed in Section II.D.1.c, with many retailers under contract to provide dedicated shelf space for tobacco products, we expect that retailers will be stocked by wholesalers and distributors with other tobacco products to fill the shelf space previously reserved for menthol cigarette products. Consumers are expected to use the transferred value of previous menthol cigarette product purchases to instead purchase other goods at retail, including both tobacco and non-tobacco products. These purchases may result in revenues for the same retailers that previously sold menthol cigarette products or may create new revenues for different retailers. We, therefore, do not estimate any additional changes in revenue for small retailers. We request comment, including additional data, on these assumptions and other potential impacts on small retailers that may result from the proposed product standard.

Additionally, we expect that some small firms may experience long term changes to their revenue due to the proposed product standard, including changes to producer surplus. While these potential reductions in revenue are considered transfers from small tobacco product manufacturers to consumers, these transfers away from small tobacco product manufacturers may represent significant impacts for small tobacco manufacturers. As described in Section II.C (Benefits) and Section II.E (Transfers), we analyze the amount of cigarette product revenues that transfer back to consumers who would have otherwise purchased menthol cigarette products in

absence of the rule. However, some consumers are expected to use the transferred value to purchase non-menthol cigarette products, likely manufactured and imported by the same entities that currently produce menthol cigarette products. For this analysis, we assume firms would retain revenues from such non-menthol cigarette purchases and we only estimate the impact of small business revenue transfers away from the market for cigarette products.

1. Menthol Cigarettes

A review of IRI retail sales data for menthol cigarettes, aggregated by manufacturers or brand owners, suggests that three manufacturers or brand owners account for 91.1% of menthol cigarette sales in the U.S. by volume and almost all of the revenue (96.3%) generated by menthol cigarette sales [115]. Based on a review of industry submission and inspection data, Dun and Bradstreet data, and publicly available information, we do not believe these three manufacturers or brand owners are small entities under the SBA employee threshold for tobacco product manufacturing. These three larger manufacturers/brand owners account for a significant majority of menthol cigarette sales and we expect that they would consequently bear a significant majority of the impact of the estimated revenue transfers from manufacturers to consumers.

The 29 small menthol cigarette manufacturing entities, who account for approximately 4% of total menthol cigarette revenue, would likely also face reductions in revenue under the proposed product standard. While these potential reductions are considered transfers from small tobacco product manufacturers to consumers, we analyze these transfers as impacts on small businesses.

From Table 62 in Section II.E.3 (Transfers), we start with the stream of total menthol cigarette product revenues excluding excise taxes. We disaggregate this stream into the proportion of manufacturer revenue attributable to cigarettes using information from Section

II.B.2.d and estimate the cigarette-attributable proportion of menthol manufacturer revenues, excluding taxes . We then subtract the 96.3% of menthol cigarette sales captured by the three larger manufacturers/brand owners in each year to generate a stream of revenue attributable to small menthol cigarette manufacturing. We divide this stream of revenue attributable to small menthol cigarette manufacturing by 29 to generate a baseline average stream of revenue per small menthol cigarette manufacturer. As an overall average, this stream may not be reflective of any particular manufacturer and could vary considerably with the proportion of each small entity's overall sales of menthol cigarettes. We also note that this estimate of an average small cigarette manufacturer is based on the number of manufacturing establishments, rather than the number of business entities. A small entity brand owner that is supplied menthol cigarettes via contract manufacturing would have their particular revenue averaged into the estimated revenue attributable to the contracted manufacturing establishment. We present this baseline average stream of revenue per small menthol cigarette manufacturer in Table 79.

Table 79. Baseline Average Stream of Revenue per Small Menthol Cigarette Manufacturer ($2020, Million)

Year Count	Year	Total Revenue for Menthol Cigarette Products* (Million)	Menthol Cigarette Revenue (Million)	Cigarette Revenue Attributable to Small Manufacturers (Million)	Average Revenue per Small Menthol Cigarette Manufacturer (Million)
Year 0	2023	$23,178.9	$23,155.5	$852.5	$29.4
Year 1	2024	$23,744.1	$23,720.2	$873.3	$30.1
Year 2	2025	$24,309.3	$24,284.8	$894.1	$30.8
Year 3	2026	$24,309.3	$24,284.8	$894.1	$30.8
Year 4	2027	$24,309.3	$24,284.8	$894.1	$30.8
Year 5	2028	$24,309.3	$24,284.8	$894.1	$30.8
…	…	…	…	…	…
Year 39	2062	$24,309.3	$24,284.8	$894.1	$30.8
Year 40	2063	$24,309.3	$24,284.8	$894.1	$30.8
	Total	$994,984.5	$993,982.1	$36,594.8	$1,261.9

* Menthol cigarette products include cigarettes, RYO tobacco, and HTPs that meet the definition of cigarette.

To the average stream of revenue per small menthol cigarette manufacturer, we apply the three scenarios outlined in the Transfers section – 41%, 59%, and 67% revenues transfer to consumers starting in 2024 (Year 1) – and present these impacts in Table 80. This calculation assumes that consumers are generally indifferent to the size of tobacco product manufacturer from whom they purchase. To the extent that small menthol cigarette manufacturers retain greater customer loyalty than non-small manufacturers, or produce tobacco products other than menthol cigarettes to be purchased by former menthol cigarette smokers, this analysis would overestimate the impacts of potential revenue transfers to their business. Additionally, menthol cigarette revenue transfers are proportional to revenues; any small menthol cigarette manufacturer with revenue below the estimated average would also face less than average estimated impacts to their revenue.

Table 80. Estimating Potential Transfers of Revenue for an Average Small Menthol Cigarette Manufacturer ($2020, Million)

Year Count	Year	Average Revenue per Small Menthol Cigarette Manufacturer (Million)	Impact of Transfers on Menthol Cigarette Revenues for an Average Small Business (Million)		
			41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Year 0	2023	$29.4	-	-	-
Year 1	2024	$30.1	-	-	-
Year 2	2025	$30.8	$12.6	$18.2	$20.7
Year 3	2026	$30.8	$12.6	$18.2	$20.7
Year 4	2027	$30.8	$12.6	$18.2	$20.7
Year 5	2028	$30.8	$12.6	$18.2	$20.7
…	…	…	…	…	…
Year 39	2062	$30.8	$12.6	$18.2	$20.7
Year 40	2063	$30.8	$12.6	$18.2	$20.7
Total		$1,261.9	$493.0	$709.4	$805.6

We discount these potential impacts to an average small menthol cigarette manufacturer using 3% and 7% discount rates. The primary present value of total revenue impacts to an average small menthol cigarette manufacturing entity is approximately $402.79 million at a 3% discount rate (low $279.91 million; high $457.41 million), and approximately $225.50 million at a 7% discount rate (low $156.70 million; high $256.08 million). The primary annualized value of revenue impacts to an average small menthol cigarette manufacturing entity is approximately $17.20 million at a 3% discount rate (low $11.96 million; high $19.54 million), and approximately $16.84 million at a 7% discount rate (low $11.70 million; high $19.12 million). We present this summary of present and annualized values in Table 81.

Table 81. Summary of Present and Annualized Value of Revenue Transfers for an Average Small Menthol Cigarette Manufacturer

Category	Discount Rate	Estimated Revenue Transfers ($2020, Million)		
		Low (41%)	Primary (59%)	High (67%)
Undiscounted Value	N/A	$492.98	$709.40	$805.59
Present Discounted Value	3%	$279.91	$402.79	$457.41
	7%	$156.70	$225.50	$256.08
Annualized Value	3%	$11.96	$17.20	$19.54
	7%	$11.70	$16.84	$19.12

Based on these estimated revenue transfers, we find that this proposed rule would likely have a significant economic impact on a substantial number of small menthol cigarette manufacturers. As we note in Section II.B.2.c.i, our analysis of TRLM data suggests that manufacturers of currently marketed menthol cigarettes also manufacture non-menthol versions, often within the same brand. We request comment, including additional data, on this analysis of revenue transfers and other potential impacts on small menthol cigarette manufacturers that may result from the proposed product standard.

2. Menthol RYO and Menthol Rolling Paper

Overall, menthol RYO tobacco sales represent a smaller proportion of the RYO tobacco market compared to menthol cigarettes in the overall cigarette product market. As noted in Section II.B.2.d, menthol RYO tobacco accounts for only about 8% of all RYO dollar sales, approximately $25.6 million in 2020. Similar to the cigarette market, sales of menthol RYO tobacco is also highly concentrated, with three companies accounting for about 90% of menthol RYO market [115]. However, these three menthol RYO tobacco manufacturers or brand owners would likely be considered small entities under the SBA employee threshold for tobacco manufacturing. For this analysis, we consider all menthol RYO tobacco manufacturers or brand owners and 100% of menthol revenues to be from small entities.

Similar to the process for menthol cigarettes, we disaggregate the stream of total menthol sales for cigarettes, RYO tobacco, and cigarettes that are HTPs, excluding excise taxes, into the proportion of manufacturer revenue attributable to RYO tobacco using information from Section II.B.2.d.i and estimate the RYO tobacco-attributable proportion of menthol manufacturer revenues, excluding taxes. As we have assumed that 100% of menthol RYO tobacco revenue comes from small entities, we divide this stream of revenue attributable to small menthol RYO tobacco manufacturing by 12 to generate a baseline average stream of revenue per small menthol RYO tobacco manufacturer. As an overall average, this stream may not be reflective of any particular manufacturer and could vary considerably with the proportion of each small entity's sales of menthol RYO tobacco. We also note that this estimate of an average small RYO tobacco manufacturer is based on the number of manufacturing establishments, rather than the number of business entities. A small entity brand owner that is supplied menthol RYO tobacco via contract manufacturing would have their particular revenue averaged into the estimated revenue

attributable to the contracted manufacturing establishment. We present this baseline average stream of revenue per small menthol RYO tobacco manufacturer in Table 82.

Table 82. Baseline Average Stream of Revenue per Small Menthol RYO Tobacco Manufacturer ($2020, Million)

Year Count	Year	Total Revenue for Menthol Cigarette Products* (Million)	RYO tobacco Revenue attributable to Small Manufacturers (Million)	Average Revenue per Small Menthol RYO Tobacco Manufacturer (Million)
Year 0	2023	$23,178.9	$18.0	$1.5
Year 1	2024	$23,744.1	$18.4	$1.5
Year 2	2025	$24,309.3	$18.9	$1.6
Year 3	2026	$24,309.3	$18.9	$1.6
Year 4	2027	$24,309.3	$18.9	$1.6
Year 5	2028	$24,309.3	$18.9	$1.6
…	…	…	…	…
Year 39	2062	$24,309.3	$18.9	$1.6
Year 40	2063	$24,309.3	$18.9	$1.6
Total		$994,984.5	$772.9	$64.4

* Menthol cigarette products include cigarettes, RYO tobacco, and HTPs that meet the definition of cigarette.

As with the small menthol cigarette revenue analysis, we apply the three scenarios outlined in the Transfers section – 41%, 59%, and 67% revenues transfer to consumers starting in 2024 (Year 1) – and present these impacts in Table 83. This calculation assumes that consumers are generally indifferent to the size of tobacco product manufacturer from whom they purchase. To the extent that small menthol RYO tobacco manufacturers retain greater customer loyalty than non-small manufacturers, or produce tobacco products other than menthol RYO tobacco to be purchased by former menthol RYO tobacco users, this analysis would overestimate the impacts of potential revenue transfers to their business. Additionally, menthol RYO tobacco revenue transfers are proportional to revenues; any small menthol RYO tobacco manufacturer with revenue below the estimated average would also face less than average estimated impacts to their revenue.

Table 83. Estimating Potential Transfers of Revenue for an Average Small Menthol RYO Manufacturer ($2020, Million)

Year Count	Year	Average Revenue per Small Menthol RYO Tobacco Manufacturer (Million)	Impact of Transfers on Menthol RYO Revenues for an Average Small Business (Million)		
			41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Year 0	2023	$1.5	-	-	-
Year 1	2024	$1.5	-	-	-
Year 2	2025	$1.6	$0.6	$0.9	$1.1
Year 3	2026	$1.6	$0.6	$0.9	$1.1
Year 4	2027	$1.6	$0.6	$0.9	$1.1
Year 5	2028	$1.6	$0.6	$0.9	$1.1
…	…	…	…	…	…
Year 39	2062	$1.6	$0.6	$0.9	$1.1
Year 40	2063	$1.6	$0.6	$0.9	$1.1
Total		$64.4	$25.2	$36.2	$41.1

We discount these streams of potential impacts to an average small menthol RYO manufacturer using 3% and 7% discount rates. The primary present value of total revenue impacts to an average small menthol RYO manufacturing entity is approximately $20.6 million at a 3% discount rate (low $14.3 million; high $23.3 million), and approximately $11.5 million at a 7% discount rate (low $8.0 million; high $13.1 million). The primary annualized value of revenue impacts to an average small RYO cigarette manufacturing entity is approximately $0.9 million at a 3% discount rate (low $0.6 million; high $1.0 million), and approximately $0.9 million at a 7% discount rate (low $0.6 million; high $1.0 million). We present this summary of present and annualized values in Table 84.

Table 84. Summary of Present and Annualized Value of Potential Transfers of Revenue for an Average Small Menthol RYO Tobacco Manufacturer

Category	Discount Rate	Estimated Impacts of Revenue Transfers ($2020, Million)		
		Low (41%)	Primary (59%)	High (67%)
Undiscounted Value	N/A	$25.2	$36.2	$41.1
Present Discounted Value	3%	$14.3	$20.6	$23.3
	7%	$8.0	$11.5	$13.1
Annualized Value	3%	$0.6	$0.9	$1.0
	7%	$0.6	$0.9	$1.0

Based on these estimated revenue transfers, we find that this proposed rule would likely have a significant economic impact on a substantial number of small menthol RYO tobacco manufacturers.

We are unable to estimate an impact to the revenues of small menthol components and parts manufacturers that package and market their products for direct consumer purchase because we lack data and revenue information for these entities. We request comment and additional data, including revenues, for manufacturers of menthol components and parts (e.g., mentholated rolling paper and filtered tubes).

C. Additional Flexibility Considered

The regulatory alternatives analyzed in Section II.H that would reduce costs for affected manufacturers also offer potential regulatory relief options for small menthol cigarette product manufacturers, wholesalers, and retailers, as defined by SBA. Here, we show the possible reductions in costs per establishment under the alternative. Section II.H discusses additional regulatory alternatives considered.

1. Extend the Effective Date of the Rule from 1 to 2 Years

FDA is considering whether to delay the effective date from one year following publication of the rule to two years. We expect the cost estimates for reading and understanding the rule for manufacturing, wholesaling, and retailing firms would still occur in the first year (2024) and be unaffected by this alternative. The effective date included in this proposed product standard allows manufacturers one year after the publication of the rule to plan and implement any production process changes in order to comply with the prohibition on menthol as a characterizing flavor in cigarettes (including cigarettes that are HTPs), cigarette tobacco, and RYO tobacco. Under this alternative, we analyze the impacts for the proposed product standard of extending the effective date to two years following publication. We present the change in present and annualized revenue transfers for small menthol cigarette and RYO tobacco manufacturers in Table 85. This alternative results in delayed onset of benefits but is also expected to delay transfers and some costs, as discussed in Section II.H.

Table 85. Comparison of Transfer of Revenue Impacts Under a 1-Year Delay Alternative Compared to the Main Analysis

	Discount Rate	Small Menthol Cigarette Manufacturers ($2020, Million)			Small Menthol RYO tobacco Manufacturers ($2020, Million)		
		Low	Primary	High	Low	Primary	High
Present Value–Main Analysis	3%	$279.9	$402.8	$457.4	$14.3	$20.6	$23.3
	7%	$156.7	$225.5	$256.1	$8.0	$11.5	$13.1
Present Value–Alternative	3%	$268.0	$385.6	$437.9	$13.7	$19.7	$22.4
	7%	$145.7	$209.6	$238.0	$7.4	$10.7	$12.1
Present Value–Difference	*3%*	*($11.9)*	*($17.1)*	*($19.5)*	*($0.6)*	*($0.9)*	*($1.0)*
	7%	*($11.0)*	*($15.9)*	*($18.0)*	*($0.6)*	*($0.8)*	*($0.9)*
Annualized–Main Analysis	3%	$12.0	$17.2	$19.5	$0.6	$0.9	$1.0
	7%	$11.7	$16.8	$19.1	$0.6	$0.9	$1.0
Annualized–Alternative	3%	$11.4	$16.5	$18.7	$0.6	$0.8	$1.0
	7%	$10.9	$15.6	$17.8	$0.6	$0.8	$0.9
Annualized–Difference	*3%*	*($0.5)*	*($0.7)*	*($0.8)*	*($0.0)*	*($0.0)*	*($0.0)*
	7%	*($0.8)*	*($1.2)*	*($1.3)*	*($0.0)*	*($0.1)*	*($0.1)*

2. Allow Exemption Requests for Cigarette Products

FDA recognizes that certain products that meet the definition of cigarette in the FD&C Act may present different considerations with respect to this proposed product standard. For example, certain cigarettes may produce significantly fewer or lower levels of toxicants or have significantly reduced potential for creating or sustaining addiction. Recognizing that tobacco products exist on a continuum of risk, with combustible cigarettes being the deadliest, FDA recognizes that certain, specific products meeting the definition of a cigarette (e.g., some that are not combustible or are minimally addictive) may pose less risk to individual users or to population health than other products meeting the definition of a cigarette. FDA also notes that there is wide variability even within certain types of cigarettes, such as variability in toxicants or youth appeal among HTPs or minimally addictive cigarettes. Accordingly, FDA is considering

options that would allow certain products that present different considerations to seek exemptions from the product standard on a case-by-case basis.

We note that potential costs to manufacturers under this alternative are uncertain. We assume that firms would only submit an exemption request when the potential net profits from such a request are expected to be positive and outweigh the costs of submission. We request comment on the potential impact of this rule alternative on industry costs, among other impacts.

IV. References

The following references marked with an asterisk (*) are on display at in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen 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 restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only in the Division of Dockets Management. The FDA has verified the Web site addresses, but the FDA is not responsible for any subsequent changes to the Web sites after this document is published in association with the regulatory proposal in the *Federal Register*.

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V. **Appendices**

A. Appendix A. 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 in Section II.D. This appendix provides additional background information and explores the challenges of addressing potential gains and losses in consumer surplus from this proposed menthol product standard. At a higher level, our purpose 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 his or her 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 [189].

As with other tobacco products, consumer behavior in the market for menthol cigarette products is distorted by addiction, imperfect information, and internalities. The Preamble[84] and Section II.A of this preliminary regulatory impact analysis describe the internalities that influence demand for menthol cigarettes, including how menthol as a characterizing flavor in

[84] See the Preamble Section IV on how menthol as a characterizing flavor impacts cigarette use, particularly among youth and young adults, and on how menthol cigarette use is common, addictive, and harmful.

cigarette products further enhance cigarettes' addictiveness and youth appeal. These complexities and other challenges are discussed in Section II.D.3.b of the main analysis 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 [239]. 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, cigarette users 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, any reduction in cigarette use caused by regulation would create a loss in surplus, seen as a cost to the consumer once these future costs are incorporated.

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 consider forgone consumer surplus in tobacco regulatory impact analyses [182]. In contrast to the rational addiction

approach above, some argue that most consumers do not experience losses from reduced use because they derive little to no pleasure from consumption [200] [244]. Under this framework, forgone consumption would not be a cost to consumers who became regular smokers before the legal age of smoking in welfare analysis. Others argue that some consumers who reduce their cigarette use do experience some disutility (e.g., Ashley et al. (2015), Cutler et al. (2015), and DeCicca et al (2017)) [197] [240] [241].

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 [182]. As H. Levy et al. (2018) 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 [182]. One approach is to offset health gains by some factor intended to represent consumer surplus loss. This approach has been used in the past since 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, H. Levy et al. (2018) 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" [182]. The paper identifies three main questions framing the assessment of welfare[85] and lost consumer surplus:

[85] We note that H. Levy et al. (2018) uses the economic meaning of the term "welfare" [182]. 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 cigarette smokers specifically, social welfare analysis in tobacco regulations encompasses overall well-being of both cigarette smokers and non-smokers.

- "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?"

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" [182]. 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" [182]. Instead, H. Levy et al. (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" [182].

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 H. Levy et al. (2018) 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" [182]. The driving idea behind these models is that any regulation which 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 H. Levy et al. (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 H. Levy et al. (2018) would first need to be resolved before a model could be constructed.

In the context of addictive products, a white paper drafted by the Office of the Assistant Secretary for Planning and Evaluation at U.S. Department of Health and Human Services (ASPE) [198] and Cutler et al. [197] [199] outline an approach for analyzing utility, or consumer surplus, offsets to health benefits of smoking regulations based on the identification of a subset of smokers 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 smokers. Cutler et al. (2015) use several proxies for rationality, including smokers who self-report not smoking within 30 minutes of waking[86] and smokers 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 [197].[87] Individuals aged 30 or below were excluded from the analysis as their education levels had not yet been established [197]. However, the authors acknowledge that their estimated "rational" smoking rate is likely too high as "some well-educated young smokers probably initiated

[86] "A widely used measure of nicotine addiction is whether the person has their first cigarette within one-half hour of waking…" [197, citing 2014 Surgeon General's Report]. Smoking within 30 minutes of waking (time to first cigarette) is a widely used measure of nicotine dependence [243].
[87] The 30-45 age cohort analyzed by Cutler et al. (2015) 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.

'accidentally' in their teens and now would prefer to quit" [197]. Cutler et al. (2015) estimate uses withdrawal costs as a proxy for utility impacts for the population of "rational" smokers. 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%" [197].

In Jin et al. (2015), 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" [242]. 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 [242] (emphasis added). Simulations in Jin et al. (2015) are predicated on an assumption that past cigarette consumption is a determinate of future demand, regardless of whether past consumption decisions were rational [242]. 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" [242]. While Jin et al. (2015) 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 that about 33% of estimated health benefits from future, hypothetical tobacco regulations would be offset by losses in consumer surplus from reduced cigarette use [242].

With respect to tobacco product cessation, these studies and others identify a subset of smokers 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% to 99% [197]

[240] [242]. Chaloupka et al. (2015) identify only a "small fraction" of smokers 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 [200]. Chaloupka, Gruber and Warner (2015), 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" [244]. 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% to 33% of the health benefits attributable to the rule as the consumer surplus loss associated with the rule.[88] 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 flavored tobacco products.

DeCicca et al. (2017) 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

[88] The literature cited in the HUD RIA include: Levy, Helen, Edward C. Norton and Jeffrey A. Smith (2016). "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, Donald S. Kenkel, Feng Liu and Hua Wang (2016). "Behavioral Welfare Economics and FDA Tobacco Regulations." NBER Working Paper No. 22718. http://www.nber.org/papers/w22718; Cutler, D. et al. (2015); Valuing Regulations Affecting Addictive or Habitual Goods. Journal of Benefit-Cost Analysis 6 (2): 247-280, and; Jin, L. et al. (2015). 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.

consequences in the second period, and that if smokers 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 [241]. 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 et al. (2017) attempts to correct for some of the flaws in previous rational addiction modeling by allowing for the existence of internalities, moving consumer surplus evaluation of tobacco policy towards directly modeling the utility in the market.

In furthering this discussion, H. Levy et al. (2018) 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 [182]. These questions include what framework to use in building an "unbiased" demand curve (i.e., the demand of tobacco product users 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 [182]. 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 [182].

We note that while Cutler et al. (2015) and Jin et al. (2015) perform their analyses on the cigarette market, these methodologies would be analytically similar to possible evaluations of dissuasion effects in the market for menthol cigarette products. However, H. Levy et al. (2018) 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 [182]. These same

challenges would apply to an analysis of dissuasion from consumption of menthol cigarette products.

While H. Levy et al. (2018) 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 and Miera (2020) discuss an additional source of uncertainty with models like the ones suggested by H. Levy et. al. (2018) [245].[89] Such models 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 user. Thus, assuming the same elasticity of demand for addicted and non-addicted consumers is likely to overestimate consumer surplus [245]. 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 challenges specific to a menthol cigarette product standard, including the continued availability of potential tobacco product substitutes.

[89] Massin and Miéra (2020) appear to exclude Jin et al. (2015) from the list of papers that suffer from the problems mentioned here. However, we request comment on this interpretation.

Given these challenges and potential analytic approaches for modeling consumer surplus for cigarettes generally, and menthol cigarettes specifically, 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 menthol cigarette products, we would need, among other things, to estimate current unbiased market demand, the magnitude of internalities facing consumers, and the expected demand under the proposed menthol product standard. We request comment on relevant data that could inform such an approach or an alternative approach.

The proposed product standard prohibiting the use of menthol as a characterizing flavor in cigarette products presents additional complicating questions in the discussion of consumer surplus loss from tobacco product regulations. As discussed in the Preamble of this proposed rule, menthol in cigarettes enhances nicotine addiction through a combination of its flavor, sensory effects, and interaction with nicotine in the brain, facilitating repeated experimentation with cigarettes and progression to regular smoking, which repeatedly exposes the brain to nicotine [1] [190]. The proposed product standard only impacts one attribute of the product—flavor—making it even more challenging to consider welfare effects. Section II.D.3.b of the main analysis describes this issue in more detail.

3. Challenges with estimating consumer surplus for cigarettes generally, and menthol cigarettes in particular

Recent advances in behavioral economics are moving the field closer towards more reliable estimation of consumer surplus, recognizing significant challenges remain with modeling demand for cigarettes. Menthol as a characterizing flavor in cigarettes raises additional challenges relating to demand and consumer surplus. These challenges include: the addictive

nature of tobacco products and the role menthol plays in enhancing the effects of nicotine, initiation during adolescence when the brain is not yet fully developed and how menthol as a characterizing flavor affects youth appeal, 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 current smokers, desire to quit, and menthol's impact on quitting, and the availability of potential substitute products for menthol cigarettes.

The proposed product standard prohibiting the use of menthol as a characterizing flavor in cigarette products presents additional complicating questions in the discussion of consumer surplus loss from tobacco product regulations. As discussed in the Preamble of this proposed rule, menthol in cigarettes enhances nicotine addiction through a combination of its flavor, sensory effects, and interaction with nicotine in the brain, facilitating repeated experimentation with cigarettes and progression to regular smoking, which repeatedly exposes the brain to nicotine [1] [190]. The proposed product standard only impacts one attribute of the product—flavor—making it even more challenging to consider welfare effects. These challenges in modeling demand for cigarettes, and demand for menthol cigarette products in particular, are described in more detail in Section II.D.3.b.

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 the proposed menthol product standard. This applies both to non-smokers who are dissuaded from initiating the use of cigarettes, to current smokers who quit in response to the standard, and

current smokers who switch to other combustible products as a result of this proposed product standard. Although consumer surplus loss among quitters or switchers 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 of peer reviewed literature looking at approaches to modeling impact 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 current tobacco users play in welfare analysis of addictive goods?
- How should we estimate an unbiased, non-addictive demand curve?
- 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?

Additional questions surrounding demand for tobacco products and associated consumer surplus stem from the nature of the proposed product standard under consideration, which prohibits menthol as a characterizing flavor in cigarettes:

- How does menthol as a characterizing flavor in cigarette products impact the understanding and valuation of consumer utility and consumer surplus?
- 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 menthol cigarette products?

We request comment on this discussion and the questions raised; the application of consumer surplus analysis in the context of a product standard prohibiting the use of menthol as a characterizing flavor in cigarette products; and potential methods for developing and comparing biased and unbiased demand curves for tobacco products.

B. Appendix B. Stream of Benefits Over 40-Year Time Horizon

1. Stream of Undiscounted Benefits from Mortality Risk Reductions for Current Users and Potential Future Users of Cigarette Products

In Section II.C.4 of the main analysis, we valued the estimated reductions in mortality risk expected to accrue over a time horizon of 40-years due to this proposed menthol product standard. Undiscounted values of mortality risk reductions were calculated by multiplying the estimated mortality risk reductions in each year by the corresponding VSL estimates (low, central, high) in the same year. As a result of these calculations, we present the stream of undiscounted benefits attributable to this rule in Table 86.

Table 86. Estimated Value of Annual Mortality Risk Reductions for Current Users and Potential Future Users of Cigarette Products (Undiscounted)

Year Count	Year	Estimated Annual Mortality Risk Reductions	Undiscounted Value of Mortality Risk Reductions ($2020, Billion, Rounded)		
			Low Estimate	Primary Estimate	High Estimate
Year 1	2024	-	-	-	-
Year 2	2025	16,593	$91.26	$197.46	$300.33
Year 3	2026	16,593	$92.92	$199.12	$301.99
Year 4	2027	16,593	$92.92	$200.78	$305.31
Year 5	2028	16,593	$94.58	$202.43	$306.97
Year 6	2029	16,593	$94.58	$204.09	$310.29
Year 7	2030	16,593	$96.24	$205.75	$311.95
Year 8	2031	16,593	$96.24	$207.41	$315.27
Year 9	2032	16,593	$97.90	$209.07	$316.93
Year 10	2033	16,593	$97.90	$210.73	$320.25
Year 11	2034	16,593	$99.56	$212.39	$321.90
Year 12	2035	16,593	$99.56	$214.05	$325.22
Year 13	2036	16,593	$99.56	$215.71	$326.88
Year 14	2037	16,593	$101.22	$217.37	$330.20

Year Count	Year	Estimated Annual Mortality Risk Reductions	Undiscounted Value of Mortality Risk Reductions ($2020, Billion, Rounded)		
			Low Estimate	Primary Estimate	High Estimate
Year 15	2038	16,593	$101.22	$219.03	$331.86
Year 16	2039	16,593	$102.88	$220.69	$335.18
Year 17	2040	16,593	$102.88	$222.35	$338.50
Year 18	2041	16,593	$104.54	$224.01	$340.16
Year 19	2042	16,593	$104.54	$225.67	$343.48
Year 20	2043	16,593	$106.20	$227.32	$346.79
Year 21	2044	16,593	$106.20	$228.98	$348.45
Year 22	2045	16,593	$107.85	$230.64	$351.77
Year 23	2046	16,593	$109.51	$232.30	$355.09
Year 24	2047	16,593	$109.51	$233.96	$356.75
Year 25	2048	16,593	$111.17	$237.28	$360.07
Year 26	2049	16,593	$111.17	$238.94	$363.39
Year 27	2050	16,593	$112.83	$240.60	$366.71
Year 28	2051	16,593	$112.83	$242.26	$368.37
Year 29	2052	16,593	$114.49	$243.92	$371.68
Year 30	2053	16,593	$114.49	$245.58	$375.00
Year 31	2054	16,593	$116.15	$248.90	$378.32
Year 32	2055	16,593	$116.15	$250.55	$381.64
Year 33	2056	16,593	$117.81	$252.21	$383.30
Year 34	2057	16,593	$119.47	$253.87	$386.62
Year 35	2058	16,593	$119.47	$255.53	$389.94
Year 36	2059	16,593	$121.13	$258.85	$393.25
Year 37	2060	16,593	$121.13	$260.51	$396.57
Year 38	2061	16,593	$122.79	$262.17	$399.89
Year 39	2062	16,593	$122.79	$263.83	$403.21
Year 40	2063	16,593	$124.45	$267.15	$406.53
Total		647,128	$4,188.08	$8,983.46	$13,666.02

2. Stream of Undiscounted Benefits - Avoided Premature Deaths Due to Reduced Secondhand Smoke Exposure and Avoided SIDS Mortality under Proposed Product Standard

As discussed in Section II.C.5, we valued the estimated additional reductions in mortality risk reduction attributable to reduced secondhand smoke exposure and avoided SIDS mortality expected to accrue over a time horizon of 40-years due this proposed menthol product standard. Undiscounted values of mortality risk reductions were calculated by multiplying the estimated mortality risk reductions in each year by the corresponding VSL estimates (low, central, high) in the same year. FDA assumes that mortality risk reductions ("averted deaths") from reduced secondhand smoke exposure and avoided SIDS mortality are distributed similarly over time as mortality risk reductions ("averted deaths") from reduced cigarette smoking. As a result of these calculations, we present the stream of undiscounted benefits attributable to this rule in Table 87.

Table 87. Estimated Value of Avoided Premature Deaths Due to Reduced Secondhand Smoke Exposure and Avoided SIDS Mortality under this Proposed Menthol Cigarette Product Standard

Year Count	Year	Estimated Annual Mortality Risk Reductions due to Reductions in Secondhand Smoke Exposure	Estimated Annual Mortality Risk Reductions due to due to Avoided SIDS Mortality	Undiscounted Value of Mortality Risk Reductions due to Reductions in Secondhand Smoke Exposure and Avoided SIDS Mortality ($2020, Billion, Rounded)[1]		
				Low Estimate	Primary Estimate	High Estimate
Year 1	2024	-	-	-	-	-
Year 2	2025	1,566	15	$8.70	$18.82	$28.63
Year 3	2026	1,566	15	$8.86	$18.98	$28.78
Year 4	2027	1,566	15	$8.86	$19.14	$29.10
Year 5	2028	1,566	15	$9.01	$19.29	$29.26
Year 6	2029	1,566	15	$9.01	$19.45	$29.58
Year 7	2030	1,566	15	$9.17	$19.61	$29.73
Year 8	2031	1,566	15	$9.17	$19.77	$30.05
Year 9	2032	1,566	15	$9.33	$19.93	$30.21
Year 10	2033	1,566	15	$9.33	$20.09	$30.52
Year 11	2034	1,566	15	$9.49	$20.24	$30.68

Year Count	Year	Estimated Annual Mortality Risk Reductions due to Reductions in Secondhand Smoke Exposure	Estimated Annual Mortality Risk Reductions due to due to Avoided SIDS Mortality	Undiscounted Value of Mortality Risk Reductions due to Reductions in Secondhand Smoke Exposure and Avoided SIDS Mortality ($2020, Billion, Rounded)[1]		
				Low Estimate	Primary Estimate	High Estimate
Year 12	2035	1,566	15	$9.49	$20.40	$31.00
Year 13	2036	1,566	15	$9.49	$20.56	$31.16
Year 14	2037	1,566	15	$9.65	$20.72	$31.47
Year 15	2038	1,566	15	$9.65	$20.88	$31.63
Year 16	2039	1,566	15	$9.81	$21.03	$31.95
Year 17	2040	1,566	15	$9.81	$21.19	$32.26
Year 18	2041	1,566	15	$9.96	$21.35	$32.42
Year 19	2042	1,566	15	$9.96	$21.51	$32.74
Year 20	2043	1,566	15	$10.12	$21.67	$33.05
Year 21	2044	1,566	15	$10.12	$21.83	$33.21
Year 22	2045	1,566	15	$10.28	$21.98	$33.53
Year 23	2046	1,566	15	$10.44	$22.14	$33.85
Year 24	2047	1,566	15	$10.44	$22.30	$34.00
Year 25	2048	1,566	15	$10.60	$22.62	$34.32
Year 26	2049	1,566	15	$10.60	$22.77	$34.64
Year 27	2050	1,566	15	$10.75	$22.93	$34.95
Year 28	2051	1,566	15	$10.75	$23.09	$35.11
Year 29	2052	1,566	15	$10.91	$23.25	$35.43
Year 30	2053	1,566	15	$10.91	$23.41	$35.74
Year 31	2054	1,566	15	$11.07	$23.72	$36.06
Year 32	2055	1,566	15	$11.07	$23.88	$36.38
Year 33	2056	1,566	15	$11.23	$24.04	$36.53
Year 34	2057	1,566	15	$11.39	$24.20	$36.85
Year 35	2058	1,566	15	$11.39	$24.36	$37.17
Year 36	2059	1,566	15	$11.55	$24.67	$37.48
Year 37	2060	1,566	15	$11.55	$24.83	$37.80
Year 38	2061	1,566	15	$11.70	$24.99	$38.12
Year 39	2062	1,566	15	$11.70	$25.15	$38.43
Year 40	2063	1,566	15	$11.86	$25.46	$38.75
Total		61,089	592	$399.18	$856.25	$1,302.57

[1] Undiscounted values of mortality risk reductions are obtained by summing the estimated number of mortality risk reductions attributable to reductions in secondhand smoke exposure and avoided SIDS mortality, then multiplying by the appropriate VSL estimates.

C. Appendix C. Stream of Costs over 40-Year Time Horizon

1. Stream of Undiscounted Lost Producer Surplus in the Cigarette Product Market

In Section II.D.1.d of the main analysis, we estimated costs associated with lost producer surplus in the cigarette product market over a time horizon of 40-years due to this proposed menthol product standard. We present this stream of undiscounted costs in Table 88.

Table 88. Estimated Value of Lost Producer Surplus in the Cigarette Product Market (Million, Undiscounted)

Year Count	Year	Lost Producer Surplus ($2020, Million, Undiscounted)		
		Lower Bound Estimate	Primary Estimate	Upper Bound Estimate
Year 1	2024	$0.0	$0.0	$0.0
Year 2	2025	$0.0	$272.5	$545.0
Year 3	2026	$0.0	$272.5	$545.0
Year 4	2027	$0.0	$272.5	$545.0
Year 5	2028	$0.0	$272.5	$545.0
Year 6	2029	$0.0	$272.5	$545.0
Year 7	2030	$0.0	$272.5	$545.0
Year 8	2031	$0.0	$272.5	$545.0
Year 9	2032	$0.0	$272.5	$545.0
Year 10	2033	$0.0	$272.5	$545.0
Year 11	2034	$0.0	$272.5	$545.0
Year 12	2035	$0.0	$272.5	$545.0
Year 13	2036	$0.0	$272.5	$545.0
Year 14	2037	$0.0	$272.5	$545.0
Year 15	2038	$0.0	$272.5	$545.0
Year 16	2039	$0.0	$272.5	$545.0
Year 17	2040	$0.0	$272.5	$545.0
Year 18	2041	$0.0	$272.5	$545.0
Year 19	2042	$0.0	$272.5	$545.0
Year 20	2043	$0.0	$272.5	$545.0
Year 21	2044	$0.0	$272.5	$545.0
Year 22	2045	$0.0	$272.5	$545.0
Year 23	2046	$0.0	$272.5	$545.0
Year 24	2047	$0.0	$272.5	$545.0

Year Count	Year	Lost Producer Surplus ($2020, Million, Undiscounted)		
		Lower Bound Estimate	Primary Estimate	Upper Bound Estimate
Year 25	2048	$0.0	$272.5	$545.0
Year 26	2049	$0.0	$272.5	$545.0
Year 27	2050	$0.0	$272.5	$545.0
Year 28	2051	$0.0	$272.5	$545.0
Year 29	2052	$0.0	$272.5	$545.0
Year 30	2053	$0.0	$272.5	$545.0
Year 31	2054	$0.0	$272.5	$545.0
Year 32	2055	$0.0	$272.5	$545.0
Year 33	2056	$0.0	$272.5	$545.0
Year 34	2057	$0.0	$272.5	$545.0
Year 35	2058	$0.0	$272.5	$545.0
Year 36	2059	$0.0	$272.5	$545.0
Year 37	2060	$0.0	$272.5	$545.0
Year 38	2061	$0.0	$272.5	$545.0
Year 39	2062	$0.0	$272.5	$545.0
Year 40	2063	$0.0	$272.5	$545.0
Total		$0.0	$10,627.8	$21,255.5

2. Stream of Total Undiscounted Costs (Industry, Consumer, and Government)

Using estimates from Section II.D and summing one-time industry costs from reading and understanding the rule and reallocation, friction, and adjustment costs, along with costs associated with lost producer surplus, consumer search costs, and government costs, we present total costs over the 40-year time horizon for this proposed product standard in Table 89.

Table 89. Estimated Total Costs – Industry, Consumer, and Government ($2020 Million, Undiscounted)

Year Count	Year	Total Costs (Industry, Consumer, and Government - $2020 Million, Undiscounted)		
		Lower Bound Estimate	Primary Estimate	Upper Bound Estimate
Year 0	2023	$56.2	$422.5	$821.7
Year 1	2024	$0.0	$0.7	$1.3
Year 2	2025	$89.8	$452.8	$815.8

Year Count	Year	Total Costs (Industry, Consumer, and Government - $2020 Million, Undiscounted)		
		Lower Bound Estimate	Primary Estimate	Upper Bound Estimate
Year 3	2026	$89.8	$452.8	$815.8
Year 4	2027	$0.0	$273.2	$546.3
Year 5	2028	$0.0	$273.2	$546.3
Year 6	2029	$0.0	$273.2	$546.3
Year 7	2030	$0.0	$273.2	$546.3
Year 8	2031	$0.0	$273.2	$546.3
Year 9	2032	$0.0	$273.2	$546.3
Year 10	2033	$0.0	$273.2	$546.3
Year 11	2034	$0.0	$273.2	$546.3
Year 12	2035	$0.0	$273.2	$546.3
Year 13	2036	$0.0	$273.2	$546.3
Year 14	2037	$0.0	$273.2	$546.3
Year 15	2038	$0.0	$273.2	$546.3
Year 16	2039	$0.0	$273.2	$546.3
Year 17	2040	$0.0	$273.2	$546.3
Year 18	2041	$0.0	$273.2	$546.3
Year 19	2042	$0.0	$273.2	$546.3
Year 20	2043	$0.0	$273.2	$546.3
Year 21	2044	$0.0	$273.2	$546.3
Year 22	2045	$0.0	$273.2	$546.3
Year 23	2046	$0.0	$273.2	$546.3
Year 24	2047	$0.0	$273.2	$546.3
Year 25	2048	$0.0	$273.2	$546.3
Year 26	2049	$0.0	$273.2	$546.3
Year 27	2050	$0.0	$273.2	$546.3
Year 28	2051	$0.0	$273.2	$546.3
Year 29	2052	$0.0	$273.2	$546.3
Year 30	2053	$0.0	$273.2	$546.3
Year 31	2054	$0.0	$273.2	$546.3
Year 32	2055	$0.0	$273.2	$546.3
Year 33	2056	$0.0	$273.2	$546.3
Year 34	2057	$0.0	$273.2	$546.3
Year 35	2058	$0.0	$273.2	$546.3
Year 36	2059	$0.0	$273.2	$546.3
Year 37	2060	$0.0	$273.2	$546.3
Year 38	2061	$0.0	$273.2	$546.3

Year Count	Year	Total Costs (Industry, Consumer, and Government - $2020 Million, Undiscounted)		
		Lower Bound Estimate	Primary Estimate	Upper Bound Estimate
Year 39	2062	$0.0	$273.2	$546.3
Year 40	2063	$0.0	$273.2	$546.3
Total		$235.8	$11,436.0	$22,668.9

D. Appendix D. Stream of Transfers over 40-Year Time Horizon

In Section II.E.3, we valued transfers from menthol cigarette product manufacturers back to consumers over a time horizon of 40-years due to this proposed product standard. We present the stream of undiscounted menthol cigarette product revenue transfers attributable to this rule in Table 90.

Table 90. Transfer of Revenue from Cigarette Product Manufacturers to Consumers/Producers of Other Tobacco Products over 40-year Time Horizon ($2020 Billions, Undiscounted)

Year Count	Year	Total Menthol Cigarette Product Revenue, Exclusive of Excise Taxes ($2020, Billion)	Transfer of Revenue from Menthol Cigarette Product Manufacturers ($2020, Billion, Undiscounted)		
			41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Year 0	2023	$23.18	-	-	-
Year 1	2024	$23.74	-	-	-
Year 2	2025	$24.31	$9.97	$14.34	$16.29
Year 3	2026	$24.31	$9.97	$14.34	$16.29
Year 4	2027	$24.31	$9.97	$14.34	$16.29
Year 5	2028	$24.31	$9.97	$14.34	$16.29
Year 6	2029	$24.31	$9.97	$14.34	$16.29
Year 7	2030	$24.31	$9.97	$14.34	$16.29
Year 8	2031	$24.31	$9.97	$14.34	$16.29
Year 9	2032	$24.31	$9.97	$14.34	$16.29
Year 10	2033	$24.31	$9.97	$14.34	$16.29
Year 11	2034	$24.31	$9.97	$14.34	$16.29
Year 12	2035	$24.31	$9.97	$14.34	$16.29
Year 13	2036	$24.31	$9.97	$14.34	$16.29
Year 14	2037	$24.31	$9.97	$14.34	$16.29

Year Count	Year	Total Menthol Cigarette Product Revenue, Exclusive of Excise Taxes ($2020, Billion)	Transfer of Revenue from Menthol Cigarette Product Manufacturers ($2020, Billion, Undiscounted)		
			41% Transfer (Low)	59% Transfer (Primary)	67% Transfer (High)
Year 15	2038	$24.31	$9.97	$14.34	$16.29
Year 16	2039	$24.31	$9.97	$14.34	$16.29
Year 17	2040	$24.31	$9.97	$14.34	$16.29
Year 18	2041	$24.31	$9.97	$14.34	$16.29
Year 19	2042	$24.31	$9.97	$14.34	$16.29
Year 20	2043	$24.31	$9.97	$14.34	$16.29
Year 21	2044	$24.31	$9.97	$14.34	$16.29
Year 22	2045	$24.31	$9.97	$14.34	$16.29
Year 23	2046	$24.31	$9.97	$14.34	$16.29
Year 24	2047	$24.31	$9.97	$14.34	$16.29
Year 25	2048	$24.31	$9.97	$14.34	$16.29
Year 26	2049	$24.31	$9.97	$14.34	$16.29
Year 27	2050	$24.31	$9.97	$14.34	$16.29
Year 28	2051	$24.31	$9.97	$14.34	$16.29
Year 29	2052	$24.31	$9.97	$14.34	$16.29
Year 30	2053	$24.31	$9.97	$14.34	$16.29
Year 31	2054	$24.31	$9.97	$14.34	$16.29
Year 32	2055	$24.31	$9.97	$14.34	$16.29
Year 33	2056	$24.31	$9.97	$14.34	$16.29
Year 34	2057	$24.31	$9.97	$14.34	$16.29
Year 35	2058	$24.31	$9.97	$14.34	$16.29
Year 36	2059	$24.31	$9.97	$14.34	$16.29
Year 37	2060	$24.31	$9.97	$14.34	$16.29
Year 38	2061	$24.31	$9.97	$14.34	$16.29
Year 39	2062	$24.31	$9.97	$14.34	$16.29
Year 40	2063	$24.31	$9.97	$14.34	$16.29
Total		$994.98	$388.71	$559.36	$635.20