



October 15, 2019

VIA ELECTRONIC SUBMISSION

Food & Drug Administration

Attn: Center for Tobacco Products

Re: Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42,754 (proposed August 16, 2019)

Docket ID: FDA-2019-N-3065

The Institute for Policy Integrity (“Policy Integrity”) at New York University School of Law¹ respectfully submits the following comments to the Food and Drug Administration (FDA) regarding its proposal to place updated health warning labels on cigarette packages and advertisements, replacing the current “Surgeon General’s Warning” labels with color images of smoking-related medical conditions and accompanying text (“Proposed Rule”).² Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

Our comments focus on FDA’s assessment of the Proposed Rule’s costs and benefits. Specifically, we note the following:

- FDA establishes a compelling need for regulation by making evidence-based findings that (1) cigarette smoking has severe health consequences, (2) market failures affect consumers’ decisions to smoke, and (3) improved warning labels would partially correct these market failures.
- FDA can improve its break-even analysis for the Proposed Rule by providing further analysis to support the assumption that enhanced warning labels will provide at least \$0.01 of informational value per cigarette package, on average.
- As an additional, independently sufficient justification for the Proposed Rule, FDA should consider developing a second break-even analysis that focuses directly on the Proposed Rule’s potential to change consumer behavior and, in turn, improve consumer health.

¹ This document does not purport to present New York University School of Law’s views, if any.

² See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42,754 (proposed Aug. 16, 2019) (to be codified at 21 C.F.R. pt. 1141) [hereinafter Proposed Rule].

I. FDA establishes a compelling need for regulatory action

Executive Order 12,866 urges agencies to promulgate regulations “made necessary by compelling need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.”³ In the Proposed Rule, FDA establishes a compelling need for enhanced warning labels on cigarette packages and advertisements. Specifically, based on a thorough review of the available scientific literature, FDA shows that cigarette smoking has severe health consequences, that consumers’ decisions to smoke are affected by multiple market failures, and that these failures can be partially corrected by more salient and accurate warning labels.

A. Cigarette smoking has severe health consequences

As FDA shows, cigarette smoking causes a plethora of negative health consequences, for smokers and nonsmokers alike.⁴ Cigarette smoking severely increases individuals’ risk for developing heart disease, lung cancer, respiratory disease, and stroke.⁵ Smoking can also lead to cancer developing in almost every portion of the body, including in the bladder, blood, cervix, colon and rectum, esophagus, kidney, liver, pancreas, stomach, and lungs, among other organs.⁶ Smoking may also affect women in a unique manner, making it harder for them to become pregnant.⁷ Pregnant smokers face additional risks both to their own health (such as preterm delivery and ectopic pregnancy) and their child’s health (such as stillbirth, low birth weight, and SIDS).⁸

Notwithstanding extensive scientific evidence confirming the aforementioned negative health consequences, cigarette smoking remains the leading preventable cause of death in the United States.⁹ Currently, cigarette smoking claims the lives of over 480,000 people in the United States on an annual basis.¹⁰ Smoking causes approximately 90% of lung cancer deaths—an illness that causes more deaths among women than breast cancer.¹¹ Smoking also causes approximately 80% of deaths resulting from chronic obstructive pulmonary disease (COPD). Moreover, irrespective of the health concerns that cigarette smoking has raised, the risk of dying from cigarette smoking has not diminished. In fact, the risk of dying from cigarette smoking has *increased* over the last fifty years.¹²

³ Exec. Order No. 12,866 § 1(a), 58 Fed. Reg. 51,735, 51,735–36 (Oct. 4, 1993).

⁴ See 84 Fed. Reg. at 42,758-59.

⁵ See *Health Effects*, SMOKEFREE.GOV, <https://smokefree.gov/quit-smoking/why-you-should-quit/health-effects> (last visited Oct. 15, 2019) (listing the harms of smoking throughout the body); *Health Effects of Cigarette Smoking*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm (last updated Jan. 17, 2018) (listing the increased health risks of smoking).

⁶ *Health Effects of Cigarette Smoking*, *supra* note 5; see also *Health Risks of Smoking Tobacco*, AMERICAN CANCER SOCIETY, <https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/health-risks-of-smoking-tobacco.html> (last visited Oct. 15, 2019).

⁷ *Health Risks of Smoking Tobacco*, *supra* note 6.

⁸ *Id.*

⁹ Proposed Rule, *supra* note 2, at 42,755.

¹⁰ *Id.*

¹¹ See *Health Effects of Cigarette Smoking*, *supra* note 5.

¹² See *Health Risks of Smoking Tobacco*, *supra* note 6; see also Michael J. Thun et al., *50-Year Trends in Smoking-Related Mortality in the United States*, 368 NEW ENG. J. MED. 1, 2 (2013),

Additionally, smoking has severe health consequences for nonsmokers due to their exposure to secondhand smoke.¹³ Although nonsmokers may take certain steps to limit their exposure to secondhand smoke, “[s]eparating smokers from nonsmokers, opening windows, or using air filters does not prevent people from breathing secondhand smoke.”¹⁴ As a result, individuals are unwillingly exposed to secondhand smoke in their homes, workplace, public places, and many other locations.¹⁵ Secondhand smoke can cause heart disease, lung cancer, and stroke, even for individuals who have *never* smoked.¹⁶ Secondhand smoke has particularly harmful effects on children, causing ear infections, increased asthma attacks, respiratory infections and illnesses, and greater likelihood of SIDS among infants.¹⁷

B. Consumers’ decisions to smoke are materially affected by multiple market failures

In addition to establishing that cigarette consumption carries serious health risks for both smokers and nonsmokers, FDA shows that consumers’ cigarette-consumption decisions are materially affected by market failures, including inadequate information and “internalities” like time inconsistency. Cigarette demand may be further biased by the positional nature of cigarette consumption. Finally, smoking generates external costs—like secondhand smoke—that smokers do not fully internalize when making cigarette-consumption decisions.

1. Consumers are not aware of the full range of health consequences associated with cigarette smoking

As FDA explains, although consumers often consider themselves well-informed about the health implications of cigarette smoking, significant survey data indicates that a “substantial percentage of smokers are misinformed or do not know about the negative health consequences of smoking.”¹⁸ For example, while most U.S. survey respondents are able to identify lung cancer and heart disease as consequences of smoking, many are unaware of *other* serious health consequences of cigarette smoking for smokers and nonsmokers alike. In particular, across all income levels, almost one in every four Americans does not believe smoking causes stroke, and roughly two in three Americans do not believe smoking causes impotence.¹⁹

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3632080/pdf/448527.pdf> (noting that “[t]he disease risks from cigarette smoking increased in the United States over most of the 20th century, first among male smokers and later among female smokers”).

¹³ See *Second Hand Smoke (SHS) Facts*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/general_facts/index.htm.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*; see also *The Dangers of Secondhand Smoke*, HEALTHYCHILDREN.ORG <https://www.healthychildren.org/English/health-issues/conditions/tobacco/Pages/Dangers-of-Secondhand-Smoke.aspx> (last updated May 10, 2017).

¹⁸ U.S. Food & Drug Admin., Tobacco Products; Required Warnings for Cigarette Packages and Advertisements: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis 16 (2019) [hereinafter RIA]; see also Proposed Rule, *supra* note 2, at 42,762 (discussing increased understanding anticipated to result from pictorial warnings).

¹⁹ See Mohammad Siahpush et al., Socioeconomic and Country Variations in Knowledge of Health Risks of Tobacco Smoking and Toxic Constituents of Smoke: Results from the 2002 International Tobacco Control (ITC) Four Country Survey, 15(Suppl. III) TOBACCO CONTROL iii65, iii67 tbl. 2 (2006).

Moreover, there are demographic-based misinformation and knowledge gaps among consumers. Americans are “largely unaware of the health risks of smoking specific to women, including infertility, osteoporosis, early menopause, spontaneous abortion, ectopic pregnancy, and cervical cancer.”²⁰ Additionally, certain demographics and populations—including individuals of lower socioeconomic status—tend to have less information as to the negative health consequences of cigarette smoking than other groups in the population.²¹

Current Surgeon General’s Warnings do little to address these informational problems, in part because they are insufficiently salient. As FDA explains, the existing labels “do not effectively communicate information about the adverse health effects of smoking to the American public because they do not attract attention. . . are not remembered. . . and do not prompt thoughts about the risks of smoking.”²² Furthermore, consumers with lower educational attainment have greater difficulty processing the current warnings, because the warnings are written at a reading level typical of college students or graduates.²³

2. Consumer demand for cigarettes is biased by internalities

FDA cites psychology and economics literature showing that, in addition to “problems of information,” cigarette consumption decisions are affected by “intrapersonal market failures or internalities.”²⁴ One such externality recognized by FDA is time inconsistency, which leads consumers to “make current decisions that they would not make from the perspective of their future selves.”²⁵ In other words, individuals may desire to stop smoking in the long run but may continue smoking when presented with the opportunity to smoke in the short term.²⁶ This market failure is exacerbated by the addictive nature of cigarette smoking. As a result of cigarettes’ addictive properties, “[a]lthough individuals may recognize some of the risks inherent in [smoking cigarettes], they continue to make suboptimal choices that cause a divergence between the utility-maximizing consumption level and the consumption level they select.”²⁷

3. Consumer demand for cigarettes may be biased by positional externalities

In addition to the market failures cited by FDA, consumer demand for cigarettes may be upwardly biased by positional externalities.²⁸ Some consumers may feel compelled to smoke to regain status

²⁰ RIA, *supra* note 18, at 17.

²¹ See Proposed Rule, *supra* note 2, at 42,765.

²² RIA, *supra* note 18, at 16.

²³ See *id.* at 20-21.

²⁴ *Id.* at 11.

²⁵ *Id.* at 12.

²⁶ Inst. for Policy Integrity, Comment Letter on Proposed Rule for Tobacco Standard for Nicotine Level of Combusted Cigarettes (July 16, 2018), at 2, *available at* https://policyintegrity.org/documents/Policy_Integrity_FDA_Nicotine_Comments_071618.pdf; see also Helen G. Levy, Edward C. Norton & Jeffrey A. Smith, *Tobacco Regulation and Cost Benefit Analysis: How Should We Value Foregone Consumer Surplus?*, 4 AM. J. HEALTH ECON. 1 (2018).

²⁷ *Id.*

²⁸ Institute for Policy Integrity, Comment Letter on Proposed Rule for Deeming Tobacco Products (Aug. 8, 2014), at 2, *available at* https://policyintegrity.org/documents/Policy_Integrity_Comments_on_FDA_Tobacco_Deeming_Rule.pdf; see also Ori Heffetz, *A Test of Conspicuous Consumption: Visibility and Income Elasticities*, 93 REV. OF ECON. & STAT.

in a peer group, because cigarettes are positional goods that confer relative status on smokers but can inflict the negative externality of a loss of status on nonsmokers in the same peer group. This may be especially true for adolescents, who may perceive smoking as “cool,” particularly if they are surrounded by adolescents who smoke.²⁹

4. Smoking imposes other external costs for which smokers do not fully account

An additional market failure not mentioned by FDA but which contributes to higher-than-optimal cigarette consumption is the negative externality of secondhand smoke. Bystanders who are subject to secondhand smoke have no say in smokers’ decisions to consume cigarettes in their vicinity, thus preventing them from voluntarily ‘opting out’ of the transaction. Furthermore, “[t]here is no risk-free level of secondhand smoke exposure; even brief exposure can be harmful to health.”³⁰ Secondhand smoke exposure remains quite prevalent in the United States³¹ and continues to cause illness and death among nonsmokers.³² Smokers, however, are not forced to take these costs into account when making the decision to smoke. As explained in the Office of Management and Budget’s Circular A-4, this sort of negative externality is a classic justification for regulatory intervention.³³

C. Improved warning labels would partially correct the market failures described above

FDA reaches a reasoned, evidence-based conclusion that enhanced warning labels would partially correct the market failures described above. Specifically, FDA has established, through independent research and control group experiments that the proposed warning labels ameliorate the issues posed by the “invisibility” of the current Surgeon General Warnings.³⁴ The newly proposed warnings contain textual messages accompanied by large graphics. As FDA notes, this complementary two-fold approach renders the warning labels more noticeable and attention-grabbing.³⁵ Simultaneously, this makes the message conveyed by these labels more salient.³⁶

1101, 1106 (2011); Fredrik Carlsson et al., *Do You Enjoy Having More than Others? Survey Evidence of Positional Goods*, 74 *ECONOMICA* 586, 588, 593 (2007).

²⁹ See Jiaying Liu et al., *The Influence of Peer Behavior as a Function of Social and Cultural Closeness: A Meta-Analysis of Normative Influence on Adolescent Smoking Initiation and Continuation*, 143 *PSYCHOL. BULL.*, 1082–115 (2017) (discussing social dynamics and peer influences that affect adolescents’ decision to smoke cigarettes); *Why Kids Start Smoking*, AMERICAN LUNG ASSOCIATION, <https://www.lung.org/stop-smoking/smoking-facts/why-kids-start-smoking.html> (last updated Mar. 4, 2019) (noting that youths start smoking because they “[t]hink that everyone else is smoking and that they should, too” and that “[t]obacco companies shape their marketing campaigns to portray smokers as cool, sexy, independent, fun, attractive and living on the edge—images that appeal to many teens”).

³⁰ *Second Hand Smoke (SHS) Facts*, *supra* note 13.

³¹ *See id.* (noting that during 2011–2012, approximately 25.3% of nonsmokers had measurable levels of cotinine, an alkaloid found in tobacco).

³² *See id.*; *see also* Wendy Max, Hai-Yen Sung, & Yanling Shi, *Deaths from Secondhand Smoke Exposure in the United States: Economic Implications*, 102 *AM. J. PUB. HEALTH* 1, 1 (2012) (noting that secondhand smoke “exposure resulted in more than 42 000 deaths: more than 41 000 adults and nearly 900 infants”).

³³ *See* OMB, Circular A-4 at 4 (2003) (listing externalities among the “major types of market failure” and explaining that “[c]orrecting market failures is a reason for regulation”).

³⁴ *See generally* Proposed Rule, *supra* note 2, at 42,773–78.

³⁵ *See* RIA, *supra* note 18, at 13.

³⁶ *See* Joseph N. Cappella et al., *Interventions to Correct Misinformation About Tobacco Products*, 1 *TOBACCO REG. SCI.* 186, 193 (2015) (noting that cigarette packaging that provides “[c]orrective information enhanced with a visual

More salient labels would most obviously address the problem of inadequate information regarding the health effects of smoking. But the labels would also be likely to help consumers overcome internalities by rendering “information regarding possible harms . . . sufficiently prominent at the time of purchase and use to overcome the tendency to discount future harms.”³⁷ Finally, to the extent that more salient labels led to a reduction in cigarette consumption, they would mitigate negative externalities associated with such consumption, including positional externalities and secondhand smoke.

II. FDA can improve its analysis of the Proposed Rule’s informational benefits

In addition to establishing a compelling need for enhanced cigarette warning labels, FDA provides substantial support for a conclusion that the informational benefits of the Proposed Rule justify its expected costs. Nonetheless, FDA can improve this analysis by making more explicit conclusions regarding the value of information conveyed by enhanced warning labels. FDA can also employ additional valuation tools, such as willingness-to-pay studies, to supplement its existing analysis.

A. FDA should reach an explicit conclusion as to whether the Proposed Rule’s informational benefits are likely to outweigh its costs

In conducting its break-even analysis, FDA states that, “[i]f the information provided by the cigarette health warning on each cigarette package were valued at about \$0.01 (for every pack sold annually nationwide), then the benefits generated by the Proposed Rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018\$).”³⁸ FDA does not, however, expressly conclude that the information provided by the Proposed Rule *is* likely to be worth an average of \$0.01 or more per pack. In the final version of the Proposed Rule, FDA should either make such a finding or explain why it is unable to do so.

B. FDA should provide additional analysis to support a finding that the proposed warning labels will provide informational value of \$0.01 or more per package sold

FDA rightly notes that the direct economic benefits of the information obtained from the proposed warning labels are “difficult to quantify,”³⁹ given the challenges involved in pricing the information provided by the proposed warnings to both smokers and nonsmokers. Nevertheless, there are indications that the informational value of the warning labels can be at least partially monetized using conventional methods of cost-benefit analysis. By following one or more of these methods, FDA can supplement its qualitative analysis with at least a partial estimate of the information’s monetary value.

A valuation model based on consumers’ willingness to pay (WTP) may be one promising approach. For instance, a 2014 study involving more than 150 current smokers across four U.S. cities employed an experimental auction method to determine the monetary value of information provided by pictorial cigarette warnings, asking participants to bid the respective amounts they

image showing harm which is directly connected to the misinformation should enhance the effectiveness of the corrective information”).

³⁷ See RIA, *supra* note 18, at 12.

³⁸ *Id.* at 38.

³⁹ *Id.* at 7.

would pay for cigarette packages with or without graphic warning labels.⁴⁰ Finding that between 53% and 60% of participants changed their bid when confronted with a graphic warning label, the study’s authors estimated that the average value of the information presented by such labels was \$19.17 per smoker per year.⁴¹ Assuming that 9.7 billion packages of cigarettes are consumed each year in the United States by 34.3 million smokers,⁴² yielding an average of 285 packages per smoker per year, the \$19.17 estimate would equate to roughly \$0.067 per package—more than 6 times higher than the value necessary for the Proposed Rule to break even. Furthermore, these calculations only capture the informational benefits of pictorial warning labels to *smokers*; they do not account for the additional per-package benefits that would accrue to nonsmokers.⁴³

An alternative approach would look at the value consumers implicitly assign to other modes of communication that convey information about the health effects of smoking. For example, FDA maintains a “Public Health Education” portal under the “Tobacco Products” section of its website, as well as a separate webpage for “The Real Costs” campaign, which aims to educate youth on the health consequences of cigarettes and other tobacco products; other federal and state government agencies, such as the Centers for Disease Control and Prevention (CDC),⁴⁴ have similar websites about the health risks of tobacco. Presumably, consumers who navigate to these webpages are seeking new or additional information about the health effects of smoking. By analyzing the total number of page views for each site, as well as the total amount of time spent per page view, FDA could recognize a positive value for the information presented, as consumers effectively “spend” a determinate amount of time and effort in seeking such information.⁴⁵ Consumers’ undertaking of this opportunity cost demonstrates that they assign positive value to information beyond that provided by existing warning labels. In turn, this suggests that there are other consumers who may not value the additional information sufficiently to justify undertaking an independent search for it but would nevertheless benefit from its being made available to them at a much lower opportunity cost—namely, in the form of an improved warning label.

Even if FDA is unable to monetize the informational benefits of the Proposed Rule using the techniques described above, the agency could rely on studies it has already conducted to support an express conclusion that the value of the information provided by enhanced warning labels is large enough to justify the Proposed Rule’s costs. In the Proposed Rule, FDA emphasizes that pictorial warnings increase information processing and convey new information to consumers about cigarettes’ negative health effects.⁴⁶ Specifically, FDA references its own internal consumer research study involving over 2,500 participants, more than two-thirds of whom reported gaining “new information” from warning labels that presented information not currently included in the

⁴⁰ Matthew C. Rousu et al., *The Economic Value to Smokers of Graphic Warning Labels on Cigarettes: Evidence from Combining Market and Experimental Auction Data*, 108 J. ECON. BEHAV. & ORG 123, 131 (2014).

⁴¹ *Id.*

⁴² See RIA, *supra* note 18, at 17-18.

⁴³ Rousu et al., *supra* note 40, at 132.

⁴⁴ See, e.g., *Health Effects of Cigarette Smoking*, *supra* note 5.

⁴⁵ In making such a determination, FDA should also apply a reasonable multiplier to the time spent by consumers on the webpages themselves, as the time involved in the search for the desired information involves both time spent on the webpage as well as time spent accessing the computer and conducting a web search before landing on the desired page. See DEP’T OF HEALTH & HUMAN SERVS., GUIDELINES FOR REGULATORY IMPACT ANALYSIS 7 (2016) [hereinafter HHS GUIDELINES].

⁴⁶ Proposed Rule, *supra* note 2, at 42,762–63.

Surgeon General’s Warnings.⁴⁷ Likewise, the proposed warning labels generated higher “self-reported learning” among participants in comparison to the existing text-only warnings.⁴⁸ These shifts in consumer understanding have positive value, as the participants’ self-reported outcomes reflect a positive increase in knowledge. In the context of break-even analysis, it would be reasonable for FDA to exercise its professional judgment to determine that such positive increases in knowledge reflect a willingness to pay equivalent in value to at least \$0.01 per cigarette package.⁴⁹

III. FDA should consider a complementary break-even analysis focused on the health benefits of reduced cigarette consumption

In addition to analyzing the informational benefits of the Proposed Rule, FDA should consider a complementary analysis focused directly on the Proposed Rule’s potential effects on consumer behavior and the resulting health benefits. Specifically, the agency should consider conducting a second break-even analysis based on avoided smoking-related mortalities.

A. Enhanced warning labels would likely cause consumers to reduce cigarette consumption or engage in other health-improving behaviors

With respect to current smokers, FDA should consider the substantial quantum of scientific evidence indicating a shift in consumer behavior after the implementation of pictorial cigarette warnings. For example, a randomized clinical trial published in *JAMA Internal Medicine* in 2016 found that, over the course of just four weeks, the implementation of pictorial cigarette warnings led to a relative increase in participants’ quit attempts of 18%.⁵⁰ The study further concluded that pictorial cigarette warnings also led to increased forgoing of cigarettes and an uptick in participants’ stated intentions to quit—factors that are positively associated with future quit attempts.⁵¹ Likewise, a randomized clinical trial published in the *Annals of Behavioral Medicine* in 2017 found that the introduction of pictorial cigarette warnings was associated with a 7% cessation rate after a one-month follow-up period, as well as a half-a-cigarette per day reduction in average consumption among continuing smokers.⁵² These clinical trials thus strongly indicate that the implementation of pictorial cigarette warnings would produce meaningful shifts in consumer behavior, the impacts of which would yield positive gains in the market overall. Indeed, even if some individuals’ attempts to quit are ultimately unsuccessful, the aggregate benefits of their short-term cessation are likely to be significant, both for the smokers (who are not directly ingesting smoke) and nonsmokers (who are exposed to less secondhand smoke). As the 2016 clinical trial noted, an increase in quit attempts “could have a substantial benefit across the

⁴⁷ *Id.* at 42,767.

⁴⁸ *Id.*

⁴⁹ See Circular A-4, *supra* note 33, at 2 (advising that agencies “should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis”). The Department of Health and Human Services echoes this advice in its own internal guidance, noting that “[b]reak-even analysis is most useful . . . for judging whether the nonquantified effects can *plausibly* exceed the breakeven amount.” HHS GUIDELINES, *supra* note 45, at 49 (emphasis added).

⁵⁰ Noel T. Brewer et al., *Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior: A Randomized Clinical Trial*, 176 JAMA INTERNAL MED. 905, 909 (2016).

⁵¹ *Id.*

⁵² Daniel Romer et al., *Effects of Pictorial Warning Labels for Cigarettes and Quit-Efficacy on Emotional Responses, Smoking Satisfaction, and Cigarette Consumption*, 52 ANNALS BEHAV. MED. 53, 61 (2017).

population of US smokers. The recent Tips from Former Smokers campaign generated only an absolute increase of 3.7% in quit attempts, and yet this small change translated to an estimated 1.64 million quit attempts and 220,000 smokers who quit smoking.”⁵³ FDA would thus do well to consider these behavioral impacts in the final version of the Proposed Rule.

FDA should also review the likelihood that the proposed warning labels would prompt positive shifts in consumer behavior among *would-be* smokers, who may decide not to start smoking in the first place. Indeed, just as the informational benefits of pictorial cigarette labels should be expected to flow to smokers and nonsmokers alike,⁵⁴ so too should behavioral changes be expected to result among both smokers and nonsmokers. The scientific literature strongly supports this proposition. For instance, a ten-year cohort study in Canada found that nearly 30% of non-smoking youth reported feeling less likely to start smoking as a result of exposure to pictorial cigarette warnings.⁵⁵ Another study issued by the European Commission reported that three out of ten nonsmokers in Europe perceived pictorial cigarette warnings as being effective at helping prevent them from taking up smoking.⁵⁶ Such studies lend credence to the belief that improved cigarette health warnings would lead to changes in consumer behavior not just among current smokers, but also among nonsmokers. As such, FDA should more explicitly consider the expected benefits of these effects on nonsmokers’ cigarette-purchasing decisions.

Furthermore, FDA should evaluate the likely impact of the updated health warnings on other areas of consumer behavior outside of cigarette-purchasing decisions. That is to say, whatever the effects on consumer decisions to smoke cigarettes, the information presented by the proposed warning labels could well lead to other shifts in consumer behavior. This could include increased use of preventive health services, increased exercise and attention to healthy eating, or even compensatory decreases in other risky behaviors, such as drug or alcohol consumption. While such ancillary benefits have not been a focus of the medical literature, FDA should nonetheless consider their possibility in the course of its analysis, as these changes in consumer behavior would represent a positive response to the information conveyed by the proposed warning labels.

B. Reductions in cigarette consumption would result in health benefits

Any reductions in cigarette consumption prompted by the Proposed Rule would result in health benefits for both smokers and nonsmokers.

1. Declines in cigarette consumption would yield health benefits for smokers.

Although smokers have already been exposed to some negative health consequences of smoking, they can greatly improve their health and reduce their risk for serious and fatal diseases by quitting smoking. While some health consequences of cigarette smoking, such as scarring of the lungs, are

⁵³ Brewer et al., *supra* note 50, at 909.

⁵⁴ Proposed Rule, *supra* note 2, at 42,764.

⁵⁵ John J. Koval et al., *The Potential Effectiveness of Warning Labels on Cigarette Packages*, 96 CAN. J. PUB. HEALTH 353, 354 (2005).

⁵⁶ *Survey on Tobacco: Analytical Report*, at 6, EUROBAROMETER (Mar. 2009), https://ec.europa.eu/commfrontoffice/publicopinion/flash/fl_253_en.pdf.

not reversible, quitting smoking can prevent further damage.⁵⁷ Some benefits of ceasing smoking are experienced relatively quickly. For example, within twelve hours of quitting smoking, carbon monoxide levels in the bloodstream drop to normal.⁵⁸ Within two to three weeks of quitting, circulation and lung function improve, making it easier for individuals to move around and engage in activity. Even for long-term or habitual smokers, quitting smoking significantly reduces individuals' risks and exposure to various life-threatening diseases. For example, within one year of quitting smoking, former smokers face sharply decreased cardiovascular risks.⁵⁹ Additionally, within two to five years after quitting smoking, a former smokers' risk of stroke reduces approximately to the level of risk faced by a non-smoker.⁶⁰ Quitting smoking also reduces risks for mouth, throat, esophagus, and bladder cancer by about 50% within five years of quitting.⁶¹ Similarly, ten years after quitting smoking, one's risk for dying from lung cancer drops by 50%.⁶² FDA also cites to the 2004 Surgeon General's Report noting that "clinical studies show[ed] that . . . quitting smoking causes most premalignant lesions to regress and reduces oral and pharyngeal cancer incidence and mortality."⁶³ Moreover, each quit attempt that a smoker undertakes brings them closer to a complete cessation on smoking. Recent studies have found that "for many smokers it may take 30 or more quit attempts before being successful."⁶⁴ Thus, even if a consumer experiences a relapse, if they are persuaded to undertake another quit attempt on account of a cigarette package or advertisement warning message, the consumer increases their chances of experiencing the aforementioned health benefits of smoking cessation.

2. Declines in cigarette consumption would yield health benefits for nonsmokers by reducing their exposure to secondhand smoke.

As discussed above, secondhand smoke is a negative externality. Because of the significant negative health consequences associated with exposure to secondhand smoke, "approximately 2,500,000 nonsmokers have died from health problems caused by exposure to secondhand smoke" since 1964.⁶⁵ Reducing secondhand smoke would decrease this striking figure by minimizing individuals' exposure to toxins from burning cigarettes.

C. FDA could conduct a break-even analysis focused on avoided smoking-related mortalities

Given the myriad effects of cigarette smoking on public health, FDA need not quantify all the health benefits described above before concluding that the Proposed Rule is cost-benefit justified. Instead, FDA could perform a break-even analysis focused on a single category of health effects,

⁵⁷ See *Benefits of Quitting*, SMOKEFREE.GOV, <https://smokefree.gov/quit-smoking/why-you-should-quit/benefits-of-quitting> (last visited Oct. 15, 2019).

⁵⁸ See *Reasons to Quit*, SMOKEFREE.GOV, <https://smokefree.gov/quit-smoking/why-you-should-quit/reasons-to-quit> (last visited Oct. 15, 2019).

⁵⁹ See *Health Effects of Cigarette Smoking*, *supra* note 5.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ Proposed Rule, *supra* note 2 at 42,774.

⁶⁴ Michael Chaiton et al., Estimating the Number of Quit Attempts it Takes to Quit Smoking Successfully in a Longitudinal Cohort of Smokers, *BMJ JOURNALS* (2016), <https://bmjopen.bmj.com/content/6/6/e011045>.

⁶⁵ *Second Hand Smoke (SHS) Facts*, *supra* note 13; see also U.S. DEP'T OF HEALTH & HUMAN SERVS., 2014 SURGEON GENERAL'S REPORT: THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS 15 (Jonathan M. Samet et al. eds., 2014) [hereinafter SURGEON GENERAL'S REPORT].

such as avoided premature mortalities. The agency should ground its estimate of the benefits of mortalities avoided in a value of statistical life (VSL) approach, as it has done in prior rulemakings,⁶⁶ in accordance with the *Guidelines on Regulatory Impact Analysis* issued by the Department of Health and Human Services (HHS).⁶⁷

Considering the available scientific evidence, it is reasonable to believe that the Proposed Rule would avert a sufficient number of smoking-related deaths to offset its expected costs. Indeed, if FDA follows HHS's central VSL estimate of \$9.9 million (2018\$),⁶⁸ and estimates the Proposed Rule's mean annual costs to be around \$107.5 million under a 3% discount rate or \$115.3 million under a 7% discount rate (2018\$),⁶⁹ then the information presented by the proposed warning labels would have to "save" only 11 to 12 statistical lives annually in order to recoup the regulation's associated costs through mortality benefits alone. Notably, these target figures would amount to preventing roughly 0.0025% of the estimated 480,000 cigarette-related deaths that occur each year.⁷⁰

Enhanced warning labels could save 11 to 12 lives by dissuading youths from becoming smokers. According to CDC, 90% of smokers begin smoking before age 18,⁷¹ making this demographic critical to lowering smoker numbers. One third of youth smokers will eventually die from smoking-related causes.⁷² Thus, to save 11 to 12 lives per year, warning labels must dissuade 36 youths from becoming smokers annually. Each year, more than 109,500 youths become daily smokers.⁷³ To break even, therefore, the labels must prevent only 1 in every 3,000 of these youths each year from becoming daily smokers.⁷⁴

Enhanced warning labels could also save lives by persuading smokers to quit smoking. Studies show that an estimated two-thirds of smokers aged 45 and older will die from smoking-related

⁶⁶ See, e.g., U.S. Food & Drug Admin., Tobacco Product Standard for N-Nitrosornicotine Level in Finished Smokeless Tobacco Products: Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis 31 (2017) ("We value avoided oral cancer deaths using . . . a value per statistical life (VSL) approach, which uses a range of VSL estimates to measure the value of reduced cancer mortality."); U.S. Food & Drug Admin., General and Plastic Surgery Devices: Restricted Sales, Distribution, and Use of Sunlamp Products: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis 31 (2015) ("To value the willingness to pay to avoid a fatal case [of skin cancer] we . . . used the value of a statistical life (VSL) approach.").

⁶⁷ HHS GUIDELINES, *supra* note 45, at 13-18.

⁶⁸ *Id.* at 17.

⁶⁹ RIA, *supra* note 18, at 7.

⁷⁰ Proposed Rule, *supra* note 2, at 42,755.

⁷¹ *Youth and Tobacco Use*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm (last updated Feb. 28, 2019) ("Nearly 9 out of 10 cigarette smokers first try cigarette smoking by age 18.").

⁷² Ctrs. for Disease Control & Prevention, *Projected Smoking-Related Deaths Among Youth – United States*, 45 MORBIDITY & MORTALITY WKLY. REP. 971, 972 (1996) (projecting 5,318,681 smoking-related deaths among 16,620,878 smokers under age 18).

⁷³ See *Youth and Tobacco Use*, *supra* note 71 (finding more than 300 youths under age 18 become daily cigarette smokers daily). Multiplying 300 by 365 days in a year yields an annual rate of 109,500 youths converted to daily smokers annually.

⁷⁴ Assuming the pool of eligible youths to dissuade from becoming daily smokers is 109,500 each year, then dividing that number by 36 youths yields 3,041.67. Thus, for every 3,042 would-be daily youth smokers, warning labels must dissuade one such youth from becoming a daily smoker. This estimate may be conservative because the one-third smoking-related death rate among youth smokers applies not to daily smokers, but rather to those youths

conditions.⁷⁵ As discussed above, studies also show that people who quit smoking decrease their risk of dying from smoking-related causes.⁷⁶ FDA could choose a number the agency deems appropriate to characterize the risk faced by former smokers, but, for illustration, assume smokers who quit at age 45 or older have a one-third chance of dying from smoking-related causes, as opposed to two-thirds among ongoing smokers.⁷⁷ Thus, by persuading 36 smokers aged 45 or older to quit smoking, warning labels could decrease expected smoking-related deaths from 24 to 12, thereby avoiding 12 premature mortalities. Roughly 16.7 million Americans aged 45 or older are current smokers.⁷⁸ So, to break even, warning labels must persuade roughly 1 in every 464,000 of these smokers to quit each year.⁷⁹

Of course, these estimates are conservative, because each break-even analysis assumes warning labels will affect *only* youths or affect *only* smokers aged 45 and older. In reality, enhanced warning labels will likely benefit both groups, as well as smokers of all ages in between. Thus, even if the proposed warning labels fall short of the modest break-even goals associated with one category of people, the labels could still break even by combining benefits to Americans across ages and smoking habits.

As noted above, pictorial warning labels substantially increase the likelihood that smokers will reduce their cigarette consumption and substantially decrease the likelihood that nonsmokers will

who have smoked 100 or more cigarettes during their lifetimes and are still smoking at the time of study. *See* Ctrs. for Disease Control & Prevention, *supra* note 72, at 971. In the study establishing the one-third rate, CDC based its estimate of how many youths would continue smoking in adulthood off studies associated with this 100-cigarette definition. *Id.* But it is possible that *daily* youth smokers would be even likelier to continue smoking in adulthood than youths who have smoked 100 cigarettes over the course of their lifetimes. This would lead to a smoking-related death rate higher than one-third among daily youth smokers.

⁷⁵ See, e.g., Emily Banks et al., *Tobacco Smoking and All-Cause Mortality in a Large Australian Cohort Study: Findings from a Mature Epidemic with Current Low Smoking Prevalence*, 13 BMC MED. 1, 6 (2015) (concluding from a study of current smokers aged 45 and older that up to two-thirds of death were attributable to smoking and that “[t]he findings from this and contemporary estimates from the US and UK indicate that up to two-thirds of deaths in smokers in the 21st century in these settings are likely to have been caused by smoking.”); Thun, *supra* note 12, at 362 (“These studies show that more than two thirds of all deaths among current smokers in these age groups are associated with smoking.”).

⁷⁶ See Banks et al., *supra* note 75, at 5 (finding the relative risk ratios for current smokers versus never-smokers to be significantly higher than those for past smokers versus never-smokers); Sarah H. Nash et al., *Cigarette Smoking and Mortality in Adults Aged 70 Years and Older: Results from the NIH-AARP Cohort*, 52 AM. J. MED. 276, 280 (Mar. 2017) (finding that “quitting at any age was associated with lower risk of mortality”).

⁷⁷ This estimate is reasonable, given ranges provided by studies. *See* Ctrs. for Disease Control & Prevention, *supra* note 72, at 971 (finding that estimates of the number of smoking-attributable deaths among former smokers ranges from 10% to 37%); Banks et al., *supra* note 75, at 5 (finding a relative risk ratio of 1.43 for past smokers versus never smokers).

⁷⁸ According to 2010 census data, 81,489,445 Americans are 45 to 64 years old, and 40,267,984 are aged 65 and older. LINDSAY M. HOWDEN & JULIE A. MEYER, AGE AND SEX COMPOSITION: 2010 at 2 tbl.1 (2011), available at <https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf>. According to CDC, 16.5% of Americans 45-64 smoke, and 8.2% of Americans 65 and older smoke. *Burden of Tobacco Use in the U.S.*, CTNS. FOR DISEASE CONTROL AND PREVENTION (last updated Feb. 25, 2019), <https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html>. Thus 13,445,758 Americans ages 45-64 smoke, and 3,301,975 Americans 65 and older smoke, leading to a total of 16,747,733 smoking Americans in this age range.

⁷⁹ Assuming a pool of potential beneficiaries of roughly 16.7 million, dividing 16.7 million by 36 people persuaded to quit yields 463,888.89. Thus, for roughly every 464,000 smokers aged 45 and up, warning labels would need to persuade one person to quit smoking.

take up the practice. In this light, it would be entirely reasonable for FDA, based on an independent break-even analysis of mortality benefits alone, to conclude that the Proposed Rule would change the cigarette-purchasing behavior of *at least* enough current or would-be smokers to offset its expected costs.

IV. Conclusion

As FDA's evidence-based reasoning demonstrates, updating warning labels on cigarette packages and advertisements will yield significant benefits for the public. The agency has already provided ample justification for the Proposed Rule. These comments suggest ways for FDA to make its analysis even stronger.

Respectfully submitted,

John Corgan
Natalie Jacewicz
Jack Lienke
Julia Paranyuk
Jason A. Schwartz

Institute for Policy Integrity at NYU School of Law