Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

July 16, 2018

VIA ELECTRONIC SUBMISSION

Food and Drug Administration, U.S. Department of Health & Human Services

Attn: Center for Tobacco Products

Re: Tobacco Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11,818 (Mar. 16, 2018); Docket No. FDA-2017-N-6189; RIN 0910-AH86

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law[1] respectfully submits the following comments to the Food and Drug Administration ("FDA") regarding its advance notice of proposed rulemaking on nicotine levels in combusted cigarettes.[2] Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decision making through advocacy and scholarship in the fields of administrative law, economics, and public policy.

To determine whether a proposed limit on the nicotine content of combusted cigarettes will increase aggregate social welfare, FDA should take at least four actions. First, the agency should determine whether and to what extent the proposed nicotine limit will reduce cigarette consumption. Second, FDA should conduct research or compile literature reviews regarding the extent of behavioral bias in combusted cigarette consumption—that is, the extent to which actual consumption decisions differ from those that would be made by fully informed and rational consumers. Third, the agency should use a behavioral public finance model to assess how its proposed nicotine limit would affect the welfare of cigarette consumers. Fourth, FDA should estimate how the proposed limit would affect the welfare of non-smokers. Our comments offer recommendations regarding steps two through four of this process.

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

[2] Tobacco Standard for Nicotine Level of Combusted Cigarettes, Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 11,818 (Mar. 16, 2018).

I. Consumer demand for combusted cigarettes is potentially biased

To inform its assessment of the welfare effects of any reduction in cigarette smoking, FDA should conduct a thorough review of evidence on consumer bias in cigarette consumption decisions. Bias in consumer demand for combusted cigarettes could arise from multiple sources, such as: incorrect information about the health risks of smoking; incorrect beliefs about the difficulty of quitting; or "dynamic inconsistency," where an individual would like to stop smoking in the long run but is tempted to continue smoking when he or she is actually presented with the opportunity to smoke in the short run.[3]

Empirical evidence suggests that biases exist in the cigarette consumption decision and that these biases are difficult for smokers to overcome.[4] In a 2010 study, for example, researchers offered current smokers the chance to participate in an experiment designed to help them quit smoking. Each participant was given a savings account in which he or she deposited funds for six months. After six months, each had to submit to a urine test. Participants who passed the test were able to retrieve the money they had deposited; those who failed the test (i.e., tested positive for nicotine) forfeited their deposits. The study results highlighted the extent of dynamic inconsistency in cigarette smoking decisions. Of the 83 participants who accepted the contract, only 29 passed the 6-month test.[5] The researchers theorized that behavioral biases such as loss aversion, partial naiveté, projection bias, and over-optimism all may have played a role in the failed contracts.[6]

Another factor that might bias cigarette demand is the positional nature of cigarette consumption. The value of a "positional good" depends on how the good compares with things owned by others.[7] Some smokers are likely to consume cigarettes at least partially

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[3] Helen Levy, Edward Norton & Jeffrey Smith, *Tobacco Regulation and Cost Benefit Analysis*, 4 AM. J. OF HEALTH ECON. 1 (2017).

[4] Giné, Xavier, Dean Karlan & Jonathan Zinman, *Put Your Money Where Your Butt Is: A Commitment Contract for Smoking Cessation*, 4 AM. ECON. J.: APPLIED ECON. 213 (2010)

[5] *Id.* at 228.

[6] *Id.* at 230.

[7] Robert H. Frank, *The Demand for Unobservable and Other Nonpositional Goods*, 75 AM. ECON. REV. 101, 101 (1985). Classic examples of a positional goods include studying for an exam where the grade will be curved, where the value a student derives from his or her studying depends on the

for their positional value.[8] Obtaining this positional value might not increase aggregate consumer welfare, however, because positional goods generate a negative externality.[9] Accordingly, a regulation that reduces smoking among such consumers might not reduce aggregate consumer welfare. Instead, the regulation might allow the consumers to achieve what they could not in the non-cooperative open market: an aggregate reduction in the incidence of smoking that does not radically upset the status hierarchy.

If, based on a review of relevant studies, FDA determines that cigarette demand is indeed biased—whether by inadequate information, cognitive error, or positional externalities—it should incorporate an estimate of that bias into its cost-benefit analysis for any proposed nicotine limit, as discussed in Section II.

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amount of studying done by other students, or the quality of a suit for a job interview, where the quality matters largely in relation to the suit quality of other candidates. Sara J. Solnick & David Hemenway, *Are positional concerns stronger in some domains than in others?*, 95 AM. ECON. REV. 148 (2005).

[8] The positional value of goods can vary depending on the relevant population competing for social status. See Fredrik Carlsson et al., *Do You Enjoy Having More than Others? Survey Evidence of Positional Goods*, 74 ECONOMICA 586, 588, 590 (2007). In recent years and in certain segments of the U.S. population, especially at higher incomes, smoking may no longer be used to advertise social status and may in fact risk conveying the negative signal of self-control problems: "while smoking an expensive brand is likely to be perceived as more prestigious than smoking a cheap brand, forgoing this expenditure altogether (by not smoking) might be perceived as more prestigious than both." Ori Heffetz, *A Test of Conspicuous Consumption: Visibility and Income Elasticities*, 93 REV. OF ECON. & STAT. 1101, 1110 n.18 (2011). Stigma generated by regulation and informational requirements for tobacco products has contributed to this shifting social norm. Nevertheless, within certain populations, for certain products, and under certain regulatory scenarios, tobacco will continue to have strong positional value. Youths, for example, are significantly influenced by peer effects when deciding whether to begin smoking. Lisa M. Powell, John A. Tauras & Hana Ross, *The Importance of Peer Effects, Cigarette Prices and Tobacco Control Policies for Youth Smoking Behavior*, 24 J. OF HEALTH ECON. 950 (2005).

[9] If Joan begins smoking cigarettes to move up the status hierarchy in her peer group, John's own smoking is no longer as rare. John feels relatively worse off and would need to invest in other symbols of status just to restore his previous social position. John's subsequent expenditures make Joan feel once again behind the social curve, despite her tobacco purchases. As a result, consumers can get stuck on a "positional treadmill," continually chasing after enhanced welfare that never materializes. *See* Robert H. Frank, *Positional Externalities Cause Large and Preventable Welfare Losses*, 95 AM. ECON. REV. 137 (2005).

II.   FDA should incorporate any bias in consumer demand into the agency's cost-benefit analysis

Given the potential bias in the consumer decision to smoke cigarettes, the FDA should use a behavioral public finance framework to conduct its cost-benefit analysis for any proposed nicotine limit. The framework of analysis employed by Helen Levy, Edward Norton, and Jeffrey Smith in their paper *Tobacco Regulation and Cost Benefit Analysis*[10] offers a useful approach for analyzing markets with consumer bias, specifically in the context of cigarette consumption.

Levy et al. model consumers in the cigarette market as making a discrete decision as to whether to quit smoking. Consumers take this action when their decision utility exceeds a critical value.[11] The decision utility is equal to the experienced utility minus a bias parameter. The model measures forgone consumer surplus by comparing the demand for cigarettes by a rational, fully informed (unbiased) consumer against the demand for cigarettes by a biased consumer. Any factor that would lead an individual to consume more cigarettes is encompassed by the bias parameter. Non-zero bias would increase demand for the biased consumer, leading to a larger quantity of cigarettes demanded for a given price relative to an unbiased consumer.

Levy et al. examine the effect of a tax on cigarettes intended to move consumer demand back to the optimal level of the unbiased consumer.[12] The resulting models show that a tax at the optimal level improves aggregate welfare among cigarette consumers, but not as much as the health gains by smokers would suggest.[13] Furthermore, any tax above the optimal level would bring about welfare losses relative to no intervention.[14]

The three main takeaways from the model for regulators are that (1) for an unbiased consumer, a tax of any size will create a welfare loss; (2) for a consumer who is biased,

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[10] Levy et al*., supra* note 3.

[11] *Id.* at 11.

[12] *Id*. at 13.

[13] *Id.*

[14] *Id.* at 19.

taxes or other interventions to offset behavioral biases will increase consumer welfare, provided that the intervention is not too big in the sense that it pushes demand below the unbiased optimum; and (3) for a consumer who is biased, interventions that push demand below the unbiased optimum have an ambiguous effect on welfare, relative to the no-intervention state, depending on how far below the unbiased optimum the intervention reduces demand.[15]

A limit on the nicotine content of combusted cigarettes could be modeled similarly to a tax. Reducing the nicotine level of cigarettes should make them less desirable, reducing the enjoyment per dollar for cigarettes. This is symmetric to increasing the price per cigarette through taxation, with one important distinction. Unlike a tax, a limit on nicotine could theoretically cause some consumers to *increase* their cigarette consumption in an attempt to keep their level of nicotine consumption intact. Thus, before applying the Levy et al. methodology to this context, the FDA must determine whether and to what extent a given limit on nicotine will reduce demand for cigarettes.

When applying the Levy et al. methodology to a proposed nicotine limit, FDA should also take into account the recent increase in availability of non-combustible nicotine products (such as e-cigarettes). In general, a decrease in the price of a substitute good will cause demand for the original good to fall. In this case, the affordability of e-cigarettes should lead to a decrease in demand for combusted cigarettes by both biased and unbiased consumers. This could reduce the total welfare cost of any proposed nicotine limit for combusted cigarettes.

III.   FDA should also consider welfare effects on non-smokers

Adopting the behavioral public finance framework described in Section II would enable FDA to model the welfare gained or lost by smokers as a result of a proposed nicotine limit. This model would not, however, capture the welfare effects of such a regulation on society as a whole. Even if smokers are perfectly informed and otherwise unbiased, they may make

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[15] *Id.*

choices that result in a net social loss. This is because their actions result in costs that the smokers themselves do not bear, also known as negative externalities.

Secondhand smoke is a common example of a negative externality. It is a byproduct of smoking that is inhaled by bystanders, many of whom have never voluntarily consumed any tobacco products. According to a 2014 report from the U.S. Surgeon General, nearly 40,000 deaths a year are attributable to exposure to secondhand smoke.[16] In 2006, more than $5.6 billion was lost as a result of premature deaths attributable to exposure to secondhand smoke.[17] This figure is based only on mortality due to secondhand smoke. Including morbidity and other, less noticeable effects on health and productivity would likely raise this number dramatically.

Even if smokers never smoke around non-smokers, the habit may still harm others. Research shows that cancer diagnoses have pernicious effects on caregivers, who report lower quality of life, more fear of cancer recurrence, and less support than the people who actually survived cancer.[18] Late-stage cancer can also cause harm to marital relationships, especially during the last months and weeks of life.[19]

Loved ones are not the only third parties who suffer because of smoking. Cigarette butts pollute the environment, causing harm to wildlife and requiring costly cleanup efforts.[20] As of 2014, healthcare expenditures related to smoking accounted for an estimated 7 to 9 percent of total annual health care spending in the U.S.[21] Smoking is also a cause of fire-

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[16] U.S. DEP'T OF HEALTH & HUMAN SERVS., 2014 SURGEON GENERAL'S REPORT: THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS 678 (Jonathan M. Samet et al., eds., 2014).

[17] *Id.* at 666, tbl.12.9.

[18] Suzanne Mellon, Laurel L. Northouse & Linda K. Weiss, *A Population-Based Study of the Quality of Life of Cancer Survivors and Their Family Caregivers*, 29 CANCER NURSING 2, 120 (2006).

[19] Linda M. McLean & Jennifer M. Jones, *A Review of Distress and its Management in Couples Facing End-of-Life Cancer*, 16 PSYCHO-ONCOLOGY 7, 603 (2007).

[20] *See generally* Thomas E. Novotny et al., *Cigarettes Butts and the Case for an Environmental Policy on Hazardous Cigarette Waste*, 6 INT. J. OF ENVIRONMENTAL RESEARCH & PUB. HEALTH 5, 1691 (2009).

[21] 2014 SURGEON GENERAL'S REPORT, *supra* note 16, at 675, tbl.12.14.

related deaths and injuries, which can tie up firefighters and other emergency services.[22] Such costs are not incurred (solely) by smokers. Rather, they are borne by society.

FDA should consider these potential effects on non-smokers when determining whether a nicotine limit will increase aggregate social welfare. Such considerations should supplement any welfare determinations made using the behavioral public finance framework described in Section II.

Respectfully,

Jack Lienke
Jeffrey Shrader, Ph.D.
Alexander Whitelaw
Cameron Williamson

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[22] *Id.* at 661, tbl.12.5.