FDA was correct in not quantifying consumer surplus in its analysis of the proposed standard for menthol in cigarette

Docket No. FDA-2021-N-1349
for "Tobacco Product Standard for Menthol in Cigarettes"

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We agree with FDA's decision to not quantify consumer surplus in its analysis of the economic impacts of the proposed product standard prohibiting menthol in cigarettes. There is tremendous uncertainty in how to quantify consumer surplus when considering addictive tobacco products, and in any case ***the benefits of the proposed rule are expected to be so large that any value attached to consumer surplus would not change the conclusion***.

As FDA explains in its Preliminary Regulatory Impact Analysis,[1] "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." While acknowledging that it might be appropriate to consider consumer surplus *qualitatively*, FDA "decline[d] 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."

We quote FDA's reasons driving this conclusion, which are sound and based on the best available science:

(1) Cigarette smoking is driven primarily by nicotine addiction, including menthol's enhancing effect on nicotine addiction;
(2) The vast majority of adult smokers become addicted to nicotine at young ages, before the brain has completed development;

[1] Economics Staff, Center for Tobacco Products, US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, Preliminary Regulatory Impact Analysis. Available: https://www.regulations.gov/document/FDA-2021-N-1349-0295

(3) 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;
(4) 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;
(5) 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
(6) 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.[2]

Underscoring FDA's first point that smoking is driven by nicotine addiction and on menthol's enhancing effect on nicotine addiction, it is important to note that addiction is defined as compulsive seeking and consumption of a substance despite adverse consequences.[3] This means nicotine addiction is characterized by acting against one's own wishes and is synonymous with a lack of choice; therefore, quantifying consumer surplus in the context of nicotine addiction is not appropriate.

FDA stated that it did not make sense to quantify consumer surplus because it expects the benefits of the rule would be so large that any reasonable consideration of consumer surplus impacts would not affect their determination that the "benefits associated with this rule justify the costs." We agree. For example, FDA said, "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."[4]

In fact, because FDA's model only considers mortality benefits and does not consider the other significant benefits of prohibiting menthol, the benefits would be significantly higher than FDA's predictions, making it even more unlikely that consumer surplus would make a material difference. Some of these additional benefits include reducing the addictive properties of nicotine in cigarettes; reducing the appeal of cigarettes to nonusers, particularly adolescents and young adults and thereby decreasing the likelihood of tobacco use initiation; reducing the incidence of multiple tobacco-related diseases by decreasing cigarette consumption and increasing the likelihood of cessation; reducing smoking-attributable healthcare costs due to lower smoking prevalence; reducing indirect costs of lost

[2] Economics Staff, Center for Tobacco Products, US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, Preliminary Regulatory Impact Analysis, pp.168-169.Available: https://www.regulations.gov/document/FDA-2021-N-1349-0295
[3] National Institute on Drug Abuse, Drug Misuse and Addiction. Available: https://nida.nih.gov/publications/drugs-brains-behavior-science-addiction/drug-misuse-addiction
[4] Economics Staff, Center for Tobacco Products, US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, Preliminary Regulatory Impact Analysis, p. 168, fn 61. Available: https://www.regulations.gov/document/FDA-2021-N-1349-0295

productivity due to decreased tobacco-related illnesses and premature deaths; and reducing tobacco-related health disparities and advancing health equity.

Several papers support FDA's decision to not quantify consumer surplus. A 2014 paper by Song et al.[5] analyzed FDA's use of consumer surplus in analyzing the economic benefits of graphic warning label regulations on cigarette packages and its decision to discount the benefits of reduced smoking and quantify them as lost "consumer surplus" because of the lost "pleasure" smokers experience when they stop smoking. Song et al. noted that consumer surplus is grounded in rational choice theory. However, empirical evidence from psychological cognitive science and behavioral economics demonstrates that the assumptions of rational choice are inconsistent with complex multidimensional decisions, particularly smoking. Rational choice does not account for the roles of emotions, misperceptions, optimistic bias, regret, and cognitive inefficiency that are germane to smoking, particularly because most smokers begin smoking in their youth. Continued application of a consumer surplus discount will undermine sensible policies to reduce tobacco use and other policies to promote public health.

Another paper by Song and Glantz[6] addressing the difficulties of using traditional economic methods in assessing tobacco regulation concluded:

> Indeed, recent advances in neuroscience suggest that the brain continues to mature into one's 20s,[footnotes omitted] well beyond the legal age to buy cigarettes. These brain imaging studies also demonstrate that one of the last areas to mature are the areas critical for impulse control and critical thinking. [footnotes omitted] Moreover, empirical evidence consistently shows that adults cannot accurately predict their own emotional reactions and experiences, particularly when dealing with an addictive substance. [footnotes omitted]
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> Properly considering these issues and integrating them into its assessment of proposed regulations will require the FDA and the Department of Health and Human Services to move beyond the narrow view that only economists have standing to contribute to this analysis. At a minimum, behavioural scientists and neurobiologists need to be among the experts evaluating the government's approach to these issues.

A paper by Chaloupka et al.[7] evaluated FDA's analysis of the costs and benefits of the graphic warning label regulation. The authors found that by quantifying consumer surplus in its economic impact analyses, FDA substantially underestimates the benefits and overestimates the costs, leading to

[5] Song AV, Brown P, Glantz SA. When health policy and empirical evidence collide: the case of cigarette package warning labels and economic consumer surplus. American journal of public health. 2014 Feb;104(2):e42-51.

[6] Song AV, Glantz SA. Assessing tobacco regulation: moving beyond economists. Tobacco control. 2015 Mar 1;24(2):123-4.

[7] Chaloupka FJ, Warner KE, Acemoğlu D, Gruber J, Laux F, Max W, Newhouse J, Schelling T, Sindelar J. An evaluation of the FDA's analysis of the costs and benefits of the graphic warning label regulation. Tobacco Control. 2015 Mar 1;24(2):112-9.

FDA substantially underestimating the net benefits of its regulation. The authors concluded that this approach should not be used in analyzing the economic benefits of any tobacco regulations:

> Given the controversy over the FDA's approach to assessing net economic benefits in its proposed and final rules on GWLs and the importance of having economic impact analyses prepared in accordance with sound economic analysis, a group of prominent economists met in early 2014 to review that approach and, where indicated, to offer suggestions for an improved analysis. We concluded that the analysis of the impact of GWLs on smoking substantially underestimated the benefits and overestimated the costs, leading the FDA to substantially underestimate the net benefits of the GWLs. We hope that the FDA will find our evaluation useful in subsequent analyses, not only of GWLs but also of other regulations regarding tobacco products. Most of what we discuss applies to all instances of evaluating the costs and benefits of tobacco product regulation and, we believe, should be considered in FDA's future analyses of proposed rules.

Conclusion

FDA was correct to not quantify consumer surplus in its analysis of the proposed standard for menthol in cigarette. Consumer surplus analysis is not appropriate when considering the risks and benefits of regulations that concern smoking, and there is no agreement among health economists about the appropriate way to make this kind of assessment. Further, the benefits of the proposed rule would be so large that any reasonable consideration of consumer surplus impacts would not affect FDA’s determination that the benefits associated with this rule justify the costs.