



Food and Drug Administration
Docket No. FDA-2014-N-0189
Regulatory Information Number (RIN) 0910-AG38

August 8, 2014

The Center for Effective Government respectfully submits these comments expressing our deep concerns regarding elements of the preliminary regulatory impact analysis¹ supporting the proposed rule deeming tobacco products to be subject to Food and Drug Administration (FDA) jurisdiction². Specifically, CEG objects to the application of a “lost pleasure” discount that the FDA, with support from the Office of Information and Regulatory Affairs (OIRA), has applied to the health benefits expected from the rule. These “lost pleasure” reductions are based on the fundamentally flawed concept that smokers will forgo “lost pleasure” if the rules significantly reduce tobacco smoking, as intended by Congress in passing the Family Smoking Prevention and Tobacco Control of 2009 (2009 Act). We strongly urge the FDA to revise the preliminary regulatory impact analysis to eliminate the application of a “lost pleasure” discount in assessing the benefits from the final rule regulating tobacco products.

FDA’s use of the economic concept of consumer surplus to justify a 70 percent discount of the total health benefits of the deeming rule due to the “lost pleasure” smokers incur when stopping smoking is an inappropriate application of the consumer surplus economic theory.³ This extraordinary discount amount represents an *increase* from the 50 percent reduction due to “lost pleasure” that was applied to the health benefits of the Graphic Warning Label (GWL) rule⁴, the first rule FDA promulgated under the 2009 Act. The preliminary regulatory impact analysis for the Deeming rule provides no explanation or justification as to why the amount of this flawed, already significant, discount in health benefits from tobacco control was increased from the level applied in the GWL rule.

¹Food and Drug Administration, Preliminary Regulatory Impact Analysis; *Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements*, April 2014 (FDA-2014-N-0189).

²Food and Drug Administration; *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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (Proposed Rule)*, 79 FR 23142 (April 25, 2014).

³*Op. Cit.*

⁴Required Warnings for Cigarette Packages and Advertisements, 76 FR 36628 (June 22, 2011).



As discussed in more detailed in comments submitted by a group of leading economists,⁵ the application of a consumer surplus economic model is not supported when applied to addictive products such as tobacco. Consumer surplus theory presupposes consumers are fully informed and fully rational in evaluating risks and benefits in their decision-making. Overwhelming empirical evidence conclusively demonstrates that tobacco consumers, particularly adolescents, do not fit this model.⁶ As FDA notes in the proposed rule, the young age at which people begin smoking and the addictive nature of tobacco impairs rational decision-making⁷ and other studies show that consumers overestimate their ability to quit smoking in the future.⁸ Given these factors, the fundamental economic underpinning for application of a “lost pleasure” discount in its regulatory impact analysis has been misapplied to this rulemaking, and FDA must eliminate this discount and restore the full health benefits expected from the rule.

A more general problem with the use of the lost pleasure principle relates to the fact that provision of information constitutes a benefit to consumers, a concept which applies as well in other, non-tobacco contexts. There is no coercive element in the FDA’s graphic warning label proposal; it is purely a means of information conveyance. The underlying assumption of the consumer surplus approach is that consumers are acting with perfect information. Where the result of a regulation is solely increasing the provision of information, either a) consumers were already acting on the basis of perfect information and the additional regulatory-mandated information disclosure will have no effect on their behavior at all; or b) the new information actually helps provide consumers with better information, and the subsequent decisions they make *better* reflect their true, self-determined interests. There is therefore no lost consumer surplus at all. As comments submitted by Chaloupka et al. note “To the extent that rational smokers change their behavior in response to information conveyed by GWLs, it is unlikely that this would make them worse off because of the loss of the pleasure they received from smoking decisions made with imperfect, incomplete information. Indeed, to the extent that the labels are effective in moving some smokers to successfully quit -- something most want to do and that more than half try to do every year -- the reductions in smoking that result should be treated as a benefit rather than a cost that offsets the health benefits that result from quitting.”⁹

⁵ Chaloupka et al, “An Evaluation of FDA’s Analysis of the Costs and Benefits of the Graphic Warning Label Regulation” (July 2014), available at <http://tobacconomics.org/research/evaluation-fda-graphic-warning-label-regulation-benefit-cost-analysis>.

⁶ E.g., Song et al., “When Health Policy and Empirical Evidence Collide: The Case of Cigarette Package Warning Labels and Economic Consumer Surplus,” *Am. J. Public Health*, Vol. 104, No. 2, February 2014.

⁷ *Deeming Rule* at 23159, “several researchers have found that young people may not have the ability to rationally consider the risks and benefits involved with smoking and its long-term effects...Because they lack fully capable executive function, youth seriously underestimate the future costs associated with an addiction to nicotine.”

⁸ Jonathan Gruber and Sendhil Mullainathan, “Do Cigarette Taxes Make Smokers Happier,” *The B.E. Journals in Economic Analysis & Policy*, Volume 5, Issue 1 (2005).

⁹ Chaloupka, *supra* note 5.

The application of a consumer surplus discount to the rule's health benefits has significant implications for whether this rule will emerge intact through the rulemaking process, as the significantly reduced benefits ascribed to the rule makes it more likely that the rule will be blocked or weakened during regulatory review at OIRA. Further, given historical experience, the rule is likely to be litigated by the tobacco industry who will emphasize the limited health benefits of the rule as grounds for overturning the rule. As the FDA is well aware, a federal court of appeals in 2012 sustained a lower court ruling striking down the GWL rule based in part on the court's finding that the health benefits were not significant enough to justify the rule.

In conclusion, CEG finds that FDA's application of the concept of "lost pleasure" to justify discounting of regulatory benefits in the regulatory impact analysis of the proposed Deeming Rule is unjustified and irresponsible. We urge the FDA to reject the use of a "lost pleasure" concept when regulating in the interest of public health, particularly when dealing with harmful and addictive products, and to revise their regulatory impact analysis for this rule accordingly. In addition, we urge the FDA to focus future regulatory actions on fulfilling the agency's mission of protecting and enhancing public health, particularly with respect to harmful and addictive substances, and to not undermine these efforts by applying economic concepts such as "lost pleasure" that rest on incorrect and inappropriate assumptions.

Sincerely,

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