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RE: FDA, Docket No. FDA-2014-N-0189, Regulatory Information Number (RIN) 0910-AG38

August 8, 2014

On behalf of our over 300,000 members, Public Citizen, a national non-profit consumer advocacy organization, respectfully submits comments expressing our deep concerns regarding elements of the preliminary regulatory impact analysis[1] supporting the proposed rule deeming tobacco products to be subject to FDA jurisdiction. Specifically, we object to the way in which the Food and Drug Administration (FDA), along with support from the Office of Information and Regulatory Affairs (OIRA), has dramatically reduced the health benefits expected from the rule. These reductions are due to the so-called "lost pleasure" that smokers would forego if the rules significantly reduced smoking among the public as Congress intended in passing the Family Smoking Prevention and Tobacco Control of 2009 (2009 Act).

We strongly urge the FDA to correct this deeply flawed regulatory impact analysis by making it clear in the final rule that the concept of "lost pleasure" has no place in the context of regulating tobacco products. In addition, the FDA must reassure the public that their future regulatory actions will focus on fulfilling their mission of protecting and enhancing public health, particularly with respect to harmful and addictive substances, and are not undermined by incorporation of economic concepts such as "lost pleasure" that rest on incorrect and inappropriate assumptions.

Public Citizen has a long history of advocating for strong and effective public health standards, including calling for our government to take strong measures to curb smoking. Thus, we were dismayed to see the FDA once again employ a traditional economic concept, consumer surplus, in the context of tobacco regulation, where its application is wholly without merit. In relying upon consumer surplus theory, FDA reduced by 70 percent the total health benefits of the deeming rule due to the "lost pleasure" smokers incur when stopping smoking.[2] This actually constitutes an *increase* from the Graphic Warning Label (GWL) rule[3], the first rule FDA promulgated under the 2009 Act, where health benefits of that rule were already reduced by 50 percent due to "lost pleasure." The regulatory impact analysis for this rule provides no explanation for the allowed increase.

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[1] 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).

[2] *Id*.

[3] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628 (June 22, 2011).

As more fully detailed by a group of leading economists in comments submitted on this rule,[4] the relevance of consumer surplus to economic analysis rests on certain assumptions that do not hold when it comes to addictive products such as tobacco. Consumer surplus theory presupposes consumers who 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.[5] Instead, FDA's itself has concluded that the addictive nature of tobacco trumps rational decision-making[6] and other studies show that consumers overestimate their ability to quit smoking in the future.[7] In light of this, FDA must reverse course by dropping any reliance on "lost pleasure" metrics in its regulatory impact analysis and restoring the full health benefits expected from the rule.

There is a more general problem with the reliance on the lost pleasure principle, 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. In a case where a regulator 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.

More plainly stated: when the government provides truthful information to consumers and this affects consumer behavior, the change in consumer behavior is a consumer benefit (wholly apart from the societal benefits). This is common sense.

As the economists group explained: "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."[8]

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[4] *See*, 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.

[5] *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.

[6] *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), at 45-48.

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

[8] Chaloupka, *supra* note 4.

FDA's use of consumer surplus theory to lower benefits of tobacco regulation is not simply an academic or intellectual exercise devoid of any practical consequences. Discounting health benefits makes it more likely that the rule will be blocked or weakened during regulatory review at OIRA. Even if the rule is finalized, it is likely to be challenged in court by tobacco industry litigants who will seize upon the limited health benefits of the rule as grounds for reversal. Indeed, as the FDA is well aware, a reviewing court struck down the GWL rule in 2011 based in large part on the court's finding that the health benefits were not significant enough to justify the rule.

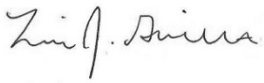
Finally, the FDA must consider the harmful message it is sending to the public, especially children and adolescents, by sanctioning the concept of "lost pleasure." It is simply unacceptable and downright irresponsible for the FDA's official policy position to be that smoking provides such significant pleasure that it comes close to surpassing the enormous health benefits of stopping the practice. By endorsing this concept, that is exactly the message FDA is sending to the public and it is the wrong one.

For the preceding reasons, FDA's continued endorsement of the "lost pleasure" principle in the regulatory impact analysis of this proposed deeming rule is dangerous, irresponsible, and deplorable. In the strongest possible terms, we urge the FDA to reject the "lost pleasure" principle 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.

Sincerely,

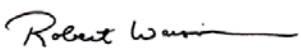
Amit Narang

Regulatory Policy Advocate, Public Citizen



Lisa Gilbert,

Director, Public Citizen's Congress Watch



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