

August 8, 2014

Director Mitch Zeller  
Center for Tobacco Products  
Food and Drug Administration (FDA)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re Docket ID: FDA-2014-N-0189: Deeming Tobacco Products to Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act

Dear Director Zeller:

We write to register our considerable alarm about an economic calculation included in a preliminary regulatory impact analysis of e-cigarettes by the Food and Drug Administration (FDA). Without any statement of justification in the economic analysis or proposed regulation, economists at FDA, under the influence of reviewers from the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), applied an enormous discount of 70 percent to the benefits of the proposed regulation on e-cigarettes (the so-called "deeming rule").<sup>1</sup>

Congress assigned FDA the task of promulgating new safeguards in the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31 (2009), due to the serious risks that tobacco and nicotine addiction pose to public health and to the health of minors. Congress sought to save lives. As the findings to the Act note: "Reducing the use of tobacco by minors by 50 percent would prevent well over 10 million of today's children from becoming regular, daily smokers, saving over 3 million of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately \$75 billion in savings attributable to reduced health care costs."

Despite the clear significance of its assignment to protect public health and the health of young people, FDA and OIRA are playing politics with numbers. Like FDA's rule on cigarette warning labels, which included an unjustified discount in benefits of 50 percent (*see* 75 FR 69546, dividing the benefits "in half to account for smokers' lost consumer surplus associated with the activity of smoking"), the deeming rule contains a similarly troubling and ill-explained provision discounting the benefits of the rule. On this occasion, the discount applied is 70 percent.

Although there is no explanation whatsoever for this factor in the agency's preliminary regulatory impact analysis, a separate paper by several FDA economists and an OIRA economist contends that benefits to rules intended to reduce consumption of harmful products should be discounted by as much as "two-thirds" to account for the lost "consumer surplus" associated with their consumption.<sup>2</sup> The effect is to transform a rule that may save between 3,727 and 5,885 (already discounted) life-years into one that looks barely justified on paper.

In comments published in a *Reuters* article about this absurd and disturbing development, both former OIRA Administrator John Graham and the American Enterprise Institute indicated their belief that this is an unprecedented and unwarranted use of cost-benefit analysis by an agency.<sup>3</sup> We could not agree more.

First, a consumer surplus analysis should not be applied to addictive products like tobacco. These analyses assume that consumers make rational choices in which the benefits outweigh the costs. However, those who are addicted to tobacco make *irrational* choices.<sup>4</sup> Research shows that while many smokers may begin smoking for novelty or pleasure, they often keep smoking primarily to avoid withdrawal symptoms,<sup>5</sup> challenging the idea that smokers lose “pleasure” from quitting. For this and many other reasons, FDA’s analysis is deeply inappropriate.

Second, sound public health policy takes account of the need for cues for healthier choices to be embedded in the environment, and of the high social and shared costs of poor health decisions. While the benefit discount proposed by FDA applies to tobacco, economists at the FDA and OIRA who support the theory for the discount have been explicit about their ambitions far beyond that sphere, mentioning junk food, alcohol and gambling as other likely targets for such discounts in benefits.<sup>6</sup> The precedent set in the deeming rule could be used to undermine other important regulations designed to protect public health.

The notion that consumption patterns (whether for tobacco, junk food, alcohol, or gambling) represent anyone’s “natural state” is absurd; for years, consumer preferences in the areas of food, alcohol and other areas have been shaped by billions of dollars of advertising. The dietary choices that individuals make, for example, have been impacted by the availability of an abundance of cheap, unhealthy calories and addition of salt, sugar and fat in many processed, and highly profitable, foods and beverages.

Recent findings from many studies indicate what advertisers have known for decades: that the context for consumption is critical and that cues and other factors in the food environment can greatly impact individuals’ decisions. Evidence suggests that external factors can prompt more consumption without any conscious knowledge of the prompt, even affecting consumers’ “willingness to pay” for products:

- In one study, researchers exposed people to an image of a happy, neutral, or angry face so briefly (less than 1/50 of a second) that they could not consciously detect it. Participants then poured themselves a sugary drink and consumed as much as they wanted. Those exposed to the happy face drank 50 percent more than those exposed to the neutral face – and the people exposed to the angry face drank the least. In a second related experiment, thirsty participants were *willing to pay twice as much* for a can of the sugar drink after seeing flashes of happy faces than after seeing flashes of angry faces.<sup>7</sup>
- Other studies have demonstrated that changing the layout of cafeteria food, placing items in prominent positions on a menu can improve dietary choices.<sup>8</sup> Similarly, merely displaying photos of salads in a cafeteria can reduce the consumption of desserts.<sup>9</sup>
- Google recently used a simple placement change to get its employees to eat more fruit and nuts rather than candy. The Internet giant was concerned that workers were gorging on free M&Ms instead of the healthier options it offered. Simply by putting the chocolate candies in opaque containers and prominently displaying dried figs, pistachios,

and other nutritious snacks, the company reduced consumption of the candy in its New York office by 3.1 million calories over 7 weeks – the equivalent of 9 packages of M&Ms per employee.<sup>10</sup>

The simple interventions here demonstrate the folly of the kind of benefit calculation imposed by the FDA and OIRA economists: the more effective such interventions might be in generating healthier choices, the larger the discount that would be applied. This dubious discount – related as it is to a capacious concept like “lost pleasure” – could equally be applied to speeding laws, or to measures to rid the marketplace of unsafe toys, as well as countless other areas in which our basic social contract requires a small sacrifice by individuals to create a safe and orderly community.

In sum, there is clear evidence for many public health interventions that aim to alter costly and harmful behavior. The FDA and other agencies are tasked by Congress with sensible decision-making that sensitively and scientifically examines the case for protective health and safety rules. The Supreme Court has made it clear that the health, safety and environmental laws that reflect Congressional intent should not be compromised by considerations laid over top of them by an executive order.<sup>11</sup> Even where the scope or impact of a rule is not being altered by the econometric analysis, the government’s calculation of their benefits to individuals and societies should not and cannot be reduced in such an arbitrary and baseless fashion.

Sincerely,

American Federation of State, County and Municipal Employees  
Campaign for Tobacco-Free Kids  
Caney Fork Headwaters Association  
Center for Effective Government  
Center for Food Safety  
Center for Science and Democracy at the Union of Concerned Scientists  
Center for Science in the Public Interest  
Center for Tobacco Control Research and Education, University of California San Francisco  
Consumer Federation of America  
Cornucopia Network/NJ/TN Chapter  
Cumberland Countians for Ecojustice  
National Consumers League  
Natural Resources Defense Council  
Network for Environmental & Economic Responsibility of United Church of Christ  
Protect All Children's Environment  
Public Citizen

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<sup>1</sup> 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*, at 52, April 2014.

<sup>2</sup> Ashley, Nardinelli, and Lavaty. "Estimating the Benefits of Public Health Policies that Reduce Harmful Consumption," *Health Economics Letter* (2014).

<sup>3</sup> Begley, Sharon. (2014, June 2). FDA calculates costs of lost enjoyment if e-cigarette rules prevent smoking. *Reuters*, Retrieved from <http://www.reuters.com/article/2014/06/02/us-fda-tobacco-insight-idUSKBN0ED0A620140602>

<sup>4</sup> Song, Brown, and Glantz. "When Health Policy and Empirical Evidence Collide: The Case of Cigarette Package Warning Labels and Economic Consumer Surplus," *American Journal of Public Health* 104(2), pp. 42-50 (February 2014).

<sup>5</sup> Mathew, Wahlquist, Garrett-Mayer, Gray, Saladin, and Carpenter. "Affective Motives for Smoking Among Early Stage Smokers," *Nicotine & Tobacco Research* (2014).

<sup>6</sup> Ashley, Nardinelli, and Lavaty. "Estimating the Benefits of Public Health Policies that Reduce Harmful Consumption," *Health Economics Letter* (2014).

<sup>7</sup> Berridge and Winkielman. "What is an unconscious emotion? (The case for unconscious 'liking')," *Cognition and Emotion* 17(2), pp. 181-211 (2003).

<sup>8</sup> Kremers, Eves, and Anderson. "Environmental Changes to Promote Physical Activity and Healthy Dietary Behavior," *Journal of Environmental and Public Health* (2012).

<sup>9</sup> Meengs, Roe, and Rolls. "Vegetable variety: an effective strategy to increase vegetable intake in adults," *Journal of the Academy of Nutrition and Dietetics* 112(8), pp. 1211-1215 (August 2012).

<sup>10</sup> Kang, Cecilia. (2013, September 1). Google crunches data on munching in office. *Washington Post*, Retrieved from [http://www.washingtonpost.com/business/technology/google-crunches-data-on-munching-in-office/2013/09/01/3902b444-0e83-11e3-85b6-d27422650fd5\\_story.html](http://www.washingtonpost.com/business/technology/google-crunches-data-on-munching-in-office/2013/09/01/3902b444-0e83-11e3-85b6-d27422650fd5_story.html).

<sup>11</sup> See *Whitman v. Am. Trucking Ass'ns.*, 531 U.S. 457, 467 (2001) (an agency may not consider costs in setting standards in the absence of such instruction in the law from Congress).