Congress of the United States

Washington, DC 20510

August 6, 2014

Director Shaun Donovan
Administrator Howard Shelanski
Office of Information and Regulatory Affairs
Office of Management and Budget
725 7th Street, NW
Washington, DC 20503

Commissioner Margaret Hamburg
Director Mitch Zeller
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Donovan, Administrator Shelanski, Commissioner Hamburg, and Director Zeller:

We write to express our grave concern about a preliminary regulatory impact analysis conducted by the Food and Drug Administration (FDA) of the proposed "deeming rule," which would extend the FDA's regulatory authority to electronic cigarettes, cigars, pipe tobacco, and other novel tobacco products.[1] The FDA, supported by the Office of Information and Regulatory Affairs (OIRA), applied an unprecedentedly large lost pleasure discount, 70 percent, to the benefits of this proposed rule. The FDA's calculations assume that individuals who stop using these tobacco products lose so much enjoyment that they, in effect, experience only three years of benefit for every ten years of life gained. We reject the premise of this analysis, which significantly underestimates the benefits of the deeming rule. We urge the FDA and OIRA to remove this exaggerated discount and to consider whether an accurate assessment of the public benefits from smoking cessation justifies a more robust rule.

Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to empower the FDA to reduce the serious risks that tobacco and nicotine addiction pose to public health and the health of adolescents and teens. The law requires the FDA to issue rules that would lower the high health costs of addiction to tobacco and nicotine products. The FDA's recently proposed deeming regulations were issued pursuant to this important law. We are disappointed that when entrusted to take action to protect the public's health, FDA and OIRA appear instead to be employing analytical tools that vastly understate regulatory benefits.

The FDA's decision to discount the benefits of the deeming rule by 70 percent is inconsistent with Congress's effort to reduce smoking and ignores empirical evidence on when consumer surplus theory can validly be applied. The analysis relies on the premise that the benefits of longer life and improved health should be offset by 70 percent because tobacco users have lost "consumer surplus," pleasure that comes from consuming a harmful product. When public policy successfully encourages individuals to give up a harmful habit, those individuals

[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).

not only live longer, they enjoy a higher quality of life.[2] Indeed, smokers might actually experience *increased* pleasure as a result of quitting. For example, studies have found that higher cigarette taxes are associated with higher levels of reported well-being among smokers.[3] Moreover, more than nine out of ten current smokers now wish they had never started and nearly seven out of ten report that they now want to quit.[4]

The FDA's approach is particularly troublesome when applied to the regulation of addictive products. Consumer surplus calculations are grounded in the assumption that consumer behavior is fully-informed and rational. However, a strong body of empirical evidence shows that neither of these assumptions holds in the context of addiction.[5] The regulatory analysis ignores FDA's own conclusion that nicotine rewires the brain, creating a biological barrier to the exercise of self-control that is an essential element of the model of rational decision-making on which consumer surplus analysis is based.[6] In addition, the regulatory analysis ignores the fact that nearly nine out of ten smokers tried their first cigarette by the age of eighteen.[7] Given the quick transition among adolescents from experimentation to addiction, these smokers cannot accurately be characterized as rationally choosing a lifetime of smoking. More than anyone else, teenagers are the most likely to have trouble making fully-informed, forward-looking decisions, and they severely underestimate the probability of addiction.[8]

Furthermore, the leading economic research on addiction suggests that all individuals have "time-inconsistent preferences" when it comes to addiction.[9] This means that although they would like to quit smoking, their impatience causes them to reach for the cigarette today and put off quitting until tomorrow. The problem is that tomorrow becomes the next "today," and rather than quitting, the process repeats. The diet that starts tomorrow never really starts. The leading research suggests that smokers would like "commitment devices" to help them quit and this would increase, rather than decrease, their consumer surplus.[10] Thus, any decrease in tobacco use resulting from the regulation should be counted as an increase in consumer surplus.

---

[2] *See* et al., "Smoking Cessation and Quality of Life: Changes in Life Satisfaction over 3 Years Following a Quit Attempt," 2012 Apr;43(2):262-70. doi: 10.1007/s12160-011-9329-2.

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

[4] Fong, GT, et al., "The near-universal experience of regret among smokers in four countries: Findings from the International Tobacco Control Policy Evaluation Survey," *Nicotine & Tobacco Research* 6 (Suppl 3):S341-351, 2004. U.S. Centers for Disease Control and Prevention, "Quitting Smoking Among Adults—United States, 2001-2010," *Morbidity and Mortality Weekly Report (MMWR)* 60(44):1513-1519, November 11, 2011.

[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] HHS. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General.* Centers for Disease Control and Prevention, Office on Smoking and Health, 2014.

[8] Jonathan Gruber, "Smoking's 'Internalities'," *Regulation*, Winter 2002-2003 (online at: http://object.cato.org/sites/cato.org/files/serials/files/regulation/2002/10/v25n4-12.pdf).

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

[10] *Id.*

The FDA and OIRA's analysis has the potential to undermine public health regulations in a variety of areas, not just tobacco and nicotine. According to the FDA's reasoning, a morbidly obese child who reduces his intake of fatty foods and thus adds 10 years to his life expectancy should be seen as effectively gaining only an additional three years of benefit. The benefits that flow from improving nutrition, controlling alcohol abuse, and reducing the overuse of other dangerous products may all be underestimated.

We strongly oppose the use of the FDA's misapplied methodology. A number of economists, some quoted in the appended news article critiquing the FDA's approach, do as well.[11] The FDA's analysis artificially diminishes the benefits of a rule that is necessary to reduce the serious harm caused by tobacco and nicotine product consumption. Addiction is a costly and painful condition for individuals and society at large, and sensible legislation like the Tobacco Control Act was enacted to address this condition. Moreover, we are concerned about the expansion of such a dubious principle to other areas in which the sound approach taken by Congress may be compromised. We urge the FDA to finalize a health-protective deeming rule, and the FDA and OIRA to stop applying unwarranted discounts.

Sincerely,

RICHARD BLUMENTHAL
United States Senate

DICK DURBIN
United States Senate

HENRY A. WAXMAN
Member of Congress

[11] Sharon Begley, "FDA Calculates Costs of Lost Enjoyment if E-cigarette Rules Prevent Smoking," *Reuters*, June 2, 2014.

SHERROD BROWN
United States Senate

JOHN D. ROCKEFELLER IV
United States Senate

SHELDON WHITEHOUSE
United States Senate

ED MARKEY
United States Senate

MARK BEGICH
United States Senate

JACK REED
United States Senate

ELIZABETH WARREN
United States Senate

JEFF MERKLEY
United States Senate

BARBARA BOXER
United States Senate

TOM HARKIN
United States Senate

PATRICK LEAHY
United States Senate

FRANK PALLONE, JR.
Member of Congress

DIANA DEGETTE
Member of Congress

MIKE HONDA
Member of Congress

CHRIS VAN HOLLEN
Member of Congress

ROSA L. DELAURO
Member of Congress

JAN SCHAKOWSKY
Member of Congress

TED DEUTCH
Member of Congress

GENE GREEN
Member of Congress

ZOE LOFGREN
Member of Congress

FDA Calculates Costs of Lost Enjoyment if E-cigarette Rules Prevent Smoking

Mon, Jun 2 2014
By Sharon Begley

NEW YORK (Reuters) - As U.S. health regulators consider what rules to impose on electronic cigarettes, in their tally of costs and benefits they have placed a value on the lost pleasure consumers may suffer if they used the products less or not at all.

The U.S. Food and Drug Administration says in a little-noticed document released alongside its proposals for regulations in April that the projected benefits of the new rules, which also apply to cigars, hookahs and other vapor products, should be cut by 70 percent to account for the deprivation consumers would suffer.

That means if the agency puts a value of $100,000 on the longer and improved life that might be achieved by deterring someone from smoking, then it would cut that benefit assessment to $30,000 because of the pleasure they lost.

The approach is regarded as radical among those who have done cost-benefit studies for regulators.

Some public health advocates warn it will help the tobacco industry argue that the cost of complying with restrictions on new nicotine products exceeds any benefit to the public, making it easier to scuttle those rules. They also fear it could be applied more broadly to regulation of products, such as food and alcoholic beverages, that is meant to protect public health.

"This makes it a lot harder to justify regulations on cost-benefit grounds," said Dr Stanton Glantz, a professor of medicine and a tobacco control expert at the University of California, San Francisco, who favors tough regulation of e-cigarettes and cigars. "It will undermine anything they try to do about anything."

Under a 1993 executive order signed by then President Bill Clinton, U.S. regulators are required to show the benefit of a regulation would exceed its costs. A proposal that would make a manufacturer spend $1 billion to avert $100 million in pollution costs, for instance, would likely not see the light of day.

But with novel tobacco and nicotine products, the FDA is putting its thumb on the cost-benefit scale in a way no other agency has before, according to current and former regulators and economists who specialize in such studies.

In its proposed rules, the FDA has already treaded lightly. It would ban the sale of e-cigarettes to anyone under 18, but would not restrict flavored products, online sales or advertising.

The FDA used the same lost-pleasure analysis when it assessed the costs and benefits of requiring graphic warning labels on tobacco products - regulations the industry opposes and that have been blocked by a federal court. That was also little noticed outside a small group of public health advocates and other policy experts.

In response to questions from Reuters, an FDA spokeswoman said that even with the inclusion of the lost-pleasure factor, the benefits of its proposed e-cigarette regulations will still exceed the costs. She also said the tobacco industry did not pressure the agency to include it in the analysis, which was conducted by in-house economists with no input from political appointees.

As to whether using such a large lost-pleasure factor could weaken regulations, the spokeswoman said, "We will not prejudge any potential regulatory action."

FDA economists have previously hinted that the agency should apply the idea of lost enjoyment in areas beyond tobacco.

In a paper published online this year in the journal Health Economics, they argued that guilty pleasures like junk food and alcohol are so enjoyable the benefits of reducing their use through regulation should be discounted by up to 99 percent.

The authors were FDA economists Clark Nardinelli and Rosemarie Lavaty, as well as Elizabeth Ashley from the White House Office of Management and Budget.

The cost-benefit analysis of the FDA's e-cigarette proposal was written by the agency's economics staff, which Nardinelli heads. Nardinelli and Lavaty declined to comment.

Ashley referred a request for an interview to the OMB press office, which said in a statement that "the economics profession is still in the process of determining appropriate data and methods that would allow for estimation of consumer surplus in the context of tobacco."

E-cigarette makers are not focusing on FDA's lost-pleasure calculation, said Ray Story, chief executive of the Tobacco Vapor Electronic Cigarette Association, an industry group. Lorillard, the biggest seller of e-cigarettes in the U.S. with its blu brand, did not return calls seeking comment. A spokesman for Altria, which owns Philip Morris USA, did not provide a comment from the company when contacted on Friday.

A NOVEL FORMULA

John Graham, who headed the White House Office of Information and Regulatory Affairs, which vets agencies' cost-benefit analyses, under President George W. Bush, said he could "not recall a specific instance" during his 2001-to-2006 tenure "where lost enjoyment played a significant analytical role."

Loss of pleasure had occasionally been used when analyzing proposals to ban products, Graham said, but was not treated as a deduction from benefits, as the FDA is doing.

The U.S. Environmental Protection Agency, for instance, has incorporated the concept to reflect that people value things like clean air in ways the market does not always capture, officials said.

The EPA has also used lost pleasure when calculating the costs of pesticide regulations to account for the possibility that the price of apples may rise if growers have to switch to using more expensive chemicals or lose more of their crop to pests. Consumers would lose some pleasure if they could afford to buy fewer apples.

In such cases, former officials said, the adjustment was relatively small, much less than FDA's 70 percent.

WILLING TO PAY MORE

To be sure, the pleasure factor is a well-established concept in economics, dating back half a century. Known as the "consumer surplus," it is the difference between what people pay for a product and the maximum they would be willing to pay.

It may seem counterintuitive that sellers would not charge the maximum tolerable price. But whatever price they pick, there are always consumers willing to pay more, explained economist Stan Veuger of the American Enterprise Institute, a conservative think tank in Washington, D.C.

The additional amount is the consumer surplus, which economists interpret as the dollar value of the extra utility, or enjoyment, users get. Calculating the precise size of the surplus is not straightforward and economists often debate how large it is, Veuger said, but he added that the 70 percent used by the FDA "feels really, really difficult to justify."

More problematic, he and others argue, is applying the idea of consumer enjoyment to an addictive product like nicotine. Once a product becomes addictive, rational consumer choice goes out the window, said economist Ken Warner of the University of Michigan. The consumer surplus concept "should never be applied to an addictive product," he argued.

In addition, nearly three-quarters of smokers say they would like to quit. Their frustration at their inability to do so means many experience "incredible levels" of displeasure, said Warner, a leading cost-benefit scholar. He said that means the concept is not relevant to the vast majority of tobacco users.

The public has until July 9 to submit comments about the FDA's analysis, which the agency could change as a result.

Public health advocates are concerned about what will happen if agencies charged with protecting consumers also give considerable weight to the enjoyment people get from all kinds of things that have been a focus of regulation - from eating food containing trans fats to riding motorcycles without a helmet.

In the FDA document published online, the staff economists cite a 2002 paper by health economist Jonathan Gruber of MIT as a source for their 70 percent assessment. After Reuters called the analysis to his attention, Gruber said the fact that a majority of smokers pick up the habit as teenagers and become addicted before they are fully aware of the consequences, meant the FDA was wrong to invoke the "consumer surplus" concept.

"I think this is really a misapplication of my work," Gruber said.

(Reporting by Sharon Begley; Editing by Michele Gershberg and Martin Howell)
7/23/2014 Business & Financial News, Breaking US & International News | Reuters.com
http://www.reuters.com/assets/print?aid=USKBN0ED0A620140602