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June 2, 2014

BROAD RANGE OF ECONOMISTS AGREE THAT FDA'S USE OF CONSUMER SURPLUS IS WRONG, INCLUDING JONATHAN GRUBER, WHOSE WORK FDA CITES AS JUSTIFICATION FOR DOING SO

Docket No. FDA-2014-N-0189

On June 2, 2014, Reuters published a long article about the FDA's application of a 70% consumer surplus discount to account for the "lost pleasure" due to any health benefits generated by the proposed deeming rule because people smoke less.[*] (The FDA had discounted the health benefits of its failed warning labels by 50%.)

Not a single outside economist Reuters contacted supported the FDA's decision, including several conservative economists and Jonathan Gruber, whose work the FDA quoted to justify what it did.

Here is what they said:

> **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."
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> 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. ...
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> 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."

[*] Sharon Begley. FDA calculates costs of lost enjoyment if e-cigarette rules prevent smoking. Reuters. June 2, 2014. http://www.reuters.com/article/2014/06/02/us-fda-tobacco-insight-idUSKBN0ED0A620140602

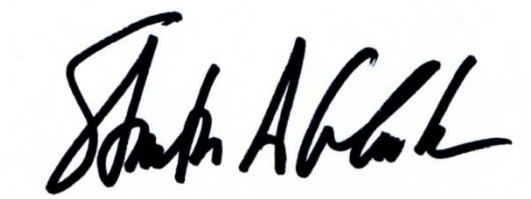
More problematic, he and others argue, is applying the idea of consumer enjoyment to an addictive product like nicotine. Once a product becomes addictive, rational consumer choice goes out the window, said economist **Ken Warner of the University of Michigan**. The consumer surplus concept "should never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

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.

A copy of the full story is appended to this comment.

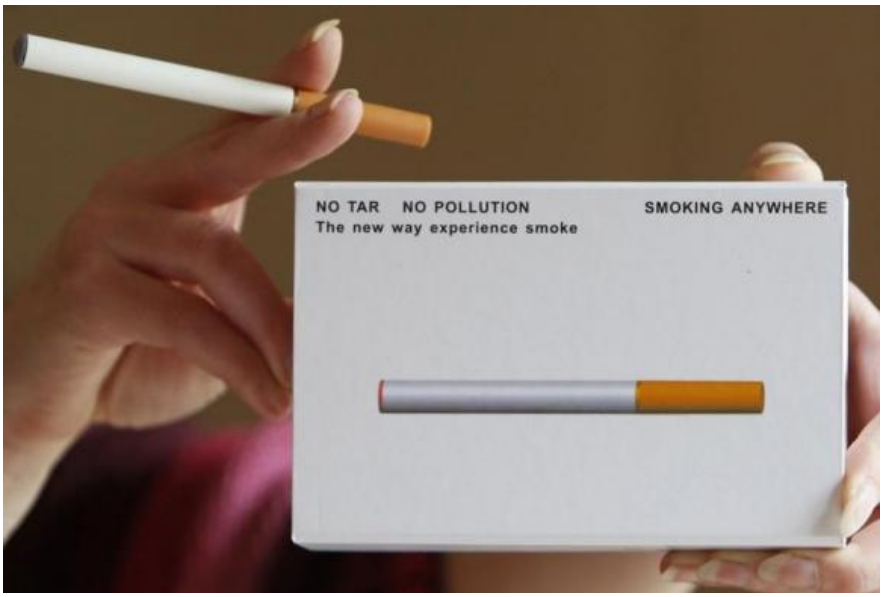


Stanton A. Glantz, PhD
Professor and Director

FDA calculates costs of lost enjoyment if e-cigarette rules prevent smoking

BY **SHARON BEGLEY**

NEW YORK Mon Jun 2, 2014 1:20am EDT



A woman displays a package of E-cigarette, an electronic substitute in the form of a rod, slightly longer than a normal cigarette, in Bordeaux, southwestern France, on March 25, 2008

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(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.

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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

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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."

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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.

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(Reporting by Sharon Begley; Editing by Michele Gershberg and Martin Howell)

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