Huffington Post
White House Weakened Tobacco Regulations of FDA's Draft Proposal
Toni Clarke and Sharon Begley , June 24, 2014

WASHINGTON, June 25 (Reuters) - White House changes to proposed rules for tobacco products significantly weakened language detailing health risks from cigars and deleted restrictions that might have prevented online sales of e-cigarettes, published documents show.

The White House's Office of Management and Budget (OMB), which analyzes the potential economic consequences of proposed regulations, deleted language in the U.S. Food and Drug Administration's recently proposed regulations describing how the rules would keep thousands of people from taking up cigar smoking and have enormous public health benefits.

The OMB also weakened language detailing the FDA's concerns about the safety of e-cigarettes, according to documents published Tuesday in the Federal Register.

Emily Cain, a spokeswoman for OMB, said that as with any rule, OMB's office of information and regulatory affairs conducted an interagency review process "to ensure that the regulations through which agencies implement policies are efficient, well-designed to achieve their objectives, and based upon the best available evidence." "

It is routine for agencies to make changes to their draft rules during the course of OMB review," she added. "The goal is to maximize the effectiveness and benefit of the rules we complete."

An FDA spokeswoman, Jennifer Haliski, said the FDA does not comment on changes to a proposal during the review process but said the period for the public to comment on the proposal is still open until Aug. 8. "All comments will be carefully considered as the final rule is being developed," she said in an email. "As the science base continues to develop for these products, the agency has the ability to take additional regulatory actions designed to further minimize the public health burden of tobacco use in this country."

The FDA has authority under a 2009 law to regulate cigarettes, smokeless tobacco and roll-your-own tobacco, but must issue new rules before regulating e-cigarettes, cigars, hookahs, water pipes and other tobacco products.

In April, the FDA issued a proposal which would subject the $2 billion e-cigarette industry to federal regulation for the first time. It would ban the sale of e-cigarettes to people under the age of 18 and vending machine sales.

The proposal disappointed public health advocates who criticized the agency's failure to restrict flavored products or television advertising, which they say attracts children, and criticized the agency for not moving to restrict online sales, where it can be harder to verify a person's age.

In its draft, the FDA had proposed "prohibition of non-face-to-face sales (e.g. vending machines)." That would have opened the door to a ban on online sales. But OMB edited the sentence so that the prohibition refers only to vending machines.

In another significant change, OMB turned the FDA's proposal as it relates to cigars from a two-part rule - one for traditional tobacco products and one for products that have not previously been regulated - into a "two-option" rule, one of which would exempt "premium cigars."

The cigar industry, backed by some members of Congress, had lobbied OMB heavily for such an exemption. In a December 2013 letter to FDA Commissioner Margaret Hamburg and Sylvia Mathews Burwell, who was director of OMB at the time and is now Secretary of Health and Human Services, 24 Republican lawmakers asked that premium cigars be exempt.

"As you know," they wrote, "premium cigars are a niche product with an adult consumer base, much like fine wines. The majority of people who enjoy a cigar do so occasionally, often in social or celebratory settings."

When the proposed rule came out in April, some public health advocates expressed dismay.

"The part of the proposal we are deeply troubled by is the sweetheart deal for the cigar industry," Erika Sward, assistant vice president for national advocacy at the American Lung Association.

OMB also deleted an FDA analysis showing that exempting premium cigars from a proposal to require large warning labels would save manufacturers $1 million to $3 million but incur costs to public health of $32.6 million to $34.2 million.

The White House office also deleted an extensive section in which the FDA calculated how many lives would be saved by regulating cigars, as well as the value of those lives. And it deleted a similar analysis for the improvements in health that would come from dissuading people from smoking cigars, such as through warning labels.

The "welfare gain" from reducing the number of cigar smokers, FDA calculated, would be $16 million to $52 million. Similarly, OMB modified or deleted FDA concerns about the safety of e-cigarettes, including manufacturing quality.

It deleted FDA draft language saying it would review electronic cigarette cartridges to respond to evidence of poor quality control, variable nicotine content or toxic ingredients such as diethylene glycol, a chemical that the FDA said has caused mass poisonings in products such as the painkiller acetaminophen and cough syrup.

Last week a panel of U.S. senators excoriated the chiefs of two of the biggest e-cigarette companies, blu eCigs, which is owned by tobacco giant Lorillard Inc, and privately held NJoy, saying they were irresponsibly targeting children with advertisements depicting cartoon characters, movie stars and other celebrities.

Both companies defended the advertisements, saying they target adult smokers.

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