

FDA Should Prohibit All Non-Face-to-Face (Including Internet) Sales of Tobacco Products as FDA Originally Proposed to the OMB

Docket No. FDA-2014-N-0189

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July 23, 2014

FDA should prohibit *all* non-face-to-face sales of tobacco products, including internet sales, as it did in the draft rule that was submitted to the Office of Management and Budget (OMB) for approval.

In addition to proposing minimum age and identification restrictions to prevent sales to underage youth, the proposed rule that FDA originally submitted to OMB included the following provision that would apply to covered tobacco products:

Prohibition of non-face-to-face sales (e.g., vending machines), unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time.¹

This language was removed by the OMB before the draft rule was released for public comment.

The regulation as originally drafted by the FDA is appropriate for protection of public health and should be reinstated as part of the final rule.

Although FDA provided only one example of “non-face-to-face sales” (vending machines), FDA’s intent was clearly to prohibit *all* non-face-to-face sales to ensure that individuals under 18 years of age are prohibited from purchasing tobacco products. Even more than with vending machine sales, it is virtually impossible to ensure that Internet sales transactions are restricted to individuals over 18 years of age.

UCSF² and Stanford University researchers³ previously submitted comments to this docket that discuss the explosion of internet sales of e-cigarettes and other tobacco products, and the facts that while the Internet serves as a predominant means of purchase for young people, the minimum age requirements FDA proposes in this rule and age verification are virtually non-existent or meaningless. We incorporate those comments here by reference.^{3 4}

Congress mandated a public health standard in section 906(d) of the Family Smoking Prevention and Tobacco Control Act.

The finding as to whether [a] regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the populations

as a whole, including users and nonusers of the tobacco product, and taking into account

- (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.⁴

FDA recognized that to adequately protect the public health as mandated by Congress, it must adopt regulations that prohibit all non-face-to-face sales, and explained its reasoning using language that tracks the language of the Tobacco Control Act in the draft rule that was submitted to OMB for approval:

FDA believes that these restrictions will make it less likely that youth and adults will start using tobacco products and more likely that existing users will quit using tobacco products.¹

This language originally drafted by the FDA and submitted to OMB and its rationale are proper from both legal and public health standpoints.

The proposed prohibition of all non-face-to-face sales appropriately is aimed at protecting the public health with respect to the risks and benefits to the *population as a whole* as is required by the Tobacco Control Act. Moreover, the proposed rule seeks to protect the public health by making it less likely that youth, and especially under-age youth, and adults will acquire tobacco products.

However, the redlined version of the proposed rule that shows that OMB deleted the prohibition of non-face-to-face sales, and instead included a prohibition of “vending machine sales, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time.”¹ OMB also deleted the entire sentence quoted above explaining the public health rationale for the proposed rule.¹

Although prohibiting sales of tobacco products to persons younger than 18 years of age was clearly a goal of the proposed rule as originally drafted by FDA, and meaningful age verification of Internet sales is extremely difficult if not impossible, the redlined version reveals that OMB added the following language to explicitly exclude Internet sales from the prohibition on sales from electronic devices:

This prohibition on sales from electronic or mechanical devices is not intended to impact the sale of any tobacco product via the Internet.⁵

Although OMB’s intention to exclude Internet sales from the prohibitions is articulated clearly, it is hidden in the “Paperwork Reduction Act of 1995” section of the proposed rule.⁶

For the reasons articulated above and in the previously submitted comments, OMB should not have eliminated the prohibition for non-face-to-face sales and should not have

excluded Internet sales from the prohibition on sales from other electronic and mechanical devices.

FDA should prohibit non-face-to-face sales (including Internet sales) of tobacco products as it originally proposed. The changes made by OMB should be reversed. The final rule should use the FDA's original language.

¹ OMB Redline CTP20092 4160-01-P, pp.10-11. TAB B Deeming NPRM Redline Changes re Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, <http://www.regulations.gov#!documentDetail;D=FDA-2014-N-0189-20873>

² Lempert L, Glantz S. Comment on the Need for FDA to Eliminate the Exemption for Internet Sales of Deemed Products to Youth. May 14, 2014. <http://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-comment-internet%20sales-%201jy-8c3i-wy64.pdf>

³ Halpern-Felsher B. FDA Should Restrict Internet Sales of All Tobacco Products Including E-Cigarettes. June 13, 2014. https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FDA-Comment-BHF-Submitted%20in%20Response%20to%20FDA%20Deeming%20Rule_Internet%20Sales_FINAL.pdf

⁴ Family Smoking Prevention and Tobacco Control Act, section 906

⁵ OMB Redline CTP20092 4160-01-P, p. 196. TAB B Deeming NPRM Redline Changes re Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, <http://www.regulations.gov#!documentDetail;D=FDA-2014-N-0189-20873>

⁶ 79 FR 23184