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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Docket No. Docket No. FDA-2014-N-0189

RE: FDA's failure to impose meaningful controls on internet sales

In 2011 the FDA announced an Advanced Notice of Proposed Rule Making on "[Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products](#)" [Docket No. FDA-2011-N-0467] and solicited public comments on "data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the Internet, e-mail, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients.

Three are particularly relevant to the deeming rule. (Copies of the full comments are appended to this letter so that they will be formally submitted to the current docket.)

Rebecca S. Williams, MHS, PhD, Kurt M. Ribisl, PhD, and Catherine Jo, BA from the [University of North Carolina at Chapel Hill](#) provided a detailed 22 page summary of the scientific evidence that demonstrated that internet sales of tobacco products were easily accessible to youth and that existing rules and procedures, including those by which sellers nominally conducted age verification were ineffective at preventing easy access to tobacco products. Their bottom line is:

Non-face-to-face tobacco sales represent a major challenge to policy efforts to restrict youth access and collect taxes. Unless the FDA can develop, implement, and effectively enforce regulations to ensure that (1) minors are unable to obtain tobacco products through non-face-to-face sales and (2) state and federal taxes are collected on all non-face-to-face sales, such sales should be banned. [page 2]

The [National Association of Attorney Generals](#), provided a 19 page summary of the current legal situation, including "the results of a study that NAAG commissioned to test the effectiveness of age and identify verification methods used on the promotional websites of certain major tobacco companies." The Attorneys General's bottom line is:

The basic conclusion we wish to convey in our comments is that, despite the enactment of the PACT Act, the existing legal framework with respect to non-face-to-face sales is not adequately protecting the public health. The reason for this conclusion is that, as discussed in more detail below, the promotion and sale of tobacco products through non-face-to-face

sales continue to take place without adequate age and identity verification; such sales continue to evade state tax laws; and states' efforts to enforce their laws continue to be frustrated by jurisdictional limitations and the ability of direct sellers to put up new websites even if a state successfully enforces its law against such sellers. [page 2]

A [large group of health organizations](#) submitted a 16 page comment that summarized both the scientific data and legal problems that internet sales created for implementing effective tobacco control policies. Their bottom line is:

Non face-to-face sales present a serious challenge both to effective enforcement of age verification requirements and to effective enforcement of state laws. As a result, remote sales threaten two of the most important pillars of tobacco control policy. ... FDA might consider requiring non-face-to-face sellers of tobacco products to agree to comply with all federal and state laws, to implement effective age verification measures, and to submit to regular inspections of their books and records as a condition of being permitted to sell such products. However, unless FDA can develop and implement regulations that ensure in practice that remote sales undermine neither age verification requirements nor the enforcement of state laws, such sales should be prohibited. [page 5]

It is exceptionally troubling that after the FDA specifically invited public comment on these issues through a formal advanced notice of proposed rulemaking and these organizations invested considerable effort in preparing these sophisticated and detailed scientific and legal analyses, the FDA failed to even acknowledge any of this information in the proposed deeming rule, much less use it to propose either meaningful controls on internet sales or prohibit them all together (which these commenters make a strong case for doing).

The FDA and the White House need to use this information in developing the final rule to ensure that the online sales loophole is closed.



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