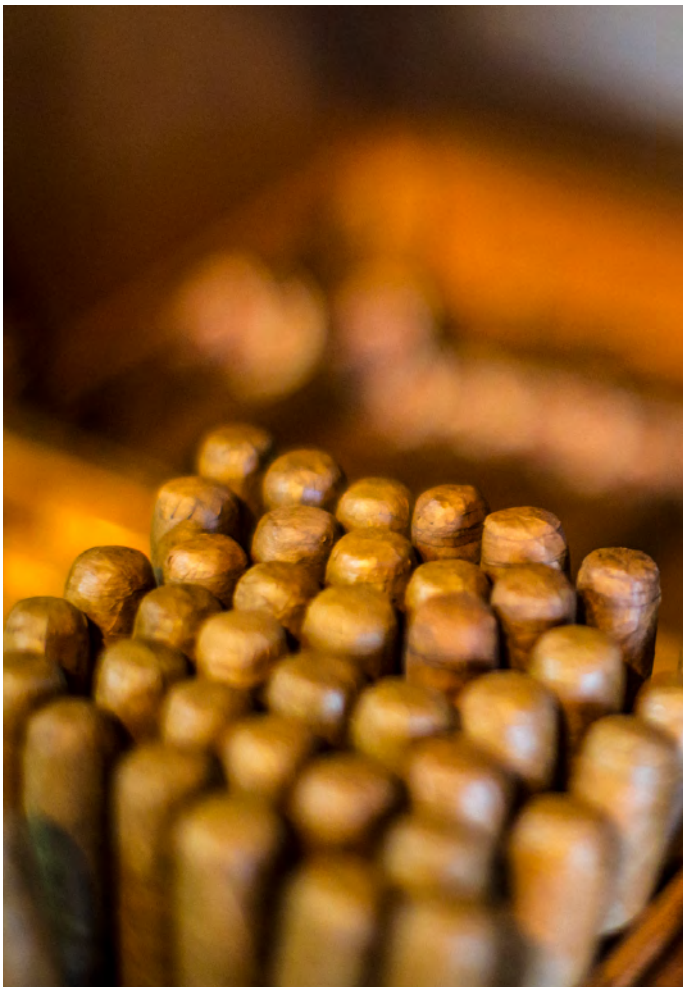
FDA REGULATION OF PREMIUM CIGARS

Questions & Talking Points for the Public Health Community

On March 24, 2018, the FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) to collect information related to the regulation of premium cigars.

In 2014, when the FDA proposed to regulate cigars, e-cigarettes, and other previously unregulated tobacco products, the agency solicited comments on whether it should exempt premium cigars from its regulation. In 2016, the FDA issued the final deeming regulation and determined that the agency would regulate all cigars, including premium cigars. In that rule, the FDA concluded, "(1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults." Despite these strong conclusions, on July 28, 2017, the FDA announced a new regulatory plan for tobacco and nicotine, which included the possibility of exempting premium cigars from FDA regulation,



essentially invalidating the agency's conclusions in the 2016 deeming regulation.

While the patterns of use and the health effects of premium cigars may be different from other tobacco products, cigars are combusted just like cigarettes and have the potential to cause disease and death to users. There is little question that FDA regulation of tobacco products will create public health benefits. There is no public health justification for exempting any tobacco product from FDA regulation. The agency agreed with this as recently as 2016, stating, "we find there is no appropriate public health justification to exclude premium cigars from [regulation]."

The FDA's notice asks many specific questions related to the populations that use premium cigars and their health effects on users. Unlike other recent ANPRMs that seek to promote public health through regulation, here the FDA seeks input to help guide this deregulatory action. Rather than provide the data requested by the FDA, you could consider urging the agency to continue to uphold the public health standard. As you draft and submit your comment, you could also consider telling the FDA that:

- There is no public health justification to exempt any tobacco product from the FDA's regulation. This is the paramount consideration in the FDA's decision making in the regulation of tobacco products.
- An exemption for any class of product creates an incentive to receive the exemption. This has proved harmful to public health in the past.
- The FDA should consider additional restrictions on the sale, distribution, advertising, and marketing of cigars, beyond the restrictions in the Deeming Rule.

For guidance as you prepare your comments, researchers and professionals can reference the Public Health Law Center's publications *Getting Scientific Research to the FDA* and *Telling the Public Health Story to the FDA*.

Visit the Public Health Law Center's FDA Action Center for the latest developments related to the FDA's regulation of tobacco products, including additional information on the cigar ANPRM.

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