



Hon. Robert Califf
Commissioner
U.S. Food and Drug Administration

Re: Docket No. FDA-2021-N-1309
Proposed Tobacco Product Standard for Characterizing Flavors in Cigars

Dear Commissioner Califf:

Consumer Action for a Strong Economy (CASE) is the nation's foremost non-profit, non-partisan organization devoted to the singular cause of promoting consumer interests through the advancement of free-market principles. As a voice for consumers, we believe the heavy-handed, top-down, and virtually evidence-free approach represented in FDA's proposed product standard banning characterizing flavors in cigars violates the core principle of empowering consumers at every avenue.

Consumer trust in public-health agencies is at a low ebb¹ after two years of intrusive and freedom-sapping quarantines, lockdowns, closures, and mandates – most lacking any scientific backing and in fact, often handed down in the face of contrary research. The evidence indicates that these dictates crushed state economies,² forced the closure of thousands of small businesses, drove up federal spending, ushered in a mental health crisis,³ cost young people months and even years of educational advancement⁴ and potentially social and language development,⁵ all without effect on mortality. Moreover, FDA and CDC missteps were behind delays in testing that could have arrested COVID's initial advance, and more recently, seemingly precipitous agency action is behind a baby formula shortage that is driving up prices and even endangering the lives of infants.

Now FDA is back with yet another top-down edict to bar a product used by at most five percent of adults, the vast majority consuming no more than two cigars a day with little effect on morbidity or mortality,⁶ and less than one percent of middle-and-high-schoolers (past month).⁷ The Agency is straining mightily yet unpersuasively to come up with any scientific evidence of the effect any flavor ban would have on initiation, youth usage or mortality, extrapolating from a handful of mostly out-of-date research studies relating to state and local flavor bans that ignore the potential effect of sales shifts to other jurisdictions. FDA ignores the likelihood that banning popular products will lead to counterfeiting and contraband sales that will sap the clear effectiveness of recently passed Tobacco 21 laws, even as it forwards abundant evidence of the potentially devastating effect of the rule on small manufacturing, distribution, and retail businesses.

¹ www.npr.org/2021/05/13/996331692/poll-finds-public-health-has-a-trust-problem

² www.nber.org/system/files/working_papers/w29928/w29928.pdf

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www.aap.org/en/advocacy/child-and-adolescent-healthy-mental-development/aap-aacap-cha-declaration-of-a-national-emergency-in-child-and-adolescent-mental-health/

⁴ <https://cepr.harvard.edu/files/cepr/files/5-4.pdf?m=1651690491>

⁵ www.aier.org/article/masking-children-tragic-unsentimental-and-damaging/

⁶ www.ncbi.nlm.nih.gov/pmc/articles/PMC7789747/

⁷ National Survey on Drug Use and

Health, www.samhsa.gov/data/sites/default/files/reports/rpt35323/NSDUHDetailedTabs2020v25/NSDUHDetailedTabs2020v25/NSDUHDetTabsSect2pe2020.htm

Even CDC has come to recognize, in relation to COVID decision-making,⁸ that public health should be about empowering citizens, as consumers, with the information they need to make educated choices about their own well-being. If that's true about a disease that has killed more than 1 million Americans, why should it not be the case with a lifestyle choice that the FDA, reaching with all its strength, would result in, at best, marginal improvements in morbidity and mortality, and which science experts doubt would even achieve that?

FDA doesn't need to engage in further costly empire-building in the area of tobacco regulation in pursuit of a possibly moderately beneficial, but more likely counterproductive, rule. In the name of adult consumers enjoying a mostly harmless lifestyle choice, small businesses facing extinction, and taxpayers being asked to underwrite yet another quixotic, unnecessary, and even potentially harmful public health crusade, CASE calls on FDA to pull the plug on the proposed flavor product standard in favor of empowering citizens with accurate information about the minimal risks of cigars as used.

Sincerely,



Gerard Daniel Scimeca
Chairman
Consumer Action for a Strong Economy (CASE)

⁸ <https://twitter.com/CDCDirector/status/1393312416373645317>