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**To:**  
**Dockets Management Staff (HFA-305)**  
**Food and Drug Administration**  
**5360 Fishers Lane Rm. 1061**  
**Rockville, MD 20852**

**RE: Docket No. FDA-2019-N-3065 - Tobacco Products; Required Warnings for Cigarette Packages and Advertisements**

**Recommendation to Extend FDA Warnings for Cigarette Packages and Advertisements to Cigar Packages**

Commissioner Sharpless:

With this letter, we would like to provide scientific data in support of inclusion of cigar products, including large cigars, little cigars, and cigarillos in the proposed rule **Tobacco Products; Required Warnings for Cigarette Packages and Advertisements**. We are researchers of the Yale Tobacco Research in Youth (TRY) and the Yale Tobacco Center for Regulatory Science (Yale TCORS) and we study use of tobacco products in youth and young adults. Below we present our recommendations based on research published by our group between 2014-2019 demonstrating the importance of including large cigars, little cigars, and cigarillos (henceforth referred to as cigars) in the proposed regulations:

**FDA should extend proposed warnings for cigarette packages and advertisements to other combustible tobacco products including large cigars, little cigars, and cigarillos.**

We support the Proposed Rule, “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” which details new regulations for required cigarette health warnings on cigarette packages and advertisements as an important step to promote greater public understanding of the negative health consequences of cigarette smoking for both smokers and non-smokers. Specifically, we believe this proposed regulation can target youth and young adults who are likely to be experimenting with and initiating tobacco product use. However, we believe this proposed regulatory effort could be undercut by the omission of other combustible tobacco products, such as cigars in this regulation. Cigars are as or potentially even more toxic than traditional cigarettes.<sup>1</sup> Rates of cigar use in youth and young adults are similar to rates of cigarette use.<sup>2</sup> To omit cigars from the described regulations could indicate differential harm to potential and current users. We are specifically concerned about the impact that this may have on youth and young adults, who are relatively inexperienced and new users.

**Cigars are used at similar rates as cigarettes in youth and young adults and are associated with increased risk of future combustible product use.**

National data among high school students indicate that 7.6% have smoked cigars in the past 30 days compared to 8.1% who have smoked cigarettes in the past 30 days.<sup>3</sup> Research from our group has indicated that not only do youth engage in use of cigars, but are likely to use them in tandem with other tobacco products, including cigarettes.<sup>4,5</sup> We also have observed differences in use by sociodemographic characteristics, specifically that black youth may be higher users of cigars than white youth,<sup>6</sup> and youth who have tried a cigar are more likely to be in lower socioeconomic brackets than youth who have never tried a cigar.<sup>4</sup> Furthermore, we observed that compared to not using either cigars or cigarettes, using cigars among youth is associated with increased risk of transition to future exclusive cigar or cigarette use, as well as dual cigar and cigarette use.<sup>7</sup> Taken together, these findings suggest that regulations that apply to only cigarettes may miss subsets of youth populations who are engaged in use of these equally harmful products.

**Cigars and cigarettes should have similar packaging and marketing restrictions, as they have similar harm potential.**

Notably, there is far less regulation in the current promotion of cigars on their packaging compared to cigarettes. Cigar packages are available in bright colors, a variety of sizes, feature appealing flavors such as “sweet,” fruit, and alcohol, and advertise cheap prices and discounts (Figure 1). Additionally, cigars can be legally sold in lower quantities than cigarettes, which are required to be sold in no less than packs of 20. This lack of regulation has allowed for cigars to have packaging and features that appeal to youth, which are otherwise disallowed on cigarette packages. Our research has shown that youth find flavors, price promotions, brand names/logos, marketing claims, product features (e.g., images and words describing the product), number of cigars, package features (e.g., re-sealable) and colors featured on cigar packaging appealing.<sup>8</sup> The appealing and distinct packaging on these products serves as a distractor and appears to reduce attention to the current warning labels.<sup>8</sup> Cigar packages often can serve as a point-of-sale advertisement to both users and non-users unlike more regulated tobacco products, such as cigarettes. With these additional proposed restrictions, there will be even greater discrepancy between packaging of these products. Proposed regulations of packaging of cigarettes include a text and image warning label that comprises 50% of packaging (Figure 2). If cigar packaging remains the same, current users and non-users will see one combustible product (i.e. cigars) available in brightly colored packaging advertising flavors and discounts with a warning label that comprises approximately 10% of the packaging compared to another combustible product (i.e. cigarettes) with a much larger warning label communicating a higher level of risk and more specific risks to users (Figure 2). *As the health risk of using cigarettes and cigars are similar and cigars are currently packaged and advertised in a way that is demonstrated as appealing to youth, we urge the FDA to extend the Required Warnings for Cigarette Packages and Advertisements to cigars to prevent youth initiation of harmful combustible tobacco products.*



Figure 1. Sample Images of Current Cigar and Cigarillo Packaging<sup>8</sup>

Note: Cigar packages are available in bright colors, a variety of sizes, feature appealing flavors such as “sweet,” fruit and alcohol, and advertise cheap prices and discounts, lower quantities than cigarettes. Although the health warning label is present, they are often obfuscated by other prominent marketing features.

(A)



(B)



Figure 2. Sample Image of Current Cigar and Cigarillo Packaging (a) Compared to Proposed Cigarette Packaging (b)

## REFERENCES

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