



American Association
for Dental Research

October 15, 2019

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket number: FDA-2019-N-3065 Required Warnings for Cigarette Packages and Advertisements

On behalf of the 3,350 individual and 107 institutional members of the American Association for Dental Research (AADR), thank you for the opportunity to comment on the proposed rule, "Required Warnings for Cigarette Packages and Advertisements" (Docket number: FDA-2019-N-3065). The FDA has recognized that the current text-only labels are ineffective for both adolescents and adults and identified a need to increase the impact of its cigarette warning labels in order to better convey health information and educate the public about the lesser known health consequences of smoking. Therefore, AADR commends FDA for developing the evidence base for more effective warnings and for proposing large graphic warning labels as 91 other countries have.¹

In particular, AADR is writing to express support for the revised warning, "Smoking causes head and neck cancer," and the associated pictorial warning. According to the National Cancer Institute, an estimated 53,000 new cases of cancers of the oral cavity and pharynx, types of head and neck cancer, will be diagnosed in 2019 and over 10,000 people will die from those cancers this year. Tobacco use is a major risk factor for these cancers.² Therefore, raising awareness of the risk of head and neck cancer associated with smoking is an important strategy for averting cigarette use among smokers and nonsmokers alike.

The proposed rule also states that the 2014 Surgeon General's Report causally linked cigarette smoking to orofacial clefts from maternal smoking during pregnancy. Orofacial clefts are the second most common birth defects amongst live births in the United States and carry significant treatment costs. Children with orofacial clefts may have challenges with eating, speaking, breathing, hearing and with their teeth.^{3, 4} Therefore, AADR encourages FDA to explore a future graphic warning label about the link between smoking and orofacial cleft in addition to the two warnings about the effect of smoking on children, "Tobacco smoke can harm your children" and "Smoking during pregnancy stunts fetal growth." A pictorial representation of a child with an orofacial cleft with the text "Smoking during pregnancy increases risk of orofacial clefts" may be particularly impactful.

¹ WHO Report on the Global Tobacco Epidemic, 2019. Geneva: World Health Organization.

² Cancer Stat Facts: Oral Cavity and Pharynx Cancer. Bethesda: National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services; [accessed 11 October 2019]. <https://seer.cancer.gov/statfacts/html/oralcav.html>.

³ Facts about Cleft and Cleft Palate. Atlanta: Centers for Disease Control and Prevention; [accessed 11 October 2019]. <https://www.cdc.gov/ncbddd/birthdefects/cleftlip.html>.

⁴ Cleft Lip and Palate. Bethesda: National Institute of Dental and Craniofacial Research; [accessed 11 October 2019]. <https://www.nidcr.nih.gov/health-info/cleft-lip-palate/more-info>.

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AADR encourages FDA to move quickly to finalize the currently proposed graphic warning labels and to explore a future warning about the causal link between smoking and orofacial cleft. These actions will have a significant positive public health effect by encouraging cessation among current smokers and discouraging initiation by nonsmokers. Please do not hesitate to contact Dr. Seun Ajiboye, AADR Director of Science Policy and Government Affairs at sajiboye@iadr.org if you need any other information.

Sincerely,

A handwritten signature in blue ink, appearing to read "Chris Fox".

Christopher H. Fox, DMD, DMSc
Chief Executive Officer

A handwritten signature in black ink, appearing to read "Tim Wright".

J. Timothy Wright, MS, DDS
President