AMERICAN ACADEMY OF FAMILY PHYSICIANS

October 1, 2019

Norman E. Sharpless, Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Eric D. Hargan, Deputy Secretary
Department of Health and Human Services.
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Commissioner Sharpless and Deputy Secretary Hargan:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write in support of the proposed rule to establish new required cigarette health warnings for cigarette packages and advertisements as published in the August 16, 2019 *Federal Register*.

The proposed rule implements an important provision of the *Family Smoking Prevention and Tobacco Control Act* of 2009 that requires the Food and Drug Administration (FDA) to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. This proposed rule specifies the color graphics that must accompany the new textual warning statements.

The AAFP fully supports this FDA proposal as it will promote greater public understanding of the negative health consequences of cigarette smoking. The AAFP believes textual and graphical warning labels and child-resistant packaging must be required on all nicotine and nicotine delivery devices. Currently, 120 countries utilize graphic warning labels (GWLs) that are proposed under this rule. A 2016 study supports earlier data indicating that graphic images are more influential than text warnings. It also showed that the images support emotional and cognitive decision making, better information recall, and produce stronger motivation to quit smoking. The research shows that graphics can be effective at discouraging youth tobacco usage. **Therefore, we urge the FDA to promptly utilize its enforcement authority in this area**.

It is the AAFP's policy to oppose the use of all forms of nicotine and the advertisement of nicotine delivery products. Furthermore, it is the AAFP's position to support efforts to protect children from electronic cigarette advertising.

The AAFP continues to call for the FDA to have full jurisdiction to regulate the manufacture, sale, labeling, distribution and marketing of tobacco products and nicotine delivery devices, including e-cigarettes. The AAFP also believes the FDA should require child-resistant packaging for liquid

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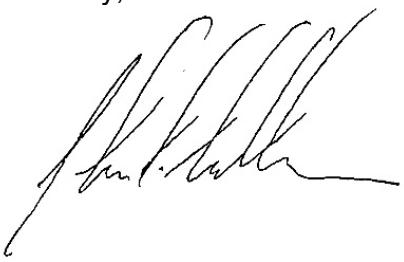
nicotine and all other novel tobacco products. Given that nicotine is an addictive drug, child-resistant packaging and graphical warnings are immediate and common-sense steps that manufacturers should be required to take to prevent infants and children from inadvertently consuming or being exposed to liquid nicotine. Furthermore, since nicotine is a toxic substance, it should be treated as any other poisonous chemical and include text and graphic warnings on child-resistant packaging. Not all children and adults are literate and graphic messages further explain the potential health hazard. The message should detail the risk of ingestion and exposure rather than consist only of a general statement.

There are concerns about the lack of any regulatory oversight on the manufacture, distribution and safety of liquid nicotine and nicotine delivery devices. Therefore, the AAFP calls for rigorous research in the form of randomized controlled trials of e-cigarettes to assess their safety, quality, and efficacy as a potential cessation device. The AAFP also recommends that the marketing and advertising of nicotine delivery devices, especially to children and youth, should cease immediately.

We appreciate the opportunity to comment on this important issue. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 or rbennett@aafp.org with any questions.

Sincerely,



John S. Cullen, MD, FAAFP
Board Chair