AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

August 28, 2015

Leslie Kux, Associate Commissioner for Policy
U.S. Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA–2015–N–1514

Dear Associate Commissioner Kux,

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I write in response to the request for comments titled, "Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing ELiquid(s), and other Tobacco Products" as published by the Food and Drug Administration (FDA) in the July 1, 2015 *Federal Register*.

The FDA seeks comments regarding actions the agency "might take with respect to nicotine exposure warnings and child-resistant packaging for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks."

The AAFP believes textual and graphical warning labels and child-resistant packaging must be required on all nicotine and nicotine delivery devices and we urge the FDA to promptly utilize its enforcement authority in this area. We appreciate the FDA soliciting such feedback since it is our longstanding position to strongly oppose the use of all forms of nicotine and the advertisement of nicotine delivery products. It is the AAFP's position to support efforts to protect children from electronic cigarette advertising. In a December 22, 2010 letter to the FDA, the AAFP adamantly supported the required use of color graphic warnings and new textual warning statements on cigarette packages and advertisements as an important step toward reducing the existing and future use of tobacco products. The AAFP therefore supports the required use of nicotine exposure warning texts and graphics on all tobacco products including novel tobacco products.

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 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 both

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 provide these comments. For any questions you might have please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Reid B. Blackwelder, MD, FAAFP
Board Chair