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Contacts:
Dave Lemmon, Campaign for Tobacco-Free Kids, 202-738-7983
Devin Miller, American Academy of Pediatrics, 202-724-3308
Emily Rohloff, American Cancer Society Cancer Action Network, 262-352-4610
Suniti Bal, American Heart Association, 916-390-1860
Stephanie Goldina, American Lung Association, 312-801-7629
Nicole Dueffert, Truth Initiative, 202-997-1470

As E-Cigarette Makers Face Critical September 9 Deadline, Leading Health Groups Urge FDA Not to Allow Sale of Any Flavored Products

Health Groups Endorse Key Principles to Guide FDA Review of E-Cigarettes and Other Tobacco Products, Call for Rigorous Scientific Evidence and Prompt Removal of Products that Don't Meet Deadline

WASHINGTON, D.C. – As manufacturers of e-cigarettes and certain other tobacco products face a September 9, 2020, deadline to apply to the U.S. Food and Drug Administration to keep their products on the market, six leading public health and medical organizations today urged the FDA not to authorize the sale of any flavored product given the overwhelming evidence that flavored products appeal to kids and the lack of evidence such products help smokers quit.

The health groups also called on the FDA to require manufacturers to provide rigorous scientific evidence demonstrating that a product will benefit public health before authorizing its sale, to promptly remove those products that have not filed the required applications by the September 9 deadline, and to ensure that decisions on product applications are made in a timely, transparent manner without further delay.

These key criteria and principles to guide the FDA's review of e-cigarettes and other tobacco products were developed and endorsed by six health organizations that are longtime leaders in the nation's fight against tobacco use – the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative. The groups sent the principles to the FDA today.

The same groups successfully sued the FDA after the FDA extended to 2022 a deadline for e-cigarette manufacturers to apply to the agency to keep their products on the market. A federal judge ruled the FDA acted illegally in extending the deadline. By court order, manufacturers now have until September 9, 2020, to submit applications to the FDA and those failing to do so are subject to having their products removed from the market. The September 9 deadline applies to e-cigarettes and certain other tobacco products, including cigars, covered by the FDA's 2016 "deeming rule" that established the agency's authority over previously unregulated tobacco products.

To gain FDA authorization to sell a product, the manufacturer must submit an application to the FDA, called a premarket tobacco product application (PMTA), and demonstrate that the product is "appropriate for the protection of the public health," taking into account the impact both on current tobacco users and on whether youth and other non-users will start using the product. In applying this standard and reviewing applications, the health groups urged the FDA to apply the following principles:

The FDA should not authorize the sale of any flavored tobacco product, including e-cigarettes or e-liquids, because of the clear evidence that flavored products appeal to youth and have driven the current epidemic of e-cigarette use among youth and young adults, and the lack of evidence that flavored products help smokers quit.

- Research shows that 97% of youth e-cigarette users report using a flavored product in the past month and 70% say they use e-cigarettes "because they come in flavors I like." In contrast, there is no credible evidence that flavored e-cigarettes help adult smokers quit. In a report issued earlier this year, the U.S. Surgeon General concluded, "There is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."

To determine whether a product will actually benefit public health, the FDA must require that manufacturers provide rigorous scientific evidence addressing each of the following critical concerns for each product they are seeking to market:

1) Direct evidence from U.S. studies sufficient to establish that availability of the product will not lead youth and adults who currently do not use nicotine to initiate or to continue to use the product or other tobacco products;
2) Data that the product does not deliver nicotine at levels that increase the risk of abuse and addiction among youth (Juul and some other current e-cigarette products deliver as much nicotine, if not more, as a pack of 20 cigarettes);
3) Evidence sufficient to establish that the product will predominantly be used by smokers who otherwise would continue to smoke; the product will not deter or lead to a significant decrease in the number of users who would otherwise have quit using tobacco products altogether; a significant majority of those who use the product switch completely to the product and stop the use of other tobacco products altogether; and the product is significantly less harmful than other tobacco products;
4) Given the disproportionate burden of tobacco use on certain populations, such as youth and minority groups, and the industry's history of targeting such populations, specific evidence to assess the product's impact on vulnerable populations and health disparities.

There should be no further delays in the September 9 deadline, and the FDA should make decisions on product applications in a timely, transparent manner:

1) The FDA should take prompt enforcement action to remove from the market products for which applications are required but are not submitted by the September 9 deadline.
2) The FDA should disclose the products for which applications are filed by the September 9 deadline and other information necessary to allow the public to assess industry compliance with, and FDA enforcement of, the deadline.
3) The FDA's review process should be sufficiently transparent to allow the public to assess the evidence manufacturers provide to demonstrate that a product meets the public health standard and to enable the public to provide input on specific applications to the FDA.

The September 9 deadline involves tobacco products that are highly popular with kids. From 2017 to 2019, e-cigarette use more than doubled among U.S. high school students (from 11.7% to 27.5%), according to the 2019 National Youth Tobacco Survey. More than 5.3 million kids used e-cigarettes in 2019 – an increase of over 3 million in two years.

Cigars also remain popular with kids. In 2019, more high school students smoked cigars than cigarettes (7.6% vs. 5.8%), and cigar smoking was particularly high among Black high school students at 12.3%. Both e-cigarettes and cigars are sold in a huge assortment of flavors that appeal to kids.