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## 51 Health Groups Urge Administration to Defend and Enforce FDA Rule for E-Cigarettes, Cigars

## Letter Raises Concern over Judicial and Regulatory Delays

WASHINGTON, D.C.—Fifty-one leading health groups today urged the current administration to defend and fully implement the 2016 Food and Drug Administration (FDA) rule establishing public health oversight of electronic cigarettes, cigars and other previously unregulated tobacco products, also known as the deeming rule.

In a <u>letter</u> to Health and Human Services (HHS) Secretary Tom Price, the groups expressed concern that the administration is taking steps to reconsider the rule, putting kids and public health at risk. Twice in recent months, on March 1 and May 1, 2017, the Department of Justice (DOJ) has delayed filing legal briefs defending the rule against tobacco industry challenges. In addition, the FDA on May 1 announced it was delaying enforcement of future deadlines set by the rule for three months to "allow new leadership at the FDA and the Department of Health and Human Services additional time to more fully consider issues raised by the final rule that are now the subject of multiple lawsuits in federal court."

"The public health justification for regulation is as compelling now as it was a year ago, when the FDA issued the final deeming rule," the health groups wrote. "There is, therefore, no basis for reconsideration of the rule or a failure to defend it strongly in court. Every day of delay in its full implementation subjects the public to the continuing public health threat of unregulated, highly addictive and dangerous tobacco products, many of which come in sweet or candy flavors which are designed and marketed to appeal to children."

Tobacco companies have waged a multi-front attack on the FDA rule through legislative, regulatory and legal means. Congress rejected industry efforts to include provisions weakening the rule in the recently-approved spending bill for the rest of fiscal year 2017, but the industry is expected to continue its efforts in future spending bills. The industry has also filed several lawsuits challenging the rule.

Last August, the DOJ strongly defended the rule as essential to protecting public health in a case called *Nicopure Labs LLC v. FDA* that is pending in the U.S. District Court for the District of Columbia. The health groups' letter cites the government's key findings in issuing and defending the FDA rule.

The health groups expressed particular concern that e-cigarettes and cigars are marketed in a wide assortment of candy and fruit flavors that have helped fuel their popularity with kids. Youth use of e-cigarettes has skyrocketed in recent years, surpassing use of regular cigarettes, and more high school boys now smoke cigars than cigarettes.

A government study, published in the October 2015 issue of the Journal of the American Medical Association (JAMA), found that flavors play a key role in youth use of these products. According to the study, 85.3 percent of current e-cigarettes users aged 12-17 had used a flavored e-cigarette in the past month and 81.5 percent of current youth e-cigarette users said they used the products "because they come in flavors I like." Similarly, 71.7 percent of current cigar smokers aged 12-17 had used a flavored cigar product in the last month, and 73.8 percent of current youth cigar smokers said they smoked cigars "because they come in flavors I like."

"In light of the overwhelming record evidence compiled by the FDA, persuasively presented as to ecigarettes by the DOJ in the *Nicopure Labs* case, there is no public health justification for the FDA to reconsider the deeming rule, or to postpone the implementation of its provisions," the letter states.

Groups signing the letter include the Campaign for Tobacco-Free Kids, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Thoracic Society, Tobacco Control Legal Consortium and Truth Initiative. The full list of signatories is as follows:

Action on Smoking & Health American Academy of Family Physicians American Academy of Oral and Maxillofacial

Pathology

American Academy of Pediatrics

American Association for Cancer Research

American Association for Dental Research

American Association for Respiratory Care

American Cancer Society Cancer Action

Network

American College of Cardiology

American College of Occupational and

**Environmental Medicine** 

American College of Physicians

American College of Preventive Medicine

American Congress of Obstetricians and

Gynecologists

American Dental Association

American Heart Association

American Lung Association

American Medical Association

American Psychological Association

American Public Health Association

American School Health Association

American Society of Addiction Medicine

American Society of Clinical Oncology

American Thoracic Society

Americans for Nonsmokers' Rights

Asian Pacific Partners for Empowerment,

Advocacy and Leadership

Association of Women's Health, Obstetric &

**Neonatal Nurses** 

**Big Cities Health Coalition** 

Campaign for Tobacco-Free Kids

ClearWay Minnesota

Community Anti-Drug Coalitions of America

Eta Sigma Gamma - National Health Education

Honorary

March of Dimes

National African American Tobacco Prevention

Network

National Association of County and City Health Officials

National Association of Pediatric Nurse

Practitioners

National Center for Health Research

National Hispanic Medical Association

National Network of Public Health Institutes

National Physicians Alliance

**Oncology Nursing Society** 

**Prevention Institute** 

**Prevention Partners** 

**Public Health Solutions** 

Society for Cardiovascular Angiography and Interventions

Society for Public Health Education

**Students Against Destructive Decisions** 

The Society of State Leaders of Health and

**Physical Education** 

**Tobacco Control Legal Consortium** 

Trust for America's Health

**Truth Initiative** 

United Methodist Church- General Board of

**Church and Society**