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

Submitted to: <https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars#open-comment>

RE: Docket No. FDA-2021-N-1309, Tobacco Product Standard for Characterizing Flavors in Cigars

To Whom It May Concern:

On behalf of the American Association for Cancer Research's (AACR) more than 50,000 laboratory researchers, physician-scientists, other health professionals, and patient advocates who constitute our national and international membership, we thank you for the opportunity to express our support for the U.S. Food and Drug Administration's (FDA) proposed tobacco product standard that prohibits cigars with characterizing flavors. Our comments also provide some recommendations on how the FDA can further strengthen public health.

More than 480,000 premature deaths are caused by tobacco every year in the United States (1). Tobacco causes 18 types of cancer, which comprise 19 percent of all cancer diagnoses in the United States and almost 30 percent of deaths from cancer each year (2). Additionally, smoking is attributed to more than 85 percent of cases and deaths from lung cancer. The highly addictive properties of nicotine result in high levels of exposure to carcinogens from burning tobacco (3–5).

The Family Smoking Prevention and Tobacco Control Act (TCA) granted FDA the authority to develop tobacco product standards that are “appropriate for the protection of public health.” The TCA also explicitly prohibited flavored cigarettes, except menthol, while permitting flavored cigar products that appear very similar in design to cigarettes. This is concerning as cigar, water pipe, and pipe smoke emit carcinogens and other toxicants at functionally identical levels to cigarette smoke (1,6–8). Numerous studies have found cigar and pipe smoking cause several types of cancer, heart disease, and chronic obstructive pulmonary disease, including up to a 25-fold increased risk of lung cancer associated with heavy cigar smoking (8). While past 30-day cigar smoking rates among Americans 12 years and older have fallen 28 percent between 2009 and 2020 (5.3 percent vs 3.8 percent), the decrease in cigar use is lower than the 36 percent decrease in past 30-day cigarette smoking rates during the same period as measured by the National Survey on Drug Use and Health (9,10). The discrepancy in trends between cigarette and cigar smoking can be partially explained by the prevalence of flavored cigars while the TCA prohibited most flavored cigarettes.

The scientific evidence has been clear for more than a decade that flavors increase the appeal of all tobacco products and are associated with increased initiation and progression to regular smoking among youth (7,11–17). Several studies have found that a key reason a majority of youth and young adults who use any type of tobacco product, including cigars specifically, is because products “come in flavors I like” (13,14). In 2021, the National Youth Tobacco Survey (NYTS) found that 79.1 percent of youth who used any tobacco product in the past 30 days use flavored products, including 44.4 percent of youth who use cigars (18). The most popular flavors among youth for cigars are fruit flavors, followed by desserts/candy and then mint/menthol flavors. Additionally, an analysis of wave 4 of the Population Assessment of

Tobacco and Health survey also found high rates of flavored cigar use among adults who smoke cigars (14). Among adults older than 25 years who smoked cigars in the past 30 days, approximately half smoked flavored products. These findings demonstrate the impact of flavors on increasing the appeal of tobacco products that promote initiation and ongoing use.

While all flavorings mask the harsh taste of tobacco smoke, cooling agents like menthol also reduce irritation and elicit other pharmacological effects that increase the addictiveness of nicotine (19–21). Use of mentholated tobacco products also increases the difficulty of quitting tobacco (19,22,23). For these reasons, AACR issued a policy statement in 2010 urging FDA to prohibit all flavored tobacco products that were in the marketplace at that time (17). We appreciate the opportunity to provide a comment supporting this necessary rule to protect public health.

AACR Supports a Tobacco Product Standard that Prohibits Flavored Cigars

AACR supports the proposed product standard to prohibit flavored cigars and offers recommendations to further strengthen public health. AACR especially appreciates the inclusion of tobacco product accessories, flavoring added to packaging, and product labeling within the product standard to address potential loopholes. However, further clarification for the definition of characterizing flavor that establishes definitive limits on the amount of small molecule flavoring, sweetening, and cooling agents could improve implementation and enforcement of the product standard. AACR is concerned tobacco manufacturers may argue a small amount of flavoring or cooling agent may not constitute a “characterizing flavor,” but will still increase appeal of tobacco products by reducing irritation from smoke or providing a subtle change to the natural flavor of tobacco (24). While AACR recommends establishing thresholds for all chemicals that alter the sensory effects of tobacco products, the evidence base supporting a specific threshold on cooling agents is the most robust. For example, cigars that are not advertised as mentholated also contain high amounts of menthol above naturally occurring levels in tobacco plants (6,25–28).

Many independent studies and the tobacco industry’s own findings show that the cooling and analgesic properties of menthol greatly increase the appeal and initiation of tobacco products (19,29–32). Naturally occurring concentrations of the following cooling agents in tobacco plants were measured by Paschke, *et al*: menthol (0.30 ppm), linalool (0.31 ppm), and carvone (0.28 ppm) (28). In contrast, two types of cigar that were not branded as mentholated were found to emit menthol concentrations of 300 ppm in mainstream smoke (6). This concentration of menthol is 37-fold greater than the level demonstrated to attenuate irritation from smoke and smoke constituents in mice via activation of the TRPM8 receptor (33,34), the primary protein responsible for eliciting a cold sensation in mammals. Furthermore, in the European Union, the tobacco industry switched to alternative cooling agents following a ban on menthol as a characterizing flavor for cigarettes (27). This is a critical weakness in basing a product standard on a characterizing flavor instead of definitive concentration. We are particularly concerned about odorless and colorless synthetic Wilkinson Sword (WS) cooling agents that activate the TRPM8 receptor to provide a cooling sensation (27,28,35,36). Setting a clear limits for natural and synthetic TRPM8 agonists would support transparent implementation of the product standard by creating a clear metric for enforcement actions. Therefore, AACR recommends FDA modify the product standard to specify maximum allowed concentrations of natural and synthetic cooling agents, which should not exceed concentrations naturally found in tobacco plants (i.e., no flavoring or cooling agents may be added to tobacco products in any way). In essence, masking the taste or harshness of tobacco products by adding small molecules should not be allowed in order to decrease tobacco product appeal and initiation. As the scientific evidence evolves, FDA should examine specific thresholds on sweeteners and additional additives for tobacco products and accessories..

Responses to Solicited Questions:

AACR Strongly Encourages the Product Standard be Expanded to Cover Pipe, Water Pipe, and Any Other Form of Combustible Tobacco

AACR believes it is vital to prohibit flavors from all tobacco products to reduce cancer caused by tobacco use. It is clear that flavors increase the appeal of all tobacco products for youth and young adults who have never used tobacco products.

The draft product standard argued pipe and water pipe tobacco were excluded due to low rates of use among youth. However, the 2021 NYTS estimated that 130,000 middle and high school students smoked either flavored hookah or flavored pipe tobacco in the past 30 days (18), which was only 19 percent lower than the number of students estimated to have smoked flavored cigars (160,000) in the past 30 days. The NYTS also found disproportionately high rates of hookah use by non-Hispanic Black students compared to Hispanic or non-Hispanic white students. The AACR believes it is important to utilize evidence-based approaches to address tobacco-related disparities. Pipe tobacco use is most prevalent among younger adults (37); in 2020, 2.1 percent of adults aged 18-24 years smoked pipe tobacco compared to 0.6 percent of adults aged 45-64 years. Water pipe and pipe tobacco use exposes individuals to the similar harmful toxicants as other forms of combustible tobacco, increase the risk of tobacco-related illness, and also increase the likelihood of progression to regular cigarette smoking (1,7,38). While the current use trends of flavored pipe and water pipe tobacco are lower than flavored cigars among youth and young adults, the level of use is concerning for public health.

Additionally, the history of flavors in tobacco products indicates some youth and young adults would switch tobacco products to follow the flavors if exemptions are permitted. As mentioned in the draft product standard, use of flavored cigars and pipe tobacco increased significantly in the United States following prohibition of flavored cigarettes (39,40). Most notably, pipe tobacco use by youth increased 55 percent following the flavored cigarette ban. Similarly, prohibition of most flavors in cartridge-based e-cigarettes resulted in a dramatic 11-fold increase in use of the exempted disposable flavored e-cigarettes among high school students between 2019 and 2020 (41). It is reasonable to expect a large increase in the use of flavored tobacco products exempted from this product standard based on these recent historical examples. A comprehensive flavor ban on all tobacco products would remove a key tool the tobacco industry uses to addict America's youth to nicotine.

Defining "Combusted Tobacco Product"

AACR has considered three criteria to define the term "combusted tobacco product:" 1) the presence of the chemical reaction of combustion; 2) tobacco product operating temperature; and 3) emission of combustion-related carcinogens. "Combustion" is a chemical process whereby oxygen reacts with hydrocarbons (e.g. tobacco leaves) to produce carbon dioxide, water, and heat. However, incomplete combustion results in the formation of carcinogenic aldehydes and polycyclic aromatic hydrocarbons (PAHs). The temperature of combustion greatly influences the abundance of specific chemical species, whereby hotter temperatures are associated with increased production of carcinogens. For example, the carcinogen acrolein is formed at temperatures greater than 270°C (42), and temperatures exceeding 300°C result in PAHs (5,43–46); further raising temperatures above 300°C increases the amount of PAHs (47). While most electronic nicotine delivery systems (ENDS) operate at temperatures below 270°C and may not utilize a chemical reaction between oxygen and hydrocarbons (48,49), there is evidence they may still expose consumers to carcinogenic aldehydes, nitrosamines, and heavy metals (50–53). Furthermore, one

“heat-not-burn” ENDS product operates at 330°C and correspondingly emits PAHs (43); this is a similar temperature at which pipe tobacco burns (54). In summary, there is a continuum of health harms associated with the operating temperature of tobacco products where higher temperatures result in more harmful smoke and aerosol constituents. Relatedly, tobacco products that consume oxygen and emit carbon dioxide also emit greater amounts of combustion related carcinogens. However, there is no such thing as a safe tobacco product, due to the presence of carcinogens in all tobacco leaf products. Additionally, nicotine itself can increase blood pressure, weaken the immune system, and impair memory and learning (55–57). If FDA deems it necessary to distinguish flavor regulations between combusted and non-combusted tobacco products, AACR believes the definition of combusted tobacco product should reflect a chemical reaction of hydrocarbons and oxygen, operating temperature, or the emission of combustion-related carcinogens or toxicants.

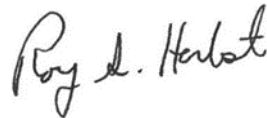
In conclusion, AACR supports the proposed product standard to prohibit flavored cigars. However, allowing other flavored tobacco products to remain on the market will enable the tobacco industry to continue addicting youth to nicotine by promoting the exempted flavored products. AACR therefore urges FDA to expand the product standard to cover all combusted tobacco products, as well as apply a clear limit for cooling agents allowed in tobacco products. We recommend FDA also investigate a similar threshold for other flavor additives and sweeteners in tobacco products. These comments are based on careful discussion and evaluation by the AACR’s Tobacco and Cancer Subcommittee (roster attached) and are approved by the AACR’s CEO, Chair of the Tobacco Products and Cancer Subcommittee, and Chair of the Science Policy and Government Affairs Committee. If the AACR can provide any additional information or assistance to FDA, please do not hesitate to contact Dana Acton, Director of Science Policy and Legislative Affairs, at dana.acton@aacr.org.

Thank you again for the opportunity to comment on this important issue.

Sincerely,



Margaret Foti, PhD, MD (h.c.)
Chief Executive Officer
American Association for Cancer Research



Roy S. Herbst, MD, PhD
Chair, Science Policy and Government Affairs
Committee
Chair, Tobacco Products and Cancer
Subcommittee
American Association for Cancer Research

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AACR Tobacco Products and Cancer Subcommittee Roster

Roy S. Herbst, MD, PhD
Chairperson

Ensign Professor of Medicine
Professor of Pharmacology
Chief of Medical Oncology
Associate Director for Translational Research
Yale Cancer Center
Smilow Cancer Hospital at Yale-New Haven
Yale School of Medicine
New Haven, CT

Christopher I. Amos, PhD

Director, Institute for Clinical and Translational
Research
Associate Director, Quantitative Sciences
Daniel L. Duncan Comprehensive Cancer Center
Baylor College of Medicine
Houston, TX

Barbara A. Burtness, MD

Professor of Medicine Oncology
Interim Associate Cancer Center Director
Yale University School of Medicine
Yale Cancer Center Yale
New Haven, CT

Paul M. Cinciripini, PhD

Professor and Chair, Department of Behavioral
Science
Director, Tobacco Treatment Program
University of Texas MD Anderson Cancer Center
Houston, TX

Maciej L. Goniewicz, PharmD, PhD

Professor of Oncology
Department of Health Behavior
Roswell Park Comprehensive Cancer Center
Buffalo, New York

Dorothy K. Hatsukami, PhD

Associate Director, Cancer Prevention and Control
Forster Family Chair in Cancer Prevention
Professor of Psychiatry
Masonic Cancer Center
University of Minnesota
Minneapolis, MN

Suchitra Krishnan-Sarin, PhD

Professor of Psychiatry
Chair, Human Investigations Committee
Yale University School of Medicine
New Haven, CT

***Stephanie R. Land, PhD, ex officio (NCI liaison)**

Program Director and Statistician
Tobacco Control Research Branch
Behavioral Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute
Bethesda, MD

***As ex officio NCI liaison, Stephanie Land is not
an author or signatory to this comment.**

Scott J. Leischow, PhD

Professor and Director of Clinical and Translational
Science
College of Health Solutions
Arizona State University
Phoenix, Arizona

Timothy R. Rebbeck, PhD

Vincent L. Gregory, Jr. Professor of Cancer
Prevention, Harvard TH Chan School of Public
Health and Division of Population Sciences,
Dana Farber Cancer Institute
Boston, MA

Nancy A. Rigotti, MD

Professor of Medicine
Professor of Population Medicine
Harvard Medical School
Director, Tobacco Research and Treatment Center
Massachusetts General Hospital
Boston, MA

Peter G. Shields, MD

Deputy Director, Comprehensive Cancer Center
Professor, College of Medicine
Julius F. Stone Chair in Cancer Research
James Cancer Hospital
The Ohio State University Wexner Medical Center
Columbus, OH

Avrum E. Spira, MD, MSc

Professor of Medicine, Pathology and Bioinformatics
Global Head, Johnson & Johnson Lung Cancer
Initiative
Boston University School of Medicine
Boston, MA

Benjamin A. Toll, PhD

Professor of Public Health Sciences and Psychiatry
Vice Chair for Research, Public Health Sciences
Chief of Tobacco Cessation and Health Behaviors
Co-Director, Lung Cancer Screening Program
Hollings Cancer Center
Director, MUSC Health Tobacco Treatment Program
Medical University of South Carolina
Charleston, SC

Kasisomayajula (Vish) Viswanath, PhD

Lee Kum Kee Professor of Health Communication
Harvard T. H. Chan School of Public Health
Dana-Farber Cancer Institute
Director, Center for Translational Health
Communication Science, DFCI/HSPH
Director, Harvard Chan India Research Center
Co-Director, Lee Kum Sheung Center for Health and
Happiness
Boston, MA

Wendell Gray Yarbrough, MD, MMHC, FACS

Chair, Thomas J. Dark Distinguished Professor
University of North Carolina at Chapel Hill
Otolaryngology, UNC Comprehensive Cancer
Support Program
Chapel Hill, NC