

August 2, 2022

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD, 20852

Re: Docket No. FDA-2021-N-1349 for “Tobacco Product Standard for Menthol in Cigarettes”

Dear Commissioner Califf:

The American Lung Association appreciates the opportunity to submit comments in strong support of the proposed product standard prohibiting menthol as a characterizing flavor in cigarettes, which will reduce youth smoking, save lives and advance health equity. These comments are intended to supplement comments the Lung Association also submitted with the broader health and medical community. If finalized and implemented as proposed, this rule will result in enormous public health benefits both in the short and long term. The Lung Association urges the Food and Drug Administration (FDA) to move quickly in finalizing this proposed rule by the end of 2022.

The Lung Association is the oldest, voluntary public health organization in the United States and is committed to eliminating tobacco use and tobacco-related disease. One of the Lung Association’s strategic imperatives is to create a tobacco-free future which will be significantly advanced with the implementation of this rule. The Lung Association first called on FDA to issue product standards ending the manufacture and sale of menthol cigarettes when the Tobacco Products Scientific Advisory Committee (TPSAC) first concluded that removing menthol cigarettes from the marketplace was appropriate for the protection of the public’s health. As research continues to find, menthol cigarettes are disproportionately used by priority populations including Black Americans and attract young people to initiate tobacco use.

Removing Menthol Cigarettes Will Promote Public Health and Advance Health Equity

Ending the sale of menthol cigarettes is pivotal to eliminating the dramatic health inequities in who uses tobacco products in the United States and who is most affected by tobacco-caused disease and death. Menthol flavoring has been marketed and falsely perceived as a healthier alternative to non-menthol tobacco products.ⁱ For generations, the tobacco industry has intentionally targeted Black, Brown, youth, LGBTQIA+ and other communities with the marketing of menthol cigarettes. This relentless marketing has resulted in increased initiation with menthol cigarettes and high usage of menthol cigarettes, contributing to more tobacco-related death and disease as well as tobacco-related health disparities.

Tobacco use is the number one cause of preventable death in the U.S., and claims 45,000 lives every year among Black Americans alone.ⁱⁱ A recent study quantified the disproportionate harms from menthol cigarettes to Black Americans, finding that menthol cigarettes were responsible for 1.5 million new smokers, 157,000 smoking-related premature deaths and 1.5 million life-years lost among Black Americans from 1980-2018.ⁱⁱⁱ Halting the sale of menthol cigarettes lays the groundwork for reversing decades of disparities in tobacco use, disease and death in Black and Brown communities.

In addition to its detrimental impact on Black and Brown communities, menthol also disproportionately impacts young people. Menthol cools and numbs the throat, which reduces the harshness of tobacco smoke and makes cigarettes more appealing to new smokers, particularly young people.^{iv} That is why flavors, including menthol, are one of the primary reasons kids start using tobacco products. As is well-documented in the proposed rule, menthol facilitates experimentation, progression to regular smoking of menthol cigarettes and contributes to greater nicotine dependence.^v Half of youth who have ever tried smoking started with menthol cigarettes^{vi} and menthol cigarettes were responsible for 10.1 million additional new smokers between 1980 and 2018.^{vii} Evidence suggest that young people who smoke menthol cigarettes are not just physically dependent on nicotine, but also experience emotional attachments to cigarettes compared to their non-menthol smoking peers.^{viii}

Given how prevalent menthol cigarette use is among young people, there is no rationale for continuing to permit the sale of menthol cigarettes. The public health impact of menthol cigarette sales restrictions has been documented domestically and internationally. Domestically, there have been several state and local restrictions that provide evidence of decreases in use and sales of tobacco products after policy implementation.^{ix, x, xi, xii} More evidence is forthcoming given that these restrictions were passed in recent years. It is noted that the current body of evidence around menthol cigarette sales restrictions underestimates the potential impact of a national policy. Some local policies have retailer exemptions and under a national policy - menthol cigarettes will not be available in neighboring jurisdictions. Ending the sale of menthol cigarettes will decrease the likelihood of young people experimenting with tobacco products that results in life-long tobacco dependence.

FDA Must Take Proactive Steps to Prevent Loopholes and Industry Manipulation

The tobacco industry has a long-documented history of manipulating products to take advantage of regulatory loopholes, which underscores how important it is that FDA's final rule include all products. The *2009 Family Smoking Prevention and Tobacco Control Act* prohibited the sale of flavored cigarettes but exempted menthol cigarettes. Cigar manufacturers changed flavored cigarettes so that they technically qualified as flavored cigars. Cheyenne International was even caught adding sepiolite, a clay material used in kitty litter, waste treatment and industrial cleaners in an effort to increase the weight of their 'heavy weight' cigars to avoid higher tax rates that were charged on smaller cigars and cigarettes due to the federal cigarette tax increase that took effect in 2009.^{xiii}

This type of gross manipulation and exploitation of regulatory loopholes expanded the sales of flavored combustible non-cigarette products, including cigarillos. Many of these products are functionally indistinguishable from cigarettes and continue to be sold – all of which has resulted in expanding the gap in health disparities. This was a clear effort to circumvent the *Tobacco Control Act's* prohibition on flavored cigarettes.

Another example of industry manipulation includes R.J. Reynolds Camel Crush Bold cigarettes. These were one of many Reynolds products that FDA said could no longer be sold in 2015. The Camel Crush product had a little capsule of menthol in the filter that was new. R.J. Reynolds was unable to show that this capsule did not change the product's risk or change consumer perception. This was developed for no other reason, but to make a deadly product more attractive, addictive and appealing to specific segments of their target market demographic, including young people.

FDA must prohibit flavor representations in or on the labeling or advertising of cigarettes. Evidence shows that many people who smoke base their perceptions of risk on pack colors. Cigarette manufacturers used labels including light, mild or low tar to brand those products as less harmful than regular cigarettes; however, research clearly shows that was not true. In places where manufacturers are no longer able to use that language, including the U.S., cigarette manufacturers simply changed their “light” cigarettes to silver and gold brands. For instance, Marlboro Lights have become Marlboro Gold.^{xiv} Altria placed inserts in the last packs of Marlboro Lights that said “Your Marlboro Lights package is changing, but your cigarette stays the same... In the future, ask for Marlboro in the gold pack.” In response to the industry’s “color coding”, FDA sent a letter to the Altria Group asking about these notes and opened an investigation into the marketing of the cigarettes.^{xv} Many companies have already changed the packaging of their menthol products to green to align with how mint is portrayed. The Lung Association urges FDA to prohibit tobacco companies from changing language on cigarette packs that make smokers think they are cooling, easy to smoke or similar to menthol.

To maximize public health efforts, FDA must also prohibit the sale of flavored cigars concurrently on the same effective date. Flavored cigars have proliferated in recent years and are sold in hundreds of kid-friendly flavors.^{xvi} As a result, cigars are now the second most popular tobacco product among high schoolers and are incredibly popular among Black youth.^{xvii} Issuing both rules concurrently with the same effective date will maximize the public health impact and prevent the tobacco industry from selling menthol cigarettes posing as cigars. Without a rule prohibiting the sale of flavored cigars, individuals who smoke menthol cigarettes may shift to using flavored cigars, especially menthol flavored little cigars, undermining the public health impact of a menthol cigarette product standard. The American Lung Association is submitting comments to both dockets.

FDA Should Prohibit Menthol Cigarettes to Be Manufactured for Export

In addition to moving forward with prohibiting the sale of flavored cigars, the Lung Association also urges FDA to extend the prohibition to include all menthol cigarettes, including those designated for export. It is unconscionable that the U.S. could allow products it has determined to be detrimental to the public health to be exported to harm citizens of other countries. While the U.S. is slowly beginning to limit the type of tobacco products that are sold domestically, the tobacco companies continue to help expand tobacco markets abroad. Tobacco companies have aggressively exploited trade and investment agreements to expand their reach in low and middle-income countries. As FDA has found time and time again, no tobacco product is safe. Further, the domestic manufacture of menthol cigarettes may result in illicit sales of menthol cigarettes in the United States.

Removing Menthol Cigarettes Will Promote Tobacco Cessation

More than two thirds of individuals who smoke say they want to quit.^{xviii} Unfortunately, menthol cigarettes have been found to increase both the likelihood of becoming addicted and the degree of addiction.^{xix} Research also indicates that menthol smokers are less likely than non-menthol smokers to successfully quit smoking despite having a higher urge to end their tobacco dependence.^{xx} This is seen in the available data around interest and success in quitting. Black persons who smoke report a greater interest in quitting and more past year quit attempts than their white counterparts. However, Black individuals have been less successful in quitting due in large part to their preference for menthol cigarettes, which are more difficult to quit.^{xxi} Eliminating menthol in tobacco products is expected to substantially reduce smoking initiation and tobacco product use among current menthol smokers.^{xxii} The evidence suggests that many people who

smoke menthol cigarettes would not find a non-mentholated cigarette as an acceptable substitute and are therefore more likely to quit smoking in response to a prohibition on menthol cigarettes.^{xxiii}

Given that Black individuals disproportionately smoke menthol cigarettes, prohibiting the sale of menthol cigarettes will have a greater impact on increasing smoking cessation among Black persons who smoke and help reduce health disparities. In fact, the proportion of smokers who say they would quit in response to this prohibition is higher among Black and young people who smoke. In the first 13-17 months of removing menthol cigarettes from the marketplace, one study estimates 923,000 people who smoke would quit, including 230,000 Black Americans.^{xxiv} This study, which evaluated Canada's law prohibiting the sale of menthol cigarettes, also concluded that removing menthol cigarettes from the marketplace was significantly associated with higher rates of quit attempts and quit success among menthol smokers compared to non-menthol smokers and may have helped to prevent relapse among menthol smokers who had quit smoking before the prohibition. FDA's regulatory impact analysis for the proposed rule estimates over 647,000 deaths would be averted by 2060 under the proposed rule — approximately 104,000 among Black Americans.^{xxv}

As FDA advances these two new product standards, we urge other HHS agencies, including the Centers for Disease Control and Prevention, National Institutes of Health and the Centers for Medicare and Medicaid Services, to prepare to assist current smokers to end their addiction entirely. The United States Preventive Services Task Force has repeatedly found the seven FDA-approved cessation medications and three forms of counseling to be safe and effective in helping smokers quit.^{xxvi} All 10 of these treatments are considered first line in helping smokers quit. These are not only cost-effective cessation strategies, but also increase likelihood of successfully quitting smoking, particularly when used in combination.

Individuals who smoke in the U.S. have several opportunities to get help with quitting. Individuals can call 1-800-Quit-Now and access their state quitline. Quitlines are effective, evidence-based cessation interventions that help tobacco users quit through a variety of service offerings, including counseling and referral to other cessation resources. Some state quitlines also offer free cessation medications or provide tobacco users with vouchers or discounts to receive these medications at reduced cost. These treatments are also required to be covered without cost-sharing in most types of health insurance plans, including Medicaid expansion plans.

While these treatments are highly successful, we support more research into new medications that will eventually gain FDA-approval for cessation, especially among youth. Evidence shows individuals who use menthol cigarettes want to quit, not switch to a new product.^{xxvii} When FDA finalizes this rule, we urge that HHS agencies also partner with states, non-profits, state quitlines and others to promote available cessation resources – the seven FDA-approved medications and three forms of counseling.

The American Lung Association stands ready to help all tobacco users quit, including people who smoke menthol cigarettes, with proven effective quit smoking methods. This would consist of delivering evidence-based cessation programming through our Freedom From Smoking Program.

FDA's Rule on Menthol Cigarettes if Properly Enforced is Unlikely to Create a Large Illicit Market

The tobacco industry and other organizations have argued that FDA should not impose any product standard concerning flavored tobacco products because any tobacco control measure will cause illicit sales. The Lung Association and our partners submitted [detailed comments](#) on this topic to FDA on July 18, 2018, which we resubmit to this docket now.

The tobacco industry has consistently overestimated the size and significance of illicit markets to discourage tobacco control measures from being implemented. Their vocal opposition to effective tobacco control measures, including prohibiting the sale of menthol cigarettes, comes from a fear of reduced sales and a decrease in profits. FDA should be skeptical of the tobacco industry's claims about illicit markets. Instead, the Lung Association recommends FDA rely on its own research and that of organizations who are champions for improving the public's health.

In addition, because the proposed rule applies to sales of menthol cigarettes from all potential locations in the United States, including the tribal lands of Indigenous Peoples, and Canada has prohibited the sale of menthol cigarettes across the country, this removes two potential avenues for an illicit market in menthol cigarettes to develop.

The Lung Association also urges FDA to implement the track-and-trace system it is mandated to do in the Tobacco Control Act. There is currently an outstanding [citizen petition](#) that the Lung Association and several partners filed in 2013 to which FDA has yet to respond. The petition requests FDA fulfill its responsibilities to implement a track-and-trace system. Under this system, FDA and other law enforcement authorities would be able to identify the source and distribution history of product packages and increase the effectiveness of law enforcement. This would have great value in enforcing compliance with product standards, prevent an illegal market and maximize the public health benefits of strong oversight.

Prohibiting the manufacture of menthol cigarettes for export will also help prevent the illicit sale of such products in the United States.

The most important action FDA could take to prevent an illicit market in menthol cigarettes from occurring is to vigorously enforce its final rule against cigarette manufacturers and distributors.

FDA's Proposed Rule Will Not Lead to Further Criminalization in Black and Brown Communities

The tobacco industry has argued that a prohibition on the sale of menthol cigarettes will result in a higher rate of criminalization among Black and Brown communities. In 2021, multiple civil rights and health groups, including the NAACP and the National Medical Association, sent a [letter to HHS Secretary Becerra](#) that countered the arguments that the FDA ending the sale of menthol cigarettes would lead to the further criminalization of Black individuals in the United States. As described in the proposed rule, FDA will only enforce these rules against manufacturers, distributors, and retailers. The rule clearly states that there will be no enforcement against individuals who use or possess tobacco.

The Lung Association agrees that criminal penalties for individuals addicted to tobacco products would be harmful. Prohibiting the sale of menthol cigarettes is about addressing the death and disease that menthol cigarettes have caused in the Black community and in other communities that use menthol cigarettes at high rates. As our nation works to address a myriad of racial and

social injustices, it can and must also address the immense public health injustices caused by the tobacco industry targeting Black and Brown communities with menthol cigarettes.

FDA Should Not Allow Exemptions for Any Type of Menthol Cigarettes

The American Lung Association stands firm against any exemptions from a rule that prohibits menthol as a characterizing flavor in cigarettes on the market. Any cigarette with menthol as a characterizing flavor may lead to an increase in youth initiation of cigarettes and could dissuade current individuals who smoke menthol cigarettes from cessation efforts. Any sort of exemption would undermine the public health impact of a menthol cigarette product standard. This would include exemptions for any products granted a pathway to the market via Section 911 of the Tobacco Control Act such as the VLN Menthol King 95% reduced nicotine content cigarettes from 22nd Century. FDA must be prepared to enforce the rule against all menthol products on its effective date. This includes components of cigarettes that may have a menthol flavor, such as rolling papers or filters.

FDA Should Allow No More Than One Year for the Effective Date

FDA has requested comments as to whether there should be a shorter effective date. The American Lung Association respects that section 907(d)(2) of Tobacco Control Act states that any regulation establishing a tobacco product standard may become effective one year after the date of publication of the final rule.^{xxviii} The Lung Association would be strongly opposed to any attempts at extending the effective date beyond one year and urges FDA to be prepared to enforce the rule on the effective date. Additional delay, beyond one year, will only increase the numbers of young people who experiment with menthol cigarettes and become regular smokers, delay smoking cessation efforts by current smokers and worsen tobacco-related health disparities.

FDA has also requested comments on whether it should provide a sell-off period of 30 days after the effective date of a final rule. The Lung Association is firmly against authorizing a sell-off period. Retailers will have one year post publication of the final rule to sell off their inventory of menthol cigarettes and minimize any adverse financial impact of such removal. One year is sufficient time for retailers and thus, there is no justification for a sell-off period. Additionally, maintaining a single day for these products to no longer be manufactured, sold or distributed will reduce confusion for retailers and individuals who smoke menthol cigarettes.

A sell-off period will also make it harder to coordinate tobacco cessation campaigns.

Conclusion

The American Lung Association strongly supports FDA's proposed rule to remove menthol cigarettes from the marketplace. It is long overdue and has the potential to impact longstanding public health inequities and save millions of lives. Ending the sale of these products will stop kids from being lured by menthol and becoming addicted. It will also help reduce the unjust disparities in tobacco use, primarily caused by the tobacco companies targeting historically underserved and underrepresented communities with menthol cigarettes. FDA should work to help people end their addiction for good and not switch to another tobacco product, such as a menthol-flavored e-cigarette.

The American Lung Association urges FDA to act by the end of 2022 to issue this lifesaving rule in final form. When finalized, we believe this product standard and the product standard removing flavored cigars from the marketplace will be the most significant actions taken by FDA in its 13-year history of regulating tobacco products.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Harold Wimmer". The signature is written in a cursive style with a large initial "H".

Harold P. Wimmer
President and CEO

Appendix

The Lung Association submits the following documents for the docket that supplement our comments in support of the proposed rule to remove menthol cigarettes from the marketplace.

FDA Tobacco Products Scientific Advisory Committee (TPSAC) Menthol Report (2011)

- TPSAC came to two primary conclusions:
 - Menthol cigarettes have an adverse impact on public health in the U.S.
 - Menthol cigarettes offer no public health benefits, compared to the non-menthol cigarettes.
- The overall recommendation TPSAC made to FDA was:
 - It is appropriate for the protection of the public health for menthol cigarettes to be removed from the marketplace.

Addressing Tobacco Use Among Black Communities Toolkit (2022)

- A comprehensive toolkit that explores the racial injustices and health inequalities faced by the Black community concerning tobacco use, including use of menthol cigarettes.

Lung Association's Black Men & Lung Cancer Report (2010)

- This report provides a comprehensive discussion defining the impact of cancer-causing agents, primarily, but not limited to, inhaled tobacco on the development of lung cancer and its disproportional impact on the lives of Black Americans.

ⁱ Anderson, Stacey J. "Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents." *Tobacco control* vol. 20 Suppl 2, Suppl_2 (2011): ii20-8. doi:10.1136/tc.2010.041939

ⁱⁱ HHS, "Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General," 1998, http://www.cdc.gov/tobacco/data_statistics/sgr/1998/complete_report/pdfs/complete_report.pdf

ⁱⁱⁱ Mendes D, Le TTT. Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018. *Tob Control*. 2021 Sep 16:tobaccocontrol-2021-056748.

^{iv} FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes (2013)

^v Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396, 26463-26466 and 26469-26470 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166)

^{vi} Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.

^{vii} Le, TT, "An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018," *Tobacco Control*, published online on February 25, 2021.

^{viii} Cwalina et al - Adolescent menthol cigarette use and risk of nicotine dependence-Findings from the national PATH study - 2019 DAD

^{ix} Gammon, D.G., T. Rogers, J. Gaber, et al. "implementation of a Comprehensive Flavoured Tobacco Product sales Restriction and Retail Tobacco Sales." *Tobacco Control*, 0:1-7, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056494>.

^x Yang, Y., E.N. Lindblom, R.G. Salloum, et al. "The Impact of a Comprehensive Tobacco Product Flavor Ban in San Francisco Among Young Adults." *Addictive Behaviors Reports*, 11:100273, 2020. Available at <https://doi.org/10.1016/j.abrep.2020.100273>.

^{xi} Olson, L.T., E.M. Coats, T. Rogers, et al. "Youth Tobacco Use Before and After Local Sales Restrictions on Flavored and Menthol Tobacco Products in Minnesota." *Journal of Adolescent Health*, 2022. Available at <https://doi.org/10.1016/j.jadohealth.2022.01.129>.

^{xii} Asare S., M.A., J.L. Westmaas, et al. "Association of Cigarette Sales with Comprehensive Menthol Flavor Ban in Massachusetts." *JAMA Internal Medicine* 182(2):231-234, 2022. Available at <https://doi:10.1001/jamainternmed.2021.7333>.

^{xiii} Edney, Anna. Tobacco Firms Save \$1 Billion with Kitty Litter in Cigars. *Bloomberg*. 1 Mar, 2013.

^{xiv} *Partner Comments to FDA re Descriptors*. September 10, 2009. Available at: [Partner Comments to FDA re Descriptors \(lung.org\)](https://www.lung.org/partner-comments-to-fda-re-descriptors)

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- ^{xv} Wilson, Duff “F.D.A Seeks Explanation of Marlboro Marketing.” *The New York Times*. 17 Jun. 2010.
- ^{xvi} Delnevo, CD, et al. “Cigar Sales in Convenience Stores in the US, 2009-2020,” *JAMA* 326(23):2429-2432. 87 Fed. Reg. 26396, 26403 (May 4, 2022).
- ^{xvii} U.S. Centers for Disease Control (CDC), “Tobacco Product Use Among Middle and High School Students—United States, 2020,” *MMWR*, 69, December 18, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950a1-H.pdf> (2020 National Youth Tobacco Survey).
- ^{xviii} U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Center for disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.
- ^{xix} Tobacco Products Scientific Advisory Committee, U.S. Food & Drug Administration, Menthol cigarettes and Public Health: Review of the Scientific Evidence and Recommendations (2011)
- ^{xx} “Menthol and Other Flavors in Tobacco Products.” U.S. Food & Drug Administration, April 29, 2021. <https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products>
- ^{xxi} FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes (2013)
- ^{xxii} “Menthol and Other Flavors in Tobacco Products.” U.S. Food & Drug Administration, April 29, 2021. <https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products>
- ^{xxiii} O’Connor, Richard J et al. “What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand.” *Addiction (Abingdon, England)* vol. 107,7 (2012): 1330-8. doi:10.1111/j.1360-0443.2012.03822.x
- ^{xxiv} J. Chung-Hall, G.T. Fong, G. Meng, K.M. Cummings, A. Hyland, R.J. O’Connor, A.C.K. Quah, and L.V. Craig, “Evaluating the impact of menthol cigarette bans of cessation and smoking behaviors in Canada: longitudinal findings from the Canadian arm of the 2016-2018 ITC Four Country Smoking and Vaping Surveys,” *Tobacco Control*, 31-Mar-2021. [Online]. Available: <https://tobaccocontrol.bmj.com/content/early/2021/03/31/tobaccocontrol-2020-056259>.
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- ^{xxvi} US Preventive Services Task Force. Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;325(3):265–279. doi:10.1001/jama.2020.25019
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- ^{xxviii} H.R. 1256 – 111th Congress (2009-2010): Family Smoking Prevention and Tobacco Control Act. (2009, June 22). [PUBL031.PS \(congress.gov\)](https://www.congress.gov/bills/111/1256)