



# FDA CENTER FOR TOBACCO PRODUCTS: LISTENING SESSION TRANSCRIPT

June 13, 2022

The U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) recently proposed two product standards: one that would prohibit menthol as a characterizing flavor in cigarettes and another that would prohibit characterizing flavors (other than tobacco) in all cigars.

From 10 a.m. to 4 p.m. EDT on June 13, FDA held a virtual listening session to give the public an opportunity to verbally provide open public comment on the proposed product standards.

FDA invited members of the public to either comment (utilizing their video camera or audio-only) during a Zoom meeting or to participate by just viewing and listening to the meeting.

FDA aimed to make the sessions as inclusive as possible and to create an opportunity to hear a range of ideas and perspectives. While anyone could have requested to provide open public comment during the sessions, FDA was especially interested in hearing from those with relevant lived experience and those who may be less likely, or less able, to provide formal written comments through the standard docket submission process.

The following is the written transcript of the June 13, 2022 listening session.

## Timeline

Commenter	Organization (if applicable)
Carol Coram	American Cancer Society Cancer Action Network
Gary Ewart	American Thoracic Society
Elliot T. Bryce	
Edgar Domenech	
Catherine Beane	YWCA USA
Ella Paligo	Tennessee Department of Health and Tobacco-Free Kids
Minister King X Pyeface	
Janet Williams	Respiratory Health Association
Charlie Gagen	American Lung Association
Julia Choi	
Anthony Carothers	
Patricia Nez Henderson	
Lorraine Taylor	
Edward Longe	American Consumer Institute
Henry Ortiz	
Charles Billups	The Guardians
Peter Krueger	Nevada Petroleum Marketers and Convenience Store Association
Lindsey Stroud	Taxpayers Protection Alliance Consumer Center
Alicia Butler	National Action Network
Lori Bremner	
John Clymer	National Forum for Heart Disease and Stroke Prevention
Stanton Glantz	
Sairam Jabba	Duke University School of Medicine

Commenter	Organization (if applicable)
Lester Hartman	
Daniel Treacy	
Sydney Shaffer	
Neill Franklin	
Minou Jones	Making It Count Community Development Corporation
Ashok Patel	Your Choice Convenience Stores
Art Way	Equitable Consulting
Timothy Andrews	Americans for Tax Reform
Michael Myers	
Marguerite Pennoyer	
Tony Cooper	Cooper's Country Corner
John Rotunno	
Yolanda Dickerson	
Shannon Baker	
Brianna Holmes	
Christine Peters	
Francis Armstrong	Blue Ridge Tobacco
Sophia Allen	Department of Public Health Sciences at the Penn State College of Medicine
Rich Mariano	
Jeff Stier	
Mike Seelbach	
John Dixon	
Carol McGruder	African American Tobacco Control Leadership Council
Desmond Jensen	Public Health Law Center

Commenter	Organization (if applicable)
Erika Sward	American Lung Association
Charles Giblin	Center for the Advancement of Public Safety and Security

NECOLA STAPLES: Good morning. Welcome to today's listening session about FDA proposed product standards to prohibit menthol as a characterizing flavor in cigarettes and characterizing flavors in all cigars. I'm Necola Staples with the Office of Health, Communication and Education at FDA Centre for Tobacco Products for CTP. I am one of several moderators that will serve as your host for today's listening session. Thank you so much for joining us. The purpose of today's meeting is for FDA to hear your comments about the agency's recently proposed product standards, which were issued under the Federal Food, Drug and Cosmetic Act. I'm happy to share that we will have individual speakers as well as several groups represented on today's call, including members of the law enforcement community, National Public Health, community and faith-based organizations, state, local and public health, healthcare, academia and research, as well as different sectors of the industry. I want to note that we have received many requests to speak and We are not able to accommodate them all. It is critically important to U.S. to hear from all voices who would like to comment on the proposed rules so I would like to emphasize that the docket is open and every person, group, or organization can provide written comments through July 5, 2022. I also want to acknowledge that FDA has received a number of requests to extend the comment period beyond July 5, 2022. At this time, FDA cannot provide an update on those requests. All comments are given careful consideration, whether delivered in writing or verbally. As a reminder, the links and information to submit written comments are listed on the screen and are available on multiple pages on our website. In just a moment, I will turn it over to Michele Mital, CTP's Acting Director, RDML Richardae Araojo, FDA's Associate Commissioner for Minority Health, and the Director of FDA's Office of Minority Health and Health Equity for a brief welcome. Then we will hear from CTP's Office of Regulations, Beth Buckler, Senior Regulatory Counsel, and Nathan Mease, Regulatory Counsel, who will share a high-level overview of the proposed rules We are discussing today. Our priority for today is to hear from the public so we will keep our introductions and overview brief. After that, we will invite our confirmed speakers to provide their prepared comments. As a reminder, this meeting is being recorded and the transcript will be added to the dockets of proposed rules, as well as to the CTP website. Finally, today's sessions will be closed captioned and an ASL interpreter will be on the call as well. With that, it's my pleasure to introduce CTP's Acting Director, Michele Mital.

MICHELE MITAL: Thanks, Necola. Welcome, everyone. Thank you for being here to provide comment on FDA's two proposed product standards. One that would prohibit menthol as a characterizing flavor and cigarettes, and another that would prohibit characterizing flavors other than tobacco and all cigars. These proposed product standards are part of FDA's commitment to making tobacco-related disease and death part of America's past and

addressing health disparities. If the proposed rules become final, they will help prevent youth from becoming the next generation of smokers and help current smokers quit. These actions are an important step forward to reduce the appeal of tobacco products, protect youth, advance health equity, and save lives. When we propose regulatory actions, we consider how they will impact people who currently use tobacco products, as well as those who do not use any tobacco products and broader communities and populations at large. An important part of this process is considering comments from stakeholders, including individuals sharing their own perspectives, organizations with expertise in public health, social justice and health equity, academia, as well as different sectors of the industry. While we know many individuals and groups have already provided written comments to the docket, we are pleased to be able to conduct these listening sessions, which provide an alternative format for individuals, communities, and organizations to share their perspectives with FDA. Years of scientific research and analysis stand behind these proposed rules as to voices from a wide array of affected communities seeking better health and health equity. I'm proud to be part of this important step and the process, and grateful to everyone who takes the time to commend on the rules. We look forward to hearing a broad representation of ideas and perspectives during these listening sessions. Thank you for your participation in the rulemaking process. It is now my pleasure to introduce RDML Richardae Araojo to provide some opening remarks.

RADM RICHARDAE ARAOJO: Thank you, Michele and thank you to everyone for joining U.S. today. At FDA's Office of Minority Health and Health Equity, we aim to promote and protect the health of diverse populations through research and communication of science that addresses health disparities. Our office works collaboratively with FDA centers and offices such as CTP to address health disparities and ensure that FDA's health equity goal is prioritized throughout all our work. We have made significant progress over the past 55 years and encouraging people to stop smoking but the reality is that not everyone has been included in that progress. For far too long, certain populations, including communities of color, low-income populations, and LGBTQ+ individuals have been disproportionately impacted by tobacco use. Despite our progress, we know that each year 480,000 lives are lost prematurely from a smoking-attributable disease making tobacco use the leading cause of preventable death and disease in the United States. An estimated 18.6 million people currently smoke menthol cigarettes in the United States. These smokers include people from all walks of life and all demographic backgrounds but the prevalence and the public health burden of menthol cigarette use is not the same across different communities. Nearly 85% of all black or African American smokers use menthol cigarettes compared with just 30% of white smokers. It is also important to note that in the United States, significantly fewer African American smokers report long-term quitting compared with non-Hispanic white smokers. Furthermore, African American smokers are more likely to die of tobacco-related disease than white smokers. As for cigar use, data show that flavored cigars are disproportionately popular among youth, young adults, and communities of color. Some research demonstrates that among past 30 days cigar users: Hispanic, Latino, black African American, and Asian, the young adults have greater odds of using flavored cigars compared to their non-Hispanic white peers. I know that some are concerned that these actions if finalized could result in increased state and local policing actions, and even criminal penalties, and some of the very same communities that have advocated for these rules and are expected to see health benefits as a result. We take these concerns seriously. It is

important to remember that FDA's enforcement authority is limited to manufacturers, distributors, wholesalers, importers, and retailers only. Consumer possession will not be governed by this rule. We encourage the public to submit comments on how FDA can clarify the respective roles of FDA and state and local law enforcement within the rules. If finalized, these rules will represent powerful science-based approaches that will have a significant and long-lasting public health impact and including helping to significantly reduce youth initiation and address tobacco-related health disparities. These product standards will save lives and improve the public health of our country. That's why I'm pleased to be part of today's listening session and hear your perspectives about FDA's proposed product standards. Our next speaker is Beth Buckler from CTP's Office of Regulations.

BETH BUCKLER: Thank you and good morning, I will provide a brief overview of the tobacco products standard for menthol in cigarettes proposed rule. The proposed rule would prohibit menthol as a characterizing flavor in cigarettes. Menthol's minty flavor and sensory effects reduce the harshness of cigarette smoking and make it easier for new users to continue experimenting and progress to regular use. By prohibiting menthol as a characterizing flavor in cigarettes, FDA expects a significant reduction in the likelihood of youth and young adults' initiation and progression to regular cigarette smoking, which is expected to prevent future cigarette-related disease and death. In addition, the proposed rule, if finalized, would improve the health and reduce the mortality risk of current menthol cigarette smokers by substantially decreasing cigarette consumption and increasing the likelihood of cessation. The proposed rule would prohibit menthol as a characterizing flavor in cigarettes as well as cigarette components and parts, including the tobacco filter, wrapper, paper, and menthol flavoring separate from the cigarette. The proposed rule also would prohibit persons from manufacturing, distributing, selling, or offering for distribution or sale within the United States a /cigarette or cigarette component or part that is not in compliance with the product standard. As others have emphasized, FDA's enforcement will address manufacturers, distributors, wholesalers, importers, and retailers; not individuals. FDA is proposing the menthol product standard would be effective one year after the publication of a final rule and is requesting comments on whether an earlier effective date is necessary for the protection of the public health. Thank you. I will now turn it over to my colleague, Nathan Mease.

NATHAN MEASE: Thank you, Beth. Hi, I'm Nathan Mease. I will give a brief overview of the proposed rule tobacco product standards for characterizing flavors and cigars. The proposed rule, if finalized, would prohibit characterizing flavors other than tobacco and all cigars and their components and parts. Under the proposed rule, no person may manufacture, distribute, sell, or offer for distribution or sale within the United States, acigar, or any of its components or parts that have a characterizing flavor other than tobacco. Again, consumer possession will not be governed by this rule. Characterizing flavors in cigars and other tobacco products play a key role in how users and nonusers particularly youth, initiate progress and continue using tobacco products. Characterizing flavors in tobacco products increase the appeal of those tobacco products to youth and promote youth initiation, resulting in an increased likelihood that youth and young adults experimenting with flavored cigars will progress to regular cigar smoking. If finalized, the proposed rule would reduce the appeal of cigars, particularly to youth and young adults, and thus decrease the likelihood of experimentation, development of nicotine dependence, progression to regular use, and the resulting tobacco-related disease and death. If finalized, the proposed rule would improve

public health by increasing the likelihood of cessation among existing cigar smokers. It would also improve health outcomes within groups that experience disproportionate levels of tobacco use, including certain vulnerable populations, thus advancing health equity. Thank you. I will pass it back to our moderator, Necola Staples.

NECOLA STAPLES: Thank you, Nathan and thank you to all the speakers today. We are ready to begin the next process on the agenda and welcome each of our confirmed speakers to provide their comments on FDA's proposed product standard to prohibit menthol as a characterizing flavor in cigarettes and FDA's proposed product standards to prohibit characterizing flavors in all cigars. Before we get started, I will provide you with some details about the process we plan to follow for each speaker. First, as a reminder, we ask each speaker to limit your remarks to five minutes or less. To assist comments with timekeeping, we will notify you at the one-minute remaining mark. In order to be fair and equitable to all speakers, if your remarks can continue past the time limit, you will need to move on to the next speaker so your line will be muted. We recognize there are some strongly held and differing opinions on the product of menthol cigarettes and flavored tobacco, and we look forward to hearing all of your points of view. We ask that all remarks be focused on FDA-proposed product standards to prohibit menthol as characterizing flavor in cigars and to prohibit characterizing flavors in all cigars. At the start of your comment, please clearly state your name and the organization you represent or note that you are speaking in your individual capacity. Let's get started. Once your name is called, you will be unmuted so that you can make your comments. At first, we'll hear from Carol Coram. You have five minutes for your comment, please proceed. Carol Coram.

CAROL CORAM (AMERICAN CANCER SOCIETY CANCER ACTION NETWORK): Good morning from Seattle, Washington. My name is Carol Coram and I am the State Lead Ambassador for the American Cancer Society Cancer Action Network which is the lobbying arm of the American Cancer Society. I'm also a cancer survivor and a former caretaker. I speak to you today as a concerned member of the black community, as an educator, and youth sports advocate. First off, I'd like to thank the FDA for hosting this listening session on a critically important rule. I fully support the prohibition of menthol-flavored cigarettes and cigars and I believe the FDA should do three things. One, finalize these rules quickly, and in such a way that there will be no loopholes or exemptions that could be exploited by the tobacco manufacturers. Two, provide smoking cessation support to those who smoke menthol-flavored cigarettes and cigars in anticipation of when the rules become effective. Three, ensure that equitable enforcement of the rule including clarifying that no law enforcement agency will have the authority to enforce these rules against individual consumers. Tobacco use is the number one cause of cancer in the United States. While my cancer was not caused by tobacco, I certainly do not want anyone to experience being diagnosed with this horrible disease. I believe we should all protect the health and well-being of our youth. We need to work towards a cancer-free world. Prohibiting menthol flavoring in cigarettes and cigars just might be the most important policy of my time that could create a generation of youth who never get addicted to tobacco or worse die from its effects. The tobacco industry appeals to youth through product design and aggressive marketing. The use of menthol is higher for youth, African Americans, the LGBT community, and communities that have limited income. The majority of adult smokers start as kids. Youth who smoke are almost twice as likely to smoke menthol cigarettes than adults over the age of 50. Over 65% of youth smokers ages 12 to 17 use menthol cigarettes and more than 52% of young adults ages 18 to 25 use

menthol cigarettes. It's hard to hear that some of our youth are smoking cigars and the fact is that just over 44 of them smoke flavored cigars. Just over 46% of African American cigar smokers do too. They are twice as likely to smoke cigars as their white counterparts. The availability of menthol-flavored cigarettes and cigars is the number one reason that our young people try smoking in the first place. They often mistakenly believe that flavored tobacco products are less harmful or worse not harmful at all. The reduction of flavored tobacco products and the promotion of cessation programs will also reduce tobacco-related health disparities. That is why I urge the FDA to finalize these rules quickly and as I said earlier, without loopholes and exemptions that could be exploited by the tobacco industry. Thank you so much for the opportunity to speak in support of the FDA rules to prohibit menthol as the characterized flavor in cigarettes and cigars.

NECOLA STAPLES: Thank you. Up next, Gary Ewart. You have up to five minutes for your comment. Please proceed, Gary Ewart.

GARY EWART (AMERICAN THORACIC SOCIETY): Good morning. This is Gary Ewart. Can you hear me? Hello, this is Gary Ewart, can you hear me?

NECOLA STAPLES: Yes. We can, Gary.

GARY EWART (AMERICAN THORACIC SOCIETY): My name is Gary Ewart, and I'm Director of Government Relations for the American Thoracic Society, and I appreciate the opportunity to speak this morning. The American Thoracic Society is a medical professional organization of over 15,000 physician-scientists, nurses and respiratory therapists dedicated to the prevention, detection, treatment, and cure of respiratory disease, critical care illness, and sleep-disordered breathing. That's a fancy way of saying we are lung docs. As lung doctors, we know first-hand the disease, death and destruction caused by tobacco use and it is our professional and moral obligation to reduce the toll tobacco takes on society. For this reason, the American Thoracic Society strongly supports both the proposed menthol cigarette rule and the proposed flavored cigar rule and offers the following comments on these proposed rules. First, flavored tobacco products play an essential role in luring kids into tobacco use. Nine out of 10 adult smokers started smoking tobacco before they were 18 and according to CDC in 2021, 80% of high school students and 74% of middle school students who used tobacco products in the last 30 days reported using a flavored tobacco product during that time. It is clear that the tobacco industry has intentionally used flavored tobacco products to lure children into a lifetime of addiction to deadly tobacco products. Both the proposed rules would take important steps to limit the ability of big tobacco to entice America's youth into smoking. Second, the presence of menthol in cigarettes makes it easier to start smoking and harder to quit. Menthol and cigarettes improves the taste and reduce the harshness of tobacco making initiation easier and consequently quitting harder. By removing menthol from cigarettes, we are taking important steps to improve public health for all Americans. Third, menthol cigarettes and flavored cigars have been intentionally marketed to minority and disenfranchised communities. Therefore, removing menthol cigarettes and flavored cigars from the marketplace will make important contributions to improving health equity in the U.S. Fourth, we encourage FDA to move quickly. Every day that flavored cigars and menthol cigarettes remain in the market is another day the tobacco industry can peddle its deadly products to our kids. We encourage FDA to finalize both rules as quickly as possible, but certainly by the end of calendar year

2022. Fifth, allow no exceptions in either loopholes in (INAUDIBLE). The ATS is pleased that the FDA did not propose a premium cigar exemption in the flavored cigar rule and the ATS strongly agrees with the FDA's definition of a premium cigar and urges FDA to move forward with its proposal to remove characterizing flavors from all cigars. Six, the ATS encourages FDA to extend the menthol flavor ban to all tobacco products under FDA's jurisdiction, including those that have received modified risk or exposure order authorizations. Seventh, the ATS encourages the definition of characterizing flavor to be broad and to include several elements, including flavors must not be found in any component, part, or accessory of the product, including tobacco, paper, filter, or tips. The flavor need not have to be a single or primary characterizing flavor, but simply a characterizing flavor [INAUDIBLE] not include the taste or smell of the product. The flavor cannot be either in the product, the smoke, the aerosol, or the packaging. Neither the product nor itself, nor any component of its marketing, including the package, pictures of words, advertising, and public relations communicates characterizing flavor in any fashion and this should include products with flavor additives sufficient to produce a recognizable flavor, and that the average consumer consider to have a flavor where the name of the flavor does not suggest the flavor but suggest an identifying characteristic such as wild rush or jazz and Seventh, [INAUDIBLE] in conclusion, the ATS believes that both the proposed rules are good public health policy and should be finalized and implemented as soon as possible.

NECOLA STAPLES: Thank you. Up next, Elliott Boyce. You have up to 5 minutes for your comments. Elliott Boyce, please proceed.

ELLIOTT BOYCE: My name is Elliott Boyce, can you hear me? [INAUDIBLE]

NECOLA STAPLES: We can hear.

ELLIOTT BOYCE: My name is Elliott Boyce, I'm a police officer. I've been a police officer for over 30 years. During my 10 years as a police officer, I've served multiple state and local law enforcement task force. I listen to a lot of the comments and the kind of support it this ban. I just need to give some insight on the things is going to happen when this ban goes into effect. The unintended consequences have been heard about this ban. I started an initiative to start to talk to the larger police organizations like Noble Leap and the National Association of Black Law Enforcement Officers and Police Officers around the country are great in concern because the FDA does not have a component on dealing with this ban when it comes to the local end so when you look at it from a police standpoint, the second that this menthol ban goes to effect, cigarettes are going to become contraband and once they become contraband, law enforcement officers will have no choice but to deal with the illicit market. Traditionally, when it comes to communities, which is largely using menthol cigarettes at 85% clip, which is black and Latino communities, it means that enforcement is going to increase and when that increases is going to be dangerous for the individual streets. Previously, in years, we've seen things we have [UNKNOWN] prohibition did not work. Education, treatment, and counseling has been successful for the reduction of cigarette use. I think the thing that We are not seeing is the fact that in counties, in our communities, the police officers have been dangerous and I'm saying that from the perspective of being a police officer. When you think about cigarettes being a contraband because now without the FDA governing this, what's going to happen is state and local laws will put apply, thus meaning young adults and individuals, they'll be arrested for felony and

misdemeanor charges, which creates a real dramatic strain on not only the community but also the police. We also talk about the revenue that's going to be lost. Talking about taxes, you know, the illicit market of menthol cigarettes is a \$3 billion market. You are talking about a loss of tax revenue, that's 3 billion to \$6 billion. We start looking at that, that means resources out of the community. Resources from police departments, thus meaning that We are underserved as it is be increased. Again, as a police officer, though, I do not promote smoking. I do understand that the illicit market now will have cigarettes on the streets. Whose now untaxed cigarettes are coming from overseas. The funding is illicit. It's going to be supporting overseas terrorism, among other things that we've seen that have happened already. I think when you go from a health model you go into a criminal model, what people do not realize is normal citizens will go to the corner store and buy their cigarettes. Now you are going to be forcing them into the streets and buying their cigarettes, that's going to be contraband. That's going to be dangerous for our community. Another thing that happens is what's going to be enforced is going to be federal task force. Federal task force looks like city, local, and state agencies put together with federal police officers and that means federal charges so our citizens that have chosen to smoke cigarettes will now be likely to be charged with federal crimes. Federal crimes increase the amount of sentences when it comes to being arrested for some expenses that had the dealt with cigarettes. That's really dangerous. It's called RICO. Many of U.S. remember Rico from the cracker so that's one of the things that they are concerned. When you talk about health. I've known for years that urban centers, particularly the largest cities, the health disparity really comes from the lack of health care, adequate health care within our communities so we have to take that into account. For this ruling to be really effective, we need to do an impact study, should be done on what are the things that's going to happen, things like the loss of tax revenue, health issues that we know disparity. I did a reading on [INAUDIBLE] says the number one cause of death is cancer-related illnesses but this cancer rate of illnesses or individuals over the age of 65. Meanwhile, the number one cause of death for our community, particularly black males between ages 12 to 19, is homicides directly related to gang activities across the state and across the country. We have to be aware fully that this thing is dangerous. It can be very dangerous. I support taking care of our young adults and our youth but once contraband hits the streets, it's going to be unregulated. It's going to be uncontrolled. Law enforcement across the country who I've spoken to, black, white, green, and across the board are basically saying they do not have anything to do with regulating. I strongly suggest reports through a impact study or what's going to affect or how it's going to affect the communities. We do not need any additional police. Understand that, a drug sale and a cigarette transaction look the same in law enforcement. (INAUDIBLE). Thank you.

NECOLA STAPLES: Up next, Edgar Domenech. Edgar Domenech.

EDGAR DOMENECH: Good morning.

NECOLA STAPLES: Good morning.

EDGAR DOMENECH: My name is Edgar Domenech. I'm a retired law enforcement official and I want to thank you for the opportunity to speak this morning. The [UNKNOWN] that I have are that the proposals being considered without the input of a significant stakeholder. That being the law enforcement community. Addressing their health concerns by FDA are valid but in this area, law enforcement needs a voice to ensure that implementation doesn't

create an enormous revenue stream for organized crime groups and indirectly terrorist entities. In 2015, the U.S. State Department, under President Obama issued a report that stated illicit tobacco was a national security threat so, how can the FDA propose these significant changes to the tobacco regulations without engaging the law enforcement community to understand the repercussions of these new regulations? Presently, there is no one federal agency that has a comprehensive strategy to combat the illicit tobacco activity, leaving it to state and local law enforcement to combat this significant threat. As the former Director, Deputy Director, I'm sorry, former Deputy Director of ATF, and former sheriff of New York City, I have first-hand knowledge and I've seen the challenges when there is no unified law enforcement strategy. These proposals without law enforcement input will only exasperate the situation for law enforcement. Illicit tobacco trafficking is part of the underground economy that is in fact a reality. Over 60% of the cigarettes uncovered by law enforcement in New York City are either counterfeit or untaxed and illicit tobacco products. The proposal is creating a perfect storm for organized crime groups to further entrench themselves in the illicit tobacco industry. While the regulated industry will adhere to the new regulations, the reality is that organized crime groups will saturate the market with illegitimate and unregulated tobacco products. I would hope that the FDA considers bringing law enforcement to the table so that a viable law enforcement strategy can be part and part of the proposal moving forward. Thank you very much for giving me the opportunity to speak this morning. Thank you.

NECOLA STAPLES: Thank you. Up next, Catherine Beane you have up to 5 minutes for your comment. Please proceed. Catherine Beane.

CATHERINE BEANE (YWCA USA): Good morning. I'm Catherine Beane the senior vice president for Public Policy and advocacy at YWCA USA. Thank you for the opportunity to speak today in support of the FDA's proposed rules to prohibit menthol cigarettes and flavored cigars. For over 160 years, YWCA has been on a mission to eliminate racism, empower women, and promote peace, justice, freedom, and dignity for all. YWCA is also located in more than 1200 communities across the country, serving as many as 2.3 million women, girls, and family members of all ages and backgrounds in a typical year and partnering with law enforcement in our domestic violence work. We've been at the forefront of the most pressing social movements throughout our history, from voting rights to civil rights and violence prevention to health care reform. Notably and particularly relevant to the subject of today's listening session, the YWCA network provides an array of health and wellness programs and services which reach more than 310,000 people in 2020. 88.7% of whom were people of color. 65.9% of whom were women and girls and 16.6% of whom had incomes at or below the federal poverty lines. Smoking cessation classes, resources, and programs are offered in many local YWCAs from right here in Washington, D.C., all the way to Anchorage, Alaska. In my time this morning, I will highlight two key areas that are among the issues that we will be further discussing in written comments that we will submit through the notice and comment process. First, the proposed rules to prohibit menthol cigarettes and flavored cigars are specifically tailored to block known pathways to tobacco addiction among youth and women. As clearly documented in the Campaign for Tobacco-Free Kids Report, *A Lifetime of Damage*, the tobacco industry's long history of predatory marketing, has contributed to the addiction of millions of women and girls, to tobacco products with serious health consequences on such things as youth brain and lung development, reproductive and cardiovascular health, and the development of chronic and

life-threatening disease. The report documents marketing practices that include explicitly linking tobacco products to perceptions of femininity and liberation. The proliferation of disinformation regarding low tar and light cigarettes as safer alternatives and advertising targeted towards black women and Latinas and the Digital Age, the same kinds of predatory practices are on full display, continuing to exploit, quote, the aspirations, body image concerns, and perceived insecurities of women and girls to sell them an addictive and deadly product. The proposed rules place responsibility precisely where it belongs with the tobacco industry that has aggressively targeted women, girls, and people of color in its marketing, and that has knowingly and intentionally placed sales and profit over scientifically documented health risks. Second, my second key point here is that rather than prohibiting individual consumer possession or use, FDA's enforcement of the product standards will be limited to manufacturers, distributors, wholesalers, importers, and retailers. As designed, the proposed rules should not contribute to or escalate criminalization of people of color, which is a longstanding focus of YWCA racial justice work. YWCA urges the FDA to continue to make this clear and to work with relevant agencies, including the Departments of Justice, Education and Health and Human Services, to provide guidance, training, and technical assistance to local, state, and federal law enforcement agencies, including school resource officers, so that youth and people of color are not criminalized for any individual possession or use of menthol cigarettes or flavored cigars. Finally, in closing, I think it's incumbent upon U.S. to recognize that blocking pathways to tobacco addiction is about more than statistics. It is about real lives, real families, and real impacts across generations. Like so many, I've seen first-hand the devastating health impacts of menthol products on women whom I care about and who I loved. My grandmother, who died in her mid-fifties from emphysema lung cancer due to smoking. She only had one lung left when she passed away. My mother-in-law and my childhood caretaker, both black women who smoked menthol products for decades, which contributed to the high blood pressure, stroke, and Alzheimer's disease that took their lives. My 52-year-old neighbor and friend who suffered with emphysema even as breast cancer took her life. I remember crying as a child about my father's daily smoking habit that eventually contributed to his death from a stroke at the much too early age of 60 but despite this, I didn't recognize the onramp to teen nicotine addiction posed by flavored tobacco products in time to intervene and prevent my own son's now daily habit, thus endangering the health and well-being of yet another generation just within my own family. The proposed rules are an important step.

NECOLA STAPLES: Thank you. Up next, Ashtok Patel. Ashtok Patel, you have up to 5 minutes for your comment. Please proceed. Ashtok Patel? OK. Ella Paligo, you have up to 5 minutes for your comment. Please proceed. Ella Gallagher.

ELLA PALIGO (TENNESSEE DEPARTMENT OF HEALTH AND TOBACCO-FREE KIDS): Hello. My name is Ella Paligo and I am a rising senior that attends Beach High School in Hendersonville, Tennessee. I currently serve as an Ambassador for the Tennessee Department of Health and Tobacco-Free Kids, as well as a mental health chair for my local students taking a right stand or within my high school. I am passionate about public health, equity, and protecting our youth. There is a quote by Coretta Scott King that I will encourage you to ponder today as you hear the different testimonies. King states, "It doesn't matter how strong your opinions are. If you do not use your power for positive change, you are indeed part of the problem." The Food and Drug Administration has the power of how that can be used to protect and

save the lives of thousands. I am begging you to no longer be part of the problem, but instead, be the solution. I started my journey with tobacco prevention my freshman year of high school. Overnight, I began to witness my friends, classmates, and peers get addicted to the harmful substance. Things such as vapes, e-cigarettes, cigarettes and other tobacco products such as cigars even during... through our young age. While I did not take note of the addiction until high school, it was as early as sixth grade when my classmates at school began using these items. They were fed a lie. They were told that these products were safe and that since they were flavored, they could not cause any significant harm. I have watched my friends get sick, have decreased performance in sports, suffer significant mental health effects and become reliant upon these products. They were roped in by the marketing tactics from Big Tobacco, most specifically the flavors. The FDA made a historic decision by banning flavored vape products, but we are not done yet. It is crucial that the FDA bans menthol-flavored cigarettes and flavored cigars. The banning of menthol-flavored cigarettes and cigars would greatly save lives and reduce health disparities and most importantly, it will protect kids from tobacco addiction. Half of all kids who have ever tried smoking started with mint menthol cigarettes, and 41% of all current high school smokers use menthol cigarettes. This step, if taken by the FDA, will protect my friends, the people that I'm here for. I'm here today because I want my friends to have a future and a chance. We will no longer stay silent as youth and minorities are targeted by Big Tobacco. I also would like to note that it is crucial that we focus on rehabilitation rather than punishment. Much too often, youth are criminalized without getting the help that they desperately need. We need to help our youth and not punish them. That is one of the most important things that we need to take away from today. I urge the FDA to remember that they are a federal agency of the Department of Health and Human Services. I am asking you to serve the needs of youth and please just protect your health. Please ban menthol-flavored cigarettes and cigars. Thank you.

NECOLA STAPLES: Thank you. Up next. Minister King Pyeface. Minister King Pyeface. You have 5 minutes for your comments. Please proceed.

MINISTER KING PYEFACE: This is Minister King. Can you hear me?

NECOLA STAPLES: We sure can.

MINSTER KING PYEFACE: So my name is Minister King X, also known as Pyeface. I'm a community activist. I'm also a returning citizen so tobacco hit me directly. My mother died of tobacco. From cancer so I was sitting here thinking about not talking at first, and then I start thinking about some of the things that were spoken here from some of the men and women, ladies and gentlemen here today and I'm always out in the community as an activist, bolstering the stories of the people and I'm always thinking about half the people I look at the unhoused and how sometimes they do not have nothing to hold on to except their freedom, their freedom of use, the freedom of thought and sometimes they sit there on the [UNKNOWN] and they smoke their tobacco, just like the chief used to use tobacco was medicine. You know, the government legalized medical marijuana as a profit and this is like a political chokehold. Pun intended. Eric Garner died from the framework in the booby traps that was delivered and we think about people, humanity, share humanity. We think about these roles and these policies and procedure that invade people's space and we think about the black and brown. Brothers and sisters as always talking about their struggles and

then we look [UNKNOWN] more positive procedures just go snatch away whatever little bit of liberty that you have and I say stop criminalizing freedom of use because nobody has the right to regulate anybody else's space. We think about the situation of how we want to end and stop mass incarceration or stop solitary confinement but then I remember being in prison when they eradicated the use of tobacco. Well, if you do not get rid of menthol, you got to get rid of all. You can't just discriminate on menthol. It became implicit and you think about the people that's going to go into the underground use of selling menthol and what it does is create a public nuisance, right, so you have a person in front of the store, his energy, but he probably does not have the job skill or the vocation so we decided to sell a cigarette for a dollar. Next thing you know, he loses his life. He can't breathe. She can't breathe so these are the things we could use these big political words and use this political chokehold you talk about but the reality is, we talk more people lives, we talk more use, we talk more. What can happen afterwards once the policy and procedure change, when you have these underground activities going on and next thing you know, it become a contradiction of been there to this. How do you stop a mass incarceration? So again, it directly affects me in the issue where family and community ties and also directly affects others like the unhoused, when we know that they are going to be out here with this. Because that's their free will so how can we create something and then snatch it away without an alternative? What kind of programs are going to be implemented afterwards? So those are just some of the things I think that we should think about as humans. Again, my name is Minister (UNKNOWN). I'm the Director of California Prison Folk's.

TRACY GALLOWAY: Thank you for your comments. Hello. My name is Tracy Galloway from the FDA. Up next, we have Janet Williams. Please state your name and organization or share that you are speaking as an individual. Janet Williams, you have 5 minutes... Janet Williams you have up to 5 minutes for your comment. Please proceed.

JANET WILLIAMS (RESPIRTORY HEALTH ASSOCIATION): Hi. Thank you. Can you hear me?

TRACY GALLOWAY: Yes.

JANET WILLIAMS (RESPIRTORY HEALTH ASSOCIATION): Excellent so, hello. My name is Janet Williams, and I'm speaking today on behalf of the Respiratory Health Association, a public health leader in Illinois since 1906. Respiratory Health Association's mission is to prevent the medical, social and economic cost of lung disease through education, research, research and policy change. I have more than 30 years of public health program and policy development experience, including my time as Director of Tobacco Control and Prevention for the Cook County Department of Public Health. I currently work for a physician led association, and I work with clinical practices and health systems on improving prevention at the clinical and community levels. Thank you for the opportunity to provide comments today on the FDA's proposed rule to eliminate menthol from cigarettes and cigars. This rule is a long time coming, by my estimates, it's been at least ten years when the FDA could have and should have done something. The evidence was clear then and it's clear now. Menthol serves one purpose. It makes smoking less harsh. It works as an anesthetic and diminishes the burning sensation and Big Tobacco knew this. They also knew they could use this smooth smoke to appeal to black people who smoke at lower rates than whites. The industry heavily marketed their menthol cigarettes to a population that is historically impacted by negative health consequences associated with tobacco use and although black Americans smoke

fewer cigarettes and start smoking cigarettes at an older age, they are more likely to die from smoking-related diseases. Lung cancer rates are higher in black men than white men. I feel it's important to reiterate some of these startling impact data we've heard today. Sales of menthol-flavored cigarettes made up 37% of all cigarette sales in the U.S., the highest proportion since major tobacco companies were first required to report this data in 1967. Flavored cigars are making smoke make smoking more palatable, especially for youth. A report on menthol and flavored cigars from Tobacco-Free Kids reports that in 2020, cigars were the most commonly used tobacco product among black high school students. Tobacco companies aren't just targeting black individuals, they are targeting LGBTQ smokers. From the National Institute of Health, menthol use was significantly higher among LGBT smokers, with a 36% reporting that cigarettes they usually smoke were menthol, compared to 29% of heterosexual straight smokers. Tobacco companies prey on people, especially in historically marginalized communities, by perpetuating advertising marketing discounts and accessibility in those communities. We know that rates of chronic health conditions are higher in black individuals, COPD, asthma and heart disease as well as type two diabetes. The Respiratory Health Association concurs with the FDA's findings and the provisions in the proposed rules. We agree that individuals should not be targeted for violations. The focus should be on manufacturers, marketers, importers and distributors. We are concerned that the FDA leaves the door open for a wide variety of exemptions. If history has taught U.S. anything about Big Tobacco is that they are already most likely prepared to create a product or products that mimic menthol appeal. We asked the FDA to unequivocally confirm that menthol in its derivatives be prohibited from use in any combustible tobacco product and we also ask FDA to eliminate exemptions for flavored cigars. My father died at 42 years old, leaving my mom a widow at 34 with two small children. My father smoked three packs of Salem's a day and preparing my testimony, I learned that Salem's were the first menthol filter tip cigarette launched by R.J. Reynolds in 1956. My father would be dead in 1963. When my father died, the medical community had little evidence about the deadly impact of cigarettes. Today, we know that devastating consequences. This is no time for inaction. Smoking is not good for anyone and any component flavors that makes it easier for people to become addicted is predatory and problematic. The impact of smoking is cumulative, and health consequences take years to progress. While addiction can occur much sooner, that is why FDA needs to act now, not next year. FDA has dragged its feet for far too long. For more than ten years. Please continue the work that needs to happen to ban menthol and cigarettes and flavored cigars. Thank you for your time.

TRACY GALLOWAY: Thank you and up next, we'll have Charlie Gagan. Charlie Gagan, you have up to about 5 Minutes to provide your comment.

CHARLIE GAGAN (AMERICAN LUNG ASSOCIATION): Hi. My name is Charlie Gagan. I am a community tobacco advocate in Austin, Texas, as well as the State Advocacy Director for the American Lung Association. I'm here today in support of the proposed rules on menthol flavoring and flavored cigars, and I appreciate the opportunity for public comment. As you consider my comments, I urge you to finalize these rules before the end of this year in order to save lives. As you know, the tobacco industry has long targeted black and other specific population groups with their products, leading to significant health disparities. Menthol cigarettes make it easier to start smoking and harder to quit, robbing families of their loved ones and contributing to lost wages, lost lives and lost productivity, not to mention substantial health care costs. Several years ago, we removed flavored cigarettes from the

market but left menthol leading to thousands more deaths. It is time to rectify that mistake and remove all menthol cigarettes from the marketplace, even those that have received modified or reduced risk authorizations. In Texas, specifically, more than 40% of calls the state quitline or from individuals who smoke menthol cigarettes. These people never intended to become lifetime smokers and are asking for help but as long as these products are on the market and their gas stations and grocery stores, they will continue to struggle with addiction, disease and death. This rule will increase cessation among menthol smokers and especially black menthol smokers. I also urge you to keep in mind the next generation, our kids. I remember when I was in high school, I tried tobacco-flavored cigarettes and couldn't stand the flavor, not to mention the burn, but those menthols and crushed cigarettes, they were just smoother and they smelled better. I count myself incredibly fortunate not to have developed an addiction like so many others. I count myself fortunate the tobacco industry wasn't developing products and marketing campaigns aimed directly at me and my community. A white male but many of my friends were not so lucky and what started as teenage experimenting has now led to decades of smoking. They are replacing the older generation who have already died. In addition to supporting the menthol rule, I joined the American Lung Association in strongly supporting the flavored cigar rule and encourage you to remove all flavored cigars, including flavored hookah and pipe tobacco from the marketplace and finalize the rule by the end of 2022. Like menthol-flavored cigars, as well as flavored hookah and other flavored tobacco products are marketed toward an easy initiation of smoking among teens. As a teen myself, I remember thinking, obviously the cigarettes are bad, but this watermelon-flavored hookah surely it's safer, right. These days, the flavors aren't even obvious. Instead of watermelon and grape, there is ice and tiger but they continue to serve the same purpose. To make smoking smoother and attract teens and those who would not otherwise smoke. I also want to iterate the importance of including premium cigars in this rule. The term premium is devised by the industry to circumvent regulations established for all tobacco products by the FDA. Premium cigars are not inherently less risky than other cigars and should not be exempt from this rule. Finally, as we finalize these rules, I urge you to be creative and remember how the tobacco industry operates. Make your definitions broad and think of what products might create loopholes. For example, the flavor should apply to any part of the product be it the tobacco, the filter, flavor, pellets, etc. It need not be defining, but merely characterizing flavor. It should include the taste or the smell. The product include whether it's present in the product or just a smoke or aerosol. In short, be as broad as possible to avoid companies evading the intent and what is that intent? To save lives so please, let's leave minty menthol to chewing gum in toothpaste and flavors to actual candies and dessert. Not cancer-causing products that kill hundreds of thousands every year. Thank you.

TRACY GALLOWAY: Thank you. Up next, we have Julia Choi. Julia Choi, you have up to 5 minutes for your comments. Please proceed.

JULIA CHOI: Can you hear me?

TRACY GALLOWAY: Yes.

JULIA CHOI: Oh, Hi. My name is Julia Choi and I'm a freshman at South High School. I strongly support this policy in prohibiting menthol cigarettes and flavored cigars for the safety of our community. The uses of these products has drastically increased and is

continuing to affect the lives of many adolescents. Especially in society today, using these cigarettes have become a new norm or a trend that more and more youths are following. As a result, I saw my community falling into this mindset that these cigars did not harm their health. As a result, it's no longer surprising seeing some of our peers using these products. It's no longer a surprise seeing these tobacco shops being located just a few blocks away from schools. Without this policy, it will be an indication to U.S. students that there are no problems with using these products. Thank you.

TRACY GALLOWAY: Thank you. Up next, we have Patricia Nez Henderson. Patricia Nez Henderson. You have up to 5 minutes for your comment. Please proceed. Patricia Nez Henderson? Patricia Nez Henderson. Up next, we have Anthony Carothers. Anthony Carothers, you have up to 5 minutes to present your comment. Please proceed. Anthony Carothers?

ANTHONY CAROTHERS: Hello? Can you hear me?

TRACY GALLOWAY: Yes, we can.

ANTHONY CAROTHERS: Thank you. First of all, thank you so much for allowing me to be here and speak today. Speaking as a person who's former law enforcement, I spent four years as a Chicago... well Cook County Deputy Sheriff, and I also spent 28 years with the Chicago Police Department so I'm speaking purely from a law enforcement perspective. [INAUDIBLE] In those years I've worked as a patrol officer all the way through the rank of commander in working undercover capacity. I've always had a high interaction with the public. I can tell you that I understand the concept, of what you are saying but the fact of the matter is. You already have... We are not talking about creating a problem as far as crime in menthol cigarettes. It's already here. Most people just do not know about it. They do not know that it's a multi-million billion-dollar industry, illegal right now. Now, as it stands today, people have a higher price for cigarettes. You can cross our border, you can cross to the county across the state and buy cheaper and then they sell them so you can buy a pack at some places for \$10, but you can go across the border and possibly buy for seven and then sell them for \$1, \$2, or \$3 each. I've seen it happen. I've watched it happen. I have watched [UNKNOWN] we used to call dope lines or drug lines and I turned over to investigate. Came to find out, there was some marijuana being sold but there is also loose cigarettes being sold. I'd like to tell you that for the people who say that We are doing it for the children, was a man who's been in law enforcement all these years. A black male who's past 60. All of my life I was told, we were told, that marijuana is a gateway drug to other drugs. That was fine and good until about the past ten years. Well, now you have at least 30 plus states that have some form of marijuana law available and at least 21 states that have recreational marijuana allowed. As a rule, bans are not...Not effective. In Chicago in 1982, there was a ban - and still exists a ban - on gun stores working within the city limits and it was done to help curb violence. Well, I think that most people who know anything about Chicago, that hasn't worked well. What it did do? As a law enforcement colleague said earlier, taxes that could have been collected from law enforcement officers, security officers, private citizens, people have a lawful right to have guns and ammunition and all of these that go along with it are now going to a suburb or wherever outside the city. Bans... In 2012, the detergent pod became a new thing and a lot of people liked it, a lot of people used it and the problem with it was it was a pretty color and it had a feel and texture where children put them in their

mouths. A lot of children were sick, they were rushed to hospitals, rushed to emergency rooms. Horrible situation but then that industry, millions of dollars was spent in public service announcements and in newspapers and in magazine articles and changing the locks, the caps on these to make it hard for children to open but they weren't banned. We banned alcohol for 13 years many, many years ago for a lot of good and noble reasons. The fact of the matter is, hundreds of millions of dollars were created illegally. Thousands of people were injured, shot, killed during that time of prohibition. The best thing to do is like you've already done, is that education, explaining to people why they should not use the product if that's what you believe and let me be clear about something that I've heard too many times, people talk about young people using smoking cigars. Let me tell you how I've watched young people in gas stations and the like and they've done this... (MUSIC PLAYS) Truth of the matter is, what they've done is they take the cigar, empty out the tobacco and fill it with marijuana so, do not think that all the young people running around are smoking flavored cigars. They are using the wrapper to use for marijuana. I do not want to be too repetitive. There is so many things I could say but again, a lot of my law enforcement colleagues have already spoken about it, the loss of revenue to the cities, councils and states I think is extremely uncommon and how would you recoup that money? Normally, property tax is the only thing they can go after. You want to collect the tax from something, a revenue that you can use positively and then ban that item. It's illogical. I can't understand it, I never could but as for the law enforcement part, please keep in mind this is already a large situation, is only going to be worse. Thank you so much for your time.

TRACY GALLOWAY: Thank you. Up next, we'll go back to Miss Patricia Nez Henderson, we had some technical difficulties earlier so, Miss Patricia Nez Henderson you have up to 5 minutes for your comment. Please proceed. Patricia Nez Henderson?

PATRICIA NEZ HENDERSON: (SPEAKS AN INDIGENOUS LANGUAGE) Good morning everyone, I'm calling from the beautiful lands of the Black Hills, the homes of the Lakota, Nakota, Dakota people. Again, I've been listening to the conversation this morning and I just have a couple of comments. I'm calling in as an advocate. I'm a scientist by training, but as an advocate. I was born and raised on the Navajo Nation, where my grandfathers used ceremonial tobacco, (SPEAKS AN INDIGENOUS LANGUAGE) in all forms of ceremonies in cultural settings but what has happened over the years is that the tobacco industry has come into our communities. First of all, they stole our tobacco. Number one, they stole our tobacco and, you know, mass produced it and now it's all over the world, a product that was sacred to us so, today I'm asking the FDA to move forward on this proposed ruling. I was a member of [UNKNOWN] in 2011 when we proposed to ban all forms of menthol products, including cigarettes and We are still waiting so many lives have been lost up to this point because that ruling has not moved forward and in order to establish (SPEAKS AN INDIGENOUS LANGUAGE) which in the Navajo language is balance, we have to do something about it. Children are becoming addicted to cigarettes. People are losing their lives because they are addicted to cigarettes and the science is clear. We know my colleagues have done all the work to say that menthol cigarettes are not healthy for our communities. How much more are we going to wait? How long are we going to wait? Another ten years? I think not. You know, these products specifically target people of color and I'm a person of color and I have family members that are smokers that are using menthol products so, I'm coming to you as a mother, as a sister to move forward with this proposed legislation or to propose... I'm sorry, for what is happening right now. I'm sorry and I just encourage you to really look

at the science and create a community that is based on (SPEAKS AN INDIGENOUS LANGUAGE), the philosophy of balance and I just want to thank all of you. I'm doing this because our tobacco is sacred, number one and We are here to really advocate for our tobacco products to be eliminated, these commercial tobacco products, and restore what is important to us, which is sacred tobacco. Thank you.

TRACY GALLOWAY: Thank you. Up next, we have Daniel Lee. Daniel Lee, you have up to five minutes for your comments. Please proceed. Daniel Lee. Daniel Lee. Up next, we have Justin Berry. Justin Berry. You have up to 5 minutes for your comments. Please proceed. Justin Berry. Justin Berry. Up next, we have Lorraine Taylor. Lorraine Taylor, you have 5 minutes for your comment. Please proceed.

LORRAINE TAYLOR: Hello, good morning. My name is Lorraine and, as a person of color, I do not want to make this about race. Yes, my own race has (UNKNOWN). We have our own challenges as black and brown people, fights that we deal with every single day as people. We fight among ourselves. We do not always agree and this is one of those moments. You hear from a small group of black and brown advocates that (UNKNOWN), but have you truly considered what the [UNKNOWN] majority that do smoke think? Have you asked U.S. those questions of why? No, you haven't and shame on you and the Biden administration, who is already on historic lows among people of color for not listening to us. The American Cancer Society, Tobacco-Free Kids, etcetera, was supposed to make this about the youth. How did it become to adults who are 18 and up, who are legally supposed to make our own decisions. Like we have opposed this ban, maybe in the minority and it's a slippery slope to fight but this is my own right to ask you to stop and listen to the people who are impacted by this, both on businesses and [UNKNOWN] had already hurt our communities, the black and brown and now you want to take our free choice to smoke what makes me happy without going to cannabis or other cultural ways? Because you are not listening to us so, please just do not ban menthol. Thank you.

TRACY GALLOWAY: Thank you. Up next, we have Edward Longe. Edward Longe, you have up to five minutes for your comments. Please proceed. Edward.

EDWARD LONGE (AMERICAN CONSUMER INSTITUTE): Hello. My name is Edward Longe and I'm a Policy Manager at the American Consumer Institute. We are a 501 C3 nonpartisan educational public policy research organization with a mission to identify, analyse and protect the interests of consumers in selected legislative and rulemaking proceedings. While disincentivizing the use of harmful combustible products is usually good policy in the interest of public health, we are deeply concerned that the prohibition of flavored menthol products and flavored cigars is not adequately paired with measures to help smokers transition to less harmful alternatives, with the view to them completely quitting. By failing to provide consumers with this alternative path, we believe the Food and Drug Administration is not empowering smokers with the tools necessary to stop. We are also concerned that a prohibition on flavored menthol products and flavored cigars will force consumers to purchase unsafe and unregulated products on the black market. This will not only lead to poorer public health outcomes, but could see further criminalization among African Americans who use menthol cigarettes at higher rates than other groups. As the Food and Drug Administration moves forward with rulemaking, I would encourage the agency to consider measures such as allowing greater access to electronic cigarettes and

non-combustible products that have been scientifically shown to help smokers quit and lead healthier lifestyles. In approaching public health questions in this way, in a way that follows the science as opposed to ineffective prohibitions, we believe the FDA will be better placed to meet its mission of protecting public health. We look forward to working with you in crafting regulatory environment that incentivizes Americans to quit smoking. Thank you.

TRACY GALLOWAY: Thank you. Up next, we have John Clymer. John Clymer, you have up to five minutes for your comments. Please proceed. John Clymer. John Clymer. Up next, we have Lindsey Stroud. Lindsey Stroud, you have up to five minutes for your comments. Please proceed. Lindsey Stroud. Lindsey Stroud. Up next, we have Lester Hartman. Lester Hartman, you have up to five minutes for your comments. Please proceed. Lester Hartman. Lester Hartman. Up next, we have Henry Ortiz. Henry Ortiz, you have up to five minutes for your comment. Please proceed.

HENRY ORTIZ: Hi. My name is Henry Ortiz. I'm here to talk about the tobacco ban and the negative impact it's going to on our black and brown people in regards to U.S. becoming hyper-criminalized because whether we like it or not, this product is still going to be available, but [UNKNOWN] now in the black market where it won't be regulated so, we do not know what kind of substances are going to be put out there, right? People are going to have to pay double. Because the reality is we suffer from severe stress and trauma of being abused by these systems every day of petty policies, of harsh sentencing laws that make our lives so stressful every day, just to go to work and that is a challenge. Just to get up is a challenge. We suffer from severe anxiety and different disorders and, you know, legalizing cannabis has helped a lot of our population because we suffer from so much severe stress. We do not like relying on these pharmaceutical medications that are leading to severe addictions and creating a big public health issue in our communities. We want our people rather smoke something to deal with those anxieties, something that's at this point legalized to cope so, you really need to have a conversation with the people that that use these. You know, this type of smoking practices to overcome the stressors that they face every day and surviving, you know, in our communities and this is also going to create more barriers, people now, you know, getting arrested and criminalized, especially our young people. You know, as they are already doing so with getting caught with cannabis or whatever, right? Of course, we want to keep our communities healthy. We want to keep our youth healthy but, you know, making policies that are ill informed and are not considering those that are actually impacted, those people, those communities that are actually in the streets that are going to see the ripple effect in those communities that always are left in the shadow, you know. I'm here on their behalf to tell you that this is going to have ripple effects on our community, because now you are causing U.S. to even seek other addictions to cope with the stress or the anxieties and that's something that we need to prevent at this point in time with the public health crisis is that We are already currently suffering. To take any other substances that can reduce stress and anxiety on people, you know, that it's the only remedy that some of these people can find, you know, because as you can see, our people are suffering from historical trauma of racism constantly and then there is also, you know, relationship issues. There are job related issues. We live very stressful lives every day surviving and, you know, having what we need, you know, to cope with that is sometimes the only thing that gets U.S. by through life and so, we need to be considerate of our people so that we do not create another public health crisis that leads now to, you know, black market products that are not regulated by the FDA. They are still going to make it to true to

the hands of the community, only now at double price and true that might cause them to go seek other severe, you know, addictions to compensate with those anxieties, those disorders, the PTSD and I tell you this. As a formerly incarcerated person who spent half of my life in prison and I've work with all kinds of gentlemen who've had all kinds of addictions and I've got to do work on trauma and healing and gotten to identify the root causes and a lot of the reasons were these addictions were childhood trauma, systemic abuse, and long flight of flight thinking that has people on edge and so, if people do not get, you know, something that could come, that edginess people have... (MUSIC PLAYS) depression so, you know, on behalf of the common citizen, on behalf of the black and brown people that are constantly being targeted by policies that are never considering them at the table, I'm here on the table on their behalf to ask that you consider our voices in our community's needs. Because you are just going to create another bigger public health crisis because you are not evaluating the bigger impact, the macro impact in this issue so, thank you for your time. I hope that you that you all consider, you know, our proposal and our concerns in this matter. (UNKNOWN). Thank you.

TRACY GALLOWAY: Thank you. Up next, we'll hear from Charles Billups. Charles Billups, you have up to five minutes for your comments. Please proceed. Charles Billups?

CHARLES BILLUPS: Yes. Can you hear me?

TRACY GALLOWAY: Yes, we can.

CHARLES BILLUPS (THE GUARDIANS): Alright, great. Thank you and thank you for giving me the time to speak. I'm coming on as a law enforcement person with over 25, close to 30 years of law enforcement and I represent a large law enforcement, fraternal organization here in New York State called The Guardians. It is a concern for us. Now, keep this in mind, we are not promoting people to smoke and stuff, but we do understand the consequences that comes out of this. Right now, our main concern is, is putting the menthol in prohibition where it becomes illegal, because our main concern as law enforcement, particularly here in New York City, is that our concern is trying to create another issue around Eric Garner. We do not want to see another one and we do not want officers being involved in those kind of situations. So, those are some of the main concerns we are having about the idea of putting menthol in prohibition and the idea of realizing that over the years it's been shown and proven that through education and studies and also through conversations, the numbers of people who have stopped smoking has decreased by such numbers so, the sort of question comes up now is that why aren't we trying to continue that or at least put more information and definitely more tools out there in the idea of generating more education to teach people how to stop smoking versus trying to criminalize it? I mean, one of the main concerns is that the numbers of our black and brown people who will be affected here in New York City particularly, will go up. The numbers of people that are actually, will be locked up will probably go up because the idea of selling an illicit cigarette so, those are some of the main concerns we are having today. I mean, this is one of the reasons why we are hoping that they will put a pause on U.S. and think this over properly and talk to the right people and have real conversations around the concern, because we do not want to see this happen because it affected our communities and law enforcement do not want to be out there chasing behind people over selling loosies. I mean, we truly believe that a pause should be in effect right now and more conversation should be dealt with in the idea

of dealing with this situation. I mean, I heard from the other law enforcement people who came on and I mirror and echo the same thing they are saying, which is true. This is something that should be included, and everyone should be at the table to talk about it. I'm not going to keep it any longer or stress this out. I just want to thank you for giving me the opportunity to speak.

TRACY GALLOWAY: Thank you. Up next, we have Dakari Tucker. You have up to five minutes for your comments. Please proceed. Dakari Tucker. Dakari Tucker. Up next, we have Stanton Glantz. You have up to five minutes for your comments. Please proceed. Stanton Glantz. Stanton Glantz. Up next, we have Peter Krueger. Peter Krueger, you have up to five minutes for your comment. Please proceed.

PETER KRUEGER (NEVADA PETROLEUM MARKETERS AND CONVENIENCE STORE ASSOCIATION): Hi. Good afternoon. I am Peter Krueger, state and Executive for the Nevada Petroleum Marketers and Convenience Store Association. We are a state-wide trade group and represents Nevada liquid fuel distributors, [INAUDIBLE] Our mission is simple, to advance the role of our members as a positive contributor to the economic, social and philanthropic well-being of the communities we serve. Convenience stores and fuel distributors are critical components of the Nevada economy, with stations and stores in every county. Nevada has more than 1,200 fuel stores, employing more than 18,000 employees, with annual gross sales in the excess of \$4.7 billion. As a state association such as ours, we help prevent the sale of underage products. With the help and resources of the National Association of Convenience Stores, We Card Program and State and Local Health Agencies, we provide retail awareness and training for our members. [INAUDIBLE] and digital materials such as We Card, train new employees and proper age verification techniques, how to store and safely store tobacco products and have the proper signage in their stores.

New and online electronic age verification tools such as True Age are being designed to help our sister employees detectives stop underage customers from buying tobacco products nationally and in Nevada. Our efforts are helping to reduce underage purchase of tobacco products. The Nevada tobacco retailers are the first line of defense in preventing underage sales, and I'm proud of our members efforts. Retailers have been the key to reducing underage tobacco use. Today, according to the National Survey of Drug Use and Health, youth smoking rate is 1.3%, the lowest in the generation.

The rate is even lower for the use of menthol cigarettes. About eight tenths of 1% and youth use of cigars is also less than 1% of eight tenths, a record low. None of this progress could have been made possible without retailers checking IDs and stopping kids from access to tobacco products. That's why it is so important to keep these products and remain in license than regulate the stores. Nevada is a well regulated tax system, it's working. It starts with manufacturers who are subject to your ingredient disclosures and product and facility oversight, tax compliance and product control at the wholesale level. Age and [INAUDIBLE] at 21 and over and FDA oversight have the ability to remove non-compliant products. Menthol and flavored cigar market has broad consumer base. Menthol accounts for roughly 30% of all cigarettes and flavored cigar markets are roughly 50%. That's according to a 2019 report. If retailers are removed from the menthol, cigarette and flavored cigar market, who will prevent underage sales, check IDs and ensure that only FDA approved products are

sold? Users of menthol and flavored cigarettes will not simply just quit. In many cases, they'll turn to black market and other illicit markets to find their product.

Nevada knows from experience, especially in Las Vegas, where a large black market distribution system has existed, FDA proposed regulations will only exacerbate this problem. Black and gray market sellers will sell to anyone. Black market purveyors sold products in [INAUDIBLE] about how the [INAUDIBLE] threat to public health and are not under FDA scrutiny. We know from the 1930s that prohibition does not work for a product that has marketed and de marketed and has a large existing user base. My experience of working in tobacco, more than 30 years, tells me that users will seek other outlets and in the process hurt themselves and many small business retailers who have made significant investments to sell these products. Therefore, I'm asking the FDA not to move forward with this proposed ban on the sale. Thank you for hearing my concerns on behalf of Nevada's legal and regulated tobacco markets. Thank you.

TRACY GALLOWAY: Thank you. Thank you for your comments. At this time, we will take a 15 minute break and we will resume our commenting period at 11:45. Thank you.

DR. KENDRICK DARTIS: Hello. My name is Dr. Kendrick Dartis from the FDA. Up next, we have Alicia Butler. Please state your name, organization or share that you are speaking as an individual. You have up to five minutes for your comments. Please proceed. Alicia Butler? Lindsey Stroud?

LINDSEY STROUD: Yes. Can you hear me?

DR. KENDRICK DARTIS: Yes, we can. You have up to five minutes for your comment. Please proceed.

LINDSEY STROUD (TAXPAYERS PROTECTION ALLIANCE CONSUMER CENTER): OK and thank you for getting me on. Thank you for your time today to discuss the U.S. Food and Drug Administration's proposed rulemaking to ban menthol in combustible cigarettes. My name is Lindsey Stroud and I'm Director of the Taxpayers Protection Alliance Consumer Center. While the FDA assumes that banning menthol in combustible cigarettes products will benefit public and health in America, the rule will do nothing to impact youth smoking, which is already declining, will lead to severe problems for states and negates FDA role in promoting public health, namely harm reduction.

FDA was given authority to regulate tobacco products in 2009. According to the then President, Barack Obama. The new law, the Federal Smoking Prevention Tobacco and Control Act, would reduce the number of American children who will pick up a cigarette and become adult smokers and this is true. According to the Centers for Disease Control and Prevention, percent of high school students that are reported ever trying smoking decreased by 48% between 2009 and 2019 and the number of current smokers defined as having smoked at least one cigarette on one occasion in the past month, decreased by 69.2%.

LINDSEY STROUD: And this is despite menthol cigarettes being available for sale and retail outlets. Moreover, youth smoking has essentially become a thing of the past, with rates continuing to decline in the years after the TCA went into effect. Between 2015 and 2019,

every use of cigarettes among high schoolers decreased by 25.4% and current use decreased by 44%. It is rather interesting that FDA is moving forward with a proposed rule that is unnecessary as there has now been significant reductions in combustible cigarette use among youths.

The proposed rulemaking also unfairly burdens states, causing a likely decrease in regulated, untaxed menthol cigarettes, coupled with increases in illicit products and enforcement costs and this has already been seen at the state level. Massachusetts has banned the retail sales of tobacco products in June 2020, and therefore this has been felt sharply in both excise tax, revenue loss and enforcement costs between fiscal year 2020 and 2021, state cigarette excise taxes in Massachusetts has decreased by 23.7%.

And at the same time, the state has been forced to allocate additional state funding to its illegal tobacco tax force to enforce the ban. In fact, in between fiscal year 2020 and 2021 budgets, the state funding increased by 73%. This increase in funding to the task force is likely due to an increase in smuggling. The McConnell Center for Public Policy has estimated that in 2020, the Massachusetts smuggling rate rose to 26.5% from 20.4% in the previous year and this is maybe limited data because it was measured in only six months of post ban data. Also deeply troublesome is that the FDA Center for Tobacco Products is completely funded by user fees based on the sales of six different type of tobacco products, including menthol cigarettes. Perhaps mentally, one third of American adults smokes menthol cigarettes and should these be banned, CTP would actually stand to lose funding to both enforce the ban and oversee the marketing and regulation of all tobacco products. Sending existing CTP enforcement revenue into the pockets of smugglers and other black market actors is just simply irresponsible.

And finally, there are better priorities of the CTP you can take. As mentioned, young adult smoking has decreased significantly. According to CDC in 2020, only 9.6% of smokers. Our current smokers were 18 to 24 years old, that is a 46.6% decrease from 2010. During the same time period, menthol cigarettes have been widely available at retail stores, and there are numerous studies indicating that the introduction of novel tobacco harm reduction products have correlated with these steep declines. Despite the TCA assigning the agency the task of helping manufacturers bring these products to market and in some cases permit them to market their products with reduced risk labels, the FDA continues to delay in authorizing such products. Instead, here we are today discussing banning a currently regulated product that users are overwhelmingly using while delaying authorization to hundreds of thousands of less harmful products. TPA urges FDA to use its limited resources to authorize less harmful tobacco reduction products that have helped millions of Americans to quit smoking. Thank you for your time today.

DR. KENDRICK DARTIS: Thank you. Next we have Lester Hartman. You have up to five minutes for your comments. Please proceed. Lester Hartman. You are up next. Charles Billups.

CHARLES BILLUPS (THE GUARDIANS): Yes, I spoke earlier, but if you want out, I do not mind speaking again for some reason. You'll have me twice.

DR. KENDRICK DARTIS: OK. We'll see moving forward with the next person. Thank you so much for your time.

CHARLES BILLUPS: No problem.

DR. KENDRICK DARTIS: Stanton Glantz. Stanton Glantz. Stanton Glantz. Alicia Butler. Alicia Butler

ALICIA BUTLER: Hello. Alicia Butler is here.

DR. KENDRICK DARTIS: Hi, Alicia. You have up to five minutes for your comments. Please proceed.

ALICIA BUTLER (NATIONAL ACTION NETWORK): Yes. Hello, everyone. I am Alicia Butler and I serve as the health awareness associate for the National Action Network. The National Action Network is one of the leading civil rights organizations in the nation with chapters throughout the entire United States, founded in 1991 by Reverend Al Sharpton, where we work within the spirit and tradition of Dr Martin Luther King Junior, to promote a modern civil rights agenda and we are here today requesting a commission study on the unintended consequences of the proposed rule as a standard before deciding on consumer goods that the government decides to ban in the interest of the general public's health. The FDA should carefully reconsider moving tobacco products in the opposite direction from legally regulated adult sales to prohibition. Advocates for the proposed rule have not been able to explain why the preferred product for black adult smokers will be subject to ban, while the select products for most white smokers will remain legal and readily available.

The Federal Trade Commission estimates that menthol cigarettes account for around one third of all cigarette sales, with a customer base numbering in the millions and a highly profitable product. There is little doubt criminal networks will seek to capitalize on prohibition. Because menthol is disproportionately the choice of black smokers, black neighborhoods will be a target for sales in those neighborhoods. CDC reports show that black adults smoke at a similar rate to white adults, yet the ill liberal ban doesn't target the preferred product of white smokers.

ALICIA BUTLER: CDC report also show that black youth have lower cigarette smoking rates than other groups, yet the children's cigarette products of different groups with higher smoking rates aren't targeted. The CDC report shows, again, that proponents of the ban say reducing youth smoking rates is one of the key reasons for banning menthol cigarettes. However, states with higher menthol consumption have lower youth smoking rates, and cigarette consumption is the lowest in today's generation. Recent history shows U.S. that drug prohibitions and bans increase negative interactions between law enforcement and people of color.

The New York Police Department's stop and frisk program resulted in nearly 700,000 stops in 2011, with drugs serving as a legit pretext from most of these stops. 90% of those stops were black and Latinx people. We are concerned that law enforcement's attempts to enforce the menthol and flavor tobacco ban will undoubtedly lead to fines, arrest and eventual, I'm sorry, incarceration for those who consider to use and sell menthol flavored tobacco products. Historically, policies that lead to prohibitions have profound racial justice

implications. Menthol prohibitions will create illicit markets and more police interactions, especially in minority communities.

For example, Eric Garner was a black man killed by the NYPD for selling loose, untaxed cigarettes, banning menthol cigarettes and flavored cigars while excluding others and not all cigarettes and cigars that also have health implications and are no more dangerous than non-menthol cigarettes or more addicting, puts a microscope on those same minority communities. We fully support intentional policies that support health needs with harm reduction policies emphasizing education for adults and minors, cessation, well-funded health care for communities of color, and other measures that do not have serious implications for unintended consequences. In conclusion, we do not believe that the proposed law will reduce the number of people smoking, but instead will increase the number of people who use illicit tobacco, creating an underground black market for menthol cigarettes and flavored cigars that will go unregulated.

Prohibition will entice black market suppliers and criminal networks to meet that demand, just as alcohol and drug prohibitions have historically demonstrated. Underground markets will trigger criminal penalties disproportionately impacting people of color and prioritizing criminalization over public health and harm reduction. Thank you.

DR. KENDRICK DARTIS: Thank you. Next, we have Lori Bremner. Lori Bremner?

LORI BREMNER: Can you hear me?

DR. KENDRICK DARTIS: I can. Thank you. You have up to five minutes for your comments, please proceed.

LORI BREMNER: Thank you so much. Thank you for this opportunity to bring my voice to this conversation. I speak as an individual, a mom of three. I'm also a cancer survivor and I lost my dad too young to tobacco related illness so, this is very personal for me, as it is for every parent who's trying to navigate through the youth nicotine epidemic, all fuelled by flavored tobacco. I'm also a long-time volunteer for the American Cancer Society Cancer Action Network, ACSCAN and a volunteer for parents against vaping e-cigarettes, PAVE.

But today I speak on my own behalf, and I am here to tell you that parents need help. Alongside other volunteers for ACSCAN, we worked so hard to pass the Family Smoking Prevention and Tobacco Control Act, which gave the FDA authority to do what we are talking about today. The FDA had that authority back in 2009. I brought my three young sons into the Senate chambers in Washington, DC, when the Senate voted to send the act to the president's desk and I cried tears of joy at that step that I and my fellow volunteers had worked so hard for, for so many years and when President Obama signed that act on June 22nd, 2009, I celebrated. But we have been waiting for the FDA to step up and make meaningful change with the authority that we fought to give you in 2009. Back in 2009. Do you know how many youth have become addicted to menthol-flavored cigarettes and cigars since then? The inaction by the FDA has condemned to death so many bright lights in our communities and why is it so important to prevent menthol from being added to cigarettes and cigars? Because it makes it easier to start and harder to quit. My good friend and fellow advocate Carol Baker tried her first cigarette when she was 13. It tasted terrible. She

coughed and choked and decided smoking was not for her. Shortly thereafter, a friend gave her a menthol cigarette. It tasted good. It felt good on her throat and soon she was addicted and suffered greatly until finally, she was able to quit. To quote my friend, Dr. Philip Gardiner, who is the co-chair of the African American Tobacco Control Leadership Council. The menthol helps the poison go down. Do not make us wait any longer. Do not accept the industry's tactics. I have three requests. First, that menthol be prohibited as an ingredient, not as a characterizing flavor. Any amount of menthol will make the tobacco more enticing and more harmful and more addicting. The industry is a shapeshifter. If only characterizing flavor is prohibited, they will find ways to include menthol as an ingredient, but not as a characterizing flavor. Make it comprehensive. My second request. Make the rule take effect within three months. They do not need a year to sell off their products. The industry's own agencies recommend carrying no more than three months of tobacco products in stock so that they are fresh when sold. How many more kids get addicted during that year? What if it's your kid? What if it's mine? My third request is do not fall for the industry lie that ending the sale of menthol is racist. Leaving menthol on the market when other flavors were removed, that was racist. It is a matter of social justice that you remove this product that has been perniciously targeted towards black, brown, and LGBTQ communities. The black, brown, and LGBT communities deserve the same rights as their white neighbors. We also need to proceed with this matter to be good neighbors to Canada and Mexico. Canada. Long ago ended the sale of menthol and Mexico is ahead of U.S. in this process. Once the entire continent of North America does not allow the sale of menthol, it will be so much easier to protect our kids. Do not place your children in the same boat as mine as having never met their grandfather because tobacco killed him before they were born. Thank you so much for hearing my voice.

DR. KENDRICK DARTIS: Thank you. Next, we have John Clymer. John Clymer. John Clymer.

JOHN CLYMER: Good afternoon. Can you hear me?

DR. KENDRICK DARTIS: We can you have up to 5 minutes for your comments, please proceed.

JOHN CLYMER (NATIONAL FORUM FOR HEART DISEASE AND STROKE PREVENTION): Thank you. My name is John Clymer. As you said, I am Executive Director of the National Forum for Heart Disease and Stroke Prevention, which is a non-profit, nonpartisan organization focused on advancing health equity and preventing heart disease and stroke. We represent over 100 for-profit, non-profit, and public sector members throughout the country. Our mission is to spark and lead collaborative action to achieve health equity and optimize cardiovascular health and well-being throughout the lifespan. Smoking, prevention, and cessation is a primary means to achieve this mission. The National Forum appreciates the opportunity to voice its strong support of the proposed product standards, prohibiting menthol is a characterizing flavor in cigarettes and cigars. The proposed rules will have an enormous beneficial health impact, both in the short and long term. Cigarette smokers are 2 to 4 times more likely to get heart disease than non-smokers, and cigarette smoking doubles a person's risk for stroke. It is an indisputable fact that smoking causes hypertension. Hypertension is the only modifiable risk factor that kills more people prematurely than smoking itself, kills. Hypertension, causes heart attacks, strokes, heart failure, and kidney failure, and multiple additional types of cardiovascular disease. The surgeon general of the

United States has issued a call to action to control hypertension, signifying it is a national priority in preventing heart disease and stroke, which are the first and fifth leading causes of death in the US, respectively. Hypertension is becoming more prevalent at earlier ages. People who develop high blood pressure before age 40 have a higher risk of heart disease and stroke in middle age. Prohibiting menthol flavorings in tobacco products will reduce youth smoking. Menthol cools and numbs the throat. It reduces the harshness of tobacco smoke and makes cigarettes and cigars more appealing to new smokers, particularly young people. Prohibiting menthol cigarettes will increase smoking cessation and save lives. Smoking remains the leading cause of preventable death and disease in the US. 5% of Americans are living today with a smoking-related disease. Smoking-attributable health care spending exceeds \$170 billion per year, and that does not include the costs and hardships suffered by people with smoking-related disease who cannot work and their caregivers who cannot work. Prohibiting menthol cigarettes, which are more difficult to quit, and non-menthol will reduce this burden by increasing smoking cessation as described in the rule. Modeling studies have estimated that 324,000 to 654,000 smoking-attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available in the United States. Prohibiting menthol cigarettes and cigars would decrease tobacco-related health disparities and achieve health or advance health equity, especially among black Americans. Menthol cigarettes would cause substantial harm to public health, and particularly to black Americans, as we've heard from previous speakers today. For more than 60 years, the tobacco industry has targeted black Americans with marketing and price promotions for menthol cigarettes and as a result, 85% of black smokers who smoke menthol cigarettes compared to 29% of white smokers. Consequently, black Americans are less likely to successfully quit smoking and suffer disproportionately from tobacco-related death and disease. The National Forum for Heart Disease and Stroke Prevention, on behalf of its more than 100 member organizations, urges the FDA to act swiftly to issue these lifesaving rules in final form.

DR. KENDRICK DARTIS: Thank you. Next, we'll have Stanton Glantz. Stanton Glantz.

STANTON GLANTZ: My name is Stanton Glantz. I am a retired professor of medicine at the University of California, San Francisco and until I retired, I was the Principal Investigator of the UCSF Tobacco Center of Regulatory Science. I'm here to generally support the rule. The FDA did an excellent job of summarizing the science on the effects of menthol to build a justification for ending the use of menthol cigarettes. In particular, FDA pointed out that the effects of menthol go well beyond its use as a characterizing flavor to interact chemically and biologically with nicotine at the level of brain receptors in a way that makes nicotine more addictive, particularly to the developing brain. Specifically in the cigarette rule and FDA said the following, "In addition to its flavor and sensory effects, menthol contributes to a greater risk of nicotine dependence by enhancing the addictive effects of nicotine in the brain by effecting mechanisms involved in nicotine addiction." Clinical data show that menthol cigarette smokers have a higher level of brain nicotinic receptors compared to non-menthol smokers. Studies demonstrate that menthol, like nicotine, binds to the nicotine receptors in the brain, and menthol alone could increase the number of nicotinic receptors in the brain. Evidence demonstrates that the combined effects of menthol and nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine compared to nicotine alone and the rule goes on to provide a great deal of detail to support this summary. Indeed, there is tobacco industry research in the tobacco industry documents

showing that the industry has known for a long time that you can tune the level of menthol to compensate for lower nicotine levels. Not only does the science in the proposed rule justify moving forward with the rule, but it highlights the need to strengthen the rule in two ways. First, FDA should prohibit menthol and menthol analogues as ingredients, not just characterizing flavor. Under the proposed rule, tobacco companies could continue to add menthol to cigarettes to maximize their addictiveness. If they simply stop calling them menthol cigarettes. This is also important because menthol is an important ingredient and many non-menthol cigarettes precisely to increase addictiveness as the FDA so clearly describes in the proposed rule. Second, FDA should drop the proposed exemption for low nicotine cigarettes and heated tobacco products. The biological effects of nicotine on the brain and its interaction with nicotine that FDA describes so carefully have nothing to do with combustion. Menthol and menthol analogues should be prohibited in all tobacco products for precisely the same reasons. FDA prohibit proposals to prohibit menthol cigarettes for the same reasons. I also support the FDA's proposed cigar rule. In that proposed cigar rule, FDA asked for comment on whether water, pipe, and pipe tobacco should be included. The answer is yes. The effects of menthol and its interaction with nicotine on the brain depend on chemistry and biology that has nothing to do with the product used to deliver the menthol nicotine. Indeed because of the fundamental interaction of menthol and nicotine, menthol and menthol analogues should be prohibited as ingredients in all tobacco products. Thank you.

DR. KENDRICK DARTIS: Thank you. Next, we'll have Sairam Jabba. Sairam Jabba. You have 5 minutes for your comments. Please proceed.

SAIRAM JABBA: Can you hear me?

DR. KENDRICK DARTIS: I can, you have 5 minutes for your comments. Please proceed.

SAIRAM JABBA (DUKE UNIVERSITY): Okay. Hello, everyone. I would like to... Hello, everyone. I would like to thank the FDA for giving U.S. the opportunity to comment on today's FDA-proposed tobacco product standards that would prohibit menthol as a characterizing flavoring in cigarettes and also prohibiting all kind of present flavors and cigars. I'm Sairam Jabba a Research Scientist in Sven Eric Jordt Laboratory at Duke University where I study the toxicological and addiction properties of flavor chemicals in tobacco products. I'm providing these comments as someone who has extensive expertise in the field of tobacco regulatory science, including basic science research, toxicological research, regulatory policy, and advocacy. I also speak as a member of the Jordt lab that conducted foundational studies on the effects of menthol on tobacco, smoke inhalation, and oral nicotine impact with FDA citing several of these studies in their proposed rule-making to ban menthol cigarettes. Current ongoing studies in our lab focus on the behavioral effects of synthetic cooling agents that are mostly derived from menthol and on sweetness and sweet associated flavors. Further, I speak on behalf of other Duke University researchers conducting tobacco-related science, such as (UNKNOWN). We strongly support both rulemaking proposals intending to ban menthol cigarettes and characterizing flavors in cigars. On the basis of our own research and of published literature, we recommend FDA that addition of menthol or menthol analogs that have similar pharmacological effects like menthol should not be permitted to be added to cigarettes. Menthol, through its cooling and reinforcing sensory perceptions, increases tobacco product consumption, especially in beginning smokers, by

contracting throat and lung irritation through the smoke. Menthol thereby increases the risk of nicotine dependence and makes it harder to quit smoking, and increases the abuse liability of tobacco products. Further, menthol has been well documented to increase tobacco health disparities in marginalized and vulnerable populations, especially African Americans, young people, and the LGBTQ community. Smoking also causes approximately 30% of all cancer deaths in the United States and quitting smoking reduces cancer risk more than any other behavioral change. Tobacco related health disparities exist even in cancer deaths, particularly from lung cancer, with African Americans more likely to die from lung cancer than white Americans. One of the cause of this disparity comes from the disproportionately high use of menthol cigarettes among African American smokers, which is up to 70 to 80% or more. Assimilation of an hypothetical menthol ban in the U.S. that is based on Canada's menthol ban outcomes projects 1.4 million quitters with overall reduction in smoking rates, cancer incidence, and deaths from tobacco use. A menthol ban is also estimated to reduce cumulative smoking attributable deaths and lead to higher cessation rates among African Americans. While we support both rulemaking proposals, we are concerned they contained loopholes allowing tobacco companies to continue adding menthol and other entities affecting flavor. Though the FDA intends to ban characterizing flavors including menthol as a characterizing flavor in cigarettes and all characterizing flavors and cigars, FDA has not clearly defined what a characterizing flavor is. Our research recently revealed that tobacco companies are adding chemicals to their products that impart a cooling effect similar to menthol but lack menthol's minty smell. Since these chemicals are odorless, they may not count less characterizing flavor. The concept of characterizing flavor is also not clear regarding the importance of pharmacological actions of flavorings. These synthetic coolants have similar pharmacological and cooling properties as menthol that are mediated by the menthol receptor. To evade the proposed menthol ban in cigarettes. The tobacco industry can introduce these odorless menthol derivatives to provide cooling sensations without the characterizing menthol or menthyl odor. Even menthol cigarettes might continue to be marketed as seen in the European Union, where tobacco companies reintroduce menthol cigarettes, claiming menthol levels are too low to be considered as a characterizing flavor. Coming to cigars, the presence of flavors especially sweet and candy flavors, helps cigarillos and little cigars to become popular among youth and assists in increasing tobacco use in this group. Studies have demonstrated that compared with conventional cigarettes, flavors, cigarettes, cigarillos, and little cigars deliver higher levels of tobacco toxicants. In collaboration with our health chemistry group, we have demonstrated that tobacco companies have artificial sweeteners such as saccharin, acesulfame...

DR. KENDRICK DARTIS: Thank you. Up next, we'll have Anthony Carothers. Anthony Carothers. Anthony Carothers. Next, we'll have Lester Hartman. Lester Hartman. Lester Hartman.

LESTER HARTMAN: Can you hear me?

DR. KENDRICK DARTIS: Yes, you have 5 minutes for your comments. Please proceed.

LESTER HARTMAN: Yes, OK. My name is Dr Lester Hartman, and I'm an Adjunct Pediatrician, just retired, after 35 years, was very involved in turn in Massachusetts to Tobacco 21 and I was involved in getting the flavor menthol, the characterizing flavor of menthol, as they call

it, and to the ruling with Massachusetts that's banned menthol related products as well. I worked on this piece that am about to present with Carol McGruder and Philip Gardner. We've been waiting for over ten years for this rulemaking process to begin. Let's start with some data. Consequences of a match made in hell for 30 years 'till 2019, 1.5 million new African American smokers, 157,000 smoking-related preventative deaths among African Americans, 1.5 million in life years lost among African Americans. Next these are the proposals that we want, we see as imperatives to be put into the regulations, as everybody many have spoken about removing menthol from the tobacco products as an ingredient, which is not just lowering the levels to levels that we think are not addictive or numbing as well. Cessation services should be targeted to by the public health community to increase culturally sensitive, tailored services that address the social and political determinants of health. Stop the production of menthol tobacco products for export. The current rule states that menthol can still be produced for sale overseas. This encouraged, this ensures that other vulnerable populations will be targeted and killed with these deadly products and again, in the final ruling, remove menthol and flavored tobacco products from the marketplace within 90 days. I would also add that the tobacco industry has perniciously and racially targeted the black community for decades. They are in fact federally adjudicated racketeers under the Racketeer Influenced Corrupt Organizations Statutes. Their racist practices are in violation of the International Treaty for the Elimination of Racial Discrimination. This interest has no place, absolutely none, in the negotiating table, and it is unacceptable for the FDA to allow them to interfere and further delay with this process. As we speak, the tobacco industry continues to try and paint black leaders to say that taking menthol off the market will criminalize the black community, resulting in increased police interaction brutality from police officers. We encourage police officers who espouse tobacco industry rhetoric to disclose their relationship with tobacco, the [UNKNOWN] industry. We ask them to go back and clean up the police departments that they have intimate knowledge of past harms among the black community. We refuse to let the biggest profiler and killer black men to hide behind their racist practices and keep the deadly products on the market. Thank you.

DR. KENDRICK DARTIS: Thank you so much. Next, we have Anthony Carothers. Anthony Carothers. Anthony Carothers. We will resume after a break at 12:45. Thank you. Next up will be Daniel Treacy. Daniel Treacy.

DANIEL TREACY: Hello.

DR. KENDRICK DARTIS: Hi, Daniel Treacy you have five minutes.

DANIEL TREACY: Great. My name Daniel Treacy. I'm a member of the American Society Cancer Action Network. I'm here today as a concerned citizen, as a caregiver, scientist, a member of LGBTQ team. I was a resident of the first state, to implement a sales restriction on flavored tobacco products, including menthol cigarettes. I'd like to thank the FDA in this listening session on the critically important proposed rules and support of a prohibition of menthol as characterizing flavor in cigarettes and all characterizing flavors and cigars for protection of public health. I believe the FDA should finalize these two rules quickly and not allow exemptions or loopholes for tobacco manufacturers to exploit. Personally, my grandfather died of tobacco use, but that was back in the seventies. I think we are healthy, we can progress further and move the needle to better for patients (UNKNWON). Tobacco

use is still the number one cause of cancer in the U.S. and we know that disparities in who is using tobacco products has led to a disproportionate burden of cancers on specific populations, including the LGBTQ community. We also know that these disparities in who is using tobacco products as a result of tobacco industry targeting targeted marketing, in particular flavored products like menthol cigarettes and cigars. Tobacco use is sexy, there is nothing sexy about smuggling. There is nothing sexy about addiction. We are talking about people's health here and we need to stress that. This is what we care about and there no need for these targeted ads. I am fortunate to live in a state that took action to limit the sale of flavored tobacco products as a tobacco industry tactic used to addict new users, especially youth, and to target specific populations like the LGBTQ+ and black communities. In June of 2020, Massachusetts became the first state to implement the sale tobacco products, including cigars and menthol cigarettes. We worked day and night to get this through. It was a last-minute effort that was really about the State House before, during the pandemic. We were calling our senators and our legislators to the wee hours of the morning. It was such a huge success to be the first and such a huge success to know that our legislators are working with us and we need to make sure that the FDA is also working with us to ensure public health. We are seeing benefits of that law. At first, this study published earlier this year shows that the law tremendously decreased overall cigarette sales in the state and that this decrease was due to a significant decrease in cigarette sales specifically. While the study showed the overall decline was partially offset by increases in menthol cigarettes. It does not change the fact that the law significantly reduced overall cigarette sales and the sale of menthol cigarettes. I believe it is long overdue for the entire nation to be free of tobacco products, including menthol cigarettes and flavored cigars. Tobacco products, including flavored products, are responsible for half a million deaths in the U.S. each year and as I mentioned earlier, because of tobacco industry deliberate efforts, certain populations, including my own LGBTQ community, are bearing the brunt of the suffering and death from tobacco use. My home state of Massachusetts is also working hard to provide support to people who use tobacco products in light of sales restriction. I recommend the FDA also provide outreach and cessation of support for people who use menthol cigarettes and flavored cigars in anticipation of an implementation of these rules. Thank you for the opportunity to speak in support of FDA rules to promote to prohibit menthol as a characterizing flavor in cigarettes, and characterizing flavors in cigars. Thank you.

DR. KENDRICK DARTIS: Thank you. Next we'll hear from Sydney Shaffer. Sydney Shaffer

SYDNEY SHAFFER: Hi, can you hear me?

DR. KENDRICK DARTIS: Yes. You have up to 5 minutes for your comments. Please proceed.

SYDNEY SHAFFER: Thank you. I'm Sydney Shaffer. I am 16 years old and I'm here to give you the teenage perspective. Researchers have estimated that by showing the decline in smoking prevalence during the 38-year period from 1980 to 2018, menthol cigarettes are responsible for 10 million extra smokers and 378,000 smoking-related deaths during that time. That is 10,000 deaths every single year. As a teenager, I've seen the effects of this issue first-hand, starting in schools. Since I went to middle school, I began seeing people my age smoke, whether it is menthol vapes or authentic menthol cigarettes, I've seen them use them. The tobacco industry has long targeted youth as well as other minority groups. After

watching my papa die from lung cancer and seeing him smoke my entire life, I know how this ends. He was too, a young teenager when he started smoking targeted by the tobacco industry and for him, it was the only contributor to his death. We urge that you stop this problem at the source and remove all these menthol cigarettes and cigars from the marketplace by the end of 2022. This will keep our teens from becoming part of that 10,000. Additionally, we are aware that another group of minorities are being targeted with threats, the black community. Research says that a deliberate targeting of the black community has led to drastic increased use of menthol cigarettes. Tobacco is claiming 45,000 lives each year. This targeting is wrong and prohibiting menthol as a characterized flavor in cigarettes would result in significant numbers of menthol smokers quitting. Furthermore, the proposal to prohibit menthol. OK, excuse me. Another point to be made is that menthol flavoring that attracts new smokers is not just menthol, it is other flavors as well. Cigars continue to target youth as well as black Americans. Surveys that show that flavors are a major factor leading to youth usage of cigars. 74% of youth who use cigars said it was because they enjoyed the flavor. Also, given the higher levels of cigar use in the African American youth, prohibiting flavors would advance health equity groups. The targeting of minority groups is wrong, and just all kinds of flavoring must be removed from the market. These rules will prevent new smokers from starting, decrease the death in our country, and help to save health care costs by thousands of dollars. Each year the U.S. spends more on a \$225 billion (UNKNOWN). For each member who quits because of this rule at least 11,000 in [UNKNOWN] health care costs. People's lives are on the line, and I urge FDA to act on these rules by the end of 2022. People's lives should not turn into statistics. This is an important step we need to take to get this part of the products banned. Thank you.

DR. KENDRICK DARTIS: Thank you. Next, we hear from Neill Franklin. Neill Franklin. Neill Franklin.

NEILL FRANKLIN: I'm here. Can you hear me?

DR. KENDRICK DARTIS: Yes. You have 5 minutes for your comments. Please proceed.

NEILL FRANKLIN: Thank you. I'm a 34 year Maryland police veteran and retired from the Maryland State Police as a Major. During that time, I spent a majority of my career in criminal and narcotics investigation focusing upon organized crime and illicit markets. I've been also accepted as an expert witness in Maryland circuit courts, federal district courts, on police policy practices, training, use of force and criminal in narcotics investigations. I'll be speaking to illicit markets from a law enforcement perspective. Illicit markets that are created from problematic public policy, like alcohol prohibition of the 1920s, when it was illegal to manufacture transport and to sell alcohol, it was illegal to possess. There is a fallacy that if you ban a product, it will disappear from society. Alcohol, prohibitionists and drug free America once believed this. It's all about product demand. This proposed FDA rule to ban the selling of all cigarettes in the United States is placed into effect would undoubtedly give birth to yet another very profitable illicit market in all of its harms and here's why, it's about product demand. In 2020, of the 203 billion cigarettes sold in the United States, 37% were methylated. This was a significant number of cigarettes that were easily transitioned from a regulated market to an illicit market and at an average cost of around \$8 per pack. That's about \$30 billion per year in an illicit market. Profitable, illicit markets are commonly managed by organized crime syndicates, cartels and gangs.

Trafficking routes in local distribution markets are tamed and controlled by using force, fear, violence and as such the use of firearms have become common management tools. We in law enforcement also recognize the use of children by these organizations in transporting and selling illicit market. The reason for using children is that they cost less, they are easier to manage and when caught, the penalties are far less severe. An illicit menthol cigarette market is even more problematic for black communities. A black adult smoker, 85% prefer and use menthol cigarettes. Most report that, if available by way of an illicit market, they would buy and use from that market, especially since they believe that it would not be that they would not be criminally charged and or prosecuted. This translates to a robust trafficking and selling network within black communities. As such, law enforcement would have no option other than to aggressively enforce smuggling and selling prohibitions bans. At a time when communities are struggling to reduce their policing footprint within their communities of color, this would be an unwelcome enforcement initiative. It has the potential to undermine many of the policing reform efforts currently underway. Although menthol users cannot be arrested for simply possessing menthol cigarettes in an effort to identify smugglers, police will creatively interact with citizens for minor crimes like jaywalking, ordering, trespassing, traffic violations. Using those crimes as leverage for information on their tobacco sources. This is the very same tactic we use for locating guns and drugs. In closing, if children are concerned. The current national regulator retail rate for not selling cigarettes to minors is close to 97%. In an illicit street market that picks zero, every child buys many children sell. I recommend that we conduct a proper adverse impact study to include all stakeholders, especially law enforcement. As stated above, law enforcement will be a crucial tool in suppressing illicit tobacco markets, and there will be a significant fiscal note attached to this. Community relations challenges are also a problem. Let's bolster smoking cessation efforts. They work. Education and treatment programs have been extremely successful in reducing smoking among adults and children and let's keep that pressure on and refrain from attempting to solve a health condition with cops, courts and prisons. Believe me, if I thought the bans would work in removing menthol cigarettes from our communities, I would be 100% in support of it but my work in policing tells me that is not the case.

DAVID OLIVERA: Hello. My name is David Olivera from the FDA. Up next, I believe we have Alyssa Montanas. Please state your name and organization or share that you are speaking as an individual. Alyssa, you have up to 5 minutes for your comment. Please proceed. Thank you. OK, We'll move on ahead. Do we have Neill Franklin available? Neill Franklin? Minou Jones. OK. How about Minou Jones? You are up next to speak.

MINOU JONES: Can you hear me?

DAVID OLIVERA: Yes. That's great. Thank you.

MINOU JONES (MAKING IT COUNT COMMUNITY DEVELOPMENT CORPORATION): Hi. Thank you for allowing me to speak today. My name is Minou Jones. I am the founder and CEO of Making It Count Community Development Corporation, a non-profit organization whose mission is to advance health. Equity and equality in underserved communities through volunteers who dedicate lived experience, professional expertise, and resources that count towards making a positive change. I currently serve as the chair of the Detroit-Wayne Oakland Tobacco-Free Coalition and sit on the board for Tobacco-Free Michigan. Previously,

I served as the CEO of the Black Caucus Foundation of Michigan, and I have worked at both the Detroit Health Department, and the Michigan Department of Community Health on tobacco prevention, and population health issues. The data is clear, eliminating menthol cigarettes will have immediate, and far-reaching benefits for public health, expressly among African Americans, and I unequivocally support the two proposed tobacco products standards. I won't repeat our national statistics however, I want to underscore one point, from 1980 to 2018, Black Americans made up 12% of the U.S. population, but represented 15% of the additional smokers, and 41%, let me repeat that 41% of the premature deaths due to menthol cigarettes, 157,000 premature deaths among Black Americans together, and we know that this is no answer to accident or coincidence. For decades, the tobacco industry has deployed aggressive advertising, and other tactics, dedicated and designed to hook African Americans on menthol cigarettes, my family has suffered because of that. Growing up in Detroit in the '70s and '80s, so many people in my immediate circle smoked menthol cigarettes, including both of my parents, we were surrounded by flashy ads in magazines like Jet, and we read in places we went, and shops we hung out at. I have a vivid memory of models in gold jumpsuits hanging out at the jazz festivals, you know, and the African festivals. I later learned that they were paid \$10 an hour, and this is when the minimum wage was \$3.85. Menthols were everywhere you turned, including in the hands of some of my most beloved Black music idols, civil rights leaders, and family role models and now we know, we were playing, the tobacco industry documents provide clear evidence that we were played. I have seen the horrible consequences of tobacco addiction affect my family. I've lost my grandmother, my uncle, my aunt, my best friend, and my cousin, way too soon because of their addiction to menthol cigarettes. My father, a former menthol smoker, struggles with emphysema and COPD today, I can't help but wonder if my father right now would have been able to quit smoking if menthol was banned ten years ago when FDA banned all other flavored cigarettes and my family is just one of the millions of Black families who live this experience every day. This is our history, it does not have to be our future. Eliminating menthol cigarettes, and flavored cigars will save lives and I know some have voiced concerns that this policy could lead to increased criminalization, even though the proposed rules clearly focus on manufacturing and I understand where this comes from. I'm a Black mother of five Black boys, and when Michigan considered increasing state-wide tobacco sales to age 21, I testified at our State Capitol with genuine concerns about the proposed policy because our state still has antiquated penalties on under-age tobacco users. I have no concerns whatsoever about the proposed rules leading to increased interaction with law enforcement, or an increase in criminalization. I refuse to let an industry that makes money off of death, and disease, and manipulate our collective trauma and stand in the way of meaningful, overdue change that will save lives. It was an honor to speak today on behalf of my family, and my community, I implore you to move forward with the proposed rules and implement them as soon as possible, our lives are depending on it, thank you.

DAVID OLIVERA: Thank you, next, we have Dan Stevens. Dan Stevens, you have up to five minutes for your comments, please proceed. Dan Stevens, OK, we'll skip ahead to Ashok Patel, you are up next to speak and you have five minutes for your comment.

ASHOK PATEL (YOUR CHOICE CONVENIENCE STORES): Hi, my name's Ashok Patel.

DAVID OLIVERA: Yes, please proceed.

ASHOK PATEL: I'm the owner of the YourChoice chains in central Pennsylvania, and I'm opposing the menthol ban, because like for the community store and gas station, I'm owning YourChoice chains in Pennsylvania so, the menthol is like, you know, in our area. The menthol is not a great seller, but people do buy the menthol cigarettes in our area, too, but people are like, you know, they buy all kinds of stuff like, you know, the regular, all kind of flavors, tobacco products, and also like in other states. They are like more towards like, they legalized the marijuana, so this is worse for everyone too instead of menthol. I am opposing not to ban the menthol, but we always watch like, not to sell to the kids and other things so, we've had to educate all of our employees, and people too not to sell to underage people, so like we try to save the kids too so. That is my request not to ban the menthol, thank you, sir.

DAVID OLIVERA: Thank you, OK, up next, we have Art Way. Art Way, you have five minutes for your comment, please proceed.

ART WAY (EQUITABLE CONSULTING): Yes, I'm here, can you hear me?

DAVID OLIVERA: Yes, we can, thank you.

ART WAY (EQUITABLE CONSULTING): Alright, once again, Art Way, I am a Drug Policy Consultant with Equitable Consulting, I have a history in police accountability work, drug policy reform, and harm reduction and so that history is really what brings me here primarily as an individual to speak to you all. I have three primary concerns with a menthol ban, and before I get into those three, I want to quickly address the cigar issue. You know, those cigars are not purchased for their intended use, I believe a police officer let you all know that those products are popular in the communities of color because they are used for blunts and so, you know, I bring this up because, in my history, I've seen the public health community have blind spots in regards to what's really happening on the streets. You know, we do not have an issue in our communities of young Black, and Brown people, smoking strawberry-flavored cigarillos from beginning to end, that is just not an issue. You know, I'm concerned with blind spots and that's one of them, and when it comes to menthol cigarettes, I think we have more. First, my issue is regarding preparation, I may sound like many of the proponents here, you know, what are we doing in regard to any type of economic impact assessment, any type of racial impact assessments? And I'm not just talking about public health cherry-picking of certain data that was funded to show an issue with menthol, I'm talking about broader assessments that include poverty, diet, education, and the impact of the illicit market in certain communities. What's being done to publicly educate people about the incoming ban? Are we just simply going to just throw this ban out there and then worry about educating the consumers later? What's being done in regard to youth initiation from an illicit market? Major Franklin spoke on that, what's being done in regard to prevention and cessation? And most importantly, what's being done when it comes to providing law enforcement guidance? The FDA claims that they are only dealing with manufacturers, that this is not about criminalizing users, and possessors, but local states and municipalities, and governments, can go about this how they wish so, what is the FDA doing to ensure that localities do not engage in this? This ban will be a litmus test for law enforcement. Law enforcement has a history of ignoring policy-long directives, and like I said possession charges are not the dispositive issue, this ban will essentially create contraband. Contraband will create touchpoints between law enforcement, and

communities of color, you cannot hide behind the fact that possession charge is not a part of this, that is not the bigger, broader, umbrella issue of criminality that my community faces. Essentially, were playing with fire, and adding fuel to the fire between a bad relationship with law enforcement, and poor Black, and Brown communities, an awful ban that is not likely to achieve its stated goals. Within the proposal, you are looking for a 15% reduction in cigarette use over the next 40 years with this ban, can we not achieve that in any other way? I think the way we achieve that is to target public education for the communities, that the proponents of these bans claim to care about. The money spent on bans, and prohibition, could have gone into these communities in regard to prevention, and cessation efforts, and you can still get a 15% reduction over the next 40 years without engaging in these problematic, unintended consequences. You all know better than anybody that the related illnesses, and tobacco-related deaths, where people of color are largely due to our broader, social determinants of health, and our lack of health access. That is decent, that is the root, this issue of menthol cigarettes is just another example of the government dealing with a symptom, instead of dealing with the root and there also needs to be some truth and reconciliation on behalf of the FDA, everything the tobacco industry did, the government allowed them to do. Of course, they target any and everybody, that's what capitalism and capitalists do. It's not like they just targeted our communities and we are still smoking in many places at lower rates, despite this targeting of us, throughout the history. So deal with the broader determinants of social inequities, and social health inequities. This is not a health equity approach; this will only make equity situations worse in our communities and cessation in our communities. Thank you so much, I appreciate it.

DAVID OLIVERA: Thank you, OK, so at this time, which I have around 1:15, We are going to be taking a break until 2:00 o'clock so again, we will resume at 2:00 pm, thank you very much, see you then.

KARI APPLER: Good afternoon and welcome back, my name is Kari Appler from the FDA Center for Tobacco Products Office of the Centre Director. Our next speaker this afternoon is Evelyn Rodriguez, you are up to speak, Evelyn, and you may proceed. You have five minutes to speak. Evelyn Rodriguez, you may proceed. Timothy Andrews, you are up next to speak, please proceed with your comments, you have five minutes. Timothy Andrews, are you online, and are you ready to speak?

TIMOTHY ANDREWS (AMERICANS FOR TAX REFORM): Yes, thank you very much, and thank you for the opportunity to present. My name is Tim Andrews, I'm here representing Americans for Tax Reform, where I'm the Director of consumer issues but I'm also speaking as somebody who has lost uncles to the scourge of lung cancer caused by smoking. I'm also speaking as a father of a 20-month-old child, who I want to grow up in a smoke-free world. However, what we need to look at in achieving a smoke-free future is policies that work and policies based on evidence, and science, and not purely emotion. Unfortunately, while perhaps well-intentioned, the evidence clearly shows that the FDA's proposed rulemaking will do nothing to reduce smoking rates, and in fact, will come with an entire host of negative consequences, potentially with a tragedy that can result. Looking at the evidence underpinning these proposals from other jurisdictions, what we have seen is that menthol bans have no statistically significant impact on smoking rates. What we have seen in Canada is that while smoking rates did decrease, they didn't decrease in any significant difference, right to non-menthol smokers. What we have also seen is that there is absolutely no impact

on youth uptake of smoking, and indeed, youth smoking in the United States is now so low that the FDA doesn't even measure this in a lot of the tracking surveys, youths' combustible smoking is a scourge that we have almost eliminated. Yet, what will the impact of this ban be? What we will see is that the people who do smoke menthol cigarettes will simply go to the black market, these are sophisticated international criminal syndicates who will move into this space. These are groups that have, according to the State Department, terrorist connections, these aren't just the mom and pops who will be smuggling things out of the borders, these are people who will be involved in sex trafficking, and ironically, in criminal activities, drug smuggling and ironically, because we've already eliminated essentially youth smoking through, age verification, 21 plus, and so forth. By moving things to the black market, you are not going to have these practice same protections. People selling cigarettes out of the back of their car won't be checking for ID, so the problems could get worse but even more importantly, by creating this entire illicit market, you are going to be criminalizing so many vulnerable Americans who will continue to use these products, whether we want them to or not and while the FDA may say, "well, We are not going to enforce this against consumers," untaxed cigarettes are a crime in every single state. Police will have the legal authority to arrest people, we saw in New York the tragedy of Eric Gardner, who was killed by police for selling untaxed cigarettes. This is a tragedy that it's going to happen, and the FDA can't simply say "We are not going to be enforcing this," because police can, they will, they have, and this is a tragedy waiting to happen, which is why law enforcement experts, the ACLU, Reverend Al Sharpton, so many minority representative organizations, are so bitterly opposed to this because it will lead to tragedy. It's also going to lead to prop, I mean this is why we are moving away from criminalization. We are moving away from prohibition, in terms of cannabis, in terms of other illicit programs, because of the disproportionate effect that they have on minorities. It is absolutely mind-boggling that we have made so much progress in other areas, that we are now moving back to this prohibition approach that is proven to have tragic consequences. This isn't even touching on the impact on law enforcement, moving resources away from violent crimes and other crimes, and trying to focus on this, law enforcement officials do not want to stop, so why take limited resources and actually make them try and see what cigarettes people are smoking when violent crime is on the rise in many major cities? This doesn't even go to the impact on state government, and local government revenue, not only will they need to fund police more, they will lose all of this tax revenue and again, the revenues are not actually going to get lost because of people stopping smoking, it's going to be lost 'cause the money is going away from state governments, from local governments, and it is going into the hands of international criminal syndicates so, once again, I urge everyone at the FDA to listen to the evidence, listen to the science, listen to the data, listen to the bipartisan coalition, that brings together people on all sides of the policies who saw these tragic consequences on minority groups. Instead, embrace tobacco harm reduction, embrace science, and proven techniques, to help people quit through reduced risk alternatives, and not absolutely...

KARI APPLER: Thank you for your comments. Up next, we have Michael Myers, you are up next and you may proceed. Michael Myers, you are up, then you may proceed with your comments.

MICHAEL MYERS: Hello.

KARI APPLER: Hello.

MICHAEL MYERS: Hi, sorry about that.

KARI APPLER: We can hear you

MICHAEL MYERS: Perfect, well, hello, my name is Michael Myers, and I'm from King of Prussia, Pennsylvania, I want to speak to you today as a concerned citizen and a cancer advocate, and a member of the LGBTQ+ community. I would like to first thank the Food and Drug Administration for hosting this listening session today on these critically important proposed rules, and I support the prohibition of menthol as a characterizing flavor in cigarettes and all characterizing flavors in cigars. I believe that the FDA should finalize these two rules as quickly as possible without allowing any exemptions, or loopholes, for tobacco manufacturers, that exploit individuals, and communities. To start some outreach sensitization support groups for people who smoke menthol cigarettes, and flavored cigars now, in anticipation of when the rule becomes effective, and also to ensure an equitable enforcement of the rules, including clarifying that no law enforcement agency has the authority to enforce these rules. individual customers. Tobacco use is the number one cause of cancer in the United States. Well, my experience with cancer has likely not been caused by tobacco. I do not want any person in my family or my friends to experience what tobacco-related cancers cause and other health issues. Tobacco is the number one cause of cancer deaths in the United States, and my family has experienced devastating cancer effects, devastating effects from cancer and tobacco use. I have five nieces and nephews all between the ages of ten and 15, and I'm here to fight for them so that they will never begin smoking. If they were to begin or even try smoking, the addictiveness of them would increase their risk of cancer or other deadly illnesses, ultimately ending their lives early. Flavor tobacco products, including menthol, are a way for tobacco manufacturers to recruit and help keep new users by masking the harsh effects of cigarettes or cigars and the vast majority of those who smoke start when they are kids. Use of flavored cigars is associated with increased addiction and when it comes to menthol, the science is clear. Menthol increases inhalation, decreases successful quitting, and leads to greater addiction. All independent of damaging effects of nicotine. It is not by accident but by tobacco industry design that tobacco use overall and menthol cigarettes use in particular are higher in LGBTQ+ individuals, black individuals, and individuals with limited income and youth. Among youth, almost half a million teens who identify as LGBTQ+ are using tobacco products, more than double the rate of their peers who identify as heterosexual. The same is true for transgender teens who use tobacco at twice the rates of those teens who do not identify as transgender. We are not sure. Teens who are from communities that have been marginalized, like the LGBTQ+ community, are more likely to use cigars regularly and more frequently after starting than teens from communities who have not been marginalized. Among adults, those who identify as LGBTQ+ are more likely to smoke, smoke menthol cigarettes, and smoke flavored cigars. In fact, women who identify as LGBTQ+ who smoke have the highest rates of menthol cigarettes compared to heterosexual men and women of any sexual orientation who smoke. LGBTQ+ women also have higher rates of flavor cigar use. The consequences of the tobacco industry targeting the flavored products has been great and likely not fully qualified, especially because LGBTQ communities have not been fully qualified, especially since the LGBTQ communities, the data has not been collected for them. However, prohibiting menthol is characterizing flavor, and cigarettes and

characterizing flavors and cigars are some of the important actions the FDA can take to reduce initiation, promote sensation, and reduce tobacco-related health disparities. Thank you for the opportunity to speak with you today on these rules, and I hope that you will make these changes successful. Thank you.

KARI APPLER: Thank you for your comments. Julie Waters, you are up next to speak. Please proceed. Julie Waters, you are up next to speak. Please proceed. Julie Waters, if you are online now is your chance. Please proceed. Next up is Marguerite Pennoyer. Marguerite Pennoyer, if you are with U.S. now is your chance to speak. Please proceed. Marguerite Pennoyer you are up next to speak.

MARGUERITE PENNOYER: Hello. My name is Marguerite Pennoyer. I'm a physician specializing in allergy, asthma, and immunology. I also volunteer as board chair of the American Lung Association in Maine and as vice board chair of the ALA in the Northeast mid-Atlantic. I thank you for the opportunity to share my concerns on the use of menthol in any tobacco product and to voice my support for the proposed rules on both menthol cigarettes and flavored cigarettes. Menthol and flavorings clearly enhance enjoyment and mask the harshness of tobacco products and [UNKNOWN] to use its potential first-time smokers. Many of my patients shared with me that they started smoking menthol cigarettes when they were young and patients admit that they would very likely have been less inclined to start or to continue smoking, plain unflavored tobacco products. Flavors were important to my patients' initial smoking enjoyment. Menthol has clearly helped enhance early addiction to tobacco. It has started my patients smoking and it has kept my patients smoking. The tobacco industry has targeted the black American population and minorities in its quest for new smokers. During my medical training in Upper Manhattan New York City, TV advertising had just been banned. However, billboards were everywhere throughout Harlem advertising the cool flavors and cool factors of menthol cigarettes with giant images of sophisticated, chic black American smoking. Tobacco advertisers next moved these targeted ads to magazines and glossies as billboards were banned. We know that the tobacco industry was deliberately targeting black Americans with calculation and that they continue to do so. Already faced with increased risks of hypertension, cardiovascular disease, cancer, and strokes, this targeting was and continues to be disastrous to the health of black Americans, as smoking dramatically magnified each of these health threats, as well as posing its very significant own health threat. Smoking is an important equity issue for minorities. The menthol cigarette smoking rate among black Americans is approaching 85% when compared with white smokers who smoke menthol cigarettes at only 29%. Studies show it is also harder for black Americans to quit. Menthol cigarettes increase addiction and reduce smoking cessation, particularly among black American smokers. Menthol is keeping minorities hooked. Canada banned menthol cigarettes in 2017, and there has been an increase in quit attempts and cessation among their menthol smokers. The science is clear. Menthol and cigarettes makes it easier to start using the products and to become addicted and it makes it harder for people, notably black Americans, to quit. Spurious arguments are made that indicate banning menthol will contribute further to racial inequity. These arguments from the industry could not be further from the truth. Smokers themselves will not be penalized. Instead, industry will be held accountable and we know as physicians and health care providers that we will be easily able to meet the increased needs of these patients for tobacco cessation programs, and we will be more than happy to do so. Flavored cigars also now pose a replacement risk if menthol cigarettes are removed. The second

proposed ruling on flavoring and cigars needs and must accompany the first ruling. [INAUDIBLE] an immediate shift otherwise to flavored cigars. The second rule banning cigars must be instituted simultaneously so that menthol cigars do not slip and slide over into that empty menthol cigarettes slot. Already flavored cigars are the most important common item smoked by kids next to e-cigs. Flavored cigars are deliberately marketed to youth, especially to African American youth. Prohibiting them will help reduce this health disparity. Manufacturers are poised and ready to replace menthol cigarettes with cigars if flavored cigars are also exempted under the proposed ruling. Please remove all flavored cigars and similar products from the marketplace regardless of the type of cigar, its cost, or other factor. If any loopholes are created, the industry will find a way to exploit them. Please protect my vulnerable asthmatics and my adult patients in their efforts to quit or to not start in the first place.

KARI APPLER: Thank you. Good afternoon Karen Beard, you are up next to speak and you may proceed. Karen Beard, you may proceed when you are ready to speak. Karen Beard, if you are online, now is your chance to speak. We are going to move on. Next up to speak is Bishop Demmer. You are allowed to proceed when you are ready. Thank you. Bishop Demmer, you are up next to speak. Please proceed. Bishop Demmer, you are up next to speak. We are going to move on. Skip Stanford, you are up next to speak. Please proceed. Skip Stanford, you are up next. Please proceed when you are ready. Skip Stanford, if you are online now's your chance. We are going to move on. Up next, Tony Cooper. You may proceed when you are ready. Tony Cooper, you are up next to speak and may proceed.

TONY COOPER: Hi. Can you hear me?

KARI APPLER: Yes.

TONY COOPER (COOPER'S COUNTRY CORNER): Thank you. Good afternoon. My name is Tony Cooper and I'm the president of Cooper's Country Corner. We operate ten stores in northeast Texas and I'd like to give a little bit of my background. My mom went to work for a tobacco distributor as an accounting clerk in 1975 so that she could afford to buy a carpet for my baby bedroom. By the time I was 15 years old, Mom was running that company and she made me work in the warehouse, presumably to keep me out of trouble. When I graduated from high school, I went to work for that same distributor full time. When I was 25 years old, I left that job and started Coopers Country Corner. I have been in the tobacco industry for 30 years and the comments I'm about to give are based on that pedigree. With respect to the proposed rules, FDA has already attempted a similar strategy with vapor products. We've seen a large number of flavored and unauthorized products removed from the market. This has created a huge underground trade. You've removed most of the reputable companies from that space and the void has been filled with bad actors and now FDA is on the cusp of using that same heavy-handed hammer on menthol cigarettes and flavored cigars. Right now, today we have five or six reputable tax-paying manufacturers producing almost all menthol cigarettes and flavored cigars. From a regulator's perspective that has to be a dream scenario. If this rule goes into effect, you are going to trade that for thousands of bad actors filling the void left behind. As it currently exists, we have an industry that is generally reputable and committed to age verification. I can swear to you that the largest manufacturers placed the greatest emphasis on age verification. As a retailer, the largest manufacturers penalize us for failing to achieve age verification

benchmarks. In an underground market scenario, all that ceases to exist. It'll be the Wild West, just like the vapor market space. The underground market is going to be so pervasive because there are between 25 and 35 million of these products. There is substantial organic demand, not demand that was manufactured by somebody making a menthol cigarette. The demand is already there so this brings me to my next point, 25 to 35 million people use these products that the FDA proposes to ban. This listening session should be filled with people from that group. They are the ones most impacted by this rule. Most of these people can't take off work two hours to come give testimony to FDA. What's going to happen is they are going to get off work at five, stop by a store, buy beer and a pack of Newport and head home to relax. Do you imagine that person sitting on their back porch unwinding from a long day hoping the FDA will ban their Newport. Do you think that person agrees with the various rationales in the proposed rules? No, I do not believe either is true. I believe these competent adults want to be left alone to relax and enjoy their life on their own terms. I suggest that FDA find a solution that doesn't involve abolition. Abolition is a lazy and ineffective approach to solving this problem. Enhanced warning labels should be considered as an alternative. If these products are indeed more dangerous, as FDA indicates, I believe it's completely reasonable to communicate those facts to consumers. Stiffer penalties for violations, grants to local law enforcement for retail sting operations, these are some other tools that can be employed. The FDA is regulators - use your power to regulate. Abolition is not regulating. Thank you for your attention.

KARI APPLER: Thank you. Angela Pratt, you are up next to speak. You may proceed. Angela Pratt, you were up next and may comment when ready. Angela Pratt, if you are online now is your chance. Please proceed. We are going to move on to the next speaker. Dr. Julia McKay. Dr. Julia McKay you are up next to speak and may proceed. Dr. Julia Mackay, if you are on now's your chance to comment. We are going to move on to the next speaker. John Rotunno, you are up next to speak. Please proceed when ready.

JOHN ROTUNNO: (INAUDIBLE).

KARI APPLER: Yes. Thank you. You may proceed. John Rotunno, if you are online, you may speak now.

JOHN ROTUNNO: OK. Can you hear me?

KARI APPLER: Yes.

JOHN ROTUNNO: Alright. Yes. John Rotunno, thank you for having me. Whoevers listening. Again, my name is John Rotunno. I am a retired ATF agent. I was on the job for 30 years. Prior to ATF, I was DEA, so I know a little bit about the drug and the gun trade that's going on these days in our cities. I'm going to base my comments on my experience, and I hope for some of you who are listening to me, you can identify with the things that I'm saying. Alright so I worked undercover into Chicago street gangs for quite a while and after I outgrew that my mold I was also involved as a control agent working with confidential informants into the gang trade and the gun trade and the cigarette trade within the gangs. Putting it simply, I'd been trading menthol cigarettes during the time I was undercover which was like 1986, I retired in 2012. I've been trading menthol cigarettes for guns and dope since the early two-thousands and according to my informants and my personal experience. In this day and age,

gangs prefer cigarettes over cash. They are able to use the cigarettes far more. They can make more money selling cigarettes out on the street than they can trading dope or guns for trading dope for guns for money. Alright. Over my years, I've watched open air loose sales. Loose is a common street term. It refers to loose cigarettes sales so over the years, I worked undercover into these gangs. I was able to observe a lot of these open air loose sales. Actually, they operated with impunity alongside with the with the gun narcotics sales. Alright so loose sales, cigarettes is more lucrative. The menthol in particular, the gangs prefer the menthol. It's more lucrative than the than the narcotics sales. In my experience, we used menthol cigarettes to enhance our undercover operations and to enhance our undercover mode into gaining access into the gangs. It created a lot of trust between law enforcement and organized groups of criminals. Alright. My point is this the demand and the market for menthol cigarettes is already here. It's not it's not going anywhere. If you decide to ban menthol in tobacco, you going to be creating crime. I equate this menthol ban with prohibition. What did prohibition do back in the twenties? They created crime. That's exactly what the FDA is going to do. If they decide to ban menthol in tobacco products, they going to create organized crime that's already there and I'm not talking about mob-mafia. I'm talking about organized groups of criminals. OK, black market. You are going to see a large influx of imports from overseas with good. Smash and grabs are going to be become even more prevalent than they are now and last but not least, you are going to get homemade menthols where individual groups, individual criminal organizations are going to grab regular, regular cigarettes, roll them into a swimming pool liner, and buy the menthol online and use, you know, the everyday garden sprayers and used to make their homemade menthol cigarettes so, essentially if you ban the menthol in cigarettes, I just believe you going to be creating a bigger crime issue for law enforcement. Thank you and that's all I have.

KARI APPLER: Thank you for your comments. Yolanda Dickerson, you are up next to speak. Yolanda Dickerson. Yolanda Dickerson, you were up next to speak. Please proceed. Yolanda Dickerson, if you are online, now is your chance to comment. Please proceed.

YOLANDA DICKERSON: Can you hear me?

KARI APPLER: Yes. Now again. Thank you.

YOLANDA DICKERSON: Alright. OK. Hi. Thank you for taking the time to listen to us. For removing menthol cigarettes from the marketplace. I'd like to start by saying that I fully support the proposed rule, encourage you to act quickly. This rule must be made final and go into effect as soon as possible. My name is Yolanda Dickerson, and I was born with congenital heart disease. Smoking is one of those habits that immediately affects everyone sitting in the vicinity of a smoker. Despite this fact, I grew up with two smokers as parents. My parents grew up in a time where the dangers of smoking were not quite enough. My father started smoking at 14 and my mother started smoking, ironically, the day of my open heart surgery to ease her nerves. Due to their and many of their predominantly black friends, smoking habits, often surrounded by cigarette and cigar smoke in our home and family car, I still remember the distinct smell of menthol cigarettes and cigar tobacco throughout our home long after their friends have left. We kids were exposed to this for years and it remains to be seen how it will affect U.S. directly. Though every doctor on this call will agree but will not benefit from years of second-hand smoke inhalation. Menthol and

flavors make smoking easier to do, and it has been targeted to young people and communities of color like mine for decades. The overall health benefits of not smoking, as well as the devastating financial impact on families and our health care system, should be reason enough to prohibit anything that increases the likelihood of smoking. My father died nearly eight years ago from lung cancer and COPD after battling for more than two years. After three years of multiple strokes. My mother passed in 2017 from heart failure, which as you know, are frequent deadly effects of smoking. While not only the only two factors in this day and age, no one should be in denial as to smoking significant contribution to a slow, painful death. As an adult congenital heart disease survivor and the daughter of two former lifelong smokers, I urge you to move quickly and issue a final rule prohibiting menthol cigarettes and flavored cigars by the end of this year. Many families like mine continue to suffer the devastating effects of menthol, tobacco and flavored cigar use and it's far past time to remove these products from the marketplace. Thank you for listening.

KARI APPLER: Thank you. Shannon Baker, you are up next to speak. You may proceed when you are ready. Shannon Baker. You are up next. Please proceed when ready.

SHANNON BAKER: Hello.

KARI APPLER: Well, we hear you.

SHANNON BAKER: Thank you. Thank you very much. I'm Shannon Baker and I'm calling in as an individual from Kentucky where we currently have the second highest smoking rate in the country, as well as the highest lung cancer incidence rate and the highest lung cancer mortality rate in the entire nation. This conversation is a more relevant or more important anywhere in the United States than it is right here in Kentucky and I'm glad to have this opportunity to share my strong support for FDA's proposal to remove all menthol cigarettes and cigars from the market. I'll start with what I know, what FDA knows and what the tobacco industry knows. It's the flavors. The science is clear. Menthol makes it easier for kids to start using nicotine products and to become nicotine addicted and it makes it harder for people, especially black Americans, to quit. Menthol cigarettes increase youth initiation of smoking. The menthol mellows the harshness of the tobacco smoke for new smokers and I read that half of youth smokers report, starting with menthol cigarettes. In fact, we know that cigarette companies have long regarded menthol products as good and I quote "starter products". These menthol cigarettes make it more likely that youth experimentation with cigarettes will lead to nicotine addiction and to long term use and since 90% of long-term smokers begin smoking as teenagers, the impact of menthol cigarettes on youth initiation has an enormous impact on smoking prevalence in general, too. The industry knows that menthol cigarettes are critical to their strategy of hooking young people to be the replacement smokers for the 50% of long-term smokers who die of tobacco related diseases. The tobacco industry has long targeted our kids, but also black Americans and other vulnerable populations causing significant health disparities so prohibiting these products will substantially advance health equity too. For decades, the tobacco industry has targeted black Americans with marketing for menthol cigarettes, and this targeting continues even today. This has led to a dramatic increase in the prevalence of use of menthol cigarettes in the black community from 5% of black smokers in the 1950s to 85% today. Compare that to just 29% of white smokers. Black smokers are also less likely than white smokers to successfully quit smoking. Tobacco use is the number one cause of

preventable death among black Americans claiming 45,000 black lives every year. We know that tobacco use is a major contributor to three of the leading causes of death among black Americans heart disease, cancer and stroke and black Americans die from these conditions at far higher rates than other Americans. Researchers have estimated that during the period 1980 to 2018, among black Americans, menthol was responsible for 1.5 million extra smokers and 157,000 smoking related premature deaths. Prohibiting menthol as a characterising flavor in cigarettes would result in significant numbers of menthol smokers quitting smoking. Most black smokers want to quit, and while black smokers are more likely than white smokers to try to quit, they are less likely to succeed. This rule will increase cessation among menthol smokers and especially black. The fact is that the availability of menthol cigarettes contributes substantially to disease and death from smoking. Researchers have estimated by slowing the decline in smoking prevalence during the 38-year period from 1980 to 2018, menthol cigarettes were responsible for 10 million extra smokers and 378,000 additional smoking-related deaths during that period, or almost 10,000 deaths every year. It's well past time to remove all menthol cigarettes from the marketplace, including those that have received modified risk or exposure orders or authorizations. Look, given the continuing toll on public health from menthol tobacco products and the fact that FDA has consistently maintained since 2013 that prohibiting menthol as a characterising flavor in cigarettes would promote public health. A proposed rule should be issued without any further delay. Please finalize this rule before the end of 2022. It really is a matter of life or death.

KARI APPLER: Thank you for your comments. Next up, Brianna Holmes here next to speak. Please proceed with her comments.

BRIANNA HOLMES: Hello? Can you hear me?

KARI APPLER: Yes, thank you.

BRIANNA HOLMES: Hi. Yes, I am Brianna Holmes and as a woman of color, I come to you today as a concerned citizen as well in regards to the ban on flavored tobacco. It is clear that banning and prohibiting items should not be an option, based on the past history of prohibition, laws and bootlegging here in America as it is today, black and brown citizens experience more police contact than any other citizen in the nation. As a person of color, many of U.S. choose menthol flavored cigarettes. I have concerns about the unintended consequences that will occur in cities across the nation. Here in California, Sacramento, California, the state capital of California. There was a beating of a 14-year-old kid by the name of Elijah for just having a flavor tobacco product and the murder of Eric Garner in New York because of his sales of loose cigarettes. This all proves that our community will be subjected to over policing and more violence. It is already a federal law to the sale of tobacco to a minor so if you going to ban flavored tobacco products, you may as well ban all tobacco products. It is bad for your health regardless of the flavor. It is an adult's choice as an American to buy and smoke tobacco, flavored or not. Our current president and his administration has been hard at work to demote racial injustice and promote equality. Banning menthol cigarettes that are commonly preferred by the people of color would encourage the support of underground black markets and they do not really care who buys the products, even children will have that purchase power. It is my hope that you look deeper into the research in the statistics of cities with this ban already occurring in our

towns. America does not need it. Please allow the voters to decide, as it our responsibility as citizens and it is in the 15th Amendment. It is our right. Thank you.

KARI APPLER: Thank you for your comments. Christina Peter, Christine Peters, you are up next to speak. Please proceed. Christine Peters. You are up next to speak. Please proceed when you are ready.

CHRISTINE PETERS (MAINE SMOKE SHOPS): Do you hear me?

KARI APPLER: Yes. Thank you.

CHRISTINE PETERS (MAINE SMOKE SHOPS): Perfect. Thank you. Hello. My name is Christine Peters and I am the chief operating officer of the Maine Smoke Shops. We are an employee-owned tobacco retailer that has 19 locations in Maine. We employ around 80 people. We are an adults only location that requires ID for anybody that looks under 30 as they enter the store. No children are allowed in our stores. We have a 99% ID compliance rate. We sell legal, FDA regulated products. We have yearly training for all employees. We do our own internal compliance checks. Most of our employees are also parents that do not want to see children vaping or smoking. We do not see ourselves as part of the problem. We like to think that we are part of a solution. There are many retailers, just like myself, out there, and I'm here to say that young adults are likely not buying these products at a store level. A menthol ban will only push law abiding citizens to turn to a black market. Sadly, the local drug dealer will not only be supplying heroin, but will also be supplying menthol cigarettes and trust me, that drug dealer is not going to check for age verification. Youth smoking is down based off information on the CDC website. I think in part because the PMTA process has taken most of the vape products off the market and also the law in 2019 that raised the age to purchase cigarettes to 21. Many steps have been taken to prevent youth smoking. We need to give it time to work. Data suggests it's working. I am here on behalf of legal consumers and one of the more than 250,000 retail workers that legally sell menthol cigarettes to consumers. I myself, being a former smoker, I used to steal my mom's Winstons after she went to bed. I never smoked menthol or flavored tobacco as it didn't appeal to me, but I'm sure my mother smoked menthol. That would have been what I smoked. It took me a long time to quit, but I did because it was my choice that I made personally. Being on the Canadian border, we have many people that come from Canada to purchase menthol cigarettes. They didn't just quit smoking. There is also products that you can buy on Amazon, that you can place a flavor bottle in your filter, that you can make your flavor menthol, you can make it blueberry. Those have no nicotine, so they are not regulated by the FDA. In Maine. We had two towns on June 1st that placed a full flavor ban. I have a store that's 10 minutes away in another town. One store is down 10%. The other store is up 10%. There has to be another path taken other than a flavor ban, education, fines for people providing, allowing steps that you have already taken to work. You are banning products that have no youth appeal and pushing smokers to switch to non flavors or the black market and I think we know people are not just going to quit. It's going to cost people jobs. It's also going to push people to illegal non-regulated products. Either way, adults have made the choice to smoke. I ask you not to punish retailers. I ask you not to punish the adults for choosing to smoke menthol or vape flavored cigars. We have enough government overreach. Thank you for your time.

MEGAN HICKS: Thank you. Hello. My name is Megan Hicks from the FDA. Up next, we have Frances Armstrong. Please state your name and organization or share that you are speaking as an individual.

FRANCIS ARMSTRONG: Good afternoon, can you hear me?

MEGAN HICKS: Yes.

FRANCIS ARMSTRONG (BLUE RIDGE TOBACCO): My name is French Armstrong. I am the owner of Blue Ridge Tobacco Stores. Thank you for providing me the opportunity to speak during the FDA listening session today. I currently operate seven Blue Ridge Tobacco Stores, three in North Carolina and four in Virginia. We employ 39 hardworking people who rely on their jobs to support their families. I'm proud to have such a diverse group of individuals who come to work every day. Approximately 6% of my employees are African American and truly enjoy working at Blue Ridge Tobacco. The stores are tobacco shops, with more than 70% of our sales derived from cigarettes, other tobacco products and tobacco product accessories. All of these sales occur in full compliance with the law, especially the requirement that we only sell to adults 21 and older. The store is like mine, licensed, regulated, and responsible that have helped reduce the incidence of underage smoking to the lowest levels in my lifetime. In my stores, menthol cigarettes make up just over 30%... 37% of all cigarette sales and flavored cigars about 65% of all cigar sales. If the regulations go into effect, I estimate my stores will lose 80% of the sales that are currently made up of menthol and flavored cigars. Well, the other 20% sales may shift to nonflavoured tobacco products. My stores will lose 80% of current-dollar sales because my customers will find these products from other sources, including illicit market sellers. Illicit sellers will pick up my customers and make their profits illegally. While I will lose out. I'm a small businessman, and as my small business just puts me and my family and all of our employees. At a time of such major economic problems, why would we make a decision to send all of these sales to the illicit markets? They do not care who they sell to or what age the people they sell to. I realize the FDA has stated in its proposed regulations that the effects of an illicit market in menthol cigarettes would be minimal. I strongly disagree with the agency's conclusion. We know our customer base and when factoring in that millions of Americans choose menthol cigarettes, adults are not going to let prohibition prevent them from seeking out other sources for their menthol cigarettes and flavored cigars. History teaches U.S. the prohibition of alcohol was a failure, and the FDA should not let history repeat itself. If this menthol and flavored cigar ban is fully implemented flourish tobacco or flourish tobacco will be forced to shut down stores and send these folks to the unemployment line. I did not start this business so that the federal government could put me out of business and force me to terminate all 39 employees. Moreover, these proposed regulations would discriminate against our diverse customer base. All of our customers, including African Americans, have a right to choose what kind of legal products they would like to purchase. Why should the federal government impose its will and discriminate against legal adults? For that is what these proposed regulations are, namely measures that usher in a new wave of prohibition and impose discrimination on our customers. We want to avoid having to tell our customers they can no longer buy legal tobacco products and inform our employees they no longer have a job because of discriminatory regulation. Also, there is a further trickle-down economic effect. Firms forced to close our servicing stores, the landlords who are rent space will be left with empty storefronts and unpaid rent. I ask the FDA to be as concerned about

the freedom of choice our customers want to exercise, along with the economic well-being of my business and our employee's jobs. For these reasons, I request the FDA not proceed with the proposed menthol cigarette and flavored cigar ban regulations. Thank you for your time and consideration.

MEGAN HICKS: Thank you. Up next, John Dixon. John Dixon. John Dixon, are you on the line? Moving on sophia Allen sophia Allen.

SOPHIA ALLEN: Hello? Can you hear me?

MEGAN HICKS: Yes, but you may want to speak a little bit louder, please.

SOPHIA ALLEN (PENN STATE COLLEGE OF MEDICINE): OK. Hi. My name is Sophia Allen. I'm a resident of the Commonwealth of Pennsylvania and an assistant professor in the Department of Public Health Sciences at the Penn State College of Medicine. I have worked in the fields of tobacco control and prevention and tobacco regulatory science for nearly ten years. I have personal experience with helping individuals improve their health by quitting smoking and reducing their cigarette use. I support the U.S. Food and Drug Administration's proposed tobacco product standards that will prohibit menthol as a characterizing flavor in cigarettes and would prohibit characterizing flavors in all cigars. These product standards would greatly reduce the adverse health outcomes experienced by individuals who use tobacco in not only Pennsylvania but the rest of the United States of America. In the clinical trials, I have conducted, along with my colleagues at the Penn State Center for Research on Tobacco and Health, we have heard from countless individuals that use tobacco and that have expressed their opinions to stop selling tobacco, take them out of all stores, stop selling them. Quit selling them so I implore you to approve this rule immediately. There are clear disparities in the marketing of menthol tobacco products, in keeping with tobacco industry documents that highlight how the industry targets specific populations. That is according to race, ethnicity, gender, and socioeconomic status. For example, in the United States, advertising of menthol products is predominantly targeted to blacks in African American neighborhoods, often accompanied by price promotions. The proposed tobacco standard is appropriate for the protection of public health. However, enforcement of the rule or standards should apply only to retailers, wholesalers, importers, and manufacturers and not enforce the rules against individual consumers or possession or the use of menthol cigarettes. As a public health professional dedicated to the lives of Americans, I strongly urge you to finalize the two proposed rules to end the sale of both menthol cigarettes and flavored cigars. As a tobacco control researcher and professional in health, public health, I dedicate my life to improving the health of our patients and participants in our research and our nation's public health. Menthol cigarettes and flavored cigars work in direct opposition to U.S. reaching this goal. The U.S. Surgeon General has concluded that tobacco causes dozens of serious and potentially fatal diseases, including lung and heart diseases, cancer, diabetes, and a myriad of other conditions. Tobacco claims more than 480,000 lives per year. Tobacco claims more than 480,000 lives per year. Let that settle in. Why are we standing watching this happen? Finalizing these two rules would dramatically improve the health of many Americans and assist U.S. in ensuring the well-being of our patients and the nation's public health is protected. Menthol cigarettes are often the first cigarette, youth and young adults try and can increase the chance they become regular users of cigarettes. Researchers have estimated that menthol cigarettes are responsible for 10 million more

people who smoke and 378,000 additional smoking-related deaths between 1980 and 2018, or almost 10,000 deaths each year, every year. Additional studies show hundreds of thousands of people who smoke menthol cigarettes will keep as a result, being removed from the marketplace, which would reduce disease and save lives. There are significant continuing toll on public health from menthol cigarettes and flavored cigars. The Food and Drug Administration has consistently maintained since 2013 that prohibiting menthol as a characterizing flavor in cigarettes would promote public health. Flavored cigars pose a similar risk to public health and health equity. Over 40% of current high school high schoolers who smoke cigars and nearly 60% of middle schoolers who smoke cigars use flavored cigars and youth use of cigars almost. Among black students is higher than their use of cigarettes. We beseech you to finalize both rules this year and dramatically decrease the terrible total tobacco use clauses in the US. Now is the time to make a significant step towards improving the health of our people... our nation.

MEGAN HICKS: Thank you. Up next, Rich Mariano. Rich Mariano. Rich Mariano, you are up next to speak.

RICH MARIANO: Hello? Can you hear me?

MEGAN HICKS: Yes, we can.

RICH MARIANO: Thank you so much. I'm having problems with this. Hi. My name is Rich Mariano, semi-retired assistant Director with ATF. I spent 28 years on the job and I'm currently a professor at Georgetown University. I want to speak about something that's near and dear to my heart because as being a law enforcement professional, I see right now something that is very difficult for me to swallow as a lifelong cop is a prohibition that's being put on something that is only going to create more crime and cause more problems and havoc to law enforcement and I say that is if you ban flavored products and menthol products out there. We are going to see an increase in criminal activity that's already out there, that's evidence-based of individuals that are selling on street corners, such as street gangs, high-value targets, such as terrorist organizations and We are going to see a ban, which is going to create the most violent illicit market in the nation and I honestly want to bring that point to your attention, because I need you to pay attention of what's happening around U.S. right now. We have our crime rate is the highest it's ever been before and now We are going to ask our law enforcement professionals to now jump into the arena of our policing, the sale of menthol cigarettes or flavored cigarettes. We have more important fish to fry right now and the creating of more crime is a huge, huge problem that we do not need to do considering this has been in the marketplace for 75 years, and now all of a sudden, we are going to police this? Is wasting law enforcement resources. It's wasting time, and we need to concentrate on bigger fish. Second, it's causing dysfunction in terms of police reform. We've learned since 2020 how important it is for our law enforcement officers to work in conjunction with the community. If you are asking police whose job it is to serve and protect, to go out there and to regulate and harass, you are inviting trouble. You are inviting problems and when we need our police to gather information in terms of who the shooters are, where the narcotics are being sold, where the armed robberies are taking place, we can't expect them to do that on one hand and then go out and regulate and harass citizens who are trying to buy menthol cigarettes or giving kids another opportunity to try... to buy cigarettes off the street, which are much more difficult than buying from a

consumer entity. Finally, the money that We are going to lose billions and billions of dollars from taxes that are going to be going away from this when the country is in its worst financial straits since 1981. If we look at some of the things that are happening around there, cops need training. Cops need help. Just what you are spending FDA on this initiative. If it went through the scenario of giving this money, through this whole exercise to law enforcement to come up with a solution on school shootings, school resource officers, violent crime, and that is what this country wants. This country... Look at the voters. Look at the population. This is not what we should be spending our time, resources, and money on. We have real problems here that need real leadership and real agencies to step in front of it and putting a ban on this entity that it's been in interstate commerce for 70 some years, and additionally creating a greater crime problem that's already out there is crazy. It's ludicrous and it's something we really need to put our big boy hats and big girl hats on and begin to come up with a solution that's going to help everyone. You talk about the prohibition, the Al Capone's of menthol and nicotine are salivating at the windfall of money that they are going to make out there because the dope dealers, the gangs, and everyone are going to get right back into this game with that much more fervor and that's what's important to understand here. I want to close it out of, you know, we talk about the biggest problem is the kids, the kids, the kids, the kids. I've heard a lot of rhetoric surrounding the kids and I agree. They are set out there, they are our future but we need to put our money behind what is killing these kids in schools. How do we prevent these problems and not throwing our money away at wasted proposals for somebody to look good? Again, real problems need real solutions, not silly harassment ban, but real educated programs and money put towards efforts that can help this country, not just help a select few. I thank you so much for your time and I appreciate it and I hope you look at this with open eyes and realize that this proposal is not doing anything but creating a bigger crime problem in the United States and in giving criminals what they want is more money, more funds, more ability for guns, and more problems out there. Thank you.

MEGAN HICKS: Thank you. Up next, Michael Seilback. Michael Seilback. Michael Seilback you are next. Moving on. Alyssa Schatz, you are up next. Alyssa Schatz. Alyssa Schatz are you on the line? Up next, Jeff Stier. Jeff Stier.

JEFF STIER: Hi there.

MEGAN HICKS: Hi.

JEFF STIER: Hi there. Can you hear me?

MEGAN HICKS: Yes.

JEFF STIER: Thank you. I'm Jeff Stier. Thank you for having this listening session today. Speaking as an individual who attended the FDA's TPSAC meetings on menthol over a decade ago. TPSAC cautioned that the FDA needs to consider the unintended consequences which, as a policy question rather than a science question, was outside the realm of that committee's mission and since then, times why have they changed? We finally begun having a reckoning about policing in the minority communities, a topic you heard a lot about today, and as you still have before you in the form of menthol e-cigarette PMTA is we have data to show that adult smokers use e-cigarettes to quit smoking but the FDA has done nothing to

promote the use of tobacco harm reduction even in the few PMTAs that have been authorized. The FDA has failed to educate smokers about the advantages of switching, and this is quite relevant as the FDA begins going down this wrongheaded path to ban menthol cigarettes. It could do better by authorizing menthol E-cigarettes combined with an educational campaign about the benefits of switching along the lines of what's worked very well in the UK. In his testimony before a House subcommittee this spring, Commissioner Kaye left pointed out that the FDA decisions could be overturned in the courts if it makes one single error. In reference he was speaking about the PMTAs. While here, in reference to menthol, the FDA is making multiple major errors by failing to consider smart alternatives and failing to weigh the risks of unintended consequences. This rule, if it were ever to become final, will surely be overturned. The FDA can do better and Dr Brian King, who I welcome in his new role at CTP, should have a little bit of humility in terms of his errors working in his role at the CDC as a scientific expert on EVALI, which he incorrectly repeatedly blamed in part on nicotine e-cigarettes. There is a misunderstanding in society today about relative risk of tobacco products, and Dr King furthered that misinformation and our misunderstandings about it and now I think there is an opportunity to have a reckoning not only about policing in minority communities, which will become worse as a result of this, despite the FDA's comments that it's not going to do the policing, it didn't do the policing and the Eric Gardner case, sadly and it's not going to do the policing on banning menthol but if you heard today, it will be a major problem but the FDA also should do a reckoning on terms of maybe in the ten years since TPSAC cautioned you about the unintended consequences, maybe with the advent of the success of e-cigarettes and potential for more success given accurate information and the FDA has a role there. Dr King certainly has a role to kind of undo some of the damage he did at CDC in terms of scaring people about nicotine, e-cigarettes. I know we were all distracted by COVID, but now is the time to correct those errors, to help Americans understand, especially minority Americans, who the FDA claims to be so concerned about. The FDA just began an advertising campaign about e-cigarettes in Native American communities. How about to prevent youth initiation? Well, that's great. How about a campaign to encourage menthol cigarette smokers in minority communities to switch to lower-risk alternatives? First, you've got to authorize the PMTAs and then you've got to undo some of the damage you've done. I believe that the courts will not accept this proposed rule because you didn't look at the risks and you didn't explore better lower risk. You could achieve the same benefits that you see. That you wish you can seek by banning menthol cigarettes. You could achieve those benefits by authorizing menthol PMTAs by doing an educational campaign and you won't take on the unintended consequences of a ban and you haven't looked at the potential of the unintended consequences of menthol e-cigarettes because we've got tobacco 21, we've got educational campaigns to prevent youth initiation. Times have changed. Risks of kids using e-cigarettes especially menthol have gone down along with these educational campaigns, better enforcement which is always necessary and tobacco 21 rules, the whole game has changed and the FDA is acting like it's looking at 2009 data and taking on unintended consequences of a menthol ban rather than doing simple, smart policy and I encourage the FDA to rethink this before it gets overturned (INAUDIBLE).

MEGAN HICKS: Thank you. Frank Leon, you are next to speak. Frank Leon. Frank Leon, you are up next to speak. Apologies for my technical difficulties. Up next is Josh Brown. Up next is Starletta Kamo. Starletta. Kiana Maria Stears, you are up next. Kiana Maria Stears. Kiana

Maria Stears, you are next. Moving on, Garrett Neved. Garrett Neved, you are next to speak. Garret Neved. Ned Bowman, you are next to speak. Ned Bowman, you are up next. Ned Bowman. Jennifer Speck, you are next to speak. Jennifer Speck. Jennifer Speck, you are next to speak. Mike Seelbach, you are next to speak. Mike Seelbach.

MIKE SEELBACH: Good afternoon. Thank you for giving me the opportunity to speak today. My name is Mike Seelbach and I live in Commack which is on Long Island in New York and I'm here today to speak in strong support of the proposed product standard, prohibiting menthol as a characterizing flavor in cigarettes as well as the other rule regarding characterizing flavors in cigars. These rules will reduce youth smoking, save lives and advance health equity. I'm speaking today as a long time health advocate and the parent of a 11 and a half year old and a 14 year old who you may be able to see in a picture over my shoulder. We know that prohibiting menthol cigarettes will reduce youth smoking. Flavors hook kids. Menthol acts as a coolant and it numbs the throat which reduces the harshness of tobacco smoke making menthol cigarettes more appealing to new smokers, especially young people. We know that flavoring will lead to greater nicotine dependence, and it's more likely that people that use these products, children that use these products are going to progress to becoming regular smokers. We know that kids are using these products and as a father, it frankly frightens me that another generation of kids are becoming addicted to these deadly products. As someone who's lost a loved one to a cigarette smoking, we need to do everything we could to prevent this generation, another generation from becoming addicted and also besides preventing another generation from starting these products, we also know that prohibiting menthol cigarettes will increase smoking cessation. It will encourage current users to quit smoking so if these two reasons weren't enough, we also know that prohibiting menthol cigarettes are going to decrease the health disparities that we currently see due to tobacco use and advance health equity especially among black Americans. Unfortunately today, we've seen a bunch of arguments being made from folks in the law enforcement community and we know that that is not the way that these laws are enforced. Across the country, we are seeing a whole bunch of laws even just this morning, the city of Los Angeles passed a flavors ordinance and we think that that's great but if we are going to enforce these laws, we need to get these products off the shelves in its entirety so we want to see one nationwide law that will prevent the sale of menthol cigarettes and prevent and stop the sale of flavored cigars. For more than 60 years, the tobacco industry has targeted Black Americans with marketing and price promotions for menthol cigarettes. Instead of hearing tobacco industry arguments, we know that these products have been targeted into these communities, and the best way that we can help decrease the disparities that we see is to prevent the sale of these products. Despite accounting for 12% of the population, Black Americans represented 41% of premature deaths caused by menthol cigarettes between the years 1980 and 2018 and it's not just the African American community that we see. These products have been marketed in the [INAUDIBLE] community. We know that it's disproportionately high also in Hispanic and Asian smokers so we need to do everything we could to decrease these disparities and these rules will help save lives. So on behalf of myself, my wife, my kids and their friends, we urge you to strongly, to quickly get these rules into effect and get these products off our shelves. Thank you.

MEGAN HICKS: Thank you. Up next, Vali Seng. Vali Seng you are up next to speak. Vali Seng, you may proceed. John Dixon, you may proceed.

JOHN DIXON: Can you hear me? First of all, let me introduce myself. My name is John Dixon. I have over 40 years of law enforcement work, over 60 years of being a black male within black and brown communities and over 40 years of being a parent of two black males. I want to speak to you from all of those different perspectives if I may in the next five minutes. Bans are bad policy. They do not work. As you've heard, prohibition created more problems than it has solved. We should be able to learn from our past and realize that they do not work. The war on drugs, more black and brown people went to jail during that time than all of slavery. It didn't work. Stop and frisk. More black and brown people were targeted and about 90% of those people who were stopped under the stop and frisk were black and brown people. Three strikes, you are out. Two of those strikes were being black or brown, and the second was being a male. I've never had a fear of cigarettes, but I have had the fear of the police even when I'm doing nothing wrong being behind me, concerned about being stopped, concerned about what they would do if they stopped me. As a parent, it's conversations I have to have that my counterparts do not have to have with my black sons. I have to talk about the birds and the bees as they get older and I also have to tell them about what to do when law enforcement stops you and even that, as we've seen across the country, the things that have happened is not good enough because they can get stopped, that disproportionate of black and brown males getting stopped is what creates problems, is what creates death, is what creates the distrust that the community has for law enforcement and creating a ban is only going to increase on this and make it worse within the black and brown communities. I've heard all of your speeches for the last few hours, and I'll tell you, the issue is this is an opportunity to bridge that gap, to take a look at what the folks within those communities feel like, what the folks who are smoking, what they feel like. How does those things affect them? How would a ban affect them? I think it's incumbent upon the FDA to take a look and maybe pull in one of the HBC youths or a couple of HBC youths and do a study, an impact study, or how does that affect their community. Instead of listening to all these folks who have not rode through some of these neighborhoods, who have not had to have those conversations with their sons and daughters, let's listen to the people who it affects and see what they think about it. As you all have heard, smoking is down. Youth smoking is way down and so why are we going after to solve a problem that really isn't a problem? Why not go out to try to fix the problem and satisfy the community and allow adult people to make adult choices on what they decide to do and thank you for this time and please take in consideration letting people solve their own problem and stop the governmental overreach.

MEGAN HICKS: Thank you. Up next, Floyd Alvin Galloway. Floyd Alvin Galloway, you are next to speak. Floyd Alvin Galloway. Is there anyone here with a confirmed spot to speak that wasn't able to today? Please let U.S. know if you are here. Christina Robinson, you are next to speak. Christina Robinson.

CHRISTINA ROBINSON: OK. I see it now. I just saw the link to unmute. Hello. My name is Christina Robinson and I'm in Sacramento. I just wanted to kind of express my concern over the situation with considering a ban on flavored tobacco. A lot of people had already come on here and spoke about it saying a lot of the same things, things that I even have concerns about and one of those issues is banning something is taking the right away from adults pretty much who has a choice to if they choose to smoke flavored tobacco, that should be their right. There is a lot of restrictions, you know. You got to be 21 years old now to be able to buy tobacco. There is a lot of, you know, standards that prohibit, you know, just children

buying, purchasing the tobacco so, if you ban these products, what's going to happen is it's going to of course flood our streets and then our children, teenagers mostly will be out there probably selling it and now it'll affect neighborhoods and the mom and pop stores, these small businesses are going to be losing money some of them are going to be closing down because now you are taking the money away from them when they could have been making the money legally. I have a concern about that because I would hate to see these mom and pop stores or these small businesses lose out on, you know, something that can help everybody. It's a trickle effect. If you are going to ban menthol or flavored tobacco, then you might as well ban all cigarettes. It's kind of like taking something, let's say some type of drug or alcohol and you sprinkle sugar on it. That alcohol or drug is still deadly. It doesn't change so when you put flavor to something, that's not changing anything. Yes, it is enticing to kids if you are throwing commercials out there and you are putting cartoons, you got to go after the people that are making those type of things, you know, the boxes and the, you know, enticing people. Those kids shouldn't be able, they shouldn't know about it. If you walk into a store that says that you have to be 21 and older like a bar, kids do not know what a bar looks like inside. They shouldn't know what it looks like inside and the same goes for stores that sell only alcohol and beer. It should be the same restrictions so adults can go in there and be adults and be able to purchase something that they enjoy, you know. I think it's wrong and I do think this is a racial act, you know. To me, all I could see is race all over it. If you go and look at the facts, if you look at the research, 85% of black people smoke menthol tobacco and if you go back into looking at say music videos, I'm a Tupac fan, you know. Tupac smoked Newport cigarettes and it became a trend. A lot of people wanted to smoke it because it was popular, you know and you look at back in the days, Joe the Camel, a cartoon character. A lot of people smoke those cigarettes and that was probably when I was a kid, you know, my parents were younger. A lot of kids nowadays do not know what that is. You know, you got Marlboro, you got all that type of stuff but right now you are attacking menthol cigarettes knowing that 85% of people of color, you know, predominantly black smoke that so it does sound like it's being targeted towards a racial injustice and people had already died, you know, just like among the things that has happened with cigarettes and their hands coming out of the store, you know, things like that and is ridiculous and I think that a ban is the wrong approach to it and if people look into it deeply deeper, they would understand that this is completely wrong and we've got to think about if you are going to protect our children, this is the wrong way to go and that's all I have to say and I thank you for your time.

MEGAN HICKS: Thank you. Up next, Carol McGruder. Carol, you are up next.

CAROL MCGRUDER (AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL): Hello, good afternoon. Can you hear me and see me?

MEGAN HICKS: Yes, thank you.

CAROL MCGRUDER (AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL): OK. Hi, Good afternoon. I'm Carol McGruder, and I'm one of the co-chairs of the African American Tobacco Control Leadership Council. We were founded in 2009, and since that time, we have been at the forefront of the movement to get methylated tobacco products out of the black community and off of the U.S. market. We work hard to save the lives of the 45,000 black people who die every year in this country from tobacco induced diseases and

that the reason why we have such a high smoking prevalence and death rate is because of the racist and pernicious targeting that we have endured for decades in our community at the hands of the tobacco industry. The tobacco industry are, in fact, federally adjudicated racketeers under the Racketeer Influenced Corrupt Organizations and it's interesting that we have so many former African American law officers on this call who actually are consultants with federally adjudicated racketeers. That intersection is very interesting, and we would like for people who are taking money from the tobacco industry to , to disclose that as they are speaking, to disclose that they are, in fact, consultants, paid consultants to expose the rhetoric of the tobacco industry. Our counsel works at the intersection of public health policy and social injustice and what we ,what we posit is that the, the predatory racist targeting that the tobacco industry has done on the African American community is a violation of the International Treaty for the Convention of All Forms, for the Elimination of Racial Discrimination and that when President Obama signed the Tobacco Control Act in 2009 and left menthol and they took all the other flavors out, that was in fact, the racism, the institutional racism and the benign neglect of the Food and Drug Administration in Congress to protect African Americans. African American smokers are not born whole, but the new put in their mouths. Our children deserve and merit the protection of other people's children in this country and when menthol was left in as a characterizing flavor that was discriminating against black children and as Joseph Califano put it, it was relegating black children to the back of the public health bus so we are happy to see now that our children will be allowed on the bus and that this taking menthol off is, in fact, working against the manufacturers. It's not about individuals. It's about the manufacturers of these deadly product who have seeded these products in our communities, giving them away to children as young as nine years old, giving them away to people like Dave Chappelle, the famous comedian when he was 14 years old at the Metro DC station and this happened in every city across this country, and that is the legacy that we live with today and that's why we encourage the FDA to continue and to take these products off the market. We want them to remove menthol from our products as an ingredient, not just as a characterizing flavor. We want cessation services to be provided to our people who have been disproportionately targeted, and these cessation services must be culturally tailored ,And address social and political determinants of health. We want the same vim and vigor coming from public policy, public health advocates, to help our people as was done in neglecting our people and allowing the tobacco industry's pernicious targeting. When the rule is finalized, we want products to be removed within 90 days, and we also do not want these products to be manufactured in the United States. Because that with, that would be how an illicit market would occur is if the products can continue to be made in our country and then sent to other countries sometimes those are African American communities in the confines of the United States. We know that taking these deadly products off the market is the beginning of the process. No one loves a black menthol smoker ,more than the African American Tobacco Control Leadership Council [UNKNOWN] and the Center for Black Health and Equity, That is why we exist, and so we are here for the beginning of the fight, fight of undoing the neglect of our community, and the legacy that we live with so many of our people dying every year from tobacco and dust diseases more than every other form of preventable death, including AIDS, car accidents, violence, officer involved shootings and all other forms of cancer that are not related to tobacco. Thank you for your time and we look forward to overseeing and keeping this on top of this process as we move forward. Thank you for allowing U.S. to speak today.

MEGAN HICKS: Thank you, we've gone through the list of confirmed speakers and weightless speakers for today. If you are on the line and would like to speak, please respond in the chat with your name and affiliation. You will go in order of those that sign up until 4 p.m.. All Interested in hearing from those whose organizations have not been represented today, Up next, we have Desmond Jenson. Desmond Jenson? You are up next.

DESMOND JENSON (PUBLIC HEALTH LAW CENTER): Hello, Can you hear me?

MEGAN HICKS: Yes, thank you.

DESMOND JENSON (PUBLIC HEALTH LAW CENTER): Great, thank you. Thank you, my name is Desmond Jenson. I'm the lead senior staff attorney for federal regulation at the Public Health Law Center. I want to use my time today just to make a couple of points that I hope folks at the FDA will consider as they are sifting through all the written comments and then listening to the testimony this week as well. First, the FDA is final decision on both of these proposed rules can only be based on the potential health outcomes of the action. The dockets are already filled with comments from tobacco retailers written at the behest of the largest cigarette manufacturers. You've heard plenty of testimony today. A lot of it focused on the potential repercussions for businesses. I have no doubt that you'll hear the same arguments again on Wednesday and I do not need to explain to you all that the science on menthol and other flavors and combusted tobacco products could not be more clear and so to stand before the agency and argue otherwise, would completely obliterate one's credibility so as you hear testimony this week, remember that anyone arguing that the evidence supports inaction has no credible information to share with you so in the face of the overwhelming evidence that shows that these product standards would save a tremendous number of lives, what you'll hear instead is that businesses will suffer and other countervailing effects that will mitigate the health impact of these rules. Well, they may be compelling emotional arguments. The fact of the matter is that the FDA can only make a decision based on the health effects, not the economic ones. You'll see and hear testimony about illicit trade, business losses and other issues some of them are even identified in the Tobacco Control Act as issues that the FDA must consider, after proposing a product standard. However, even a cursory reading of the statute will show you that the FDA is required to accept comments on a variety of issues but after the comment period has expired, the statute requires the FDA to either terminate the proposed standard and notify the public or finalize the standard and the decision to finalize is required if the agency determines that the standard would protect public health so in case it was unclear to anyone the moment these rules were proposed, the agency started a process that ends with a mandatory decision, a decision where the sole calculus is the impact on public health, not the impact on business. In this particular case, because of the overwhelming evidence on the health impacts, there is only one decision that the agency can make, and to do otherwise would be the very definition of arbitrary and capricious. Now, because of how much is at stake, the FDA must get these rules finalized as quickly as is possible. The deadline for comments must not be extended. The final rule must be issued quickly and that the time for implementation must be short. Every day wasted represents generations of addiction and additional lives marred by illness and death. There is no excuse for further delay. We are thrilled that the FDA has finally made it to this point but the delay has caused a catastrophic loss of life that is inexcusable. The FDA must know that its inaction is just as powerful and important as any action that it takes. Finally, I want to commend the FDA for

providing some analysis of health equity issues in the proposed rules. I think that was a terrific first step, and I want to urge the agency to do more of that in the final rules, and also to ground all future analysis under the public health standard in health equity. The FDA can join a growing list of people and organizations in public health that have recognized, that all policy making must be equity centered in order to have the biggest health equity gains. We will not reduce health disparities if we do not act deliberately. This is particularly acute in tobacco control, where most of the harms caused by the products happen to people who belong to groups that are already marginalized in our society. They are targeted by the tobacco industry. They have the least access to adequate health care, and they live in environments that do not provide them with adequate opportunities to live their healthiest lives. Now, the FDA has tremendous power to shift that dynamic in a meaningful way. These two rules are the lowest of the low hanging fruit and as the FDA continues to consider future product standards, sales restrictions, and as it's reviewing tobacco product marketing applications, the agency must conduct, conduct all that analysis under the public health standard in a way that centers health equity, not just analyses it in passing ,thank you.

MEGAN HICKS: Thank you. Erika Sward, you are up next to speak.

ERIKA SWARD (AMERICAN LUNG ASSOCIATION): Good afternoon, my name is Erika Sward, and I'm the national assistant vice president for advocacy at the American Lung Association. I'd like to emphasize and underscore the points that Desmond from TCLC, I'm sorry, Public Health Law Center just made, with regard to FDA's requirements under the standard. I'd also like to emphasize how important it is that all flavored cigars, all flavored water pipes and hookah, as well as all menthol cigarettes be removed from the market at the same time. We have seen the very real intended consequences from the tobacco companies for what happens if you leave certain flavored products on the market while removing other flavored products from the market indeed, that was how the rise of little cigars and cigarillos with candy and fruit flavors as well as menthol flavors occurred, after the Tobacco Control Act prohibited flavored cigarettes, during the passage of the Tobacco Control Act in 2009. It is also very clear that flavored cigars are marketed to use, especially African American use and prohibiting them will help reduce the health disparity associated with this. We also want to urge the FDA to finalize those proposed rules by the end of 2022, recognizing that they are long overdue and indeed, the FDA's own scientific advisory committee recommended that it be appropriate for the protection of public health to remove these products back in 2011. We know that flavored cigars play a critical role in attracting new tobacco users and increasing the likelihood of long-term addiction. We know that prohibiting flavored cigars will substantially advance health equity, since African American youth have higher levels of cigar use than their peers. We also recognize that given the flavors and the role that flavors play in attracting young people to use cigars, there is no rationale for continuing to permit any characterizing flavors in any cigar and attempts to draw clear lines to differentiate between cigar products or flavors, for the purpose of exempting some products from a flavor rule are vulnerable to evasion and amplify the risk of industry manipulation. I think we've all learned from both what happened with the, the rise of taxes and the passage of the Tobacco Control Act in 2009, that when an industry and a company within an industry is willing to add kitty litter to their product so that they can pay less in taxes, that, that no opportunities for evasion can be allowed. Indeed, we know that the industry one will take any undue advantage of any loophole, that the FDA gives them the opportunity to do so so with that, I wish to thank the FDA for moving forward with this. We urge them to finalize the

rules by the end of this year to oppose any efforts from, from political efforts and the tobacco industry to weaken them and we look forward to working with FDA to ensure that everyone who currently is addicted to tobacco is given the help they need to quit smoking, which they can do at Lung dot org, or by calling one 800 quit now. Thank you.

MEGAN HICKS: Thank you. Charles Giblin you were next to speak. Charles Giblin

CHARLES GIBLIN (CENTER FOR THE ADVANCEMENT OF PUBLIC SAFETY AND SECURITY): Public safety and security. Did you get the beginning of that, I just saw the thing come up on mute it I'll start anyway. My name is Charles Giblin. I'm representing the Center for the Advancement of Public Safety and Security. After 45 years in law enforcement, I retired as the special agent in charge of the New Jersey Treasury Department's Office of Criminal Investigation. It is the state law enforcement agency responsible for the enforcement of the laws related to tobacco and vape, as well as the criminal code violations involved. During my career, I served on the board of Directors of the International Association of Chiefs of Police, as well as a number of other professional organizations, including the Federation of Tax Administrators where I served on the tobacco section's leadership and recipient, recipient of their lifetime achievement award for that type of work. I've served as a subject matter expert for numerous agencies, both state and federal, and recognized in court system, both federal and state, as an expert witness. I have a unique perspective as a career law enforcement officer on the investigation of Portsmouth's tobacco laws both in New Jersey and nationally as a former task force officer. I have spoken before the American Bar Association and National Association of Attorneys General on this very subject. To get to the point, despite the good intentions of banning what is now a legal, highly regulated controlled product within a very strict framework across the country, this ban will have other unintended consequences. Please remember and understand that illicit sales are outside the controls established to ensure the legal age of sale and will lead to the erosion of those controls over the tobacco and vape industry. I've evaluated even the Massachusetts situation and have testified before their illicit tobacco committee. Additionally, based upon my experience and interactions with other national law enforcement associations, I'm keenly aware of the current landscape of law enforcement, even though I'm retired. I fully expect that cross-border smuggling and counterfeit products will fill the gap created by this new prohibition. Once a ban that would go nationally, we will see that ban make its way to see a significant underground economy, criminal operations run by different organized groups and in particular, we will see activity along our southern border with Mexico, as an example, We are keenly aware that the neutral fiscal cartel, an extremely violent Mexican drug crime group, has established their own illicit tobacco distribution network in the Mexican cities along the border, using old fashioned organized crime techniques of threats, coercion, violence and protection racket. The new Glasgow cartel has full authority over that marketplace, which is sourced by the Chinese National Tobacco Company. Those cigarettes that people are talking about banning being manufactured in United States, of mental design will not be manufactured here. They will be manufactured in other countries by the Chinese National Tobacco, they are the largest manufacturer of cigarettes. Most of these products will be disguised as legitimate U.S. trademark brands, including menthol, and they will flow from Paraguay, Colombia and the Southern Triangle into the United States. Counterfeit cigarettes will also, and I've not heard this mentioned, they will not be certified fire safe. They will be counterfeit state tax stamps. They make them prima fascia contraband under almost every state law. Thus, the new

dynamic of why law enforcement would be involved in enforcing this ban. We know that law enforcement internationally and nationally recognized cigarette smuggling as a term terrorist funding source, favorite money-maker for organized crime groups and our current intelligence indicates that our Chinese China tobacco interests have been investing in both physical and financial infrastructure along the southern border in Mexico. I strongly believe our nation will be inundated with counterfeit products in various ways, including traditional narcotic routes. Please understand that the sale of any cigarettes sold without the required state tax stamp or bearing a counterfeit tax stamp, will be considered a crime across the United States by those states. For instance, a second or subsequent violation in New Jersey by any person of any tax law, would expose that violated the doubling of the sentence and doubling of the fines. We will see a newly invigorated illicit market of the very product you are seeking to ban, not to mention new responsibility upon law enforcement generally, as well as our criminal justice system. This is one of the greatest challenges ever for law enforcement, as We are trying to create a better relationship with community and modernize tactics and approaches and eliminate the situation as occurred, unfortunately, in New York City. I strongly recommend that these regulations be tabled, not acted upon, as it will criminalize the sale of menthol cigarettes on the basis of the many member states. Thank you for your time.

NECOLA STAPLES: Thank you so much for your participation in today's Listening Session about FDA product standards to prohibit menthol as a characterizing flavor in cigarettes and to prohibit characterizing flavors in all cigars. Just like today, if we have more time on Wednesday, we will open up again to those individuals on the call and those organizations we have not yet heard from. As a reminder, this meeting has been recorded and the transcript will be added to the dockets of proposed rules as well as to the CTP website. If you have any additional questions, you may email U.S. at [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov), Thanks so much. Goodbye.