LISTENING SESSION: DEVELOPING FDA'S CENTER FOR TOBACCO PRODUCTS' STRATEGIC PLAN

August 22, 2023

The U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) recently initiated the development of a 5-year strategic plan to advance its mission. As part of an iterative, center-wide process, CTP has developed five proposed goal areas that have been shaped by staff and leaders from across the center. These goal areas are intended to be interconnected with four proposed cross-cutting themes: health equity, science, transparency, and stakeholder engagement.

From 10 a.m. to 4 p.m. EDT on August 22, FDA held a virtual listening session to give the public an opportunity to verbally provide open public comment on the development of the 5-year strategic plan, including proposed strategic goals.

FDA invited members of the public to request to comment (utilizing their video camera or audio-only) during a public listening session or to participate by attending the meeting without making a public comment.

FDA aimed to make the session as inclusive as possible and to create an opportunity to hear a range of ideas and perspectives.

The following is the written transcript of the August 22, 2023, listening session.

Commenter	Organization (if applicable)
Vasuki Pasumarty	
Rob Crane	Preventing Tobacco Addiction Foundation and Retired Professor of Family Medicine at The Ohio State University
Lindsey Stroud	Taxpayers Protection Alliance Consumer Center, Independent Women's Forum, and American Vapor Manufacturers
Drew Newman	J.C. Newman Cigar Company
J.B. Simko	Philip Morris International
Keith Churchwell	American Heart Association
Ana Melendez	Florida Association of Wholesale Distributors
Nkechi Taifa	Taifa Group and Justice Roundtable Convener Emeritus
Jim McCarthy	American Vapor Manufacturers
Jeff Stier	Individual
Tony Abboud	Vapor Technology Association
Stacey Gagosian	Truth Initiative
John Maa	
Elliot Boyce	Diverse Perspectives
Willie McKinney	McKinney Regulatory Science Advisors
Joshua Habursky	Premium Cigar Association
Joe Murillo	Juul Labs
Lauren Lempert	UCSF Tobacco Center of Regulatory Science (TCORS)
Willow Anderson	Public Health Law Center
Tom Eshleman	
Monita Sharma	PETA
Sairam Jabba	Duke University School of Medicine
Charles Giblin	Center for the Advancement of Public Safety and Security
Kathee Facchiano	Convenience Distribution Association
Sonia Wiggins Pruitt	Black Police Experience
Charles Gardner	
Samy Hamdouche	Lucy Goods
Will Jackson	W.L. Petrey Wholesale Company
Pamela Ling	Center for Tobacco Control Research and Education and UCSF Tobacco Center of Regulatory Science
Christopher Beaulier	Cigaret Shopper
V.J. Mayor	Northeast Wholesalers Association and Southern Association of Wholesale Distributors
Peter Krueger	Nevada Petroleum Marketers & Convenience Store Association
Doug Ball	Jacksons Food Stores
Jeffrey Smith	R Street Institute
Meredith Berkman	Parents Against Vaping E-Cigarettes
Lyle Beckwith	National Association of Convenience Stores
Michael Schoenfeld	MTC Distributing
Jiles Ship	National Organization of Black Law Enforcement Executives (NOBLE)
Thomas Briant	National Association of Tobacco Outlets

Commenter	Organization (if applicable)
Chris Howard	Coalition of Manufacturers of Smoking Alternatives
Joseph Manuppello	Physicians Committee for Responsible Medicine
Erika Sward	American Lung Association
Rachel Boykan	American Academy of Pediatrics Section on Nicotine and Tobacco Prevention and Treatment
Bryan Burd	Chemular
Cynthia Stanford	
Guy Bentley	Reason Foundation
Jon Adler	Federal Law Enforcement Officers Foundation
Doug Kantor	National Association of Convenience Stores
Greg Wilson	Altria
Diane Goldstein	Law Enforcement Action Partnership
Elizabeth Hicks	Consumer Choice Center
John Bowman	Campaign for Tobacco-Free Kids
Andrew Perraut	Cigar Rights of America
Stanton Glantz	UCSF TCORS (Retired)
Wayne Harris	
Ryan Potts	REI Services Company
Alex Clark	Consumer Advocates for Smoke-Free Alternatives Association

Listening Session: Developing FDA's Center for Tobacco Products' Strategic Plan Transcript

August 22, 2023, 10:00am – 4:00pm EDT

Sarah Lynch:
Welcome to today's Listening Session on the Development of FDA's Center for Tobacco Products' 5-year strategic plan. And thank you for joining us. I'm Sarah Lynch, commonly known as SJ, and I currently serve as the Division Director in FDA's Office of Operations, Office of Planning, Evaluation, and Risk Management, or OPERM, here at FDA. OPERM provides expertise in strategic planning and other areas in partnership with FDA executives and senior managers. Over the last few months, my team and I have facilitated discussions with leadership and colleagues across CTP about the focus of the center's new strategic plan and key elements, as referenced in the public meeting notice. I will serve as session moderator today for the first and last hours of the listening session, with other FDA colleagues covering other time windows.

The listening session provides the public an opportunity for open comment on the goals, themes, and focus areas of the plan that we are in the process of developing, whether delivered verbally today -- excuse me -- or in writing to the docket, we will consider your comments in further shaping the draft plan. As a reminder, the information to submit a written comment is also available on the FDA event page for this meeting. Today's session, as you can see, will be closed captioned, and an ASL interpreter will be on the call. This meeting is also being recorded. A transcript and recording will be available on FDA's website in a few weeks. A transcript will also be accessible on regulations.gov.

I now turn it over to CTP Director Brian King for a welcome and overview of some broader context and what we've done to develop the plans, draft themes, goals, outcomes, and objectives content.

Brian King:
Great. Thank you, SJ, and good morning, all. Thanks for attending today's listening session and for providing your comments as we develop the center's new five-year strategic plan. Now our priority today is to hear from the public. So, I'm going to keep my introduction and remarks very brief this morning.

So, as I'm sure you'll recall, in September of last year, there was an independent expert panel that was facilitated by the Reagan-Udall Foundation that began an operational evaluation of our center at the request of FDA commissioner Dr. Robert Califf. As I've noted many times publicly and also privately, I welcome this opportunity as the newly minted center director to help chart our path forward. And my perspectives have not changed on that matter. They continue to persist today. The final report was ultimately issued in December of last year, and it included 15 recommendations, all of which CTP has committed to addressing and we continue to provide updates on that progress on a newly created website. And importantly, one of those recommendations from the report was the creation of a new strategic plan. And we've had previous strategic plans since the inception of our center and welcome the opportunity for an

update, which was also particularly timely and appropriate given the arrival of new leadership at the center.

Now in terms of background, over the past several months, all CTP staff were given the opportunity to provide feedback in various ways on the draft content that we're going to be discussing today. In addition to the many valuable suggestions from staff across the center, which is critically important, public input is also important. And that said, that's why we're here today to request your input as we are further developing the new strategic plan.

And now before I hand things over to get us started, I did want to walk through the five draft goal areas for the proposed strategic plan that you've all been provided with leading up to today's session. Now the first is to develop, advance, and communicate comprehensive and impactful tobacco regulations and guidance. Now this goal includes activities related to the development and implementation of CTP's regulatory and policy agenda; the articulation and publication of clear and comprehensive public policy statements; and also efforts to advance health equity.

The second is to ensure timely, clear, and consistent product application review to protect public health. This goal includes activities related to work processes, such as optimizing the efficiency, consistency, and effectiveness of the product application review process; enhancing public understanding of regulatory requirements through transparency and stakeholder engagement efforts; and also ensuring that the review process is supported by a strong regulatory science program.

The third is to ensure compliance of regulated industry and tobacco products utilizing all available tools, including robust enforcement action. This goal includes pursuing enforcement actions to reduce violations; enhancing collaborations with federal and state agencies on tobacco enforcement efforts; and prioritizing agile market intelligence and surveillance to facilitate awareness of and effectively responses to the evolving tobacco product landscape.

And now the fourth is to improve public health by enhancing knowledge and understanding of CTP tobacco product regulation and the risks associated with tobacco product use. This goal includes timely, clear, and accessible health communications and education to diverse public audiences, including those to discourage youth initiation, encourage cessation, and to inform adults who smoke about the relative risks of tobacco products.

And finally, the fifth is to advance operational excellence. This goal includes prioritization of workforce growth, engagement, and retention, and CTP's ongoing commitment to diversity, equity, inclusion, and accessibility. Also modernizing business processes to enhance information management and programmatic efficacy and seeking and applying needed resources to support CTP's full portfolio of regulatory activities.

Now, I do want to note that there's also several cross-cutting themes relevant across the five proposal areas that we'd like your feedback on today, as well. And those include health equity, science, transparency, and stakeholder engagement. And before I begin, I do want to acknowledge that we received many requests to speak, and we have worked hard to accommodate every single one of them today. And so, in doing so, we do have a packed schedule, and I encourage you to please stick to the time allotted, so we can hear all voices who

would like to comment on the strategic plan. I know there were many folks who signed up to listen in but didn't sign up to speak. That is A-okay as well. With that said, I will emphasize that the docket remains open. And every person, group, or organization can provide written comments through August 29th of this year. And after that comment period closes, we're going to review the comments and take this input into careful consideration as we continue to develop the center's strategic plan and following that input, we intend to publish the strategic plan by the end of this calendar year, and we are on track to do so.

So, in closing, I'm grateful to everyone for sharing your input with us today. We look forward to hearing a broad representation of ideas and perspectives during this session, which I have absolutely no doubts that we will see, given the lineup today. And I will now pass it back to SJ, our first moderator who will open the floor for comments. Back to you, SJ.

Sarah Lynch:
Thank you, Brian.

We're ready to begin welcoming our confirmed speakers to provide their comments, with some general and specific process parameters. First, all comments, please, should be forward looking, constructive, and concise in addressing the following questions in the context of the goal-related information that Brian provided. As you can see on the screen, what key features, activities, or initiatives would you like CTP to consider as related to any of these proposal areas? Question one. What are the measurable, short- and long-term outcomes for the proposal goal areas over the next two to five years? Question two. What are the three specific actions CTP could take in the next five years that would have the most impact in significantly reducing tobacco-related death and disease? Question three. And are there any important features or activities or initiatives not encapsulated by these proposal areas that you believe CTP should consider as part of its strategic plan?

At the start of your comment, please clearly state your name and the organization you represent. Or please note that you're speaking in your individual capacity. Second, as Brian mentioned, please limit your remarks to four minutes or less. To assist commenters with timekeeping, we will notify you when one minute is remaining for your allotted time, to be fair and equitable to all speakers, given that we have accommodated many, if your remarks continue past the four-minute time limit, unfortunately, your line will be muted. And you will be -- we will be moving on to the next speaker. Last, we recognize that there are strongly held views and perspectives on this topic. We're committed to ensuring that all views are shared respectfully and appreciate your assistance in achieving this. Now, let's get started. Once your name or telephone number is called, you will be unmuted so that you can comment, and we have a first up, Vasuki Pasumarty. You have four minutes for your comment. Please proceed.

[audio break]

I'll say it again; Vasuki Pasumarty.

[audio break]

Vasuki Pasumarty:
Hello?

Sarah Lynch:
Vasuki?

Vasuki Pasumarty:
Hi. I apologize. There were some server issues.

Okay, let me -- thank you so much for letting me speak. My name is Vasuki Pasumarty. And I am speaking as an individual and I would -- so let me start, in designing an effective program plan encompassing the strategic vision of tobacco management and regulation, it's imperative that first an owner with the co-owner with clear stakeholder constituents of each phase in the development lifecycle be charted out with clear roles and responsibilities, scopes, and the mission vision statement. That being said, the outreach and communicating and deploying on the risks of nicotine products holds many challenges. Given that the pre-pandemic models that may have started to gain traction, based on the then social evolution and lifestyles deviated almost instantly, during the COVID crisis with spikes in mental health concerns, general restlessness, and nicotine vaping usage. For almost three years, the U.S. has struggled with a standstill and further complacency in depressive states due to forced social and physical lulls.

After reviewing some statistics around tobacco usage, and the CTP oversight, I strongly suggest and recommend that the CTP consider embarking on a design for a national awareness campaign related to a scope that comprises a small but sizable group for their strategic five-year plan. That being drivers who use tobacco products while driving, with the goal of eventually regulating smoking in the car, making it possibly ticketable nationwide, the awareness campaign would go into effect with data collected via a comprehensive survey, and an internal stakeholder deep dive where assessments on how to manage age groups or drivers who smoke locations such as local and main streets where smoking while driving would be regulated or banned, the times of the regulations, fines, and finally protecting animal ecosystems by banning smoking from all parks, owned parking lots, and many parking lots at malls and/or standalone department stores, where there may be families of ducks and other vulnerable animals walking around near or at their normal habitats.

Smoking while driving can be quite common and achieving success in curbing some of the smoking within the driver population may have -- may drive effective time to conditioning where for those 10 to 15 minutes or 30 minutes to an hour, a driver could benefit from decreases in blood pressure by not smoking. Ideally, a smoker can do whatever he or she wants outside of driving. But if controls were to be placed around driving, the time not smoking in their car could add up in health benefits albeit a little here or there. This kind of campaign for this small group could achieve some national success in a strategic and phased go-live with granular demographic hotspots from the aggregation of the survey data and further collaboration from potential stakeholders, such as major retailers who have pharmacies, malls, local law enforcement and park systems as well as sanitation and environmental.

Finally, there could be the possibility of podcasts and other products that can be developed specifically from this campaign for the success of this campaign where there could be beta testing and eventually offer drivers who smoke an opportunity to relieve any urges for the time they spend in their vehicles --

Sarah Lynch:
Thank you.

Rob Crane, please state your name and organization; confirm that it is Rob Crane. Share that you're speaking as an individual or an organization and you have four minutes.

[audio break]

Again, Rob Crane, please.

Rob Crane:
Good morning, I'm Rob -- can you hear me now? Yes?

Sarah Lynch:
Yes, we can, sir.

Rob Crane:
I'm Rob Crane, a physician and retired professor of family medicine at The Ohio State University. I head up the Preventing Tobacco Addiction Foundation, and its advocacy arm Tobacco 21. I speak on behalf of them today.

We work across the country to raise the legal sales age for all nicotine products and reduce retailer access to kids. Please note we don't use the term youth access because that implies kids are the problem. We commend the FDA and the Center for Tobacco Products, and its robust efforts to inhibit retailer access and reduce the marketing and appeal of these deadly addictive products. We heartily applaud Dr. King and his leadership that has brought renewed determination to these efforts but has not been enough. Not nearly enough. Innovation by the industry requires innovation by its regulators, and frankly, all of us are behind. The results of Monitoring the Future suggested more than 20 percent of high school seniors are vaping and NYTS indicates there's a third of those who are addicted. This calendar year alone FDA's contractors have done 64,000 underage compliance checks, revealing that one in six brick and mortar retailers sell underage. We believe this to be a gross undercount, due to the unrealistic methodology of these compliance checks. But even at one in six, this means full access to kids, as they will choose the retailers who sell.

Only about 30 percent of kids say they get their products from stores, but their social sources generally do. And now increasingly kids are being supplied online. We're still over two thirds of underage college students who say they have fake IDs. We recommend anyone listening to go online and simply search "buy fake ID," see how easy it is to obtain these. Given these facts, we have our three strong recommendations, that should be incorporated into the long-delayed issuance of the Tobacco 21 regulations by the FDA. Number one, the enforcement of brick-and-mortar underage sales and compliance checks must be tightened. This will also require congressional action and the administration and the FDA to push next year's Congress to do so. Number two, given the risks involved, there's simply no rationale for online non face to face sales of non-therapeutic nicotine. The FDA has the authority to close these down and ban the sales. They should undertake these steps to do so immediately. Number three, the problem of fake IDs is so overwhelming that the only possible solution is the use of Real ID technology scanned at the point of sale.

We thank you for your attention and hope to move forward with greater and more robust enforcement and determined efforts against nicotine. Thank you.

Sarah Lynch:
Thank you, Rob.

Lindsey Stroud, you are up next. Please state your name and organization or share that you're speaking as an individual. You have four minutes for your comment.

[audio break]

Lindsey Stroud, please.

Lindsey Stroud:
Yes, can you hear? Oh, can you hear me? Yeah, you can hear me. Sorry I was on -- I'm on two computers, so [laughs].

Thank you for your time today. My name is Lindsey Stroud. I'm director of Taxpayers Protection Alliance Consumer Center, and a visiting fellow with American -- or the Independent Women's Forum and a board member at the American Vapor Manufacturers.

The CTP at FDA severely stunted due to various provisions in the 2009 Family Smoking Prevention and Tobacco Control Act. Firstly, that was designed to limit the tobacco marketplace as an effectively favored bigger companies -- few bigger companies at the expense of everyone else. The TCA stops the FDA from being able to fully advance the development of tobacco harm reduction products. They after signed two years after the introduction of e-cigarettes to the marketplace, and long before novel products were introduced, yet products introduced to the market after February 15, 2007, are subject -- are permitted to market their products as the -- sorry. They are required to apply to the FDA in order to gain market authorization.

The very language in the TCA is confusing and misleads the public. According to line 46 of the TCA, manufacturers are permitted to market their products as approved by the FDA and they confuse and mislead the public. Yet numerous public health trade associations and harm reduction opponents continue to harp that because the FDA has not approved these products. They're just as deadly as combustible cigarettes. Ultimately, the FDA has had a major failure in communicating to the public about the continuum of risks that exist among all tobacco products, a topic first really addressed in 2017, when FDA claimed the agency was developing a plan to strike quote “an appropriate balance between regulations and encouraging the development of innovative tobacco products that may be less dangerous than cigarettes.” Yet the agency has done a poor job of communicating these reduced harms. Every single mobile survey of more than 15,000 doctors found that 77 percent of them believe that nicotine causes lung cancer. A May study in the journal *Addiction* found that most adults who smoke cigarettes do not think that e-cigarettes have fewer harmful chemicals than cigarettes. Even the CTP director recently published a commentary addressing these misperceptions, yet the agency's actions are leading to this confusion.

There are two market pathways to bring a new tobacco product on the market, the substantial equivalent SE pathway or the Premarket Tobacco Product Application, or PMTA. Between

2018 and 2022, the FDA issued 421 SE orders for numerous tobacco products, including 126 orders for combustible cigarette products. To date, FDA has only issued 45 marketing orders for products used using the PMTA pathway, and only 23 of them for e-cigarette products. Only three major companies have received PMTA ordered marketing orders for their e-cigarette products compared to about 27 different manufacturers who received SE orders.

FDA also continues to use as a reason for denying flavored tobacco -- e-cigarette products yet the agency does not have a concrete definition on what defines youth appealing and there is no definition for youth appealing in the TCA. For the past several years has issued warning letters and enforcement actions against flavored e-cigarettes citing youth vaping epidemic yet it's actively ignoring survey data that cite that flavors are not the most commonly cited reason why youth use e-cigarettes. According to the National Youth Tobacco Survey nearly half, 43.4 percent, of current and U.S. Middle and High school students that were using e-cigarettes in 2021 cited using them because they were feeling anxious, stressed, and/or depressed. Only 13.2 percent cited using them because of flavors. Conversely, in numerous adult surveys, countless studies, and the fact that the market is saturated with flavored products in adult e-cigarette use is increasing. Adults both enjoy and rely on flavors to quit smoking and remain-free.

And finally, most importantly, the FDA must reform its budget process. The FDA is completely funded by user fees from six tobacco product categories with 85 percent of its budget coming from combustible cigarettes. There's no incentive for FDA to authorize new products not subject to user fees. But it's also unfair that existing fees are being used for the enforcement action for non-user fees products. Also, it's rather ironic that FDA claims to want to advance public health and reduce smoking, yet its funding relies on the millions of people who smoke. Again, FDA must reconcile some major flaws and the TCA in order to advance tobacco harm reduction for the million Americans who smoke.

Thank you for your time today.

Sarah Lynch:
Thank you, Lindsey.

Up next, we have Drew Newman. Please state your organization or share that you're speaking as an individual. You have four minutes. Thank you.

[audio break]

Drew?

Drew Newman:
Good morning. My name is Drew Newman of J.C. Newman Cigar Company. And I'm coming to you from our 113-year-old El Reloj cigar factory in the Cigar City of Tampa, Florida. It's not a virtual background behind me. We're handcrafting cigars, just like my great grandfather did when he founded our company in 1895.

I want to thank CTP for holding today's listening session allowing small family businesses like ours to speak and share our views on the proposed goal areas of CTP’s strategic plan. I've read through the five draft goal areas that Dr. King mentioned at the beginning and want to offer three

things for your consideration. One, please remember the continuum of risk. Two, we're an industry full of small businesses. And three, compliance should include support, not just enforcement actions. First, when he announced his comprehensive regulatory plan for tobacco products in 2017, former commissioner Gottlieb said quote, "we must acknowledge that there is a continuum of risk for nicotine delivery." He noted that different products can have different levels of harm. And instead of taking a one size fits all approach for all tobacco products, Dr. Gottlieb directed CTP to tailor its work to the unique characteristics of different types of tobacco products. He also recognized the agency has limited resources and directed CTP to focus its limited resources on the products in the continuum that have the greatest risk. In reading CTP's draft goal areas, I'm concerned that this philosophy has been overlooked. As the agency continues drafting its strategic plan, please recognize that tobacco includes a wide range of products, and adopting a one size fits all policy will not work. Please include the continuum of risk in your strategic plan and let it guide the agency and direct CTP's limited resources so they can be used in the most efficient and effective way possible.

Second, for an industry full of small businesses, Section 900 of the Tobacco Control Act, Congress recognized that there are small tobacco product manufacturers. Section 901 directs FDA to direct -- to establish a Small Business Assistance Office. Section 906 provides extra time for small businesses to comply with new regulatory requirements. Small businesses and consideration for them are throughout the Tobacco Control Act and they should be a part of their strategic plan as well. I'm concerned that CTP's draft goal areas don't reflect this and don't reflect the fact that we are an industry full of small businesses. Of course, there are big tobacco companies. However, I would bet that there are thousands of small businesses like ours that grow, make, or sell tobacco products for every -- to giant tobacco product company that exists. For example, we buy our leaves from small family companies around the world, and the vast majority of our cigars are sold by 3000 family-owned brick and mortar cigar stores in the U.S. today.

Lastly, the proposed rule area on compliance is pretty intense. What I read is an aggressive focus on going after bad actors. Of course, there are bad actors in every industry, and CTP should have robust tools to address them. However, compliance should include more than just legal action and penalties. Most people in this world are good people. And I know a lot of good people in the tobacco industry who want to do the right thing but sometimes don't always know how. As a small business, it can be tough to understand how to comply with hundreds of pages of dense regulations that grow every year. And so, as you think about compliance, please include processes that help regulated businesses to understand errors and deficiencies and give them a chance to correct them and come into compliance before the heavy-handed government comes down on.

Thank you so much for this opportunity [inaudible].

Sarah Lynch:
Thank you.

We are now moving to J.B. Simko. Please state your organization or indicate that you're speaking on as an individual. You have four minutes. Thank you.

J.B. Simko:
Good morning. This is J.B. Simko with Philip Morris International. Thanks so much for your time today.

Both PMI and our new affiliates Swedish Match share a commitment to support a workable FDA process and a fully regulated market. We're far from that goal today. Each year the vast majority of adult smokers will continue smoking and they have very few FDA authorized alternatives available. CDC's most recent estimate of smoking-related deaths per year is almost 500,000. And this number has never gone down. To meaningfully change this trajectory CTP must prioritize authorizations for a range of smoke-free products as alternatives to cigarettes. As a product regulator, CTP must be pragmatic in its interpretations and change how it reviews smoke-free product applications. The current approach is favoring combustible cigarettes. CTP could make three important changes within the strategic plan.

First, CTP should empower the Office of Science as the final decision maker for the majority of smoke-free product applications. CTP has faced backlogs before, for combustible products, CTP empowered OS with decision making authority and OS created an efficient review process. Unfortunately, this is for the most harmful product formats. Now is the time to prioritize smoke-free products. We encourage CTP to survey the 500+ scientists in OS and rely on their experience and scientific expertise to gauge whether application decisions align with the available science, and if not, what changes are needed to be efficient, fair, and transparent. OS has the core expertise to decide certain applications on its own.

PMTAs that doesn't involve flavored vapor products. Applications should not be delayed by vapor specific concerns if there's no significant underage use being observed for the candidate product or category. These should follow the science and be decided by OS within the 180-day deadline. Supplemental PMTAs; these products have already demonstrated their APPH and seek minor changes to improve product quality and rates of complete switching among adult smokers. They should be expedited through OS. Combined PMTA and MRTP applications; these products present the greatest potential to benefit public health. This pathway is underutilized today. Prioritization through a single review team could incentivize its use.

Our second recommendation is that CTP should create a new performance measure focused on the number of smoke-free product authorizations. To date, the FDA has primarily measured its performance through millions of refusals and denials. Meanwhile, thousands of combustible products have been authorized with great efficiency. A better measure of performance would be comparing the number of smoke-free product authorizations to combustible products, improving this ratio is critical for changing the trajectory of smoking. After authorizations, CTP can then focus on communication. FDA's plan to educate adults on the risk continuum is an important first step, but it's unlikely to move very fast.

Our third recommendation as a near-term action would be to communicate directly with medical professionals. Recent studies have shown serious misperceptions. Targeted communications of basic information for the medical community could easily start this year. Last, I'm sure you'll hear a lot today about enforcement. Access to and information about authorized products helps close the door on illicit products.

We offer these near-term suggestions for the plan as a way to massively disrupt the current trajectory of smoking and thank you for our -- for your consideration.

Sarah Lynch:
Thank you, J.B.

Keith Churchwell. Please state your organization or show you're speaking on -- as an individual. You have four minutes. Keith Churchwell, thank you.

[audio break]

Sir, we cannot hear you yet.

Keith Churchwell:
Can you hear me now?

Sarah Lynch:
Yes, we can, sir. Thank you.

Keith Churchwell:
Thank you. Good morning. Thank you for the opportunity to present the views of the American Heart Association. I'm Dr. Keith Churchwell, I'm a cardiologist and also the president elect of the American Heart Association. AHA is pleased that the Center for Tobacco Products is developing a strategic plan and inviting public input. A plan that includes bold policies that is informed by the best available science that adapts to changes in the marketplace. And most importantly, that prioritizes public health will help CTP achieve its mission.

Today, I would like to highlight -- I would like highlight elements we will -- we believe should be included in two of the proposed goal areas. For the first proposed goal area, the development of regulations and guidance documents, CTP should prioritize the development of product standards, including final product standards that prohibit menthol as characterizing flavor in cigarettes and all characterizing flavors in cigars, and a nicotine standard for combustible tobacco products.

CTP should also release the Tobacco 21 Final Rule. While this rule may seem unnecessary, because the law took effect immediately in 2019, a few states are still not enforcing 21 as the minimal sale age because they're under the impression they must first change state law. A final rule or FDA guidance could clarify this for states. For the goal area of compliance and enforcement, CTP must prioritize removing products without FDA authorization from the market. To do this, FDA should, number one, publish and widely distribute a list of tobacco products that can be so legally and clearly state that products that do not appear on this list cannot be sold and must be removed from store shelves. Number two, monitor trade publications and industry social media accounts for new products being marketed without FDA authorization and immediately inform manufacturers that these products must be removed from the market. Number three, take enforcement action against wholesalers and distributors who distribute illegal products, keeping these products from ever reaching retailers and consumers. And number four, increase coordination with state and local enforcement officials. AHA will provide recommendations for the other goals in our written comments.

But I would like to discuss two additional elements not covered by the proposed goal areas that should be included in the strategic plan. The first is tobacco cessation. CTP must consider the downstream implications of its policies, removing menthol cigarettes and flavored cigar and lowering nicotine and cigarettes will have a huge impact on tobacco related death and disease. But we first must provide tobacco users with more tools to quit. CTP should work with the Center for Drug Evaluation and Research to encourage innovation and accelerate approval of new cessation therapies. A second related area is to clearly articulate is in the agency's plan to drive down tobacco and nicotine use. This should include CTP's thinking on how to best minimize the use of combustible products, while ensuring that other products do not attract youth and the role if any of modified risk or harm reduction products. It should also identify areas where additional research is needed to inform CTP policy.

I'll close with this final thought. This strategic plan will set the direction for CTP for five years. It is incredibly important that we get it right. So, I encourage you to focus the plan on one overarching goal: protecting the public's health. Thank you for allowing me to share the views of the American Heart Association.

Sarah Lynch:
Thank you Dr. Churchwell.

Ana Melendez, please state your organization and share that you're speaking as an individual. You have four minutes. Ana Melendez, please.

[audio break]

Ana Melendez:
Hello, can you hear me?

Sarah Lynch:

Yes, ma'am.

Ana Melendez:
Oh, perfect. Okay.

Good morning. My name is Ana Melendez, and I am the president of the Florida Association of Wholesale Distributors. Prohibition is not the answer. The FDA should not ban the legal distribution of menthol cigarettes and flavored cigars. This prohibition-based policy makes no sense because it will push these products out of licensed distributors to unregulated illegal markets, undermine the public health purposes of FDA regulation and other laws, put 18 to 19 billion dollars in wholesale value risk from menthol cigarettes and flavored cigar sales. FDA has better options that don't hurt licensed distributors like education, cessation support, and underage prevention. That's what the FDA should focus on, not prohibition.

Licensed wholesalers are essential to proper regulation of tobacco products. The licensed wholesale system is a critical component of ensuring all tobacco products are responsibly distributed and sold in the U.S. It is through licensed distributors that FDA and other government agencies ensure adult consumers receive products that are made only by FDA-

regulated manufacturers in compliance with FDA health warning requirements, not adulterated or misbranded, fully tax paid, in compliance with master settlement agreement requirements, distributed to licensed retailers, required to age verify the sales.

The distributor community has been key to making progress on the public health goals of FDA regulation. Among other things, youth cigarette smoking is the lowest in a generation, 1.3 percent, as is youth menthol cigarette use, 0.8 percent. There is a better path forward. FDA had better options for protecting public health, which keep these products within the licensed regulated system. FDA should focus on education, cessation, underage prevention, and providing adult consumers less harmful alternatives. These harm reduction policies preserve age verification at retail, ensure all products are FDA regulated, inform adults of the health risks of different products, don't lead to more illegal sales and crime, don't hurt responsible distributors and retailers.

Regarding e-vapor and the need for FDA authorization and enforcement. Over 97 percent of the e-vapor products in the market today lack FDA authorization after more than two years of FDA product reviews. FDA has denied or delayed action on vast numbers of products, even those with compelling evidence they're effective harm reduction solutions for adult smokers. Consumers are now turning to rapidly growing illicit markets and products, a circumstance FDA has said would endanger public health. FDA has been unable to remove illegal products from the system or prevent illicit channels. Nor is FDA empowering wholesalers and retailers with the basic information they need to remove illegal products from the systems on their own.

With an illicit e-vapor market growing, FDA should urgently adopt a more effective approach to enforcement. Among other things, FDA should publish a list of brands in compliance with the 2020 guidance to enable licensed retailers and wholesalers to sell only compliant products. Work with other federal and state agencies to carry out effective measures to prevent illicit products from entering the U.S. at the borders, collaborate with and provide funding for state law enforcement agencies to assist in bringing the e-vapor market into compliance with federal law, including amending its retail inspection contracts to include surveillance of non-compliant products.

There is no bigger challenge facing federal tobacco regulation today than the need to bring regulatory coherence and support to the e-vapor market. Thank you so much for your time.

Sarah Lynch:
Thank you, Ana. Much appreciated.

Nkechi Taifa. Nkechi Taifa, thank you for joining us earlier in the day, please state your organization or share that you're speaking as an individual. You have four minutes.

[audio break]

You're on mute yet.

Nkechi Taifa:
I'm trying to unmute myself. Can you hear me?

Sarah Lynch:
You're good. Yeah, we can hear you ma'am. Thank you.

Nkechi Taifa:
Okay, on behalf of myself, Nkechi Taifa, a veteran criminal justice advocate, founder of the Taifa Group and Justice Roundtable Convener Emeritus, I welcome the opportunity to provide my perspective as the FDA Center for Tobacco Products embarks on its five-year plan. Over my 40-year professional career as a criminal justice advocate, I have witnessed firsthand that well-intentioned policies geared at eradicating drug abuse when rolled out incorrectly have devastating effects on communities of color across the nation. The War on Drugs of the '80s and '90s, aimed at addressing the crack powder epidemic accomplished very little in terms of getting at the root causes of addiction to crack and powder cocaine. Instead, what we saw was a whole generation of black men and increasingly black women losing their lives to incarceration for mostly nonviolent drug offenses. This has a direct correlation to the current FDA proposed menthol ban. I urge the FDA as it thinks about the next five years to take a more holistic look at what a seemingly well-intentioned policy may cause, especially to underserved communities of color.

Having grown up in a household where my parents smoked, I have always abhorred smoking. As such, I applaud the FDA for the significant progress made in reducing cigarette smoking in the United States over the past two decades. This has been accomplished with policies emphasizing education, cessation, underage prevention, and other measures that allow for continued regulated pathways to adults 21 and older. These health gains have not been accomplished through poor vision, criminalization, and incarceration. The FDA proposed menthol ban would trigger hundreds of federal, state, and local laws criminalizing the distribution, sale, and mere possession of illicit tobacco. While an effective FDA menthol ban would activate these statutes, the FDA would have no authority over how these statutes are implemented in states.

If a quarter of current menthol smokers continued to smoke menthol after a ban, 4.8 million U.S. residents would be subjected to potential arrest and incarceration, including my parents if they were still alive. Moreover, the proposed menthol ban will undermine attempts to course correct on cannabis, slow mass incarceration for minor offenses, and reduce reasons for police and citizen confrontations. It is counterintuitive to promulgate a sweeping new core vision when Congress is debating how and when to discontinue cannabis prohibition and sanctioned legal regulated adult sale in order to reverse the human catastrophe of decades of criminalization. And while many states have already created regulatory frameworks favoring a very regulated and taxed marketplace for cannabis over illicit trade.

In closing, I would like to submit to the docket a sign-on letter released in June 2003, addressed to President Biden, Secretary Becerra, and Commissioner Califf signed by over 54 national and local organizations expressing their concerns with a menthol ban. We believe that a better way forward to curb smoking is by implementing harm reduction and other public health strategies including education and youth tobacco prevention, rather than punishing behavior. You'll see the criminal justice system which has proven time and time again, simply does not work.

Thank you.

Sarah Lynch:
Thank you very much for your comment.

Up next, we have Jim McCarthy.

[audio break]

Jim McCarthy:
Hi, can you hear me?

Sarah Lynch:
Yes, thank you. My apologies. I just got a pop up that indicated my Zoom quit unexpectedly. So, I was waiting to see if it actually did. Hello, Jim.

Jim McCarthy:
Hi.

Sarah Lynch:
Thank you. I'm getting the pop up. So, I'm going to [inaudible].

Jim McCarthy:
You tell me when you're ready. You tell me when you're ready.

Sarah Lynch:
Go ahead, sir.

Jim McCarthy:
Okay.

Thank you for including us today. My name is Jim McCarthy and I'm here on behalf of American Vapor Manufacturers. We are the leading trade association for the vaping industry. One of the challenges I think for bureaucratic agencies like FDA is that it's easy to get lost in the tangle of rules and details and procedures. So, instead of focusing on that minutia, I would like to back the frame out and talk about the big picture for just a minute. There's an apparent and obvious approach that the agency is using and its posture toward vaping products, which can be summed up as "better safe than sorry". In academic jargon, the agency and the news media use, that's called the precautionary principle. That may seem like a noble intention. But what counts in the real world is not the intentions but the outcome. There are millions of Americans that have successfully quit smoking by switching to nicotine vaping. Yet you have outlawed the products they rely on and bankrupted the businesses where they obtained those products, casting countless numbers of them back to combustible cigarettes.

There are millions of other Americans who continue to smoke cigarettes because they wrongly believe that vaping is somehow more dangerous than smoking. And it's not just ordinary people with that lethal misconception. The vast majority of physicians in this country falsely believe the same thing. And even the nicotine causes cancer. The blame for that horrendous misconception must be laid at the doorstep of FDA. No public authority or institution has done more to demonize nicotine vaping. And I mean that literally. FDA has an active big budget ad campaign

running nationally that compares nicotine vaping to being possessed by demons. And here's the outcome. Countless Americans that could be saving their own lives by switching to nicotine vaping are instead suffering from cardiopulmonary disease and dying from cigarette smoking. In other words, the FDA's precautionary approach fails on its own terms. That's because Americans are actively suffering disease and death when they are deprived or discouraged from switching to low-risk alternatives. The harm you are cautious about is already happening on a vast scale.

It's not just us and the nicotine vaping industry who are pleading with the agency to recognize the ongoing harm that you're perpetrating. Leading commentators across the ideological spectrum are saying the exact same thing that includes for example, decorated writer Mark Gunther, the leading science journalist in the country Seth Manoukian, legendary New York Times columnist John Tierney, syndicated writer Vernita Douggie. Veteran columnist Holman Jenkins, Author Michael Moynihan, esteemed constitutional law scholar Jonathan Adler, author and columnist Noah Rothman. Notice there's no other issue in American public life that has that range of consensus among leading public affairs intellectuals. And that's why it is the leadership of the agency today, Dr. Califf, Dr. King, Matthew Farrelly that are going to be held directly responsible for the vast harm that is occurring on their watch. That is the legacy they are building.

Just last week, Dr. King published an essay in the medical journal *Addiction* in which he lamented how Americans are misinformed about nicotine vaping. Yet, just two days later, Senator Richard Blumenthal held a press conference, and yet again brazenly deceived the public about the rates of youth vaping. When we reached out to FDA leadership and media relations, urging them to set the record straight on their own data, we got no response, no action, and the agencies have still done nothing. The public reputation of the FDA is already fractured. But the agency's blinkered intransigence on nicotine vaping is a failure of historic proportion. So, my suggestions are sober up, get your act together, and start telling the truth to the American public about nicotine vaping.

Sarah Lynch:
Thank you, sir, for your comments. And thank you to all of the panelists for our first session. We will take a break until a couple minutes before 11:00 -- to 11:00. And we will begin on our return with Jeff Stier and the new moderator. Thank you very much again for your comments and we will take a short break.

[music playing]

Vanessa Burrows:
Hello, welcome back. I'm Vanessa Burrows from the FDA.

Next up, we have Jeff Stier. Please state your name and organization or share that you're speaking as an individual. You have four minutes for your comment. Please proceed.

Jeff Stier:
Thank you for -- I should be unmuted now; can you hear me?

Vanessa Burrows:
Yes, we can hear you. Please go ahead.

Jeff Stier:
Thanks.

Hi, I'm Jeff Stier, I'm representing myself today. I'm speaking on behalf of thousands of smokers that I've talked with and heard from over my career in public health. Of the five goals in the strategic plan, one goal is conspicuously absent. There must be a sixth goal and that is to use the best science to proactively harness the public health benefits of tobacco harm reduction and integrate that into each of the other five categories without specifically incorporating tobacco harm reduction into the strategic plan. The plan is simply window dressing for the approach that got the CTP into the mess it's currently in. The Reagan-Udall report which prompted this strategic plan, a report that the FDA itself asked for, makes it clear that we don't need window dressing, we need specific changes with firm accountability. This is necessary because to date, the CTP has already been engaging in activities in these five categories but has failed to meaningfully incorporate harm reduction into these plans, except in circumstances where the law absolutely required it and as evidenced by CTP's many losses and legal challenges in the courts.

The CTP has even violated the law in its misguided opposition to tobacco harm reduction at almost every regulatory turn. Commissioner Califf recently claimed that misinformation is the leading cause of death in the U.S. Oh, the tragic irony. FDA has contributed to the misinformation about the risks of nicotine products vis-a-vie the risks of smoking vs e-cigarette, smoking being a leading killer in the U.S., e-cigarettes not being a leading killer in the U.S. And despite the FDA's acknowledged awareness of how woefully unaware smokers are about the clear benefits of switching to e-cigarettes completely, the FDA has failed to fight the misinformation that is truly killing people and keeping them smoking.

I'm sad to say that the FDA's words and actions since the Reagan-Udall report are for little evidence of either contrition or reform. But a careful reading of the agency statements alongside a batch of marketing denial orders issued in -- May 12 for 6,500 flavored e-cigarettes, I think gives insight into the agency's regulatory stance, as well as where it might see itself as most vulnerable in the courts. First, Director Brian King stated quote "it is the applicant's responsibility to provide scientific evidence to demonstrate that marketing a new tobacco product is appropriate for the protection of public health." This is indeed a long-standing FDA policy. However, if the -- had the agency been executing a strategic plan which followed its own July 2017 comprehensive plan for tobacco and nicotine regulation, the FDA might have acted differently. The 2017 plan envisioned moving adult smokers down a continuum of risk to FDA authorized noncombustible nicotine products. Towards that end, the agency must see applicants as potential public health partners with the agency to implement the strategic plan that includes tobacco harm reduction.

All I can say is that without incorporating tobacco harm reduction into this strategic plan, we are left with window dressing and the same problems that got us into this situation in the first place. Thank you for listening.

Vanessa Burrows:
Thank you for your comment.

Up next, we have Tony Abboud. Please identify your organization or state that you are speaking as an individual. You have four minutes for your comment, please proceed.

Tony Abboud:
Good morning, can you hear me?

Vanessa Burrows:
Yes, we can. Please proceed.

Tony Abboud:
Okay.

Thank you for the opportunity to provide input on the strategic plan. My name is Tony Abboud. I am the Executive Director of the Vapor Technology Association, which is the United States based trade association of companies in the independent vapor industry.

I'll address three core priorities in CTP's creation and implementation of the plan. First, the agency needs to immediately, loudly, and repeatedly announce its commitment to the principles of harm reduction and in so doing loudly and repeatedly communicate the public health goal of reducing risks through the use of vaping and modern oral nicotine products. If this is not the centerpiece of CTP's messaging and strategic plan and announced as such, then the cacophony of misinformation regarding less harmful nicotine alternatives about which director King has lamented himself will simply undermine whatever strategic plan CTP eventually puts in place.

Second, the plan must fix what can only be considered a broken PMTA process. A couple points here. One, the RUF, the Reagan-Udall Foundation, critiqued CTP for having undefined application requirements. They said quote "applicants will start able to address the issues necessary to meet the APPH standard unless FDA clearly articulates its expectations. CTP has a responsibility to clearly identify application requirements, if for no other reason than to reduce the burden on the agency itself and improve efficiency," close quote. But there's a more important reason, a scientific regulatory scheme which purports to determine what is appropriate for the production of public health, but which does not specify the science that is necessary for making that assessment is ultimately ineffective and subjective. CTP's plan must include a specific and finite list of studies and data, which is required to support an APPH determination, and which if provided within certain parameters will be sufficient for CTP's evaluation and issuance of a marketing order.

Two, RUF's critique also was clear on the fact that CTP's plan must quote "explain how FDA is interpreting the APPH standard." The key question they said is, quote, "how to weigh the public health benefits of the percentage of adults who use ENDS that will completely quit smoking combustible tobacco products against the potential public health harms that youth who use ENDS will acquire lifelong addiction to nicotine or proceed to use combustible products," end quote. To that end, CTP must clearly end its current subjective application of APPH, in which it has proclaimed that all flavored ENDS products are attractive to youth regardless of the specific product at issue in the application and regardless of that product's experience if any with youth.

This presumption is made without any reference to the product at issue or to science, and thus is entirely unscientific and evidence of a double standard. Very simply, the presumption imposed in CTP's July fatal flaw memo is no longer defensible in light of the RUF's findings. CTP can and should establish an objective assessment mechanism for evaluating each of the scientific studies presented on each of the prongs of the APPH tests that ultimately results in a score for each product's application based on an objective, not subjective, interpretation of the science presented.

Third, and finally, meaningful change will not come unless CTP implements safeguards to ensure that the review process is insulated from external pressures that were noted by the Reagan-Udall Foundation and that CTP scientists are allowed to unapologetically follow the science. The revelations of FDA's own scientific staff about political interference in the PMTA process must be dramatically and finally addressed. Scientists must be allowed to complete its reviews of applications without interference or changes and review protocols [inaudible] not in a place prior to the applications being filed.

Thank you very much for the opportunity.

Vanessa Burrows:
Thank you for your comment.

Up next, we have Stacey Gagosian. Stacey, please come on the microphone and state your organization or whether you're speaking as an individual. You have four minutes, please proceed.

Stacey Gagosian:
Today on FDA's [inaudible] goal areas that FDA has made public are generally a good place to start. These will ensure that FDA CTP can fulfill its overarching objective, which is to protect public health with regard to tobacco and nicotine products. As FDA further flushes out its strategic plan, it will be important to ensure that there are strategies and metrics associated with each of these goal areas. Truth Initiative will submit written comments that will provide more details, but in the short time we have today, we wanted to highlight a few things.

First, eliminating health disparities associated with tobacco use and tobacco related disease must be fundamental to each and every one of these goals. It is mentioned in the regulation goal, but it needs to be part of all of these goals. Populations targeted by the tobacco industry, including black Americans, Hispanic and Latino communities, American Indian and Alaska Natives, youth, and others, have long faced the disproportionate burden from tobacco-related death and disease. And as a result, all actions that FDA CTP takes must be viewed through an equity lens and ensure that regulations, research, and other activities CTP takes on will support these populations and reach the people who are most impacted by tobacco and nicotine use.

Second, we fully support FDA's goal to develop, advance and communicate comprehensive and impactful tobacco regulations and guidance. It is vital that, as noted before that there are metrics and deadlines associated with these rules. These measures have the ability to save lives and reduce the disease and death associated with nicotine and tobacco products. FDA must ensure that its research programs and regulatory and legal teams are all working together, not in silos,

but together to ensure that rules, guidance, and other measures are based in science, help those who are most impacted by tobacco, and are legally defensible, as we know that FDA actions are often litigated by the industry. We are also very concerned about the product application review and enforcement processes. Oh, I'm sorry, I didn't see [laughs] the start my video. It is critical that FDA CTP get the application review process under control so that consumers the public, and even the industry knows that the products we find on the market are those that have been reviewed by FDA and determined to be appropriate for the protection of public health. The situation we have right now is far from that, where products with the highest market share are on the market are completely unreviewed, further -- and further enforcement to keep illegal products off the market. We know that there are more products and more brands, and the industry is flooding the market with new products, and this highlights the need for FDA to take action to prevent these products, all of which are illegally on the market, from getting into the hands of young people. The FDA needs to shore up these processes.

Finally, we were concerned to note that there was no mention of tobacco and nicotine cessation in the goal areas that FDA released. There -- this is short sighted and while CTP doesn't provide cessation services directly, its actions through regulation and Product Review play a huge role in the demand for cessation treatments. It is imperative that CTP work with sister agencies within the FDA as well as with other government agencies to ensure that those who use tobacco and nicotine products have access to the tools they need [inaudible].

Vanessa Burrows:
Thank you for your comment.

Up next, we have Farhana Haseen. Please come on the microphone and/or video and state your organization and/or if you are speaking as an individual. You have four minutes, please proceed.

[audio break]

Farhana Haseen. Farhana Haseen, are you available to make your comment?

[audio break]

We'll move on to the next commenter then. Up next, we have John Maa. Please identify the organization you represent or if you're speaking as an individual. You have four minutes to make your comment, please proceed.

John Maa:
Good morning, my name is John Maa. I was the 2018 president of the San Francisco Marine Medical Society and I'm speaking as an individual. I appreciate the opportunity to speak today. I applaud Commissioner Califf's vision to pivot to a proactive position.

I'd like to share a recent update about a long-awaited advance in tobacco control from the Netherlands following a decades-long effort there to address what is known as the low tar myth. A Dutch court recently heard final arguments in a case that may mandate more accurate methods to analyze the levels of tar and nicotine and carbon monoxide known as TNCO from cigarettes, thereby requiring tobacco companies to redesign cigarette filters or modify cigarette composition

to reduce the levels of toxic chemicals to which smokers are exposed. I believe that this breakthrough can serve as a future blueprint for the FDA and CTP over the next decade.

The story began in 1936 when researchers developed a method to analyze cigarettes for TNCO. The protocol was adopted by the U.S. Federal Trade Commission in 1967. Cigarettes are held by a machine then simultaneously ignited and puffed by syringes, a 35-cc volume over two seconds just once a minute until a prescribed short butt length is reached and the particulate components of TNCO are collected. This FTC method has since been adopted around the globe. It's known in Europe as the International Organization for Standardization method also the ISO, but this mechanized smoking is unlike human smoking, it underestimates the exposure to toxic chemicals.

Extensive research shows that smokers inhale deeper than a 35-cc volume and puff more frequently than once a minute. More serious concern exists about how the tobacco industry has evaded the test as reported by "60 Minutes" in 2001. Small ventilation holes and filters are created by lasers away from where the machine holds a cigarette, allowing external air to dilute the smoke stream resulting in artificially lower Cancio measurements that comply with allowable standards. Smokers largely close these holes with their fingers or lips when inhaling and thereby are exposed to far more than the allowable limit. For decades, there have been calls for the FTC method to be replaced with a more accurate method that corrects their puff volume and blocks these holes. The tobacco industry has long been aware of the problem and internal industry documents stated people smoke in a way so that they get much more than predicted by the machine. But the industry used this inaccurate data to market light and low tar cigarettes, misleading smokers into believing that these were safer. For their own internal research, the industry created their human smoking simulator, which recorded tar levels more than three times higher, but industry lawyers concluded they did not have an obligation to inform the public of the higher numbers keeping the truth of the health danger secret for decades.

In 2016, Dr. Jeffrey Wigan demonstrated to Amsterdam public health leaders how the measurements were manipulated by ventilation holes. Armed with this knowledge, leaders initiated a 2018 case to require testing with a new method. They were aided by scientific data that tested 100 different cigarettes by the WHO method which comes close to actual human smoking behavior and found that almost all cigarettes exceed legal standards two to three-fold. In 2022, an EU and Dutch court both ruled that a more accurate method should be adopted. The burning question is whether the Netherlands will test [inaudible].

A final decision is due in November of 2023. The courts there could mandate that the WHO method be adopted all across Europe, and to comply with emission levels according to that standard. The industry may be required to remove cigarette filters, stop placing ventilation holes in the filters, and reduce TNCO levels or a combination of these. 13 nations in Europe have now called on the EU to adopt the WHO method in the U.S. The FDA and CTP should call on Congress and the FTC to adopt the WHO method as well. The Biden Administration should join the WHO Framework Convention on Tobacco Control and end the use of the FTC method around the globe. Ultimately, the Dutch court decision is a key in mandating a more reliable method to test cigarettes and improve the health of smokers globally.

Thank you.

Vanessa Burrows:
Thank you for your comment.

Up next, we have Elliot Boyce. Please identify your organization or state that you are speaking as an individual. You have four minutes for your comment, please proceed.

Elliot Boyce:
Hello, my name is Elliot Boyce. My company's Diverse Perspectives. It's a law enforcement type consulting company, which basically offers consulting information for police officers, as it pertains to racial profiling, recruitment, and retention versus equity inclusion within law enforcement. I'm opposed to the ban. Not a supporter of smoking in any way, shape, or form. I don't smoke. But having served in law enforcement for over 35 years, I realized something very important. Anything you ban, you make illegal, anything that's illegal is subject to police enforcement. This ban is going to add another health care concern to law enforcement's plates with police officers already taxed around the country doing a variety of different things like dealing with mental health issues, which concerns me. Not only that, but anything that you ban you increase the chance of, particularly popular products like menthol cigarettes, you increase the chances of individuals more increase in smuggling, increase in violence and in neighborhoods that's going to be subjected to these bans.

As the doctor said before, just previous to me, he mentioned smokers. He talked about smokers as a whole, not those who smoke menthol predominantly. So, why that's really important is individuals that do not smoke menthol cigarettes will not be subjected to these bans. Individuals that do smoke they will be subjected. So, what that means is there's going to be police enforcement in urban areas where over 80 percent of individuals smoke menthol cigarettes, that is a problem. Not only will it be more enforcement, it will also be more drug smuggling and more menthol cigarette smuggling.

At this point in time, the FDA has a really good plan as far as regulating these cigarettes. If you ban them, now, we're not going to know what's being put in these cigarettes. So, my concern is increased enforcement, the mental health issue. And not only that, but the aspect also that law enforcement officers would be put in harm's way because of the officer safety issue, as they continue to try to combat against it. I read the domestic Settlement Agreement of 1998 I believe it was, it deals with making sure that particular communities, any communities could no longer be targeted. So, there's no more advertisements, there's no more sports figures, there's no more, you know, rappers that can promote cigarette sales. Only at point of sale. With that type of control, and FDA levying fines against individuals that do violate the rules, this is a better control.

Putting out a ban without clear education, treatment and counseling services for the individuals or the population that use them is reckless. And we cannot have a reckless situation because lives depend on it. We've had one situation where an individual lost his life already, that's Mr. Garner in New York, over a nonviolent crime of selling or allegedly selling loosie cigarettes. We can't afford to have that again. Police commissioners from around the country are not prepared to deal with this type of engagement and they shouldn't have to. Not only with the master settlement agreement, what you do is you're subjecting individuals to basically going to the streets to buy their cigarette of choice, which is not fair. You can't have one community

which, for the most regards would be predominantly white community, being able to smoke cigarettes, while African American community is subject to criminalization. This is a really dangerous formula, and we have to be cautious of it. Along with that, if you do education treatment accounts, and one of the things someone has talked about I saw that CDC report was the number one cause of death for Americans, particularly African Americans, was cancer related illnesses. The truth is the number one cause of death for African Americans from ages one to 25 is homicide. You add menthol cigarettes as a ban to it, you're going to increase that number and we can't afford that.

Please re-think this and do not ban menthol cigarettes. Thank you.

Vanessa Burrows:
Thank you for your comment.

Up next, we have Willie McKinney. Please identify your organization or state if you are speaking as an individual. You have four minutes for your comment, please proceed.

[audio break]

Willie McKinney, are you available to make your comment?

Willie McKinney:
Can you hear me?

Vanessa Burrows:
Now we can hear you. Please proceed.

Willie McKinney:
Thank you. We thank you for the opportunity. We are grateful for the opportunity to provide comments on the Center for Tobacco Products' comprehensive five-year strategic plan.

I'm Dr. Willie McKinney, the CEO of McKinney Regulatory Science Advisors, a privately held company with a core goal of helping manufacturers responsibly bring harm reduced tobacco products to market. Today, I comment mainly on strategic goals one and two, since these goals have the greatest impact on the work that McKinney undertakes for its clients.

So, how might the CTP develop, advance, and communicate comprehensive and impactful tobacco regulations and guidance? The FDA could support this strategic goal by having a task to modify its review approaches for the administrative phase of a PMTA. We've had the opportunity to review PMTAs prepared and submitted by others. So, we understand that if applications are not structured in a certain way or complete, the reviewer will have a very difficult time understanding the information. Frequently, we hear that filings are rejected for acceptance based on administrative issues such as the use of the wrong version of a form. It is unfortunate that products that have the potential for the greatest positive impact on overall public health are rejected at the first PMTA hurdle. This could be avoided by measuring the effectiveness of communications with industry stakeholders, continual submissions of incorrect forms could signify ineffective communications. To rectify this, the FDA should consider introducing web portals that mandate the input of accurate information before generating a fully

completed form. A similar web-based portal system used widely within the European Union for scientific dataset submissions, has proven efficient in streamlining the submission process and minimizing errors.

So, how might the CTP ensure timely, clear, and consistent product application review to protect public health? The FDA could support this strategic goal by having a task to modify its PMTA categorization and prioritization approaches. Based on CTP's September 2020 stated priorities, the PMTAs of some tobacco products, such as oral nicotine products, appear to be the last products to enter the review process. Additionally, small manufacturers of other tobacco products, such as e-cigarettes, have found their PMTA stuck in the review process even after robust deficiency responses. These manufacturers have no indication of when their applications will be processed or completed. CTP should consider a separate PMTA review lane for small manufacturers in order to address this uncertainty. Furthermore, it's not clear if manufacturers of oral nicotine products and others that don't have a youth use issue should submit data demonstrating an increased public health benefit of their nontobacco flavored products. CTP should continue providing greater clarity on this issue in order to address this confusion.

Lastly, the impact of delayed regulatory decisions and ambiguous communications can lead to unintended consequences. Harm reduction requires manufacturers to innovate and bring to market novel alternative tobacco products. For small manufacturers, innovation requires external investment. The prevailing regulatory uncertainty hampers the ability of small companies to secure funding. This can lead to fewer lifesaving alternatives for adult smokers and the disappearance of small businesses that are critical to cigarette use reduction. Enhancing communication clarity with small businesses by CTP could help address uncertainties thus facilitating the achievement of the agency's strategic goals.

Thanks for the opportunity to share.

Vanessa Burrows:
Thank you for your comment.

Up next, we have Joshua Habursky. Please identify your organization or whether you're speaking as an individual. You have four minutes, please proceed.

Joshua Habursky:
My name is Joshua Habursky, and I'm the Deputy Executive Director for the Premium Cigar Association. The PCA is a leading trade association representing over 3,000 retailers and over 250 manufacturing partners specializing in premium cigars and pipe tobacco. Following the decision of CAA et al versus Food and Drug Administration, the Center for Tobacco Products should make future initiatives -- make sure future initiatives do not attempt to regulate or have the tangible effect of regulating premium cigars. Some of our retail members carry products outside the scope of the recent court decision. Our association is weighing in on the CTP's strategic plan concerning regulating these products such as pipe tobacco.

With respect to the CTP proposed goal areas, we offer the following record recommendations. Goal one, data driven policy. Political objectives promoted by activist organizations should not guide policy development, especially when it directly conflicts with prevailing scientific

research. The agency should reprioritize the policy agenda to focus on tobacco products at the highest end of the risk continuum.

Goal two, for products required to submit a premarket review application, CTP should assess the costs and benefits of these regulations, including the coordination with the Small Business Administration and conducting a small business impact review, international commerce and trade impact review and environmental impact review. Since CTP has not performed these requisite actions for the proposed tobacco manufacturing practices standards, PCA recommends that this regulatory action be withdrawn.

Goal three, T21, the policy that limits the sale of tobacco products to those over the age of 21 should be the basis for youth prevention and as an opportunity for CTP to work with retailers of tobacco products. CTP should provide further guidance on this congressionally adopted action. CTP's strategic plan should focus on regulations with clear congressional intent. The agency should collaborate with retail entities to develop guidance and best practices for point-of-sale verification and enforcement. The agency should refrain from using rhetoric promoted by anti-tobacco organizations that are not rooted in science and serve political objectives which casts doubt on the agency's credibility and fosters an adversarial relationship with industry.

Goal four, information campaigns and sponsored research should focus exclusively on risk reduction at the population level. CTP should openly discuss the continuum of risk relative to different tobacco products to provide consumers with informed choices about the level of risk they are willing to accept. Eliminate the use of hyperbolized language and overgeneralizations. When discussing risks, CTP should focus on data that represents typical use and avoid speculative statements intended to amplify potential risks. Concerns related to equity and health disparities should be addressed through information campaigns led by community-based organizations, not special regulations targeting subpopulations of consumers.

Goal five, CTP should openly acknowledge that the public risk at the population level is limited to a few types of tobacco products and focuses research and policy development in enforcement accordingly. CTP should embrace the congressional oversight and accountability and respond to inquiries, file mandated reports, and engage with members of Congress. CTP also has a wide-open revolving door feeling -- feeding leadership of billionaire backed anti-tobacco organizations and Big Tobacco corporate interests. If high ranking leadership at CTP continues to depart the agency for regulated industries within its purview or connected activist organizations, the center's judgment, strategy, effectiveness, and impartiality as a science-based regulator can be called into question.

The PCA thanks [inaudible] this Listening Session.

Vanessa Burrows:
Thank you for your comment.

Up next is Willow Anderson. Please identify your organization or state whether you are speaking as an individual. You have four minutes for your comment, please proceed.

[audio break]

Is Willow Anderson available to make her comment?

[audio break]

We'll proceed to the next commenter. Monita Sharma, please come on the microphone and/or video and state your organization or if you're speaking as an individual. You will have four minutes to make your comment and you may proceed.

[audio break]

Is Monita Sharma available to make a comment?

[audio break]

We'll proceed to the next commenter, Joe Murillo. Please come on the microphone and/or video and state your organization or if you're speaking as an individual. You'll have four minutes to make your comment and you may proceed.

[audio break]

Joe Murillo, are you available to make a comment?

[audio break]

Female Speaker:

Give us one moment; Joe is coming.

[audio break]

Joe Murillo:
Hi, I'm Joe Murillo.

Vanessa Burrows:
Please proceed.

Joe Murillo:
Thank you.

As I said, I'm Joe Murillo. I'm the Chief Regulatory Officer at Juul Labs. And thank you very much for the opportunity to speak here today. Juul Labs welcome CTP's work to crystallize the strategic plan, which should incorporate the two tenets of the 2017 comprehensive plan. That is to make combustible products less attractive and create a robust marketplace of less harmful alternatives for adult smokers who can't or won't quit. Unfortunately, the PMTA process has produced only 23 authorized tobacco flavored e-cigarettes, representing only 4 percent of the tracked market. And now, shelves are flooded with illegal disposables, which data show are driving underage use.

As CTP considers its new strategic plan, we urge the center to prioritize three key objectives. First, the application review process must become much more workable. Second, there must be a bolder approach to enforcement. Third, FDA should work toward communicating about the relative risk of products to help transition smokers away from combustibles.

With respect to application review, the goal should be a well-regulated marketplace of science backed alternatives which serves -- serve as an off ramp for adult smokers to switch. To achieve this, FDA should set forth clear rules and standards that facilitate clarity, transparency, and more consistent review of applications. We support the CTP's stated intention to enhance transparency of regulatory requirements and would note that in the past we have found workshops that include dialogue between applicants and CTP very useful. With most initial ENDS applications soon to be resolved, the center should return to its practice of iterative review and engagement with applicants throughout the application process to ensure against misunderstandings of the data. The current slow and inconsistent PMTA process also stifles innovation to create less harmful products. Those of us trying to comply with regulations are left with dated products by the time a decision is made while those skirting the rules are marketing products without any participation in the regulatory system. We need a level playing field. It should not be easier to get a cigarette to market via the substantial equivalence pathway than a less harmful alternative; this prolongs cigarette use. Moreover, Section 910 requires FDA to issue an order in no event later than 180 days after the receipt of an application. There should be more accountability for meeting deadlines.

On enforcement, we are very happy to see that youth use of Juul products has declined by 95 percent since its 2019 peak, but now illegally marketed disposable ends are the products with the highest youth use. These products pouring into the U.S. from China have tripled since 2020, representing more than 40 percent of the ENDS market. We support CTP's efforts with respect to heightened enforcement and we believe industry can play a useful role. We applaud the recent center for rapid surveillance of tobacco and are cautiously optimistic it will enhance FDA's surveillance efforts. Lastly, FDA must communicate broadly to the public on nicotine and relative risk. As manufacturers we are limited to the MRTP process which many of us have engaged in. In addition, instead of trusted authoritative sources like this FDA are better messengers to make progress in addressing misperceptions. We are encouraged by CTP's recent statements on relative risk communications. We would also encourage CTP to bring together the medical community. Even just explaining product authorizations would help.

Thank you very much.

Vanessa Burrows:
Thank you for all of your thoughtful comments. We are going to take a break until 12:00 p.m. We look forward to hearing more comments when we reconvene at 12:00.

[music playing]

Sarah Reichle:
Hello everyone, welcome back to today's Listening Session about developing FDA CTP's Strategic Plan. We're ready to get back to our comments. Lauren Lempert, you are up next, please share your organization or if you are speaking as an individual. You have four minutes.

Lauren Lempert:
Hello, can you hear me now?

Thank you for inviting me to speak. I'm a law and policy expert at UCSF T corps. Our T corps will be submitting written comments regarding CTP's Strategic Plan with many citations to the scientific literature supporting our recommendations. FDA asked what actions it could take in the next five years that would have the most impact in reducing tobacco-related death and disease. Today, I'll briefly focus on one action that CTP could take in the next four months that would meet its goals.

We recommend that CTP finalize the product standards they proposed in April 2022 that would prohibit menthol and cigarettes and characterizing flavors in cigars including menthol analogues. CTP promised it would finalize these standards by December 2023, and it should meet its self-imposed deadline. This is a low hanging fruit. The proposed product standards are based on valid scientific evidence and finalizing them will have a huge impact in advancing health equity by significantly reducing tobacco related harms, especially among youth, African Americans, and other priority populations. We submitted several public comments in June 2022 that provided significant scientific evidence demonstrating these health impacts.

As we detail in our current and previously submitted written comments, it's important that the menthol -- final menthol rules include menthol analogues, including WS-3, and similar cooling agents that mimic menthol and tobacco products. It's well understood that the perception of tastes relies not only on the sensory receptors on the tongue and in the nose, but also on the somatosensory system, which provides the mouthfeel of cooling or heating, and is an integral contributor to flavor perception. All three systems, the gustatory, olfactory, and somatosensory systems work together to create the perception of flavor. Synthetic cooling agents such as WS-3 are odorless but in part minty or cooling sensations similar to menthol.

They're found in several so-called non-menthol products that are currently being marketed in California and Massachusetts, including, for example, Newport's non-menthols, Newport ESPs, and Camel Crisps. This marketing is trying to evade the statewide laws that prohibit selling tobacco products with characterizing flavors defined in these states as a distinguishable taste or aroma other than tobacco. CTP's final rule should clarify that they are also intended to include products like these that include menthol analogues, such as WS-3 and similar cooling agents that impart cooling sensations similar functionally to menthol, even if they don't smell like menthol. FDA's proposed product standards already include the foundation for such action, since they state that FDA considers the multi-sensory experience, including not only taste and aroma, but also cooling sensations in the mouth or throat as relevant factors in determining whether [inaudible] has a characterizing flavor.

This approach is based on sound science. FDA has all the scientific evidence necessary to finalize these rules by December 2023 and we urge CTP to do so. Every month of delay in implementing the proposed menthol standard would result in more than 29,000 new cigarette smokers and 1,300 deaths. These rules would significantly reduce tobacco-related death and disease, advance health equity, and minimize the likelihood that tobacco manufacturers will evade federal and state regulations designed to protect public health.

Thank you.

Sarah Reichle:
Thank you for your comment.

Willow Anderson, you are up next. Please state your organization or share that you're speaking as an individual. You will have four minutes for your comments.

Willow Anderson:
Hello, can you hear me? There we go. Can you hear me?

Sarah Reichle:
Yes, we can hear you --

Willow Anderson:
Wonderful. My name is Willow Anderson from the Public Health Law Center, which is a nonprofit organization that is focused on providing -- advancing equitable public health policies through the power of law. Thank you for the opportunity to comment on your proposed questions.

First, we urge the FDA to center health equity in commercial tobacco product regulation by implementing policies that address the ongoing targeting of various communities by the tobacco industry and by prioritizing the health and wellbeing of all communities, particularly those have been disproportionately impacted by tobacco use. The Public Health Law Center and its partners have been convening and drafting a citizen petition to this end, which will outline a proposed regulation and specific terms. But as it pertains to the FDA strategic plan and the CTP strategic plan now, we urge that help equities is centered in the public health standard.

Next community engagement like this and more opportunities for the CTP to actively engage with communities affected by commercial tobacco use to gather insights and understand local challenges. Third, resolving pending applications and incorporating a robust enforcement policy. Fourth, collaboration with states including bilateral information sharing will help leverage state resources and expertise to enhance the effectiveness of regulatory efforts.

And to that end, we would also request that the CTP may request some funding from Congress to support collaboration with states. And as other commenters had suggested, the first things in the two-year period that are absolutely attainable, and we would support the ongoing effort to finalize the menthol and cigar rules, but then further to adopt comprehensive flavor policies over the next five years. Included with that, nicotine reduction, and we would support that, as was already articulated in the strategic plan in initial comments by the new director. And then, completing the review of pending applications and establishing robust enforcement in the marketplace.

So, those are some of the most important features and we would appreciate the opportunity to also to submit our comments in writing. Thank you.

Sarah Reichle:
Thank you for your comments.

Our next commenter is Tom Eshleman. Can you please share your organization or that you're speaking as an individual? You have four minutes for your comments, please proceed.

Tom Eshleman:
Can you hear me now?

Sarah Reichle:
Yes, we can hear you.

Tom Eshleman:
Thank you.

My name is Tom Eshleman. I am commenting as an individual, but I work for a wholesale tobacco distributor, a small family run business. And I would like to see some rules and regulations put forth that are simple for everybody to understand. The FDA needs to make clear cut decisions, so everybody knows what's going forward, as far as everything. And I hear a lot of times people talk about that tobacco people are targeting people of color and LGBTQ and I find that very incorrect. There's no ads that I've seen in many, many years that say that they target this. They talk about flavors, there's no more harm in a flavor than there is in a regular tobacco item, in my opinion. And also no one ever talks about strawberry Trulys. Do you want your child out drinking an alcoholic beverage? I think there's more harm in that than there is in a tobacco item.

There's many items that are adult only, we need to concentrate on having some more laws when these underage people get caught with it, they seem they want to do is not do anything to the people that get caught with it if you're underage. So, there's no penalty. I find that hard. And there's a lot of rules and regulations and tons and tons of forms we have to fill out on the wholesale side. They need to simplify, make it uniform, keep all the laws, rules, and regulations consistent through all 50 states. It becomes very, very burdensome to monitor all this and stay in compliance, which we do. We work very hard at it.

I think that people get their emotions more than science involved in this. There again, I don't use tobacco, but I'm speaking from a business standpoint and as an individual. And I just think that we need to get everybody on the same page going down the same road so that we're all there. Nobody ever uses a UPC when they talk about what's the flavor, what's banned. And it's like opening up a bottle of wine. If we all open up a bottle of wine all four of us are going to taste something different. You know. Who's making the rules? I can't get clear cut answers from people in government. Sometimes we get contradictory rules and regulations from different divisions. And we ask them who's right and who's wrong. We cannot get an answer. They say talk to your attorney. But then that puts the burden back on us as a wholesaler to try and monitor this. And we've got to come together as a group and make this good for everybody. And we want to do what's right. We don't want underage children using any tobacco product. But I think we're using that pulling on people's heartstrings when as a legal product is for adult consumption. I think we need to do is get the parents involved and do something with the children that are, quote "getting this," why don't we stop it there, put some teeth in it on that end.

There are some other things that we can do. But I think it's more administrative that that, we also have to not drag this out forever and a day on what's right or wrong. So, the FDA has got to, you know, get it figured out. If we have to do something they give us till the 10th of the month to get it done. You know, why can't they get their stuff done so we all know what's going on? Come to talk to the wholesale community and ask us for input, ideas, how to do this, and we'd be more than happy to give good constructive help, so that this doesn't happen.

So, thank you very much. I appreciate your time and the opportunity to testify today. And I don't think the menthol ban is the rule, I mean, people will buy it, they'll buy it in Canada, they'll buy it in Mexico, or they'll find other things to, or they'll go back to regular tobacco. So, is there any real harm in a menthol versus regular cigarette? No.

So, that's my feelings on it, so thank you for listening today.

Sarah Reichle:
Thank you for your comment.

Up next, we have Monita Sharma. Please state your organization or share if you are speaking as an individual. You will have four minutes for your comment.

Monita Sharma:
Can you hear me?

Sarah Reichle:
Yes, we can hear you. Please proceed.

Monita Sharma:
Good afternoon. My name is Monita Sharma, and I am an Inhalation Toxicology Specialist at PETA. On behalf of my organization, I would like to thank the FDA Center for Tobacco Products for the opportunity today to provide input for the development of the Strategic Plan.

Multiple in silico, and in vitro methods exist that can be used to conduct a robust toxicity analysis of tobacco products. Therefore, we encourage CTP to prioritize data only from non-animal methodologies to assess these products. No animals should suffer for the assessment of these voluntary use products that pose potential health risks that the consumers are already aware of. We encourage CTP to immediately release a policy to only accept in vitro data for MRTPs and PMTAs and to include the revision of documents that request in vivo testing as a part of its Strategic Plan. These changes will better align with FDA's predictive toxicology roadmap and goal to improve productivity while reducing animal use for the assessment of FDA regulated products.

Thanks so much.

Sarah Reichle:
Thank you for your comments.

Up next, we have Sairam Jabba. Please state your organization or share if you are speaking as an individual. And you will have four minutes for your comments.

Sairam Jabba:
Hello, can you hear me?

Sarah Reichle:
We can hear you. Please proceed.

Sairam Jabba:
Okay, thank you very much.

Hello, everyone. Good afternoon. I'm Sairam Jabba a Senior Research Scientist in Swanaric [spelled phonetically] Art Lab at Duke University School of Medicine, where I study the toxicological and addiction properties of flavor chemicals in tobacco products. I'm providing these comments as someone who has an extensive expertise in the field of tobacco regulatory science, including basic science research, menthol research or pharmacology, toxicological research, regulatory policy and advocacy. And also, I speak as a member of the ART lab that has conducted foundational studies on the effects of menthol on tobacco smoke inhalation and oral nicotine intake. Current ongoing studies in our lab focus on the behavioral effects of synthetic cooling agents that are mostly derived from menthol and also on sweeteners and sweet associated flavors. I'm also a member of the Yale Center for the Study of Tobacco Product Use and Addiction. More importantly, I provide these comments as a dad of two young children.

We would like to thank the FDA for giving us this opportunity to comment specifically we would like to bring attention to CTP for its -- for it to pursue regulations and guidance that would strengthen FDA's current flavor regulations by including menthol analogues, synthetic coolants, and sweeteners that are currently being added to a diversity of tobacco products. In this regard, we recommend that FDA CTP as part of the Strategic Plan should define more precisely what should a characterizing flavor constitute in the context of a tobacco products regulatory framework. Odorless flavor in such as synthetic cooling agents that are devoid of a main odor may not count as a characterizing flavor by definition. The concept of characterizing flavor is also not clear regarding the importance of the pharmacological actions of flavorings. For example, these synthetic cooling agents have similar pharmacological and cooling properties as menthol that are mediated by the menthol receptor. We have recently demonstrated that these synthetic cooling agents are being widely added in significant high amounts in several tobacco product categories, including e-cigarette products, smokeless tobacco products, such as oral nicotine pouches.

More worryingly, to evade the menthol ban in combustible cigarettes tobacco industry introduced these odorless menthol derivatives in combustible cigarettes to provide the same cooling sensations provided by menthol but without the characterizing menthol or minty order. We have also demonstrated that these synthetic cooling agents contain tobacco products, such as nicotine pouch products and combustible cigarettes can produce similar or stronger cooling sensations compared to that of menthol flavored tobacco products. Similar to these synthetic cooling agents, our research has also demonstrated that synthetic sweeteners, such as acesulfame K, saccharin, sucralose were being added to diverse tobacco products including snooze nicotine pouches, flavored cigars, and cigarillos. Wrote in behavioral studies in our lab has also indicated that these synthetic sweeteners are added to potentially trigger intense sweet perceptions that will further mask the harshness of nicotine in tobacco. These synthetic sweeteners like synthetic

cooling agents are odorless flavors with strong pharmacological and sensory responses, and by current FDA definition will not count as characterizing flavors.

Taken together all these studies strongly suggest that the regulation of synthetic coolants and sweetener content may represent an efficient means to control appeal and compatibility of a wide range of products and to reduce tobacco product use and initiations. More importantly, it maximizes the benefits of any proposed flavor restrictions. Finally, to further FDA CTP proposed strategic goals and strategic plans that intends to maximize the public health benefits, advance health equity, minimize risk and health disparities, and have comprehensive force to address tobacco product appeal. We strongly recommend FDA to pursue regulations that would include odorless flavor in such as sweeteners, synthetic cooling agents, and also pharmacological and multisensory reactions of these flavorings including cooling sensation into the regulatory framework and definition of characterizing flavors.

Thank you very much for the opportunity and we will submit the same as a written comment.

Sarah Reichle:
Thank you for your comment.

Next we will all welcome Charles Giblin. Please state your organization or share that you're speaking as an individual. You will have four minutes for your comment.

[audio break]

Charles Giblin are you available to make your comment?

Charles Giblin:
I should be good. Ready now. Yeah, okay, good.

Sarah Reichle:
We hear you. Please proceed.

Charles Giblin:
Okay, let me go back to my speech here.

So, anyway, good morning, everybody. My name is Charlie Giblin. I am representing the Center for the Advancement of Public Safety and Security. I'm the retired Special Agent in Charge of the New Jersey Treasury Department. Of my 45 years in law enforcement, 36 were spent in the investigation and enforcement of cigarette and tobacco laws, including e-cigarettes or END, overseeing the criminal, civil and administrative aspects of these laws and programs including writing legislation. I am not talking here to dispute potential health benefits or the methodology. But I am talking in regard to the FDA Strategic Plan concerning enforcement. My review indicates a complete lack of commitment to a viable and equitable enforcement program. You're poised to penalize legitimate regulated businesses instead of the criminal entrepreneurs who will be providing profits to transnational criminal actors. The Special Agents of your own Office of Criminal Investigation should not be diverted from their critical work protecting the integrity of pharmaceuticals and medical device industries here and around the

world. The rush to repeat the disastrous prohibition of alcohol during the '20s and '30s will fail as quickly and as soundly as the best of intention policies.

I have serious concerns with the FDA's proposed product standards, menthol and nicotine ban and the negative impact these would have on the business community, revenue agencies and law enforcement alike. No one has even suggested what the enforcement dynamic beyond the FDA Special Agents, or how criminal enforcement will take place. What forensic testing to determine product is even flavored or what laboratory will conduct this testing. I'm truly concerned that you've not controlled vape or ENDS products that are making their way into our neighborhoods. And you're now proposing additional product categories to be banned. Our Customs and Border Protection is overwhelmed, protecting our nation from fentanyl, they should not be worrying about flavored tobacco. Instead, the FDA CTP should focus its strategic vision on harm reduction, solutions, such as education, cessation support, and youth access prevention, all measures that would strengthen police community relations instead of the opposite.

It will not be the legitimate licensed manufacturers here in the United States that would distribute flavored tobacco in violation of your proposed ban. But the transnational criminal organizations who are already partnered with the south of our border cartels, who will -- how will you enforce a business enterprise outside of your jurisdiction? Are you sending your agents over to the Chinese National Tobacco Company? I think not. Finally, you've not partnered with law enforcement leadership organizations, such as the International Chiefs of Police, National Sheriffs Association, or the National Association of Law Enforcement Organizations for their input and cooperation. [inaudible] to the Federation of Tax Administrators.

Again, putting the cart before the horse here when you can't even control the END and vape products is a foolish and unwise decision. Thank you.

Sarah Reichle:
Thank you for your comments.

Next, Kathee Facchiano. Please state your organization or share if you are speaking as an individual. You will have four minutes for your comment.

[audio break]

Kathee Facchiano, are you available to make your comment?

Kathee Facchiano:
Yes.

Sarah Reichle:
I can hear you. Please proceed.

Kathee Facchiano:
My name is Kathee Facchiano and I'm presenting on behalf of the Convenience Distribution Association or CDA. CDA is the trade organization working on behalf of convenience products distributors in the United States. Its distributor members represent more than $102 billion in U.S. convenience product sales serving a wide variety of small retail formats. CDA members operate

in the legal, regulated, taxed, age restricted, responsible channel. We recommend the following to address the CTP's questions. First, rescind proposed rules FDA tobacco products standard for menthol in cigarettes and FDA tobacco products standard for characterizing flavors in cigars. Removing the distribution and sale of these products from licensed, regulated, taxed, age restricted, distribution channels will push them into the illegal, unregulated and untaxed, illicit trade. Banning these products will undermine the public health by creating an unregulated market of untraceable and potentially adulterated products.

Second, measurable short and long-term outcomes for the next two to five years. First, addressing the slowness of the premarket tobacco applications modified risk tobacco product and substantial equivalency processes is a significant concern and should be made a top priority. Second, communicate the status of submitted PT -- PMTAs to ensure only those products with authorization are in the distribution pipeline.

Three specific actions CTP can take in the next five years; expedite and complete PMTA processing of ENDS products and communicate results with industry and consumers, thus providing adult consumers with authorized legal products. Second, adopt a coherent harm reduction plan for bringing more order to the e-vapor market. This will require both accelerating authorization of products that deliver on harm reduction and enforcing the law to remove products that do not. Third, enforce current regulations incorporating other appropriate federal agencies such as the FTC, DHS, CBP and DOJ. This will not only significantly reduce currently available unauthorized products but also address radio and print advertising of these products as well as the movement of these products across the U.S. border via ports, rail, and trucking routes.

Other important initiatives include federal authorities must provide clear actionable direction to wholesalers, retailers, consumers, and regulators regarding which products are authorized by FDA for sale and which are not. Second, federal authorities must leapfrog to the most powerful enforcement tools available for the most egregious and visible manufacturers and retailers who are knowingly making and selling illicit products. Third, federal authorities must address the discrepancy between the regulation of cartridge and non-cartridge e-vape products. In January 2020, the FDA announced a ban specifically on flavored cartridge e-cigarettes excluding menthol only. However, a loophole has now been created as the market has shifted towards non-cartridge and disposable vapor products in numerous youth friendly flavors, the majority of which have entered into this country from other countries, leaving the compliant portion of the industry and consumers at risk. Finally, federal authorities must address online sales of unauthorized tobacco and e-vapor products. The power of the Internet has provided consumers a pathway to purchasing unauthorized products without any oversight. These products can come from across the globe and are often unregulated, putting consumers of all ages at risk.

We appreciate the recent opportunities that CDA has had to engage with the FDA. CDA stands ready to serve as a resource to answer any questions and provide feedback as you solidify your strategic goals. CDA urges the CTP to incorporate these items into your Strategic Plan. Thank you.

Sarah Reichle:
Thank you for your comments.

Our next commenter is Sonia Wiggins Pruitt. Please state your name, your organization or share if you are speaking as an individual. You will have four minutes to make your comment.

Sonia Wiggins Pruitt:
Hello, can you hear me?

Sarah Reichle:

We can hear you. Please proceed.

Sonia Wiggins Pruitt:
Okay, great.

Thank you for taking my remarks today. I am Sonia Pruitt, and I'm speaking as the founder of the Black Police Experience, and I'm providing comment specifically on the pending rules and regulations regarding tobacco product standards for menthol in cigarettes.

I'm a former police captain with 28 years' experience, a social advocate, and a professor of Criminal Justice. And I come from a family where close relatives were and are smokers. I do not smoke, and I do not condone smoking. I however fully support the right for consumers to choose to smoke a legal product. Carving out a subset of illegal products to be banned would be to create choice bias, but further, it would create opportunities for discrimination in those communities which favor menthol as a flavor for their cigarettes. And those communities are overwhelmingly black and brown.

Because I'm a retired police executive I follow data. To date there is no significant information that menthol increases disease risk or that it is actually associated with dependence among smokers. Even a Surgeon General report in 2020 indicated there was not enough evidence to support a menthol ban for smoking cessation. It is nicotine that is the addictive substance in all cigarettes, not menthol, and there is also no significant evidence that menthol eases the intake of cigarette smoke. It is a preference. If you remove the preference, smokers may simply pick a non-mentholated cigarette to smoke and even worse, may buy menthol cigarettes from an illegal market, which will flourish. In addition, approaching social and health issues through prohibition has not worked in this country. One example is the failed prohibition of alcohol efforts in the early 1900s. Another example is understanding that while marijuana is increasingly being legalized, the criminalization of marijuana has historically led to the incarceration of millions of black and brown people. Its use has not been approached as a health issue as opioids have been. I contend that cigarette usage should be approached with the same care, concern, and resources as opioid usage is now.

While it has been said that a ban on menthol tobacco products are a regulatory issue, which will not involve the police, I can tell you that saying that does not prevent an aggressive officer whether well-meaning or not, from asking people about the cigarettes in their possession, especially since the ban will elevate an illegal underground market, which the police will have an obligation to investigate. Since menthol cigarettes are the preferred type in the black community, this increases the opportunity for disparate interactions between the police and black community members. We do not want any other incidents such as the one that took Eric Garner's life or that

is leading to black men being physically accosted by police on the boardwalk of Ocean City for something as benign as vaping.

With an unregulated cigarette market comes other issues that place pressure on police such as unregulated cigarettes laced with dangerous substances such as fentanyl, cartels, gangs, organized crime, guns, illegal drugs, and human trafficking. Bans and prohibition are force multipliers for criminal activity. I along with my colleagues who come from law enforcement and medical communities and who are also anthropologists, sociologists, community leaders, and community members, are asking that the FDA and the Biden Administration pause any movement on prohibiting menthol as a characterizing flavor in cigarettes until more studies be conducted around the societal impact this decision would have on our most vulnerable communities. Until we have more education and cessation support be provided to smokers, more approval and accessibility for effective harm reduction products, robust enforcement of existing rules that regulate tobacco, especially amongst youth, and finally, we are asking for more opportunities for all stakeholders to be heard on this matter, especially from the communities that will be most adversely affected by such a ban.

Thank you.

Sarah Reichle:
Thank you for your comment.

Charles Gardner, you will be our next speaker. Please state your organization or share if you are speaking as an individual. You will have four minutes for your comment.

Charles Gardner:
I will turn on my camera.

And so, thank you for listening to me. I'm speaking as an individual. My name is Dr. Charles Gardner. I'm a developmental neurobiologist by training. I held senior positions in the U.S. Department of Health and Human Services for 10 years and I have served as a senior adviser to the World Health Organization for three years. And I have also taught healthcare ethics to medical students and nursing students at Howard University Medical School.

My comments have to do with the healthcare ethics of your communications plan within the new strategy. Just for context, I'm going to draw upon numbers from the CDC's National Health Interview Survey for adults and National Youth Tobacco Survey for teens. The total number of American adults who are using tobacco or nicotine products is 46 million people. And the total number of teens who are using any of these products is 3 million teens. 100 percent of all of the deaths from any of these products is among adults. Almost all of that is -- 99 percent of it is adults over the age of 50. And four out of five of the deaths are adults over the age of 70. So, it's older adults. That's from a public health perspective. That's the priority. That's what we need to try to address and to reduce.

The other issue here is that probably 98 percent of those deaths are from one particular class of product, mass produced combustible tobacco cigarettes. How will you communicate the relative risk of all of those products from premium cigars to nicotine pouches to vape products to the ones that are really causing the deaths, cigarettes, is obviously critical. And I am urging you from

a healthcare ethics perspective, to tell the truth about the relative risks because you know what the truth is. Truth telling is a fundamental moral principle in healthcare ethics. And over the past several years, your communications strategy has informed the public that vaping will cause, literally, cause worms to grow in your brain. Your communications activities have literally informed the public that vaping causes demonic possession. This is not truth telling. And so, I'm urging you because you know there are relative risks, that you inform the people who are dying, smokers, and people who are using other toxic forms of tobacco, about those relative risks and this is something that you have not done.

Thank you.

Sarah Reichle:
Thank you for your comment.

Our next commenter Samy Hamdouche. Please identify yourself, say if you are speaking on behalf of an organization or if you are speaking as an individual. You will have four minutes for your comment.

Samy Hamdouche:
I'm Samy Hamdouche, founder of Lucy, a small business making oral nicotine products.

We support sensible regulation of tobacco products and believe that regulation should be designed to move consumers away from the most harmful forms of tobacco and down the continuum of risk. Regulation should also be calibrated to the realities of operating a small business and to harness the innovative potential of small companies. Crafting a five-year Strategic Plan represents a pivotal moment in our industry, and we appreciate the chance to comment.

Modern oral nicotine includes products like nicotine pouches and gums, designed as satisfying alternatives to smoking. Despite being on the market for nearly a decade, modern oral products have very low underage use. However, CTP has yet to authorize any nicotine pouches or gums, and it's unclear how these PMTAs are being evaluated. CTP has given guidance that PMTAs for flavored ENDS, given concerns about youth uptake, would likely require a randomized controlled trial or longitudinal cohort study. But FDA has not expressed what concerns they may have in authorizing modern oral products, and what data may address those concerns.

This confuses stakeholders about whether an RCT or LCS may also be necessary for products with low youth uptake. This issue may be immaterial to big tobacco, who have the luxury of deploying cigarette profits to generate mountains of data. But for small companies, it's existential. The cost of running an RCT or LCS for single SKU could bankrupt a small business. This is but one of the challenges we face as a small company trying to comply. The 2016 deeming rule articulates these challenges, stating that small entities, quote, “may need additional time to comply with certain requirements of the statute,” and that quote, “these activities may require an investment in -- of employee time, and/or financial resources that is more challenging for the smallest entities to achieve.” Small Scale companies are singled out in the rule, to quote, “ensure that entities with the most limited human and financial resources are uniquely considered in the FDA’s decisions about enforcement of these provisions, precisely because they require

resources not as readily available to these entities." In our experience, product sales are insufficient to meet the needs of small companies in the space. And raising outside investment is a must. But uncertainty around review criteria, and timelines are anathema to investment making it difficult for companies like ours to survive during the PMTA process, do any long-term planning crucial to operations, and continue innovating new products to meet the changing needs of consumers.

We request FDA consider the following proposals. Given the low youth appeal and high public health potential, we ask FDA to devote resources to prioritize review of modern oral PMTAs. This will reduce regulatory uncertainty and allow small companies developing these products to thrive. Second, small companies should benefit from more open and frequent communication during the PMTA process to clarify questions that arise during review. In addition, small companies should have more time to respond to deficiency letters. 90 days is inadequate for companies without large regulatory departments who compete for limited lab capacity preferentially allotted to Big Tobacco clients. Finally, we propose holding public workshops to align on criteria for streamlined submissions. Streamlined PMTAs would allow small companies to focus resources on generating data that answers the most salient, scientific questions, while making more efficient use the FDA review resources.

Small companies are vital to the goals of tobacco harm reduction. Historically, innovation and reduced risk products hasn't come from Big Tobacco, yet current policy tends to advantage companies that subsidize high compliance costs with their immense cigarette sales. The loss of companies like Lucy whose success depends on innovation and reduced risk products will undermine future progress. We feel the Tobacco Control Act has given FDA latitude in making rules flexible to the realities of operating a small business and the deeming rule affirms a responsibility to do so. We urge FDA to consider our proposals and look forward to working with FDA on our shared mission of moving consumers away from cigarettes.

Thank you.

Sarah Reichle:
Thank you for your comment. And thank you to everyone for their thoughtful comments. As a reminder, this Listening Session is focused on the development of CTP's Strategic Plan and the goal-related information provided. Please provide comments on -- that relate to one of the five goal areas.

Right now, we're going to take another short break until 1:00 p.m. Eastern. We will look forward to hearing more of your comments when we can reconvene at 1:00. Thank you.

[music playing]

Ashley Roberts:
--name is Ashley Roberts. Hello and welcome back. My name is Ashley Roberts, from the FDA. We will begin this afternoon's session. As a reminder, this Listening Session is focused on the goal-related information provided in CTP's development of our Strategic Plan. Please provide comments that relate to one of the five goal areas.

Up next, we have Will Jackson. Please state your name and organization or share that you are speaking as an individual. You have up to four minutes to comment. Please proceed.

Will Jackson:
Hey. Can you all hear me?

Ashley Roberts:
Yes. We can hear you.

Will Jackson:
Hey. I'm Will Jackson, president and sixth generation in family ownership of W.L. Petrey Wholesale Company located in Montgomery, Alabama. Our primary purpose of business is the wholesale distribution of products to convenience stores located through six southeastern states. We employ about 430 full-time team members. And these men and women help facilitate deliveries to 1,800 different convenience retail locations every week.

For the year 2022, W.L. Petrey paid $47,713,287.00 in federal and state excise tax on menthol product alone. We are already fighting an uphill battle, which has been created by the perceived inability to enforce current vapor product laws. That perception is being validated by the FDA to some degree in its acknowledgement that it cannot be everywhere. Proof of this is exhibited in the fact that over 97 percent of the vapor products on the market today lack FDA authorization but are still being sold by many wholesalers and retailers across the country. The FDA, in my opinion, should focus on its approach – should focus on its approach, and the expedited authorization of products that will help accomplish the goals of combustible cessation and work diligently with other agencies in the enforcement of non-authorized product.

Furthermore, this rapidly growing illicit market with absolutely zero FDA oversight, has the potential to be infinitely more harmful to public health than any of the menthol or tobacco products that are up for discussion today. Youth smoking is at its lowest level in an entire generation. This achievement can be attributed to the joint effort of the FDA and responsible tobacco manufacturers, wholesalers, and retailers.

My question is, why penalize those of us who have worked so diligently to help enforce the laws while at the same time, allowing those illicit markets to openly manufacture, distribute, and sell products that did not consult with the FDA, did not care about the FDA's mission to protect public health, and, frankly, only care about how to make as much profit as possible with no regard to the – to the health of the public? The path forward is quite clear to me. Prohibition of any product that has as many consumers as menthol will inevitably lead to the black market that will capitalize on the opportunity available and put products into the hands of adult and youth consumers with little to no regard for laws or safety.

By maintaining the current stance on harm reduction, emphasizing a scientific approach, expediting authorization, and putting more emphasis on working with all agencies to enhance enforcement, we can see the overall, and youth usage, number continue to decrease. There is no bigger challenge facing the FDA today than the need to bring regulatory coherence and support to the e-vapor market.

The FDA's ability to manage this challenge effectively, will truly influence the two-to-five year, as well as the long-term, success rate of the FDA's tobacco regulation. By simply banning menthol and other tobacco items, the FDA will be creating a problem much larger than what exists today within e-vapor alone. The ability to successfully regulate will be crippled and the responsible manufacturers, wholesalers, and retailers will be damaged, in some cases, irreparably.

In closing, I would like to thank the FDA for the opportunity to speak and acknowledge, as well as commend them, for their most recent import alert and enforcement actions. This is an example of where our time, resources, and effort need to be focused - not on prohibition, that frankly will never work. Rather than implementing a plan that will only continue to benefit illicit manufacturers, wholesalers, and retailers, the FDA has an opportunity to implement goals and plans that will help it.

Ashley Roberts:
Thank you. Up next, we have Pamela Ling. Please state your name and organization or share that you are speaking as an individual. You have up to four minutes for your comment. Please proceed.

Pamela Ling:
Great. Can you hear me?

Ashley Roberts:
Yes. I can.

Pamela Ling:
Thanks for allowing me to speak today. I'm Dr. Pamela Ling, professor of medicine at the University of California, San Francisco and director of the Center for Tobacco Control Research and Education. I'm principal investigator of the UCSF Tobacco Center of Regulatory Science, which integrates biological, behavioral, and economic research to inform tobacco product regulation. I have over 20 years of experience in tobacco research with special interest in youth, young adults, and priority populations. The UCSF TCORS will submit written public comments with feedback on the FDA CTP product Strategic Plan with citation supporting our recommendations.

But today I'll briefly discuss two specific actions FDA can take now to enhance goal one, and one issue that should be added to CTP's five goals. First, FDA should follow through on the announced plan to develop a proposed rule by December 2023 that would establish a maximum nicotine level for cigarettes and certain other combusted tobacco products. The safest approach is a single step reduction to less than 0.4 milligrams per gram tobacco applied to all combustible tobacco products. Implementing such a policy should dramatically and rapidly reduce disease and death from tobacco use.

Second, CTP should immediately complete the process of updating its outdated list of harmful and potentially harmful constituents, or HPHCs, and can -- and commit to revisiting that every three years. FDA's 2012 list of 93 HPHCs is outdated and does not reflect the current range of tobacco products. The 2012 list focused on toxicants, primarily carcinogens, found only in

cigarettes. The 2019 proposed expansion would add many toxins found in e-cigarettes that may cause pulmonary or cardiovascular harms. Also, many oils and chemicals found in e-cigarette flavorments may be safe if ingested but may cause other harms when inhaled.

FDA received public comment in 2019 on the proposal to add 19 toxicants to the list. And it has had ample time to consider the 40 submitted comments, which were mostly supportive. CTP should finalize the updated HPHC list by December 2023, and begin using it for product assessments. Given the evolving tobacco product market, CTP's Strategic Plan should include updating HPHC lists at least every three years.

Finally, in addition to the five proposed goals, CTP should actively integrate the relationship between cannabis and tobacco use into its tobacco regulation and prepare for regulation of cannabis. Tobacco and cannabis co-use is common. And as cigarette smoking rates are falling, cannabis use rates are increasing. Cannabis use and exposure to cannabis smoke are increasingly perceived as safe. However, the risks of co-use of tobacco and cannabis are greater than use of either product alone.

Dual-use results at a higher level of dependence to both nicotine and THC and is associated with a greater prevalence of mental illness. The tobacco and cannabis markets are co-evolving. For example, the popularity of nicotine vaping was accompanied by an increase in cannabis vaping products. And regulatory action eliminating flavored tobacco products opens market opportunities for cannabis products like flavored CBD vapes.

Tobacco product regulations that can be readily applied to cannabis include prohibition of unsubstantiated health claims; limitations on advertising and packaging that appeal to youth; effective warning labels; prohibiting product formulations that increase health risks; prohibiting menthol and other flavors; and recognizing the need to prevent regulators and public employees from having conflicts of interest with the cannabis industry. As part of the Strategic Plan, CTP should identify best practices from tobacco regulation to support research and inform comprehensive regulations for cannabis. Thank you.

Ashley Roberts:
Thank you. Up next, we have Christopher Beaulier. Please state your name and organization or share that you are speaking as an individual. You have up to four minutes for your comment. Please proceed.

Christopher Beaulier:
My name is Chris Beaulier, and I am the director of retail operations for Cigaret Shopper. We operate 21 tobacco-only stores across the state of Maine. Today my comments will focus on goal number one regarding comprehensive tobacco regulations and guidance, and goal number three regarding compliance and enforcement.

When the FDA requested comments from retailers from response to the proposed regulations to ban menthol cigarettes and flavored cigars, retailers submitted tens of thousands of comments about the impact of such prohibitory regulations and the very real likelihood of an illicit market to supply the continued demand for these flavored products.

However, in the proposed menthol cigarette and flavored cigar product standard regulations, the FDA claimed that the effects of an illicit market would be minimal. This country already has a large illicit cigarette market primarily caused by high excise taxes. The Institute of Medicine estimates that between 8.5 percent to 21 percent of the current cigarette market consists of smuggled cigarettes. Also, in 2015, the federal government issued a report titled, "The Global Illicit Trade in Tobacco: A Threat to National Security." The report concluded that consumers, retail outlets, manufacturers, and governments, are all harmed by the illicit trade in tobacco products.

The FDA's new Strategic Plan needs to give serious consideration to how the agency will respond to a broad illicit market if more tobacco products are banned. Why? Because a widespread illicit market will undermine the health-related goals since illegal sellers will continue to sell banned products to anyone of any age who has cash. With some 22 million adults who buy menthol cigarettes and flavored cigars, this sheer number of adult consumers will continue to demand these tobacco products. And the illicit marketplace will seize the opportunity to meet that demand. The agency cannot minimize the likelihood of and scope of an illicit market.

Regarding enforcement under goal number three, recently the FDA began compliance blitzes on randomly selected retailers to determine if these retailers are selling particular unauthorized electronic cigarettes and vapor products. However, since these blitz efforts are localized and limited in the number of retailers inspected, enforcement is not nationwide nor all-encompassing since every retailer is not inspected.

We acknowledge that the FDA's enforcement resources are limited, and that a compliance check on every retailer in the country, in a defined period of time, is not even possible. However, this results in unequal enforcement and a real sense among retailers that some stores will continue to sell unlawful products and those stores that are the subject of an inspection will not. In other words, some stores will have a competitive advantage over others when all retailers should be operating in the same manner and under the same rules.

The Strategic Plan needs to include action so that every retailer complies with the law at the same time to avoid a patchwork of pockets of enforcement. This could include clear and concise ongoing announcements to retailers and retail trade associations about what products are lawful and not lawful to sell. It is through clear communication and ongoing education that retailers will understand what products they can and cannot sell.

In addition, the FDA needs to include in its Strategic Plan a means to conduct nationwide compliance checks on every retailer to send a clear message that all retailers need to comply with the law. Thank you for the opportunity to participate in this listening session.

Ashley Roberts:
Thank you. Up next, we have V.J. Mayor. Please state your name and organization or share that you are speaking as an individual. You have up to four minutes for your comment. Please proceed.

V.J. Mayor:
Good morning or good afternoon. My name is V.J. Mayor and I represent the Northeast Wholesalers Association and the Southern Association of Wholesale Distributors. Both organizations work on behalf of convenience products distributors in their respective regions. Our members represent more than half of the $100 billion convenience product sales, serving a wide variety of small retail formats. Convenience distributors directly employ nearly 59,000 people and support over 173,000 jobs annually. The convenience distribution sector contributes billions in economic and fiscal activity in the U.S., including $2.3 billion in tax revenue and $30 billion in tax excise taxes.

As the FDA's Center for Tobacco Products develops its strategic plan, we recommend the following to address CTP's questions. The FDA should rescind its proposed rules, FDA tobacco products standard for menthol and cigarettes and FDA tobacco products standard for characterizing flavors in cigars. Removing the distribution and sale of these products from licensed, regulated, taxed, age-restricted distribution channels will push them to illegal, unregulated, untaxed, illicit trade.

Banning these products will undermine the public health by creating an unregulated market of untraceable and potentially adulterated products. A 2015 report from five federal agencies outlines the issues already present in illicit trade. A ban on menthol will send these products to this market further exacerbating the challenges to national security created by illicit trade. Left unchecked, these growing illegal operations solidify into a corrosive mixture of crime, corruption, and circumvention of the nation's tobacco control laws, putting at risk efforts to keep tobacco out of the hands of young people, disrupting legal commerce, and putting honest businesses at a disadvantage.

Regarding measurable short- and long-term outcomes for the goals. A, addressing the slowness of the pre-market tobacco applications, modified-risk tobacco product, and substantial equivalency processes, is a significant concern and should be made a top priority. FDA's slow enforcement led to the emergence of an illicit market of disposable, flavored ENDS products [inaudible] unauthorized, unregulated, untaxed products that are being manufactured, sold, and marketed outside the system.

Many of these unauthorized products are made by companies who have no intention of ever filing a PMTA being sold through illicit channels and creating unfair competitive conditions that put legitimate wholesalers, such as my members, at a significant disadvantage. CTP should expedite and complete the processing of ENDS products currently in the PMTA pipeline.

B, communicate the status of submitted PMTAs. There's currently no way for distributors to know the status of a product's PMTA. There must be transparency and communication, not only for manufacturers submitting the application, but for the distributors distributing a product in order to ensure only those products with authorization are in the pipeline.

Regarding the question, what are three specific actions CTP could take in the next five years? A, expedite and complete PMTA processing of ENDS products and communicate results with industry and consumers, thus providing adult consumers with authorized legal products. B, adopt a coherent harm reduction plan for bringing more orders to the e-vapor markets. C, enforce

current regulations incorporating other appropriate federal agencies. This will not only significantly reduce currently available unauthorized products, but also address radio and print advertising of these products.

Four, regarding the question, are there any important features, activities, or initiatives not encapsulated that we'd like included? A, federal authorities must provide clear actionable direction to wholesalers, retailers, consumers, and regulators regarding which products are authorized by FDA and which are not. B, federal authorities must leapfrog to the most powerful enforcement tools available for the most egregious and visible manufacturers and retailers who are knowingly making and selling illicit products.

C, federal authorities must address the discrepancy between the regulation of cartridge and non-cartridge e-vape products. D, federal authorities must address online sales of unauthorized tobacco and e-vapor products. These online sales detrimentally impact domestic industry players who are heavily regulated by the government. I thank you for your time and look forward to working with you in the future.

Ashley Roberts:
Thank you. Up next, we have Peter Krueger. Please state your name and organization or share that you are speaking as an individual. You have up to four minutes for your comment. Please proceed.

Peter Krueger:
Good morning. I'm Peter Krueger with the Nevada Petroleum Marketers & Convenience Store Association. We are a statewide trade group that represents Nevada convenience store owners, liquid fuel distributors, and retailers and transporters. Our mission is quite simple, to advance the role of our members as positive contributors to the economic, social, and philanthropic wellbeing of the communities they serve. Convenience stores and fuel distributors are critical components to Nevada's economy with stations and stores in every one of our 17 counties. Nevada has more than 1,200 convenience stores and employs more than 18,000 employees with annual gross sales of more than 4.7 billion.

On behalf of my members, I want to provide a small business perspective on the CTP's five-year Strategic Plan. First, as the FDA and CTP develops its Strategic Plan, our members urge FDA to rescind its proposed ban on the sale of menthol cigarettes and characterizing flavors in cigars. In 2020, during an FDA listing session of these proposed rules, I spoke about how tobacco retailers are the first line of defense in preventing underage sales. And I'm -- I remain proud and are -- as well our members of our ongoing efforts. A well-regulated market with responsible retailers in Nevada and across the nation, are key in reducing underage tobacco use.

According to the National Survey of Drug Use and Health, youth cigarette smoking is at a generational low of 1.3 percent. The rate is even lower for menthol cigarettes and cigars at eight tenth of 1 percent, also, the lowest in a generation. And youth of -- use of premium cigars is one tenth of 1 percent. Second, over the next two to five years, we urge CTP should manage short-term and long-term outcomes of its proposed goal areas for prioritizing pre-market tobacco applications, modified risk tobacco products, and substantially equivalent processes. Increasing

the transparency and speed of these processes will enable the retailers to partner with CPT to help ensure that only authorized products are sold in a regulated market.

We believe the FDA has been slow in these processes, which has, at least in Nevada, led to the emergence of a illicit market of disposable, flavor, electronic nicotine delivery systems, or ENDS, products. Many of these unauthorized, unregulated, and untaxed products are being manufactured and sold by companies who operate outside the regulated system and have no intention of ever filing a PMTA.

CPT should expedite and complete the process of ENDS PMTAs that are currently in their -- in the pipeline. CPT should also use a published list of categories and brands of ENDS and other deemed products with delivery derived from nicotine that have been filed -- have filed timely PMTAs with details about where each of these process -- each of the applications are.

Publishing a list will protect the public health by diminishing the availability of illicit products in the marketplace. Our members are strongly, strongly in favor of getting this directory out as soon as possible. This process will enable responsible retailers, my members, to manage our inventory and business operation. A publisher list would also better --

Ashley Roberts:
Thank you. Up next, we have Doug Ball. Please state your name and organization or share that you are speaking as an individual. You have up to four minutes for your comment. Please proceed.

Doug Ball:
[inaudible] -- convenience stores in the Western U.S. At Jacksons, we take our responsibility of keeping age-restricted items out of the hands of youth members very seriously and are proud of the work, we, along with other responsible retailers have done to help drive youth cigarette usage rates down over the past number of years.

The National Survey on Drug Use and Health 2002 to 2020 combined, shows a decline in youth cigarette usage by 90 percent. In 2002, 13 percent of 12- to 17-year-olds reported smoking a cigarette in the past 30 days. In 2020, that number had dropped to 1.3 percent. That decline can't happen without responsible retailers doing their part to limit access to youth.

As you set the direction for the next five years, I urge the FDA to withdraw its proposed rules to ban the sale of menthol and cigarettes and characterizing flavors in cigars. This proposal is just another prohibition-based policy that has proven to be ineffective over the years. A menthol ban would push consumers to seek out their preferred menthol cigarettes from the illicit market. Prohibition policies have proven this time and time again. When consumers turn to the illicit market, IDs are not checked to age verify, potentially dangerous products not regulated by the FDA are sold, and local, state, and federal taxes go unpaid.

Adult tobacco consumers have been unfairly targeted as a group over the past couple of decades. Local, state, and proposed federal bans on flavored tobacco products have taken away the choice for many adult tobacco consumers under the guise that the bans are to keep these products out of the hands of our youth.

While tobacco consumers are routinely targeted, adult alcohol consumers continue to see the proliferation in choices, many which seem to be attractive to youth. Mountain Dew, SunnyD, and Monster Energy all offer alcoholic versions of their beverages today. These brands appeal to youth way more than a menthol additive in a cigarette.

On top of that, these products are on the sales floor where youth have access to them. All tobacco products are located behind the front counter, and a sales associate will only hand the tobacco item to the customer after their age has been verified. The FDA's estimates on menthol smoker behavior if a menthol ban is enacted, comes from a single study that is fundamentally flawed.

In 2021, David T. Levy conducted an expert elicitation on the effects of a ban on menthol cigarettes and cigars in the United States. This study, funded by the FDA, asked 11 experts that were chosen by the authors about their opinions on how menthol smokers might behave under a menthol ban. The experts assigned percentages to potential behaviors like quitting or purchasing menthol cigarettes from the illicit market. There was no actual consumer data used from current flavor-ban markets in the U.S. or abroad to come up with the study's conclusions.

To highlight the disparity between the expert opinions, when asked, what percentage of menthol smokers would initiate with a non-menthol cigarette in the presence of a menthol ban, one expert estimated 79 percent while another expert estimated 1.9 percent. The authors of the study averaged all the responses and arrived at a mean of 30.3 percent on that question.

With $29 billion in annual retail sales at stake, the FDA needs to do more actual scientific research to behaviors instead of relying on the opinions of 11 individuals. Studies done doing actual -- using actual consumer behavior in flavor-ban markets, show that a large percentage of menthol smokers will continue to seek out and find menthol cigarettes in the illicit market -- and the illicit market will grow exponentially.

Cigarette excise taxes, sales taxes, and settlement payments make up more than 50 cents on the dollar spent on every pack of cigarettes. In the first year after the potential flavor ban, it's been estimated that the total lost tax revenue would be $8.9 billion. Over 10 years, it's estimated that would be $79 billion.

I would like to remind the FDA that responsible retailers, like us, have been instrumental in helping drive underage usage of tobacco products to historic lows. Please continue to build on the progress with the regulated market and work with responsible retailers to continue to make progress. I urge you to choose harm reduction policies over prohibition. Thank you for your consideration.

Ashley Roberts:
Thank you. Up next, we have Jeffrey Smith. Please state your name and organization or share that you are speaking as an individual. You have up to four minutes for your comment. Please proceed.

Jeffrey Smith:
Thanks, Ashley. And a special thank you to the ASL interpreters. You guys have done a wonderful job today. My name is Jeff Smith. and I'm a senior fellow in the integrated harm reduction team at the R Street Institute. R Street is a nonprofit, non-partisan public policy

organization focusing on advancing limited, effective government in various areas, including tobacco harm reduction.

We would like to commend the Center for Tobacco Products on initializing its institutional assessment process. And thank the Center for the opportunity to provide comments today. As a former university professor, I have been involved in the assessment programs at many levels from individuals to institutional.

By far, the most important step in creating successful assessment program is clearly defining your mission statement and building your objectives and strategies with a mission statement at the forefront. For many years, the Center has stated that appropriate for the protection of public health, was their north star. Consumers, manufacturers, and policy advocates have yet to understand what this mission statement means based on the actions of the CTP. In its short history, we have seen hundreds of brands of combustible products protected within the marketplace, and only a handful of reduced-risk products receiving MGOs. How do these actions align with the APPH?

A successful assessment program with achievable outcomes requires that the APPH mission statement be clearly defined, articulated broadly, and that all actions of the center are focused to meet the defined objectives that are drawn from it. Based on the experiences thus far, the Center seems to be only acting on protecting the health of youth, not the entire population, more specifically adult smokers. So, expanding that definition should be the priority for the CTP.

Additionally, the way the Center processes are communicated with audiences, specifically manufacturers and consumers, should be improved. The PMTA pathway for novel reduced-risk products continues to be unclear and impossible to successfully navigate by any manufacturer other than the largest tobacco companies.

When the guidance was first published, it was understandable that many aspects of the requirements were unclear. There was a myriad of new products, gaps in the science, and a lack of understanding around how consumers would use the novel products. This all led to the responsibility falling on the applicant to assume what research studies, methods, and endpoints might meet the APH -- APPH standard.

However, the Center has now granted marketing orders for several reduced-risk products, albeit too few, to allow for all manufacturers, including small and mid -- to mid-sized companies to compete fairly in the marketplace, the CTP must update the PMTA guidelines to include specifics around research studies, product standards, and requirements so that manufacturers with limited resources are not forced out of the marketplace due to their limited budgets for exploratory and potentially unnecessary research.

Ideally, the applicant would only be required to submit evidence required to meet initial product safety standards defined by the Center. Additional post-market surveillance monitoring would allow for clarity around unforeseen risk in the product's overall impact on consumer health. The CTP must also better educate the whole of the public as to how reduced-risk products are pathway to better health as compared to combustible tobacco.

The confusion generated by the CTP and its messages have led consumers to believe that reduced-risk products are as harmful as traditional combustible cigarettes, which is not accurate. Future messaging produced by the Center should be focused on reducing the burden of harm for all consumers, including those that choose to continue to use nicotine. This is the only path forward for the Center if the Center intends to significantly reduce the number of lives lost due to smoking related diseases in our country.

We believe these major items should take priority and will help steer the CTP into -- in a sustainable direction. We appreciate the Center's willingness to hear us today. We want to reiterate that the fewer people smoking, the better. We believe, however, that harm reduction is an effective off-ramp to cigarette consumption and better mitigates the negative consequences that can arise regulating human behaviors. Thanks.

Ashley Roberts:
Thank you. Up next, we have Meredith Berkman. Please state your name and organization or share that you're speaking as an individual. You have up to four minutes for your comment. Please proceed.

Meredith Berkman:
Thank you so much. My name is Meredith Berkman and I'm a co-founder of Parents Against Vaping E-cigarettes, an organization founded by three moms in 2018, as a grassroots response to the youth vaping epidemic. Over the last five years, our education and advocacy nonprofit has become the first and only national parent voice, fighting youth tobacco use, and the predatory behavior of the tobacco industry. And I am truly grateful for the opportunity to address you today.

Our organization represents the millions of parents across this country whose family's lives have been upended by an ongoing public health crisis, that not only impacts our children, but also as the CDC recently reported, impacts 10 percent of young adults between the ages of 18 and 24. This is not a problem that is going away. In fact, we urge CTP along with its sister agencies, to focus on cessation for young people addicted to nicotine through their dependence on e-cigarettes.

Parents like us are desperate for resources, treatments, any help they can get to help their kids conquer severe nicotine addiction and mitigate negative health consequences. There has not been a public hearing at CTP on this topic since January 18th, 2019. It was called, "Eliminating Youth Use of Electronic Cigarettes and Other Tobacco Product Use: The Role for Drug Therapies."

We are very grateful to CTP for its willingness to engage with stakeholders like us. And we hope there will be many more public opportunities for CTP to hear what is actually happening on the ground. The industry is extremely nimble and shape shifts very quickly with new products. And, again, we hope there will be more opportunities to hear from the public and specifically from impacted groups, the so-called boots on the ground.

We all know what happened. JUUL opened a public health Pandora's box and created the youth vaping epidemic using enormous amounts of nicotine-flavored and targeted -- flavored products and targeted social media to lure teens. The agency's repeated delays and failures to comply with

the federal court-ordered PMTA deadline, and failure to close regulatory loopholes in a timely fashion, have allowed many thousands of bad actor companies to follow JUUL's example with devastating consequences for our kids.

Now, looking forward, both CTP Director Dr. Brian King and FDA Commissioner Dr. Robert Califf, have publicly stated this process will finally end at the end of December 2023 and we take them at their words. And we want to look forward not backwards because the damage is done.

But what we do want to urge is that CTP leadership focus on enforcement. Immediate, forceful, and final enforcement that takes every single unauthorized product, the majority of them flavored and which are easily accessible to kids, off the market. With all due respect, we do not think that warning letters are doing the work that they must. If you look deep into the bowels of many of the websites that say they are no longer selling flavored nicotine products, but nicotine free, you will find that the flavored, illegal, nicotine products are still for sale.

Again, we also want to urge CTP to be transparent in its communication of its enforcement. We repeatedly call after these letters are released, and ask, if in fact 15 working days later, have they received a response? And we're told that they cannot comment on an ongoing investigation. If that were true, then why would these letters be released in the first place? Again, I want to thank you for this opportunity, urge you to enforce immediately to take all these many millions of illegal flavors off the market to protect our kids and to keep this generation from becoming one of nicotine addicts. Thank you.

Ashley Roberts:
Thank you. Up next, we have Lyle Beckwith. Please state your name and organization or share that you're speaking as an individual. You have up to four minutes for your comment. Please proceed.

Lyle Beckwith:
Hello? Can you hear me?

Ashley Roberts:
Yes, we can.

Lyle Beckwith:
Great. My name's Lyle Beckwith. I'm the senior vice-president of government relations for the National Association of Convenience Stores in Alexandria, Virginia. I've also been on the board of directors of We Card -- of We Card Coalition since its inception 28 years ago. You've all seen the We Card logos, signs, the yellow, under 21 no tobacco. We are the preeminent trainer of retailers as to how to identify and not make underage sales.

I actually had a prepared statement. But I threw it away a few [laughs] minutes ago as I was listening to the comments coming in from many of the trade association and retailers. And I was basically going to make some of the same comments. So, what I want to do instead is just take my time to use just a few of the data points that we have here at our association to drive some of those points home.

And it really revolves around the comments about the proposal to ban menthol and flavored cigarettes. I'm sorry, something just popped up on the screen here. Clearly the issue for us is that there is an established market in menthol right now. 37 percent of tobacco sales are menthol. And those sales will not go away -- that demand is not going to go away with a ban. As others have said, it will create an illicit market.

Right now, I'm sure there are Chinese manufacturers and organized crime and street hustlers who are just wetting their lips at the opportunity to get into this space, this void filled by potential ban on menthol. And what I mean by that is just for the convenience store industry -- that doesn't take into account supermarkets or vape shops or tobacco shops -- but just the convenience store industry alone, there was almost $42 billion in tobacco sales in 2022. Of that 19.2 billion was in menthol. So, a $19.2 billion, just from convenience stores, market is very attractive to an illicit market.

But more importantly, because of the tax rates, our industry collected and remitted $22.54 billion to state and federal governments last year, of which 8.34 billion was in menthol tax -- tax in menthol products. We use a -- every state has different tax rates, but we have a -- use a rounded method. So, the average is 43.5 percent tax on a pack of cigarettes, be it menthol or regular. So, what does that mean? So, the illicit market, that immediately means you've got a 50 percent reduction in price coming out of the box. You're not paying taxes. You're not checking ID, as other people have mentioned. You're selling other products beyond menthol cigarettes.

So, every time that there has been a proposal to raise cigarette taxes, the argument has been given, the best way to get people to quit is to raise the price. Well, what is the inverse of that? If you're cutting the price in half and selling them out on the street and you don't know what's in them and no one's checking ID, what kind of market is that going to create? And we've already heard about the problems of enforcement. Who's going to enforce? I mean, we can't -- we're having problems enforcing -- getting illegal products off the market now. Who's going to enforce all the illicit market of menthol that's going to surely erupt if this comes through? Thank you for your time and I appreciate the opportunity.

Ashley Roberts:
Thank you. Up next, we have Michael Schoenfeld. Please state your name and organization or share that you're speaking as an individual. You have up to four minutes for your comment. Please proceed.

Michael Schoenfeld:
Can you hear me?

Ashley Roberts:
Yes, I can.

Michael Schoenfeld:
Okay. Good afternoon. First of all, I would like to thank you all very much for including me in today's conversation. Hang on one second. My name is Michael Schoenfeld and I'm one of the family owners of MTC. We have a three-generation wholesale distributor located in Manchester,

Connecticut. We sell cigarettes, tobacco, non-flavored vape, and other miscellaneous C-store items.

My grandfather started the company in 1942 with $200 in his pocket and a high school diploma. We currently are one of the largest local Connecticut distributors servicing mainly independent mom-and-pop convenience stores, package stores, and gas stations. On the surface, I understand what the federal government is trying to do. But my opposition and concern, is of a menthol cigarette and a flavor cigar ban, which is derived from the lack of ability for the federal government to enforce and implement the laws, as well as communicate to businesses what products are legal and illegal.

Currently, the industry faces large illegal trade in all aspects of cigarettes, tobacco, and vape. Products from the black web, overseas shipments from questionable countries, and counterfeit products exist within the market. Every single day, I personally receive at least one email or phone call from some random company that wants me to distribute their product that I know have not even applied for a PMTA, never mind received a PMTA approval. The companies that comply with existing laws lose, and those that do not, win.

As a local business, I interact with my retail customers closely. I see firsthand now that the counterfeit and untaxed illegal products flow into the marketplace. A prime example of this are four stores located adjacent to each other in the Hartford, Connecticut area. One store started selling illegal cigarettes and vape. When the other three stores complained to the state, there was little resources to help stop the one bad apple from continuing its illegal ways.

The retail customer is now faced with either selling the illegal product like his neighbor or going out of business. Should his conscience be his guide, or his family lose their income? So, many stores choose to buy the illegal products, causing my sales as an honest and ethical wholesaler, as well as a manufacturer, to diminish.

If the situation is not truly being adequately addressed successfully on a state or federal level currently, then how do you implement it to the scale of 7 million more products? The only solution I can extrapolate from is making sure there are strong, enforceable, unified rules between the federal government and every single state. There needs to be thousands of government enforcement employees to carry out these rules. There needs to be structured and consistent guidelines with high penalties for those who do not comply. There needs to be clarity from a federal list that businesses can utilize to make sure they do not sell inappropriate products.

Even if one state is lackadaisical, the system will crumble because those who wish to exploit it will use that specific state as a loophole opening. Timely action is also a huge concern. If it takes years to stop the illegal activity, there will be no legitimate companies left to even deal with this. So, as the process of PMTAs acceptances or denials comes to an end, and the potential of a menthol ban looms, MTC plans on adhering and honoring these rules.

As a true tax-paying businessman, I understand the FDA is here to watch over its citizens from potentially harmful products. It is my assumption that manufacturers like Altria, PMI, RJR, ITG, legitimate wholesalers like myself, reputable chains, and even most importantly, retailers

throughout the country, will follow the rules. The issue is not with individuals engaging currently on this very Zoom call. It's the ones that aren't participating. Thank you very much for your time.

Ashley Roberts:
Thank you. Up next, we have Jiles Ship. Please state your name and organization or share that you're speaking as an individual. You have up to four minutes for your comment. Please proceed.

Jiles Ship:
Okay. Can you hear me?

Ashley Roberts:
Yes, we can.

Jiles Ship:
Yes. All right. Thank you. My name is Jiles Ship. I am the -- here today representing NOBLE, which is an acronym for the National Organization of Black Law Enforcement Executives. I have over 34 years in the field of law enforcement. I have -- I'm a director -- former director of a police department in -- with -- in an urban center in New Jersey. I have been a, as I said, a past national president of NOBLE, which services over 3,500 chiefs of police commissioners as well as sheriffs and other law enforcement executives from federal, state, and county and municipal law enforcement agencies.

One of the things that I wanted to also mention is that I don't know how much research has been done in this area, but we suggest that there be more studies -- that more studies needed to be done to include law enforcement executives. Also, there are already laws in place to address all of the concerns that I've heard so far about this issue.

But let me just say to you that menthol cigarettes, which currently make up around a third of the cigarette market, are disproportionately used by black Americans. While proponents of the ban claim that a menthol ban prohibition is a matter of racial justice, the reality is that such a ban will most likely contribute to overcriminalization in black communities already struggling to determine the role that policing should play in their neighborhoods.

That is why the National Organization of Black Law Enforcement Executives, better known as NOBLE, has taken a strong stance on the issue, stating that such a ban will trigger criminal penalties, which will disproportionately impact people of color, as well as prioritize criminalization over public health and harm reduction.

We know that there's no disparity in the harm from a menthol versus a non-menthol cigarette. They are both equally harmful to all communities. Therefore, to address this issue as a singular -- in a singular way would only further strain police and community relations, while organizations, like NOBLE, work in community across the nation trying to bridge the gap between community and police.

We have 55 chapters throughout the United States and the Caribbean and the U.K. And we strongly suggest that -- and this is from our practical experience as law enforcement officials and our research. We know what does not work as it relates to addictions, using a criminal justice

model to address a medical problem. What does work is education, treatment, and counseling, which is a medical model. Let's follow the science.

Using a punitive process to address a medical problem, frankly, does not work. Examples were prohibition of alcohol and the war on drugs. We have learned over the years, especially with the war on drugs, is that it destabilizes community and erodes trust in law enforcement. Over the last approximately 20 or 25 years, smoking has declined by approximately 40 to 60 percent depending upon which community. And it has the largest dip in the African American community. This was the -- this was due to education, treatment, and counseling.

Again, I respectfully request that we follow the science and keep neighborhoods safe versus creating another underground economy that will result in more destruction and widen the gap between communities and police. Please feel free to contact me for further testimony. And thank you for this opportunity.

Ashley Roberts:
Thank you. Up next, we have Thomas Briant. Please state your name and organization or share that you're speaking as an individual. You have up to four minutes for your comment. Please proceed.

Thomas Briant:
I am the executive director of the National Association of Tobacco Outlets, a national retail trade association with 66,000 member stores nationwide. I'll be focusing my comments on goal number three, ensuring compliance of regulated industry and tobacco products, utilizing all available tools, including robust enforcement actions.

Specifically, my comments will be on enforcement related to electronic cigarettes and vapor products. We want to clearly affirm our strong support for a well-functioning, federal regulatory system and Strategic Plan in which FDA oversight leads to accelerated reductions in underage use and in tobacco related harm.

All the progress made in recent years has occurred within a legal-regulated system in which tobacco products are made, distributed, and sold by retailers committed to FDA oversight. But central to the long-term efficacy of any regulated market is the rule of law, good behavior being encouraged, and bad behavior being punished.

However, other manufacturers and sellers have rapidly emerged and took a completely different path. In the absence of a strategic plan of enforcement, they have flooded the market with thousands of new disposable e-vapor products with every flavor immange -- imaginable. As a part of a new strategic plan, the FDA should consider communicating that it will prioritize enforcement against products that entered the market after 2016 in violation of the 2016 final deeming rule.

Also, it prioritized enforcement for those companies that failed to file PMTA applications in violation of the 2020 guidance issued by the FDA. Or to companies that disregarded any other of the rules FDA has established since 2016. To help the retail trade align their conduct with these priorities, the FDA's new Strategic Plan can, and should, provide a complete list of product SKUs with properly pending PMTA applications under review since 2020. And, an ongoing list

of products which have received refused-to-accept letters, refuse-to-file letters, and marketing denial orders. Only with such a list would retailers be able to adequately and properly comply with the law.

With these actions, in conjunction with the extensive state inspection infrastructure, the FDA can focus on the presence of non-compliant products in a comprehensive way and begin to drive unlawful products out of the market. Companies not complying with FDA regulations must be held accountable. And we believe that the FDA Strategic Plan should require that the agency employ its most powerful enforcement tools on those offenders.

These actions would include the following under the Strategic Plan. First, issuing cease and desist letters immediately to all, not just some, of the offending entities. Second, imposing maximum and ongoing civil money penalties on all of the offending entities. Third, bringing injunction lawsuits against the major offending manufacturers and major distributors. And finally, commencing criminal investigations focused on the most egregious actors. Thank you. That concludes my comments. We appreciate the opportunity to present today.

Ashley Roberts:
Thank you. Up next, we have Chris Howard. Please state your name and organization or share that you're speaking as an individual. You have up to four minutes for your comment. Please proceed. Chris Howard, are you there? Please proceed. Chris Howard, can you hear us?

Chris Howard:
Yes, I can hear.

Ashley Roberts:
There you go. We can hear you now.

Chris Howard:
Great. Thank you. Well, if you're ready. I am Chris Howard. I'm a member of the Coalition of Manufacturers of Smoking Alternatives, or CMSA. CMSA is a trade coalition group representing responsible manufacturers of smoking alternatives committed to regulatory compliance and a level playing field for compliant members of industry. CMSA members focus on products that are considered potentially reduced risk on the tobacco-nicotine risk continuum, such as modern oral, white, pouch products and electronic nicotine delivery system products.

Our association is encouraged that CTP is embracing the identified need to develop a predictable, consistent, five-year strategic plan. And thanks, Director King, and the center staff for their work to implement the Reagan-Udall Foundation recommendations. And of course, for providing this opportunity to comment.

CMSA's comments will focus on two areas that CTP should consider as part of its strategic plan. With a specific emphasis on how other FDA centers have approached these objectives. The first area I'll address is key features, activities, or initiatives, measurable short- and long-term outcomes and specific actions.

Critically in defining and carrying out strategic priorities, other FDA centers have established clarity about their desired end state and specific quantifiable targets toward reaching that end. I'll

provide two examples. Number one, the Center for Drug Evaluation and Research strategic plan sets goals in relation to three long-term objectives to implement FDA's statutory responsibilities.

Currently, because long-term goals are unclear, CTP's mission appears disjointed in relation to its statutory and regulatory oversight obligations. For example, one stated purpose and obviously a long time -- long -- excuse me, a long-term objective of the Tobacco Control Act is to ensure that there's effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful products. CTP's current plan does not appear to prioritize this. Rather, since 2019 and continuing today, this effort to promote less harmful tobacco products has taken a backseat to other concerns.

Example number two, goals must be broken down into actionable tasks with measurable targets. The Center for Devices and Radiological Health set the strategic priority of partnering with patients to increase the use and transparency of patient input in decision making. And then set a target to include a public summary of available and relevant patient perspective data considered for their pre-market applications by a set date.

CTP should employ a similar approach to goal setting to ensure its goals are actionable and impactful. For example, by establishing clear goals and timelines for each phase in the PMTA review process, the center would enjoy a much more structured approach and applicants would understand the process of their -- the -- sorry, the progress of their applications. Currently, the lack of transparency in the review process leaves industry uncertain, which discourages investment in innovation of new and potentially reduced-harm products.

The second question I'll answer is, are there any important features, activities, or initiatives not encapsulated by these proposed golden areas that you believe CTP should consider as part of a strategic plan? The answer is yes. And we can look to other centers again for guidance. In this 2018 to 2020 strategic priorities, the Center for Devices and Radiological Health set the goal of simplicity. This stems from the recognition that while the issues they deal with are often complex, the solutions and processes used to address them don't necessarily have to be.

CDRH's goal of Simplicity was supported by developing decision aids to assure that anyone who will -- would apply the policy in a given case, will arrive at the same outcome. Additionally, CDRH reevaluated every device type under a pre-market application to determine whether CDR should stop requesting certain data, shift some pre-market data collection to post-market centering, or keep the regulatory approach as is.

CDP -- CTP could benefit from a similar approach that considers a different categories and subcategories of tobacco products and requirements for each. By simplifying the process for products to lower the continuum of risk, CTP would encourage innovation and create opportunities for adult tobacco product users to potentially reduce their individual risk. On behalf of CMSA and its members, I thank you for your work on this important effort and for the opportunity to comment.

[audio break]

Vanessa Burrows:
Thank you for your comment. I'm Vanessa Burrows with the FDA. I will be moderating for the next hour. Thank you, Ashley. Next up is Joseph Manuppello. Please identify the organization you represent. Or identify if you are speaking as an individual. You will have four minutes to comment. You may proceed.

[audio break]

Joseph Manuppello:
Sorry about that. Can you hear me? Can you hear me?

Vanessa Burrows:
Yes, we can.

Joseph Manuppello:
Thank you.

Vanessa Burrows:
Yes, we can.

Joseph Manuppello:
Thank you. Good afternoon. I'm Joe Manuppello with the Physicians Committee for Responsible Medicine. Thank you for the opportunity to comment. PCRM welcomes CTP's initiative to develop a five-year strategic plan to advance its mission. PCRM appreciates CTP'S progress in supporting the replacement and reduction of animal use in testing. The strategic plan offers the opportunity to further this progress by prioritizing communication that minimizes animal use. Under the first proposed goal area, develop, advance, and communicate comprehensive and impactful tobacco regulations and guidance.

While FDA has consistently stressed that information from non-clinical studies alone, including from animal toxicity studies, will generally not suffice to support its determinations. In its regulations and guidance, it has also maintained the possibility that it might, in some cases. Tobacco product manufacturer's uncertainty over CTP's expectations has already resulted in thousands of animals being used in tests that it does not appear to have needed.

I'll illustrate with two brief examples from CTP's experience regulating ENDS to date. Through FOIA, we obtained non-clinical study reports submitted with PMTAs for ENDS from Logic Technology and NJOY. Logic tested 10 ENDS products and Pall Mall Red Kings combustible cigarettes on 2,393 rats. These were nose-only exposures where rats are constrained in tubes for six hours every day for up to 90 days and forced to inhale test and control substances. By contrast, NJOY submitted only reports from CORESTA standard in vitro test battery that measures cytotoxicity and mutagenicity.

Both applicant's answer is similar, consisting of a reusable battery and a prefilled disposable capsule or pod. While CTP says that this animal testing provided evidence supporting its determination, it did not discuss whether the definitive clinical studies could have stood alone. That NJOY's ENDS were also approved just one month later, without animal testing, raises the question of whether CTP needs any animal test data for ENDS. As information is available on

fewer than 50 approved PMTAs out of the 19 million submitted, it's virtually certain that far more animals are being used.

In the second example, JUUL Labs Incorporated attempted to address positive in vitro genotoxicity results by conducting in vivo genotoxicity tests for two products. CTP claimed that while negative results were accepted as final, positive results were rejected. And products reevaluated more rigorously, including in animal testing. It concluded that it was not scientifically sound to accept the negative results from the in vivo genotoxicity studies without justifying why the positive in vitro results were rejected. And these results should have been accepted. Had CTP's concerns been effectively communicated to JLI and other manufacturers in advance, this animal testing could have been avoided.

Along with our continued support for restricting the use of characterizing flavors, adopting broad product standards, and encouraging the use of TPMFs, TCRM recommends that in its strategic plan, CTP considering developing supplemental guidance on when new non-clinical information should be developed, and on the types and sequence of studies that applicants should consider.

In addition to minimizing animal use, clearly communicating CTP's expectations would facilitate FDA's timely and consistent reviews of marketing applications, improve manufacturer's compliance, and avoid legal challenges to its determinations, ultimately preempting the need for robust enforcement actions.

It would also free resources to more effectively advance CTP's mission to protect Americans from tobacco-related disease and death by focusing on products that pose grave health risks, including combustible cigarettes. Thank you and we look forward to continued --

Vanessa Burrows:
Thank you for your comment. Up next, is Erika Sward. Please identify your organization or if you are speaking as an individual. You'll have four minutes to comment. Please proceed.

Erika Sward:
Good afternoon. My name is Erika Sward. And I'm with the American Lung Association. We applaud CTP for initiating the strategic planning process. And we look forward to submitting written comments as well. CTP is correct to put transparency, health equity, science, and engagement as cross-cutting themes as part of its new strategic plan. However, as CTP prioritizes older engagement, it must adopt a different way to deal with industry. The tobacco industry is unlike any other industry FDA oversees. And after all, the major cigarette companies are convicted racketeers. There are no shared goals or priorities between CTP and regulated industry. And if it appears there are, then that should be a red flag.

The industry does not share CTP's mission of protecting the public health or any individual's health either. Companies and their representatives should not be considered in the same category or level of stakeholder moving forward and the same level as public health and medical groups. Furthermore, none of the regulated companies and their industry partners share FDA's goal of health equity.

The companies and their industry partners, including distributors, wholesalers, importers, marketers, retailers, and others have preyed upon youth and marginalized communities,

including Black and Brown communities, rural communities, native Americans, and LGBTQ+ people, to name a few. This has further exacerbated systemic health disparities within these communities and others, including those with mental health and substance use disorders.

The single best action FDA can take to advance and promote health equity is to finish and implement the two rules that would end the sale of menthol cigarettes and flavored cigars. Based on industry's reaction to these two rules, both today and in general, they too recognize how impactful these rules would be in improving health.

State and local public health departments, including other public health organizations, cannot support CTP, its mission, and our collective efforts to promote and improve the public health, unless FDA transparency is improved and more information becomes publicly available. CTP must increase its transparency and regulatory decisions, especially concerning product applications and the pending status of these applications. Moving forward, FDA should drop the FOIA requirement for an individual to learn if FDA has investigated or pursued a reported violation.

The Lung Association is generally supportive of FDA's five -- CTP's five proposed goal areas and find them consistent with its congressional mandate. However, the Lung Association strongly urges reconsideration of, and revisions to part of goal four, notably, any promotion of the so-called relative risk of tobacco products. FDA should have no part in the industry's efforts to sustain addiction through the failed and flawed notion that adult smokers should switch to e-cigarettes.

Appropriate for the protection of the public health does not include FDA pushing a tobacco product that has initiated and maintained the addiction of millions of people. Because our public health and health systems have systematically failed to help tobacco users quit. And because both smokers and some in the public health community are desperate for something to change that.

Cessation must only be defined as ceasing the use of all tobacco products, not switching to another tobacco product. The long-term public health and disease consequences associated with e-cigarette use, especially youth initiation, will continue to be learned the hard way and CTP must not be further implicated in this debacle. Thank you for the opportunity to speak today.

Vanessa Burrows:
Thank you for your comment. Up next, we have Rachel Boykan. Please identify your organization or if you're speaking as an individual. You'll have four minutes to comment. Please proceed.

Rachel Boykan:
Good afternoon. My name is Dr. Rachel Boykan. And I am the chair of the American Academy of Pediatrics Section on Nicotine and Tobacco Prevention and Treatment. I am also a practicing pediatric hospitalist and tobacco control researcher. The academy commends the FDA for undertaking the development of a strategic plan to guide the Center for Tobacco Products work over the next five years and appreciates this opportunity.

Effective regulation of tobacco products by the FDA is essential to reducing youth initiation in tobacco product use among young people. The FDA has already undertaken multiple, high-impact regulatory efforts that will dramatically improve public health and safeguard young people. Over the next year, it is critical that FDA get the job done on these efforts.

First, it is imperative that FDA finalize and implement the proposed rules issued last year to prohibit the use of menthol flavoring in cigarettes and all flavoring in cigars. These historic proposals have the potential to dramatically reduce youth smoking initiation by removing, from the market, the products that are most attractive to young people. And to improve health equity by redressing decades of discriminatory marketing practices, targeting communities of color with these products.

We appreciate the FDA's important work on the menthol cigarette and flavored cigar rules and urge you to finalize them as soon as possible. FDA must prioritize the important work that will be needed to implement these rules, such as significant change to the tobacco product marketplace will require extensive public education efforts to help the public understand the rules, why they were put in place, and how they will and will not be enforced.

The FDA must also be prepared to vigorously defend these rules against potential industry challenges. For smokers, whose preferred products are no longer available, it is also imperative that the FDA, working with other federal agencies, ensure widespread availability of evidence-based cessation therapies.

Second, FDA must complete the pre-market review process for all e-cigarettes. Since 2020, FDA has been accepting and reviewing applications for thousands of e-cigarette products, many of which have been on the market without the required authorization from FDA. We are grateful for the FDA's work to process this backlog of applications and issue science-based decisions about whether the sale of specific e-cigarettes is in the interest of public health.

We understand that FDA projects completing this process by the end of the year, and we urge the agency to do so as soon as possible and to reject applications for all flavored products. FDA must also prioritize enforcement efforts to ensure that only authorized products remain on the market.

To date, many e-cigarettes that have been rejected by FDA remain. We urge the FDA to take legal action to the fullest extent authorized by the law to remove all unlawful products from the market. And FDA should make a list widely available of the limited set of products that have received a marketing authorization so the public can be aware of which products are and are not being sold legally.

Pediatricians are particularly concerned about disposable and synthetic nicotine products, which are popular among youth and which contain extraordinarily high concentrations of nicotine. The health consequences from youth using these products cannot be understated. The risks of nicotine to the adolescent brain are well [inaudible]. And today, we see more severe dependence and addiction in our youth than ever before. This issue requires urgent action from FDA.

As FDA works to get illegal products off the market, enforcement should focus initially on these most harmful and youth appealing products to maximize the public health impact. Tobacco

companies continue to shift their product offerings and exploit loopholes and regulation. We urge the FDA to develop a mechanism to anticipate industry changes and future product trends such that regulation is happening on a proactive rather than a reactive basis.

In closing, the FDA has an incredible opportunity in front of it to reduce the disease and death caused by tobacco products. The academy looks forward to working with you to advance our shared public health goals. Thank you.

Vanessa Burrows:
Thank you for your comment. Up next, we have Bryan Burd. Please identify your organization or if you're speaking as an individual. You'll have up to four minutes to comment. You may proceed.

Bryan Burd:
[inaudible] my video. Hi, everyone. This is Bryan Burd. Can you hear me all right?

Vanessa Burrows:
Yes, we can.

Bryan Burd:
Okay. Terrific. So, my name is Bryan Burd. I'm speaking on behalf of Chemular. We are a regulatory consulting group, solely focused on the tobacco and nicotine space. I'm grateful for the opportunity here to participate in the listening session by the Center for Tobacco Products.

We've attended a lot of the major science -- tobacco science conferences, industry conferences, trade shows, anything else we can, for the last seven years. We've got a great team of toxicologists, chemists, quality specialists, publishers, every discipline to assist with federal tobacco regulations. We've been keen observers of the CTP and we feel we're in a pretty unique position to provide some great input on how the CTP can improve their current regulatory process.

The Reagan-Udall report was a great first step. I think some of the things that were buried in that -- there were some comments by FDA staff and others. And it oftentimes, inexplicably, in my opinion, gets overlooked that the current CDC website shows over 480,000 Americans die annually from cigarettes directly or indirectly. And this seems to be -- should be stated in every document, in my opinion, and should be the main purpose of the CDC or the CTP to reduce death of Americans from cigarettes.

Earlier on, Dr. King -- Director King, his opening remarks wanted forward-looking comments only. So, here's my forward-looking comments. The number one CTP goal that they listed was tobacco regulations and guidance, if there was any comments on that. So, no doubt, the guidance framework needs to increase its clarity, the predictability, and transparency, with respect to the scientific benchmarks governing the application review.

General statements in the guidance, such as make your product appropriate for the protection of public health, very vague. Many people interpreted that to be just make it safer than a cigarette. Again, we noted it kills almost a half a million people annually. But it ended up turning out that

APPH meant APPH-plus flavors need to show incremental benefit over tobacco flavors and outweigh that risk to youth. So, very clear guidance would be helpful to the industry.

Another quick example. You had to demonstrate that former and never smokers were not interested in your product. Well, what does "not interested" mean? How do you demonstrate not interested? So, having very clear guidance would be helpful. The goals for application product review, it'd be great if the CTP was more transparent in showing where their status -- these company statuses are. We've had two to three years with some companies that have no communication. So, being more transparent in the status would be helpful.

We'd also like them to push more on a continuum of risk for tobacco products showing that cigarettes are the most harmful and there are other alternatives to move people down their tobacco journey. And lastly, in response to operational excellence, we would recommend that the CTP set up a dedicated team of stakeholder engagement. And I think that's my last minute. Am I out here?

Vanessa Burrows:
Thank you for your comments. Up next, we have Cynthia Stanford. Please identify your organization or if you are speaking as an individual. You'll have four minutes to comment. You may proceed. Is Cynthia Stanford available to comment? Is Cynthia Stanford in attendance and available to comment?

Cynthia Stanford:
Oh my gosh. Can you guys hear me?

Vanessa Burrows:
Yes, we can. Please proceed.

Cynthia Stanford:
Oh, wonderful. Thank you for waiting for me. I don't know what happened with my connection. My name is Cindy Stanford. And I am an individual, but I'm also an owner of an e-liquid company that filed with two PMTA. And the failures made by the CTP has bankrupted my company due to improper application review and misstatements of the youth vaping epidemic.

I believe the CTP continues to ignore the fact that vaping is a verb and what youth are vaping is THC, drugs, spikes, and other black-market, unregulated product. This has been confirmed by the CDC after they made erroneous claims about vaping and the EVALI epidemic. I think this ignorance is using children as a shield in preventing tobacco harm-reduction products from moving forward and further harming the adult smokers who could use or could benefit from flavored nicotine products.

Flavor bans and prohibition do nothing for public health. And flavors are instrumental for adults to be successful in transitioning from deadly, combustible, carcinogenic, tar-filled cigarettes, to something less harmful. I ask again for the CTP to look to the U.K. for guidance. The U.K.'s forward thinking and current tobacco harm reduction has allowed them to place flavored, e-liquid, nicotine vapor stores in places such as hospitals.

The only difference between the U.K. and the USA is the Master Settlement Agreement fund. The U.K. takes no funds from this agreement and regards public health higher than monetary funding, which is very disturbing as an American citizen, an ex-smoker, and an ex-business owner. Thank you for letting me speak.

Vanessa Burrows:
Thank you for your comment. Guy Bentley, you are up next. Please identify your organization or if you're speaking as an individual. You will have four minutes for your comment. Please proceed.

Guy Bentley:
Thank you so much. Can you hear me?

Vanessa Burrows:
Yes, we can.

Guy Bentley:
Perfect. Thank you so much. Good afternoon. Thank you for the opportunity to provide comments on CTP Strategic Plan. My name is Guy Bentley. I'm director of Consumer Freedom with the Reason Foundation. And we're a nonprofit, public policy think tank. As part of its mission to communicate comprehensive regulations and guidance, CTP needs to state clearly what are and aren't its overarching goals regarding tobacco product regulation.

The mission that most coherently adheres to the letter and the spirit of the Tobacco Control Act is to reduce the burden of tobacco-related death and disease while adhering to the limitations set out in the TCA. These goals, however, should not be mistaken or blurred with unrelated or undesirable goals to eliminate non-medicinal nicotine use in the adult population, as this is both unachievable and does not align with Congress's intention when it passed the TCA. It should be made clear by CTP in its strategic plan that this is not its mission or intention.

Regarding the PMTA review process, it's clear that as currently constructed, it has worked as an enormous barrier to entry for safer alternatives to cigarettes, advantaging large tobacco industry incumbents. It's neither sustainable nor desirable for products with similar toxicological profiles and risk liabilities to those already authorized by FDA to fail to gain authorization. Because they do not have the resources to comply with current pathways.

As the Reagan-Udall evaluation suggested, CTP must clarify, in guidance, the specific data expectations and consider whether certain products would benefit from the creation of new pathways established based on currently scientifically supportable standards. As the RUF suggests, CTP should consider adopting processes by which products may secure authorization and then serve as model product submissions or be used to establish review expectations for similar products, much like the predicate approach path that exists in the substantial equivalence route.

The slow progress on reforming product pathways is especially pressing as the agency prepares to publish its rule banning menthol cigarettes. Not a single menthol e-cigarette has been authorized despite a large portion of the projected gains of the menthol ban derived from menthol smokers switching to menthol-flavored ENDS.

Furthermore, the goals of greater compliance and enforcement FDA outlines cannot be divorced from the current dysfunction in the application review process. They are, in reality, indivisible. The FDA can't celebrate, on the one hand, more than 99 percent of PMTA is being rejected and decry the proliferation of the illicit market for ENDS on the other. The greatest enforcement and compliance mechanism is a well-functioning, intelligible, scientifically-sound authorization process.

Regarding the FDA's fourth strategic goal in enhancing public understanding, Brian King recently noted in a commentary that only around 10 percent of smokers believe e-cigarettes are less harmful than combustible cigarettes. Dr. King suggests there are opportunities to educate adult smokers about the relative risks of tobacco products, particularly e-cigarettes, and it's heartening to see this problem addressed.

Given these figures were cited by Dr. King as being a specific concern, over the next five years, FDA should aim for a complete reversal of these misperceptions as part of its strategic plan. So that within five years, fewer than 10 percent of smokers believe ENDS products are just a dazzle more dangerous than cigarettes.

Finally, on advancing operational excellence, it's misguided to prioritize workforce growth. The agency's success should be measured on outputs, not inputs. Larger budgets and more staffs should not be a priority in and of themselves. Instead, reforming application pathways should mitigate the need for additional funding or additional staff. Thank you so much for your time.

Vanessa Burrows:
Thank you for your comment. Up next, we have Jon Adler. Please identify your organization or if you are speaking as an individual. You'll have four minutes to comment. Please proceed.

Jon Adler:
My name is Jon Adler. And I'm the current national president of the Federal Law Enforcement Officers Foundation, which provides support to federal offices from 65 different agencies. I'm also the former director of the Department of Justice, Bureau of Justice Assistance, which is the federal agency administering the largest grant programs for the criminal justice system and provides training and technical assistance and policy development.

During my law enforcement career, we learned that we cannot arrest our way out of the drug crimes problem. Drawing on lessons learned, we cannot ban our way out of the smoking health-related problem. The FDA's five-year plan should not include current plans to remove legal regulated tobacco products from sale. This would lead to the unintended consequences of empowering illicit markets circulating unregulated harmful poison puffs and placing additional strains on police-community relations.

According to FDA's published summary, FDA's enforcement of this proposed rule will only address manufacturers, distributors, wholesalers, importers, and retailers. These are pleasant business terms that ultimately refer to cartels, gangs, smugglers, and countries adversarial to our nation's interests. What is the plan for stopping them and where are the law enforcement assets that can investigate and enforce this rule?

Goal area three states, "Ensure compliance to regulated industry and tobacco products utilizing all available tools, including robust law enforcement actions." Who specifically is going to initiate these robust actions? Law enforcement assets nationwide are at historical staffing lows. Every chief, director, and sheriff have to prioritize their law enforcement assets towards violent crime and top areas of concern. This rule will likely lead to another unfunded federal mandate and finding anyone to initiate robust actions would be like searching for "Where's Waldo?"

As the saying goes, "History repeats itself," and so do criminals. Looking at the period of prohibition from 1920 to '33, the ban of alcohol products led to the empowerment of organized crime. The ban did not make the demand disappear. Tragically, the situation led to a drastic increase in law enforcement fatalities with 316 officers killed in 1930. It also resulted in Americans becoming ill after drinking unregulated alcohol products.

By way of comparison, we see how individual cigarettes called loosies are sold in poorer communities. If tobacco products were banned, this would increase the sale of loosies, which would now be unregulated cigarette-type products smuggled into our country. These illicit loosies are typically front loaded with tobacco and then filled with any leafy, grainy, or, possibly, toxic substance. We do not want our children smoking poison puffs and we do not have any robust means to prevent them from getting into the poorer communities.

We have experienced an unprecedented number of drug overdose fatalities in the past five years, many attributed to fentanyl. What doesn't get discussed is that drug users often have no idea what they're actually taking. And they run the risk of inhaling, shooting, or injecting a drug buffet of death.

Hence, we do not want our children or adults smoking mystery loosies. It would make better sense to continue coordinating with community leaders, law enforcement, and the tobacco industry to discuss harm-reduction initiatives. It seems that FDA has not convened the requisite group of law enforcement leaders to provide guidance and explain the inevitable negative consequences of a ban.

I strongly urge the FDA to engage with the leaders of the International Association of Chiefs of Police. This nonpartisan, professional association represents police chiefs nationwide and can offer meaningful input. The same goes for the National Sheriff's Association. They take an evidence-based approach towards researching and evaluating the anticipated impact of prospective policies on law enforcement resources and community relations.

Please engage with the IACP and the NSA and any other national law enforcement leader that is dedicated or in a dedicated environment to discuss this goal area and the broader impact a ban will have on policing to --

Vanessa Burrows:
Thank you for your comment. Up next, we have Doug Kantor. Please identify your organization and if you're speaking as an individual. You'll have four minutes to comment. Please proceed.

Doug Kantor:
Hi. My name is Doug Kantor. I am general counsel of the National Association of Convenience Stores. Thank you for the opportunity to present today. For retailers, like convenience stores that sell tobacco products, their top priority is to do that in a responsible manner. And that means, to the greatest extent possible, restricting youth access while legally selling these products to adult consumers.

As you heard from a number of folks today, there have, in fact, been some very real achievements on that front in reducing youth access to tobacco products over time. And we should build on that success, and we urge CTP to build on that success. A couple of things I would note.

One, you've already heard from a number of folks who have warned about the dangers of an illicit market developing and increasing if menthol cigarettes are banned, if flavored cigars are banned, and if nicotine and tobacco products is reduced. I would take that threat seriously. There are -- there's already a very large, illicit market built around other things like tax avoidance.

And so, the mechanisms are in place. It's a real danger, and the illicit market does not prioritize or care at all about limiting youth access. It will be a tremendous detriment to that goal if we go down that road and the illicit market grows.

But we're also at a moment where compliance in these areas is changing. It's changing because the primary method by which retailers verify age in order to prevent youth access is the driver's license. And more and more states are now beginning pilots and will soon move into mobile driver's licenses that appear on cell phones. And that new technology will bring additional complexity to it. It will change the compliance atmosphere. And I urge CTP to look at this very closely.

Here at NACS, we've developed a technology product, TruAge, in order to assist with that transition and allow for electronic verification, both of current driver's licenses. But also, with a view to the future and be the cutting-edge way to verify age. You heard my colleague, Lyle Beckwith, speak earlier about the We Card Program. We Card has been out there for decades and it keeps at the cutting edge of how to comply and keep up with new things that are happening in the marketplace and new technologies that are going on.

We urge you, at CTP, to engage in rulemaking and guidance to approve training and compliance programs. To date, what the CTP has put out has been much too complicated. It does not make clear what programs are fit to use and what programs are not. It leaves it to retailers to figure out, and that is not sufficient assistance.

There needs to be a real incentive for the best compliance possible. And CTP needs to point the way by showing if they're good enough programs, like We Card, technologies like TruAge, and being more specific with the market about the best ways to reduce youth access to these products. Thank you very much for your time.

Vanessa Burrows:
Thank you for your comment. Up next, we have Greg Wilson. Please identify your organization or if you are speaking as an individual. You'll have four minutes to comment. Please proceed.

Greg Wilson:
Great. Thank you. I'm Greg Wilson. I'm the vice president of Regulatory Affairs with Altria. And I appreciate the opportunity to share a few thoughts with you today. In announcing this session, FDA posed several questions. And while we intend to submit comments to the docket that's been open, I'll use my time here today to really address the specific question that FDA posed around what three specific actions can CTP take in the next five years that will have the most impact?

The first action that CTP or FDA should take is to enhance the PMTA pathway by clearly defining the APPH standard, including providing category-specific details of the scientific evidence that FDA believes is necessary to meet that standard. Also, sharing details on how FDA evaluates and balances the risk-benefit analysis that is inherent in the APPH standard. Providing actionable feedback to manufacturers so that they can submit complete and relevant product applications. Leveraging post-market surveillance authority to monitor for unintended consequences rather than delaying or denying PMTA authorizations. And implementing the supplemental PMTA pathway in a way that accelerates harm reduction.

Most importantly, and in conjunction with providing that level of clarity on the PMTA process, we believe that FDA should move more rapidly to complete timely reviews and authorize more smoke-free products that offer significantly less risk for the approximately 30 million adult smokers in this country, including those that otherwise won't or cannot quit use of tobacco products.

Over half of these adult smokers are seeking reduced-risk products and alternatives, and no one product is going to satisfy all adult smokers. Smokers have made clear their interests in having an array of smoke-free products, including flavors and a variety of product platforms. The need for an array of smoke-free products that can satisfy a range of adult smoker preferences is especially urgent in light of U.S. public health disparities. It's imperative that there is a fully-regulated marketplace of authorized smoke-free products that are both satisfying and appealing to adult smokers if we're going to make meaningful progress on reducing the harms associated with cigarette smoking.

That brings me to the second action that we believe the FDA should take that will have a significant impact. And that would be to launch comprehensive and sustained public health communications that are aimed primarily at the 30 million adult smokers in this country that can address the widespread misperceptions that exist regarding nicotine and the overall relative risks of different tobacco products.

Unfortunately, the majority of adults who smoke think that smoke-free products are equally or more harmful than cigarettes. Left unaddressed, these misperceptions are a barrier to realizing harm reduction in this country.

Finally, the third action. We strongly encourage FDA to accelerate its compliance and enforcement. A fully regulated and enforced marketplace assures FDA oversight of all tobacco and nicotine products sold in this country. Unfortunately, today, there are a significant number of products in the market illegally and operating outside the regulated market.

As you've heard today, responsible retailers and wholesalers are asking FDA for guidance on which products can be sold. FDA should publish a list of products that can continue to be sold pending pre-market review. And FDA should partner with other federal agencies to take aggressive actions against those operating outside the regulatory system.

With the right strategic priorities, U.S. FDA can create a well-regulated marketplace that can serve as a model for positive sustained public health impact. That includes authorizing reduced-harm products for adults, establishing clear compliance standards for regulated parties, defining appropriate guidelines and marketing practices for innovative smoke-free products, maintaining strong, youth-prevention efforts, and pursuing enforcement actions.

Thank you for the opportunity to share these comments and we look forward to seeing more details as FDA continues to define its strategic plan.

Vanessa Burrows:
Thank you for your comment. Up next, we have Diane Goldstein. Please identify your organization or if you are speaking as an individual. You will have four minutes to comment. Please proceed. Diane, are you available to make a comment?

Diane Goldstein:
Can you hear me?

Vanessa Burrows:
Now, we can hear you. Please proceed.

Diane Goldstein:
I'm so sorry. I wasn't supposed to be on for another nearly 20 minutes. So, my name is Diane Goldstein. I'm currently the executive director of the Law Enforcement Action Partnership. As a 21-year policing veteran, I'm writing to express my concerns with FDA's proposed menthol ban.

Based on my experiences, I believe this policy would worsen police-community relations and lead to more problematic encounters between law enforcement and communities of color. Reacting to concerns previously mentioned from some law enforcement and civil rights activists, FDA has stated it would enforce the prohibition only against menthol cigarette manufacturers and distributors, not individual smokers.

However, this fails to account for the fact that all 50 states treat the sale and distribution of illicit cigarettes as a serious crime. Several -- street-level policing has never been under the influence and control of the FDA. When Eric Garner was killed by New York City -- in New York City for selling untaxed cigarettes on the street in 2015, it was a case of local police enforcing a state law.

If menthol cigarettes became illegal, the FDA will have no ability to prevent the resulting local enforcement efforts. If the nation's illicit drug market is any indication, the people who would operate an illicit menthol market at the levels most susceptible to police enforcement will be from the communities the market serves, which in this case are overwhelmingly Black and Latino.

Since the beginning, FDA has failed to listen to law enforcement's concern with the proposed menthol ban. And recently, the FDA has gone further and announced its intention to ban the entire cigarette category, resulting in complete prohibition of an $80 billion market, which we are turning over to cartels and bad actors -- which would turn over to cartels and bad actors. The FDA has also failed to acknowledge the potential for significant, illegal market activity that will result from such a ban.

The FDA's prohibition-based policies are remarkably like a path we've been down before and that has led to harmful places for communities of color. Given the demonstrated resilience of the demand for mentholated tobacco and nicotine products, and the immense, nationwide market that stands to be erased overnight, at least one outcome seems inevitable. People in communities of color that are marginalized, standing on street corners selling illicit substitutes. There is no reason to think local businesses and officials won't take note and call for action like they currently do.

Enter the police, history has shown us how this often ends. Instead of prohibition and criminalization, FDA should address smoking addiction through a public-health model consisting of policies such as harm reduction, education, cessation support, and youth tobacco [inaudible].

My organization and other law enforcement leaders ask that the FDA conduct meetings and/or focus groups with experienced law enforcement unions and personnel at the local state national levels to understand what enforcing menthol and flavored cigar bans would mean to their day-to-day workload, community relations, goals, and crime-deterrent strategies.

Regrettably, the FDA moved forward to this stage of the rulemaking process without meaningful, strategic engagement with the men and women of law enforcement who will ultimately be responsible for enforcing product bans at the local, state, and federal level. Thank you very much for your time.

Vanessa Burrows:
Thank you for your comment. We will be taking a break now and then going into the final hour of the listening session. So, we ask that the remaining commenters be prepared once we resume. We will regather at 2:50 p.m.

[music playing]

Sarah Lynch:
All right. Thank you. We have commenters left today for our session. Thanks for being a little bit early with us. To start, our first person is Elizabeth Hicks. Please state your organization and whether you are speaking on your behalf or for your organization. And you have four minutes. Please proceed.

Elizabeth Hicks:
Thank you. I'm Elizabeth Hicks, on behalf of the Consumer Choice Center. As a consumer advocacy group that fights for lifestyle freedom, innovative technologies, and smart policy, we appreciate the Food and Drug Administration's open call for public comment to guide the direction in which the Center for Tobacco Products is heading.

I'll be outlining three recommendations that we believe will reduce the number of tobacco-related deaths and illnesses, and ultimately help the agency improve public health within the next five years. The first recommendation is to embrace harm reduction by acknowledging that scientific evidence showing vaping is 95 percent less harmful than smoking. And that flavored vaping products play a key role in getting consumers to stop smoking combustible tobacco.

Rather than continuing down the road of prohibition, the FDA has an opportunity to follow in the footsteps of other global health regulators by embracing and promoting less harmful nicotine alternatives like vaping. Public Health England announced in 2015, that studies showed vaping to be 95 percent less harmful than smoking.

Since then, the U.K. government continues to study the effects that vaping has had on public health and produces their findings annually. The latest report shows that flavored vaping products, specifically fruit and menthol mint flavors, remain the most common aid used by people to help them stop smoking combustible tobacco.

More recently, the U.K. government doubled down on its harm reduction strategy through vaping by encouraging one million smokers to swap their cigarettes for a free vape starter kit. Providing financial incentives to pregnant women to quit smoking, as well as introducing mandatory informative inserts about vaping into packages of cigarettes.

Our second recommendation is to spread awareness of other less harmful nicotine alternatives to combustible tobacco such as nicotine pouches, snus, gums, lozenges, and others. Although vaping is arguably the most popular and effective technology to move consumers away from combustible tobacco, other nicotine alternatives also exist and should be embraced.

We can, again, look to global public health counterparts and follow in their successful footsteps, like Sweden. The World Health Organization recently announced that Sweden will likely become the first smoke-free country. Sweden has embraced the concept of tobacco harm reduction and supports its citizens to switch from cigarettes to less harmful alternatives, including vaping, nicotine pouches and snus.

Consequently, Sweden has reduced its smoking rates two times faster than any other country in the European Union. And smoking rates have declined by 55 percent in the last decade. Additionally, smoking-related deaths are 22 percent lower in Sweden than the EU average. And cancer incidents are 41 percent lower than the rest of Europe, with total deaths from cancer being 38 percent lower.

Nicotine pouches and snus are gaining popularity and provide consumers with additional options and choices to move away from combustible tobacco. While gums and lozenges are less popular among consumers, they still pose a very versatile contribution to ending smoking. It'll be crucial

for CTP to focus its regulatory scope to general product safety while continuing to listen to consumers in regard to the types of products that should be available.

Our third and final recommendation is to streamline the PMTA process to allow more tobacco harm reduction products into the marketplace within a timely manner. Despite vaping manufacturers meeting PMTA requirements to scientifically demonstrate how their products enhance public health, the FDA has failed to approve thousands, if not more, of these products.

Keeping alternative nicotine products out of the marketplace that meet the requirements outlined in the PMTA process, only emboldens the illicit market to fill the void for consumers. This poses serious public health risks as bad actors could sell faulty products that result in negative impacts for individuals. It's also important to note that the illicit market does not perform age verification, making it much easier for youth to acquire these products.

The FDA should instead simplify and streamline the PMTA process to ensure that any product which meets the standards outlined by the CTP receives immediate approval. Additionally, more transparency from the agency regarding approvals, denials, standards, and timelines would be helpful in ensuring that manufacturers can provide the necessary materials within the PMTA so that their products can reach and benefit consumers as quickly as possible. Thank you for the opportunity to comment today. And happy to answer any questions.

Sarah Lynch:
Thank you, Elizabeth. Next up we have John Bowman. John Bowman. Please state your organization or share that you're speaking as an individual. You have four minutes to comment. Please proceed. Excuse me. Please proceed. [laughs] John Bowman. We see that you're on, John. Might want to take yourself off mute.

John Bowman:
Yeah. Can you see me? Hello?

Sarah Lynch:
Yes, we can see you and hear you, sir. Go ahead.

John Bowman:
Great. John Bowman. I'm the executive vice president for U.S. programs at the Campaign for Tobacco-Free Kids. I want to thank CTP for giving us the opportunity to provide our views. My comments are going to focus on three of the goals set out for public comment, regulations, application review, and enforcement.

In each of those areas, the central objective of the strategic plan should be to provide -- to assure that the FDA's statutory authority is used to the fullest extent to protect the public from any threat held -- posed by tobacco products. Perhaps the most impactful power given by the -- given to the FDA by the Tobacco Control Act is the ability to issue rules mandating product standards to make tobacco product less hazard -- less hazardous, less addictive, and less appealing.

But in 14 years, CTP has yet to issue a single final product standard. This needs to change. The strategic plans should include a commitment to finalized rules to prohibit menthol as a

characterizing flavor in cigarettes and prohibit all flavored cigars. And this needs to happen without further delay.

Given the egregious targeting of the Black community by menthol cigarettes and flavored cigars, and the resulting disparate impact of those products on the health of the Black community, finalizing these rules will significantly advance the cause of health equity. That's why major organizations like the 100 Black Men of America, the Alpha Phi Alpha fraternity, the Delta Sigma Theta sorority, and the NAACP support the menthol rule, along with 32 members of the Congressional Black Caucus who'd recently signed a letter to the FDA supporting the rule. They also commit to issuing a proposed rule this year that would reduce nicotine in cigarettes and other combustible products to non-addictive levels.

CTP has estimated that over time, this product standard applied to cigarettes would save lives. FDA Commissioner Califf has pledged to issue a proposed rule. And this committee -- this commitment should be reflected in the strategic plan. As to product application review, the priority must be to mandate thet new -- any new tobacco product must be -- must have the correct FDA marketing authorization order.

Public health groups have alerted CTP for years about the appearance of new cigarettes, cigars, and smokeless tobacco products marketed as new, but without any marketing orders of any kind. That said, clearly FDA's most widespread failure to implement premarket review has occurred with e-cigarettes where millions of flavored e-cigarette products, highly attractive to young people, have been sold without FDA review for years. We are encouraged that CTP is now -- has now denied marketing applications for millions of flavored products and that the courts are upholding these decisions. CTP must commit to finishing the job without any further delay, ensuring that going forward, premarket review is no longer post-market review.

Finally, as to enforcement, the strategic plan must confront the reality that virtually all e-cigarettes on the market are illegal since they lack the required marketing orders. Clearing the market of these illegal products must be a priority, not only of CTP, but the entire administration to include the Department of Justice.

The administration must be prepared to use all available enforcement tools, going beyond simple warning letters, and using injunctions, substantial civil penalties, import restrictions, and others. Thank you for the opportunity to share our views. We stand ready to help CTP develop and implement it's -- the authority that it's been given to protect public health.

Sarah Lynch:
Thank you, sir. Andrew Perraut, or Perraut. Andrew, you are up next. Please state your organization and whether you're speaking as an individual or for your organization. Again, you have four minutes. And please, be ready to proceed. I see you. There we are. Perfect.

Andrew Perraut:
Hi. My name is Andrew Perraut. I'm presenting today on behalf of Cigar Rights of America. CRA is a consumer-based public advocacy group dedicated to protecting the interests of premium cigar manufacturers, retailers, and consumers. CRA is currently the world's largest

coalition of premium cigar manufacturers and consumers, with a membership that spans all 50 states. And represents over 60 diverse artists and producers of handmade premium cigars.

In the wake of the Reagan-Udall Foundation's report on the effectiveness of the Center for Tobacco Products, we commend the agency for undertaking this comprehensive exercise and setting goals and priorities for the coming five years. CRA has two broad suggestions for CTP. First, FDA should prioritize regulatory action against products that pose higher risks to human health or risks of youth appeal.

CRA has long contended that premium cigars are a distinct category of tobacco products. Since the original publication of CTP's Deeming Rule, we have argued, drawing on data from the National Cancer Institute, that there is nearly no detectable underage use of these products. That the evidence shows that the vast majority of smokers use premium products infrequently. And that while the population level health effects of these products remains understudied, the data we do have shown significantly lower morbidity and mortality than for other tobacco -- other products in the combustible tobacco category.

In short, we believe that the available science shows that premium cigars are correctly classified at the lowest level of what CTP has described as the continuum of risk for tobacco products. Since the publication of the 2014 Deeming Rule, scientific evidence has continued to accumulate to support that position.

In March 2022, the National Academies of Science, Engineering, and Medicine, or NASEM, published a comprehensive report on premium cigars, surveying the existing literature and making recommendations for future research. On July 28th of this year, the journal of the Society for Research on Nicotine and Tobacco, SRNT, published an issue devoted solely to issues regarding premium cigars and their regulation.

The data from those articles was largely drawn from NIH's most recent population estimate -- assessment of tobacco and health study and from similar high quality data sources. Both the 2022 NASEM and 2023 SRNT research are consistent with the data that we have previously cited showing no significant underage use, lower probable population health risks.

It's notable that in each wave of addition -- of additional research that appears, the evidence continues to strengthen the case against these products are correctly classified at the lowest end of the continuum of risk. As such, we believe that it's a poor use of CTP resources to impose additional regulations or re-regulation on the small sector of the industry.

We ask that FDA adhere to its own policy statements regarding the continuum of risk, rather than imposing one-size-fits-all regulations across products that bear very little similarity to one another. As such, we ask that FDA refrain from imposing additional regulations against this small, unique subsection of the industry.

Our second recommendation is that FDA should follow the science and adopt a definition for premium cigars for research and regulatory purposes. There appears to be an emerging consensus among the public health community, the industry, and the courts, that establishing premium cigars as a separate category is both scientifically appropriate and would assist FDA in efficiently promulgating and enforcing its regulations.

Notably, both the NASEM report and the SRNT journal advocated for establishing premium cigars as a separate category for research and regulatory purposes. Further, the SRNT discussion indicated that FDA's conflation of those products with other tobacco categories has resulted in the failure to adequately regulate and restrict mass market cigar products that are more likely to be used by vulnerable populations.

We believe that adopting an agency-wide definition would allow CTP to more clearly consider the costs and benefits of its regulation, and to direct its administrative and enforcement efforts towards products that pose the greatest risk to public health. It would also assist FDA and other agencies throughout --

Sarah Lynch:
Thank you, Drew. Next up we have Stanton Glantz or Glantz. Please state your organization or share that you're speaking as an individual. You have four minutes for your comment. Please proceed. Stanton Glantz or Glantz. Thank you, sir. We see you. Proceed.

Stanton Glantz:
My name is Stanton Glantz. I'm a retired UCSF professor of medicine. I served as the principal investigator for the UCSF TCORS until I retired and continued to be involved with the UCSF TCORS.

As part of its strategic plan, CTP should establish a policy of prioritizing direct epidemiological population health measures or measures for both health and behavior over indirect measures, or assumptions. And we've heard many of those assumptions in the presentation today. This would represent a substantial change.

To date, the FDA has prioritized indirect evidence, most notably biomarkers, over a population epidemiology. The rationale had been that new products have not been in widespread use long enough for health effects to be manifest at the population level. This problem certainly does not apply to e-cigarettes which have been on the consumer market for 17 years, since 2006.

There is now a large epidemiological literature on the health effects of e-cigarettes as they are actually used in the general population. It reveals elevated risks for cardiovascular, pulmonary, and oral diseases compared to non-users. Even more important, in contrast to the biomarker studies, human disease epidemiology shows that e-cigarette risks are similar to cigarettes for cardiovascular and oral diseases. And while e-cigarettes are -- risks are lower for pulmonary disease, the cigarettes are much higher than the FDA has assumed, and that you've heard quoted from other speakers.

Dual use of cigarettes and e-cigarettes, something the FDA needs to also pay more attention to, is associated with increased odds of disease for cardiovascular, pulmonary, and oral diseases. Likewise, there is a large literature that contradicts the assumption that e-cigarettes, when used by consumers, will result in switching completely from cigarettes. They do not.

To implement the policy prioritizing direct measures of health and behavioral effects over indirect measures or assumptions, the FDA should make decisions about the risk of e-cigarettes and other established products based on documented effects on disease in the population. Not just short-term measures from a limited number of cigarette biomarkers.

FDA should heed its own meta-analysis and stop assuming that reducing but not stopping smoking substantially reduces risks. FDA should prioritize the effects of dual and poly product use in regulatory decision making and public communication. FDA should complete and publish its own risk assessment of the epidemiology -- epidemiological evidence of disease risk associated with e-cigarette use compared to cigarette use, and dual use compared to cigarette use in the general population.

FDA should complete and publish its own assessment of the relationship between e-cigarette and other tobacco use among youth and young adults, particularly the extent to which e-cigarettes are attracting low risk youth to nicotine. And FDA should stop making regulatory and public communications decisions, assuming that e-cigarettes, as consumer products, help people stop smoking until there is strong population-based evidence that that is correct. By prioritizing direct human evidence, the FDA will make much better --

Sarah Lynch:
Thank you, sir, for your comment. Wayne Harris, you are up next. Please state your organization or share that you're speaking as an individual. You have four minutes for your comment. Please proceed. Wayne Harris. Wayne, we see you. Just need to get off of mute.

Wayne Harris:
Good afternoon and thank you for the opportunity to address you in this -- today for this -- the CTP strategic plan. My name is Wayne Harris. And I'm a retired deputy chief of police with over 30 years of experience. And I'm speaking to you today in opposition to the FDA's plan to prohibit menthol tobacco.

My 30 years of experience, I've seen the consequences of bad policy on our communities. And while I appreciate the FDA's purpose of improving the health of our communities, I caution them on using prohibition. Which we have seen to be a failed strategy here in the United States. It failed with alcohol. It failed with the war on drugs. It has been previously mentioned by some of the other law enforcement speakers, will in fact fail for menthol tobacco currently.

So, unlike some of the other speakers that have gone before me, many of them have talked about the possibilities of illicit markets occurring. I wanted to bring to your attention that in the states that have attempted prohibition such as this, those illicit markets are already established. In fact, in the state of New York, almost 50 percent of the cigarettes that are sold are untaxed. They're illegal, and they are already being sold illegally on the streets.

My fear is that this particular prohibition will further exacerbate that problem. And when we're talking about law enforcement on a national scale -- and please understand I'm coming from this as a law enforcement professional -- as a law enforcement expert. My opinion on smoking -- I'm not a smoker. My opinion is you should ban it all if you're going to ban it all. But my purpose here is to say, let's not create a situation that is going to make the situation worse.

The FDA has often said that this will be up to the health department to enforce. That it will only go after manufacturers and points of sale. What they have failed to understand though, is that illegal markets will create violence, and similar to gang activity everywhere else in the streets, the victimization of our neighborhoods. That's what I'm trying to get them to understand.

So, I'm strongly encouraging the FDA to sit down with law enforcement. Sit down with community leaders that are victimized in their own homes. Sit down with activists that want to see our communities healthier. And work out a common-sense policy that can address the issues that they're seeking to get a handle on.

I also have a concern that race is being used as a determining factor here. I appreciate people wanting to support the Black community and make the Black community healthy. But if, for example, the Supreme Court has said that race can't be used as a determining factor for a college admission, I'm wondering why we're suggesting that a federal agency can use race as a determining factor for a policy that it wants to issue. My recommendation is that we put a pause on this and not continue to move forward for something that is already showing to be a problem here in the United States. This is not a theoretical concern. This is something that's already happening.

The other thing I want to mention is this. The final point, simply prohibit -- prohibiting the manufacturer, will not address the Native American population that produces their own and frequently sells their own cigarettes for anyone that can go onto a reservation. So, while the FDA's purpose is commendable, I don't think it's well thought out. And I think there's more work that needs to be done before any sort of prohibition such as this is implemented.

I represent the Law Enforcement Action Partnership. I also represent the National Organization of Black -- National Organization of Black Law Enforcement Executives. And we stand ready to sit and speak with you and try to work out a common-sense policy. Thank you for an opportunity to speak with you today.

Sarah Lynch:
Thank you, Mr. Harris. Well timed. Up next, we have Ryan Potts. Please state your organization or share that you're speaking as an individual. You have four minutes for your comment. Please proceed. Ryan Potts.

[audio break]

Ryan Potts:
Hello. Good afternoon.

Sarah Lynch:
Good afternoon.

Ryan Potts:
My name is Dr. Ryan Potts. I currently serve as senior vice president in the scientific and regulatory affairs group at REI Services company, a subsidiary of Reynolds American. And thank you for the opportunity to provide public comments on CTP's five-year strategic plan.

Reynolds believe the agency should, one, allow for efficient navigation of the application review process. Number two, develop a strategy that encourages innovation. And three, promotes a well-regulated marketplace that discourages bad actors. So, firstly, to allow for efficient navigation of the application review process, CTP should prioritize development of approaches to eliminate the current submission backlog at the agency.

Now, while the agency has made some progress, it continues to face a significant backlog of applications. Indeed, presently, there remain tens of thousands of PMTAs, SEs, and exemption requests in the queue. Based on the center's current rate of action and a continued influx of applications, this backlog will take years to clear and will continue to impede the instruction of new non-combusted products that will likely produce lower health risks than combustible cigarettes.

There are over 13 million adult vapor consumers in the U.S., millions of whom are former smokers. Since 2016, FDA have -- has authorized simply too few products to meet adult consumer demand. And this failure has undermined FDA's authority and directly fueled the exploding illicit market of flavored disposable products.

Approaches to expedite elimination of the backlog could include far greater reliance on commercialization history and decrease cigarette smoking instance data, as well as FDA's powerful post-authorization tools to closely monitor and regulate marketed, provisional, and deemed products to mitigate any risks of adverse impact, including underage use.

Second, the agency should adopt a strategy that encourages innovation. CTP should establish an expedited notification pathway for safety and quality enhancements for products that have received an MGO. Such an approach will allow for continued product innovation and improvements beneficial to safety instead of having innovation lag years behind.

Similarly, the agency should consider setting forth clear guidance that allows for certain minor changes to the design of a product without a premarket notification. Clearer governance would allow companies to maintain continuity of their supply chain, and at the same time reduce the burden on the agency. Innovations, including those designed to prevent youth access, for instance, are being developed by several manufacturers globally. But the current PMTA process continues to delay availability of safety and quality enhancements available elsewhere.

Submissions containing advances in technology such as improvements in battery management or incorporation of youth-access-prevention technology, should have a similar accelerated notification pathway and should not be subject to a long-drawn-out submission process.

Third, the agency should promote a well-regulated marketplace that discourages bad actors. [inaudible] cigarette, there has never been as many alternatives to the combustible cigarette that may present less risk. And smoking in the U.S. is at an all-time-low for adults and youth.

A reduction in both smoking rates and prevalence of irresponsible market participants has been driven by a strong regulated system. Unfortunately, since 2020, the vapor category has been shifting rapidly to products made by companies ignoring virtually every rule the FDA has established. FDA must hold bad actors accountable and take direct action against them immediately. This should be an enforcement priority. Failure to do so undermines FDA authority and public confidence in the agency.

Finally, FDA should publish a complete list of products with properly pending PMTA applications under review since September 9, 2020. And so, Reynolds is committed to work -- working with the agency. And again [inaudible].

Sandra Lynch:
Thank you, sir. And for our final speaker today, Alex Clark. Please state your organization or share that you are speaking as an individual. You have up to four minutes to comment. Please proceed. Alex Clark. Good afternoon.

Alex Clark:
Good afternoon. Can you hear me?

Sandra Lynch:
Yes.

Alex Clark:
Excellent. My name is Alex Clark. I'm the CEO of the Consumer Advocates for Smoke-Free Alternatives Association. I'm here on behalf of our all-volunteer board of directors and our more than 270,000 members from all walks of life. We are consumers who have successfully switched away from, or significantly reduced our consumption of combustible tobacco by using vapor or some other low-risk, smoke-free alternative to cigarettes.

I'd like to start by acknowledging that this listening session is a step in the right direction with regard to increasing stakeholder engagement. And we urge CTP to make this an annual event, at least. Perhaps quarterly listening sessions would elicit more and higher quality feedback on a regular basis.

I'll focus our comments on goals three and four. And we'd also like to associate ourselves with several of the previous comments, particularly those calling for expedited authorizations for a variety of smoke-free vapor and oral nicotine products, including products and flavors other than tobacco, the availability of which is associated with the recent accelerated declines in smoking prevalence.

As to goal three, most of the conversation and the description of this strategic goal focuses on increasing enforcement capabilities. But it should be clear by now that as FDA tightens its grip on the nicotine market, the vacuum caused by enforcement actions creates opportunities for informal sellers.

Moreover, it is well established that FDA cannot possibly police the entire industry. Therefore, relying on states and municipalities to conform regulations to the federal standard and choose their own enforcement strategy. In more than two thirds of the country, purchase, use, or possession of nicotine products by youth is criminalized, which leads to other questions of public health.

Much of the U.S. is still living the fantasy that a drug-war-style approach to tobacco enforcement will have net positive outcomes. In order to avoid the known negative outcomes of strict unflinching enforcement, a robust and honest education and deprogramming campaign must be developed. That includes useful information about modified risk products and encouragement for people who smoke to try multiple strategies, including the use of low-risk alternatives to cigarettes.

As to goal four, we want to acknowledge the $2.5 million funding opportunity to research messages about modified risk products. I think it's fair to say that this commitment is better late than never, to figure out how to tell the truth about the risk continuum among nicotine products. We feel that -- we believe that this research must examine what's needed to undo misperceptions of risks associated with nicotine.

And we're curious how youth uptake of nicotine products is weighted when assessing outcomes of these messages. And think it's vital to note that zero tolerance and Total abstinence, are not realistic or even ideal outcomes. While the transparency promised by CTP is vital to repairing confidence in the center, so too is acknowledgement that doctor, patient, and consumer beliefs about the risks associated with nicotine are heavily influenced by misleading campaigns designed with the singular purpose of scaring kids away from tobacco and/or frightening adults to quit smoking.

In order for any corrective, adult-focused communications about nicotine, specifically modified risk products, to be effective, prior misinformation and strategies to correct it must be identified, examined, and deployed. It is simply not enough to rely on third party groups to disseminate accurate information about safer alternatives to smoking. FDA must take a leadership role in ensuring that consumers and healthcare providers are accurately informed about all strategies and products that can improve the health of people who smoke. Thank you for the opportunity to speak.

Sarah Lynch:
Thank you.

Brian King:
Hello, all. I am Brian King. I'm the director of the Center for Tobacco Products. And that concludes our session for today. It is a wrap. Thank you all for participating. And we appreciate everyone who took the time to share their input with us, but also those who were just listening in. We did accommodate every request to speak today, so I know it was a long haul. And I appreciate everyone for sticking with us. It looked like we retained slightly over 50 percent that we started with. But glad that many of us stuck around for the entire day.

As a reminder for those who would like to share your written feedback, the docket is open to submit written comments through next week, specifically August 29th. And after the comment period closes, FDA will review each comment, along with all those shared today. And we're going to take that input into consideration as we continue to develop the new strategic plan, which we are on track to do by the end of this year. In the interim, we're going to continue to share routine updates with you all and to communicate our progress on the strategic plan.

I also want to remind folks about other upcoming opportunities for the public to engage with CTP, including a public meeting and interactive discussion on the premarket tobacco product application review process that's slated for this fall. The save the date went out last week for October 23rd and 24th.

And so, some information on question submission and logistics is forthcoming. But please mark your calendars in the interim for this meeting. It's going to be in-person at FDA's White Oak

campus, but we will have a virtual option. I know there were a lot of comments today on that process. And we appreciate the opportunity for you all to share a little bit more granularity as well during that session.

And before closing, I also want to give a profound shout out to all our stellar moderators, translators, behind-the-scenes folks, who work so tirelessly to make today a reality. A lot of work goes into these sessions, whether they're in person or virtual. And we simply could not have done it without you all. So, nicely done. With that, thank you all again. And I hope you have a good rest of your day. Bye.

[end of transcript]