Requirements for Tobacco Product Manufacturing Practice (Proposed Rule)
Part 15 Hearing Transcript

April 12, 2023, 9:30am – 12:30pm EDT

Necola Staples:

Good morning. Welcome to today's public oral hearing for FDA's new proposed requirements for tobacco product manufacturing practice. I am Necola Staples with the Office of Health, Communication, and Education at FDA Center for Tobacco Products, or CTP. I am one of several moderators who will serve as hosts for today's meeting.

The purpose of today's hearing is for the FDA to hear presentations from our stakeholders about the agency's proposed rule requirements for tobacco product manufacturing practice. We're pleased to have a variety of stakeholders on today's call to provide information and views on the proposed rule. We want to hear from as many stakeholders as possible. So, we encourage all those who are interested to provide written comments to the docket of the proposed rule. The docket will remain open until September 6, 2023.

As a reminder, the links and information to submit written comments are listed on the screen and are available on multiple pages on our website. FDA considers the comments we receive in the docket, including the oral comments provided today. This hearing is being recorded and the transcript will be available to the proposed rule docket as well as to CTP's website.

In just a moment, I will turn it over to the hearing's presiding officer, CTP Director Dr. Brian King, for introductory remarks. We'll also hear from Matthew Brenner, senior regulatory counsel with CTP's Office of Regulations. Matthew will provide a high-level overview of the proposed rule we're discussing today. Then Rear Admiral Emil E. Wang, senior regulatory counsel, senior advisor for manufacturing regulatory policy, will speak on behalf of CTP's Office of Compliance and Enforcement. Emil will briefly outline the proposed rules' effective and compliance dates.

Our priority for today is to hear from the public, so we will keep our introductions and overview brief. After that, our moderators will invite our confirmed speakers to provide their prepared comments. Finally, today's hearing will be closed captioned and an ASL interpreter is on the call. With that, it is my pleasure to introduce CTP Director Dr. Brian King.

Brian King:

Great. Thanks, Necola, and good morning and welcome everyone. I really appreciate you joining us virtually today. As Necola noted, I'm Brian King, the director of the Center for Tobacco Products and I am the presiding officer for today's hearing. I want to thank you all for being here today to comment on FDA's new proposed requirements for tobacco product manufacturers, which relate to the manufacture, design, packing, and also storage of their products.

I do want to reinforce that although no tobacco product is safe, this proposed rule is intended to minimize or prevent additional risks associated with these products. Once finalized, it would

establish requirements for tobacco product manufacturers that we believe will help protect public health and also help assure products comply with the Federal Food, Drug, and Cosmetic Act. For example, the requirements we're proposing would help minimize or prevent the manufacture and distribution of tobacco products contaminated with foreign substances, things like metal and glass and plastic, which we have found in tobacco products in the past. The proposed rule would also establish several requirements related to the identification, tracing, and also corrective actions for tobacco products that don't meet specifications or are contaminated, including for tobacco products that have already been distributed.

In the event of an issue, the requirements would require manufacturers to take corrective actions which, for example, could include conducting a recall. Additionally, the proposed rule would help address issues related to inconsistencies between e-liquid product labeling and the actual concentrations in e-liquids. We do know that such variability can be misleading to consumers, which can potentially intensify addiction and also the exposure to toxins.

Now, today, you'll hear more about the specifics of the proposed rule shortly. But I do want to note that our proposed rule is comprehensive and it does encompass all aspects of the tobacco product manufacturing process. Throughout the rulemaking process, we do remain committed to transparency and also stakeholder engagement. As many of you are already aware, FDA Center for Tobacco Products did recently undergo an external review by an independent panel of experts convened by colleagues in the Reagan-Udall Foundation.

As I've noted several times publicly, we welcome this opportunity and we issued our response to that report earlier this year, including our vow to address all 15 of those recommendations that were outlined in the foundation's report. One key recommendation from that report was an opportunity for enhanced transparency with stakeholders. That said, public meetings and oral hearings just like today's are a really meaningful way for CTP to follow through on that commitment and also to enhance transparency and engage stakeholders and activities across our center and our portfolio of work.

As such, we do encourage those who are interested to participate in the rulemaking process. When the public submits a comment, they can make an important difference in the decision making. And we do read every single one of those comments and it provides critical insight into the effects of the regulation on the public and the suggestions can, and they do, influence the agency's actions.

I do want to reinforce, too, that anyone can submit comments concerning new rules and regulations being considered by FDA and it's not just organizations. And while individuals and groups have already begun providing written comments to the docket, we're thrilled to host this public hearing as an additional way for stakeholders to provide their comments on the proposed new requirements for tobacco product manufacturing practices.

As I'll note, FDA has had a long-standing commitment to the development of this proposed foundational rule. In fact, we have been collecting information to inform this proposal since 2011. So, over a decade ago, I'm including our experiences conducting inspections of tobacco product manufacturers. So, needless to say, the proposal is incredibly comprehensive. It encompasses all aspects of the tobacco product manufacturing process.

And so, with that, I do want to reiterate my sincere appreciation, everyone, for taking the time to join us today. We've got a good lineup and I look forward to hearing what you have to say about our proposal. So, with that, I'll now introduce my colleague, Matthew Brenner, from our Office of Regulations, who's going to provide a little more detail about the proposed rules. So, with that, take it away, Matthew.

Matthew Brenner:

Thank you, Brian. And good morning, everybody. As Dr. King stated, the proposed rule is intended to assure public health is protected and that the tobacco products comply with the Federal Food, Drug, and Cosmetic Act. The proposed rule covers all aspects of tobacco product manufacturing -- from design to manufacturing to packing to distribution. The rule's intended to provide a framework that would require manufacturers to establish and maintain procedures for manufacturing, designing, packing, and storing their products.

So, specifically, the proposed rule would establish tobacco product design and development controls. It would ensure that finished and bulk tobacco products are manufactured according to established specifications. It would minimize the manufacture and distribution of tobacco products that don't meet specifications. It would require manufacturers to take appropriate measures to prevent contamination of tobacco products. It would require investigation and identification of products that don't meet specifications in order to enable manufacturers to institute appropriate corrective actions such as a recall. It would also establish ability to trace all components or parts, ingredients, additives, and materials as well as each batch of finished or bulk tobacco product in order to aid in investigations of those that don't meet specifications.

This rule would allow flexibility for manufacturers to establish procedures that are unique to their facilities and activities and appropriate for a given tobacco product. The proposed new requirements would apply to manufacturers of finished and bulk tobacco products. And as outlined in the proposed rule, a finished tobacco product is a tobacco product including any component or part sealed in final packaging. For example, a pack of cigarettes or canned snuff would meet that definition. A bulk tobacco product is a tobacco product that is not sealed in final packaging but is otherwise suitable for consumer use. The proposed regulation at this time does not include manufacturers of other components or parts that are not offered for sale, sold, or otherwise distributed to consumers. That is, components or parts sold for further manufacture such as filtered material or cigarette tipping paper.

Now, I'll hand it over to my colleague, Emil Wang, with CTP's Office of Compliance and Enforcement, to share more about the proposed effective and compliance dates for the proposed rule. Thank you all.

Emil Wang:

Thank you, Matt. I am going to cover the proposed effective and compliance dates and the comment period for this proposed rule. FDA is proposing that the rule become effective two years after the final rule's publication date in the *Federal Register*. After this two-year period following publication, tobacco product manufacturers other than small tobacco product manufacturers will be expected to comply with the requirements.

However, FDA is proposing a different compliance date for small tobacco product manufacturers. Small tobacco product manufacturers are manufacturers with 350 or fewer employees. For purposes of determining the number of employees, it includes employees of all entities under the control of a manufacturer. Small tobacco product manufacturers would have an additional four years to comply after the effective date of the final rule consistent with the requirements under the statute. This proposed compliant -- compliance date would give small tobacco product manufacturers a total of six years to comply with the final rule. FDA believes that this extended compliance deadline for small tobacco product manufacturers will help make sure that manufacturers have adequate time to comply.

Additionally, I'll note that FDA inspections have demonstrated that a number of manufacturers already have implemented many measures similar to the proposed rule's requirements. We welcome feedback on all aspects of the proposed rule, including the effective and compliance dates. Starting March 10, the proposed rule opened for public comment and it will remain open for 180 days or until September 6, 2023. All those who are interested can submit electronic or written comments directly to the docket on the proposed rule at www.regulations.gov. FDA will review all comments timely submitted to the docket in the process of finalizing this foundational rule. The comment process is an essential part of any rule we develop and hearing from our stakeholders gives us a chance to make the proposed rule stronger.

Thank you for taking the time to participate today. Before we begin hearing comments, I'll pass it back to Necola for some final notes about today's hearing.

Necola Staples:

Thanks, Emil. And to all of our speakers today, thank you. Before we open up the call to speakers, I'll introduce our subject matter panelists who will be joining today's meeting to listen to comments and to clarify comments that are inconsistent with their proposed rules contents. Only our panelists will be allowed to clarify presenter's comments and they will do so if needed once the presenter is done speaking.

You've already met and heard from two of our panelists, Matthew Brenner and Emil Wang, but please join me in welcoming our other panelists. Dr. Dale Slavin, director of the Science Policy Branch within CTP's Office of Science; Dr. Matthew Walters, the deputy division director of the Division of Product Science within CTP's Office of Science; Diana Kaneva, associate chief counsel at the Office of Chief Counsel within the Office of the Commissioner; Dylan Leishchow, an economist with CTP's Office of Regulations. And finally, Cristina McLaughlin, an economist within the Office of the Commissioner, Office of Economic Analysis.

We're ready to begin the next portion of our agenda and welcome you, our confirmed speakers, to their comments on FDA's requirements for tobacco products manufacturing practice proposed rule. Before I call the first speaker, please remember, each speaker has up to five minutes to talk. To assist commenters with timekeeping, we will notify you at the one-minute remaining mark. To be fair and equitable to all speakers, your remarks continue past the time limit if they -- continue past there will need to move on to the next speaker so your line will be muted. Please make sure your comments are only about FDA's new proposed requirements for tobacco product manufacturing. At the start of your comment, please clearly state your name and the

organization you represent or note that you're speaking in your individual capacity. Let's get started. Once your name or telephone number is called, you will be unmuted so that you can make your comments.

Up first, we'll hear from James O'Reilly. You're first to comment. Please unmute your microphone. James O'Reilly?

James O'Reilly:

Good morning and thank you for taking my comment. I'm going to boil it down to meet the five-minute requirement. I was very proud when the U.S. Supreme Court in its first tobacco case voted me as the experts have written. I'm pleased that the court and the FDA since 1974 have been referring to my treatise, my encyclopedia, on FDA. My first point is well done. We did an excellent job of comprehensively capturing what needed to be done.

Second point, we need to consider where to get the additional resources. I'm agreeing with the comments in the 2023 HHS budget, page 25, which call for $100 million to be spent on the staffing of your organization. Yes, you need more people, you need more outreach, and I hope you'll encourage the people at the Winchester FDA Lab and the Cincinnati National Toxicology Lab to work with you getting the details right.

Thirdly, I encourage you to have a high-level meeting with four players, Office of Compliance in the Environmental Protection Agency's Office of Pesticide Program. They know what happens when a chemical is allowed in another nation and then you ship to the U.S. I encourage you to work with the EPA and with the U.S. EPA's foreign agriculture process as well as with the people in FDA were very familiar with imports as well as the CBP, the Customs and Border Protection. Easy to say, go do it. It's hard to get it done, but you will find that the people receiving contaminated chemical residues on tobacco will benefit if those are prevented from entering the U.S. Please consider ways in which these agencies gather and brought the import of those contaminated tobacco products. Next, I encourage you to get the staffing at the ports of entry to actually look at the incoming material. Also, consider how the best placement of FDA's field staff from the Associate Commissioner of Regulatory Affairs, then augment your work in keeping out of the U.S. tobacco that's contaminated with materials that are not approved or not allowed here.

And my last point will be on the explosion and fire risk for some of the badly made DMDS products. Please consider ways in which you can force makers of those products, this CAPA, C-A-P-A, then you get approvals needed for the technology that's going into those battery-powered electronic computers. Winchester laboratory has excellent experience with battery powered medical devices. I encourage you to talk to those people inside FDA and say, "What can we do to remove the risk of exploding or burning materials from these electronic cigarettes?" If we can do that, we might be able to aspire to a 2026 or 2025, even, level of clearance that products will not explode [unintelligible].

So, I encourage you to get the people, get the staff, to coordinate with other agencies, look at the import risks, and then look at the battery explosion and fire problems. Make sure you've done all that you can to make manufacturers accountable. We're making a lot of money in these

products, no doubt. No offense, but they need to spend some of that money on improving the pesticides they use growing materials elsewhere for inclusion U.S. and they've got to do a much better job of the materials that are being used here in batteries and electronic materials. As vice mayor of a city in Ohio, I saw a lot of our teenagers using these products and I would encourage you to think about their lungs, their risk factors, as you value what you're going to hear all the speakers.

Necola Staples:

Thank you. Up next, Drew Newman. You have up to five minutes to speak. Please proceed. Please proceed, Drew.

Drew Newman:

Good morning. My name is Drew Newman and I'm coming to you today from our 113-year-old El Reloj cigar factory in the Cigar City of Tampa, Florida. This isn't a virtual background. Behind me, we are handcrafting cigars, just like my great grandfather did when he founded our company in 1895. I want to thank CTP for holding today's public hearing and allowing small family businesses like ours to testify. I've read through the 300 pages in the *Federal Register* and in my brief time today, I want to highlight four things. One, flexibility is essential. Two, it's a ton of records. Three, qualifying suppliers is difficult. Four, batch reports are hard.

First, throughout the proposed rule, CTP writes that the proposed requirements are written in general terms, that the agency is taking an umbrella approach to allow manufacturers to tailor them to their own businesses. This is essential. We're a 127-year-old cigar company. The way we handcraft cigars is so different from how cigarettes or ends products are made. A one-size-fits-all policy would crush our industry and the small businesses like ours that make up the majority of the premium cigar industry. So, please keep flexibility in the final rule.

Second, it's a ton of records. The proposal would require us to keep detailed records on everything we do from training to cleaning to pest control, water, product testing, sampling, purchases, even the clothes that our staffs wears. It's a lot of records, a lot of work. It's going to be a lot of costs for small businesses and we are going to have to hire new staff to manage all this.

Third, I'm very nervous about qualifying suppliers. We buy our tobacco like we always have from a collection of family farmers around the world. For example, our Connecticut broadleaf tobacco is grown by an eighth-generation family farmer just outside of Hartford. Maintaining all the detailed records for our own activities will be very hard. Doing the same and being responsible for the activities of our tobacco farmers, many of whom don't speak English and live in Latin America, will be much worse.

Fourth, the proposal would require us to roll cigars in batches, keep detailed batch records, and put batch codes on every package. No one in the previous cigar industry does this. Now, it'd be a big challenge to do so and here's one reason why. When we roll cigars, we know who rolls them and when they're rolled. This is Louis and Jenny, who are rolling cigars right here, and these are cigars that they rolled yesterday in a wheel. When they roll cigars, they fill out a card.

It tells us who rolled it, when they rolled them, and it's in -- the card stays with them when these cigars go down into our aging room.

From our production floor, they go down to our aging room where they age of at least six to 12 months, and they come back up here to be packed into beautiful boxes. But for 100 years, cigars have been color sorted. When they come back up from the aging room, you'll see behind me, cigars are mixed. They're mixed with different rollers and mixed with different dates because it's the goal of the cigar maker that every box of cigars when you open it up to be the same shade of brown. Batch reports are going to be very hard.

As I'm running out of time, I'll put the rest of our concerns in our written comments, but I want to share some final few thoughts. My family has been rolling cigars the same way for 100 years. The process hasn't changed. Our one goal is to roll cigars the same way 100 years from now that we do today that we did 100 years ago. We'll fill out whatever paperwork and keep whatever records are necessary, just please give us the flexibility to continue rolling cigars like we've been doing since 1895.

If you'd like to learn more about premium cigars, please visit us here in Tampa. Just like wineries and breweries and distilleries, we've opened our doors to the public and offer guided tours, cigar rolling classes, and much more as we work to keep the centuries old tradition of American cigar making alive.

And lastly, cigars are just like wine, they are natural agricultural products. Tobacco varies greatly depending upon the seed type and the soil where it's grown and the amount of sunlight, wind, and rain causes cigar tobacco to vary from year to year and that natural variation we harness to create unique and interesting cigars. It's an art. It's not a science. There's no textbook or rulebook. Instead, it's been a tradition that has been passed down from generation to generation. Thank you so much for this opportunity.

Necola Staples:

Thank you. Up next, Huiyu Shi. You have up to five minutes for your comment. Please proceed.

Huiyu Shi:

Hello?

Necola Staples:

Good morning. We can hear you.

Huiyu Shi:

Hello. Yeah. Good morning. Thanks for giving me the chance to show my comment here. So, my name is Huiyu Shi. I'm from Shenzhen Consource Technology Service located in Shenzhen, China, a consulting company which helps industry understand and comply to any regulation in the U.S.

So, regarding the TPMP jobs rule, I have one comment on Section 1120.34: Buildings, Facilities, and Grounds. See section Water on page 272. So, this paragraph stated that the water used in the manufacturing process is supplied from sources like complying with all applicable federal, state, and local requirements. My comment here is, does it have to specifically follow U.S. requirements?

As we know, the TPMP applies to all tobacco manufacturers who wants to market their products in the United States, which includes manufacturers outside of the U.S. For example, in Shenzhen, China, which is the center of manufacturing ends product, if it is required for manufacturers in Shenzhen to comply with U.S. drinking water regulations, there will be a significant workload burden. For example, like a significant need of developing new testing items, which will lead to the procurement of specific equipment, consumables, reagents, and establishing view and an article matters.

And after comparing the Chinese drinking water regulations to U.S. National Primary Drinking Water Regulations, we noticed the two countries' regulations are very similar besides certain unique items. For example, pesticides residue level. For common items, the acceptable criteria in China are mostly similar to U.S. Some are more strict in China, while some are more strict in U.S. For example, the acceptance level of chlorides in the U.S. under the EPA regulation is 1.0, and in China, this number is 0.7.

Another one is the beta/photon emitters on the Cryptosporidium have different values of MCL or TT due to different presence of acceptance criteria. And another example is chlorobenzene. The acceptable level in U.S. is -- I'm sorry, it is 0.1 under the EPA regulation. While in China it is 0.3. However, the Shenzhen City also has a regulation of chlorobenzene in drinking water, which is the same as the EPA regulation, 0.1.

Just to make it clear, the Shenzhen City has implemented higher drinking water standards based on different regulations worldwide like U.S., Europe, Japan, WHO, and other countries or institutions when compared to the U.S. standards. Thus, when you suggest to modify the Section 1120.34 see water to allow manufacturers outside of the U.S. complying with their country's drinking water standards. Unless their country's drinking water standards are significantly lower than the U.S. standards, then they should apply -- compliant with the U.S. standards. Thank you so much.

Necola Staples:

Thank you. Up next, Dr. Jeffrey Wigand. You have up to five minutes to comment. Please proceed. Dr. Jeffrey Wigand? Up next, Lynn Yuan. You have up to five minutes to comment. Please proceed. Lynn Yuan. Lynn Yuan? Up next, Laura Searcy. You have up to five minutes to comment. Laura Searcy? Laura, you're free to come off mute.

Laura Searcy:

Good morning. Can you hear me?

Necola Staples:

Yes, we sure can.

Laura Searcy:

Fine. This is Laura Searcy and I am representing the National Association of Pediatric Nurse Practitioners. And I'm speaking today on behalf of more than 8,000 pediatric nurse practitioners and pediatric focus advanced practice nurses who are committed to providing optimal healthcare to children. I want to thank you for the opportunity to speak today and add our perspective as pediatric experts and advocates for children to this conversation. We very much appreciate the importance of this rule and commend the FDA for taking these additional steps to prevent product problems and protect the public from health risks from exposure to foreign substances, contaminants, and unintentional injuries due to product design flaws and lack of manufacturer's controls. Of particular importance of the provisions of this rule that address the current variability in nicotine concentrations within product lines, especially when nicotine concentrations exceed what is stated on the level -- on the label.

As the FDA has recognized, all tobacco products have inherent risks to public health. As the FDA considers the range of comments that you will receive, I ask you to keep top of mind the unique spectrum of risks to children in youth in the variety of flavored high nicotine content products still readily accessible by youth. Proposed Section 1120.42 would require manufacturers to conduct a risk assessment, including risk identification of all known or reasonably foreseeable risks associated with the tobacco product and its package, including normally associated risks with the use of the product.

I would ask the FDA and the industry to consider how provisions of this rule can be implemented and enforced to mitigate the already well documented inherent risk of use to these products in the pediatric population when you finalize this regulation. Nicotine in concentrations currently available are toxic, especially to young children who often mistake flavored oral nicotine products for candy or regular gum.

Since 2020, there's been a marked increase in poison control calls for nicotine containing products. I would ask that if strengthened requirements for childproof packaging products, especially where e-liquids and oral product -- oral tobacco products are concerned if it's feasible to consider strengthening those regulations in context of this regulation, would you please consider doing so?

Also, I would ask if there is an opportunity, again, in the context of FDA authority within the scope of this regulation to improve labeling in the area of warnings on labels of nicotine products in particular your gums and oral products that currently the label of FDA approved therapeutic nicotine gum states, and I quote, "Keep out of reach of children and pets. Pieces of nicotine gum may have enough nicotine to make children and pets sick. Wrap pieces of gum that are used in paper and throw away in the trash. In case of overdose, get medical help or contact a poison control center right away."

Currently, the only label on commercial nicotine gums that are in -- available in strengths that are up to three times the strength of therapeutic gum is that, I quote, "This product contains nicotine and nicotine is an addictive chemical." I also want to state a concern about the length of

time between when the rule is approved and when companies are expected to comply. Two years to six years for small tobacco manufacturers, if I can put that in context, a child who's entering sixth grade would now be in college before provisions of this rule would protect them.

And just a final statement, just to put in context, currently, we have over 3 million U.S. youth reporting using commercial tobacco products with flavored e-cigarettes being the favorite product. I have in my possession a high capacity, high nicotine content, disposable e-cigarette that, that single device contains in excess of two cartons worth of nicotine. And I would just ask the FDA in the context of this regulation with other areas within your authority to please try to get these unauthorized products off the market and protect our kids from the increasing levels of nicotine. Thank you very much.

Necola Staples:

Thank you. Up next, Barry Schaevitz. Feel free to come off mute. All right. Up next, Ibraitul Arif. Ibraitul Arif. Feel free to comment, you have up to five minutes to speak. Okay. We will be taking a 10-minute break here. We will come back right back at 10:30 a.m. Again, 10-minute break -- well, more like 20 minutes break, sorry, until 10:30 a.m. We have other commenters that are scheduled to begin at 10:30 a.m. So, we'll see you back here at 10:30 a.m.

Kendric Dartis:

Hello. I'm Dr. Kendric Dartis with Office of Health Communication and Education and we're going to continue on in today's hearing. Up next, we have Dr. Jeffrey Wigand. Dr. Jeffrey Wigand? We have Lynn Yuan. Lynn Yuan? Up next, we have Barry Schaevitz. Barry Schaevitz? Up next, we have Ibraitul Arif. Ibraitul Arif? Shanna James? Shanna James? Amber Cooper? Amber Cooper? We have Gaby Kafie.

Gaby Kafie:

Good morning, everyone. Good morning. My name is Dr. Gaby Kafie. I am here on behalf of the Boutique Cigar Association. It's a pleasure to be here with you all. I'm impressed that there's over 250 people on this call. It's an honor to represent the premium cigar industry, specifically small, handmade, premium cigars.

Let me start off by giving you a little backstory on who I am and why I am speaking with you today. I'll keep it short and sweet. I know I only have five minutes. I'm a retired physician. Our family came to this country in 1978. Their dream was to see their children prosper and flourish in ways that they could not in their respective countries. We're originally from Honduras. Both my brother and I studied medicine, we became doctors, and we dedicated our lives to doing what we love, which is helping others.

So, how do we connect premium cigars to helping others? That's a very long road but allow me to tell you that my career was cut short because I suffered from a disease which affects the retinas. So, I lost central vision in my left eye and my career was cut short and I had to -- at the age of 40—I'm 51 now —at the age of 40, I had to rediscover myself, my passions, my loves. And one of the things being from a country like Honduras, tobacco is -- in terms of premium cigars, it's a part of our culture. It's a part of our heritage. It's a part of our family. I recall my

grandfather, my uncles, all partaking in the celebration of enjoying a premium cigar on occasion. Premium cigars to me were something therapeutic. It was something non-addictive and that is the exact reason why I'm here today.

So, in 2016, once the FDA proposed the deeming regulations on premium cigars, I really saw this as a real problem for me. Here I am really believing that premium cigars are not harmful to adult men and women. However, the FDA is telling us that they are. So, in undergrad, I studied biology, that was my major. I also tutored chemistry and organic chemistry. Those were my two specialties in undergrad. In medical school, I studied sports medicine. I became a foot, ankle, and knee surgeon. My first year out, I worked for the Miami Heat as one of their sports medicine physicians. I've dedicated my life to science and understanding how the human body works and what harms the human body and what doesn't.

So, what happens is the more I got to understand the human body, the more I became obsessed with preservation of life. So, I ended up doing a fellowship in San Antonio, Texas, which focused on lower extremity amputation prevention. And what I discovered was that there were many things that affected the human body in the circulatory system. Premium cigars never came up in the conversation.

Now, due to the limited nature of this five-minute talk, I, along with the Boutique Cigar Association, have taken the liberty to prepare over 60 pages of documentation to support why premium cigars are not the problem. And they should not -- premium cigars should not only not be regulated like all other combustible or noncombustible tobacco products. Premium cigars should be exempt from FDA regulation.

The letter that I will be submitting will discuss nicotine, will discuss addiction. It will discuss the 58 member companies that are part of the Boutique Cigar Association. It will discuss the effects that these regulations will have on these family-owned businesses. We will dive into every aspect that was brought up in your *Federal Register*, which was published last month, titled, "The Requirements for Tobacco Product Manufacturing Practices." So, there's a lot of information here. I'm sitting here with piles and piles of paper. There's not enough time to go through it, but I am at your service. Anything you need from me, please do not hesitate to contact me. It would be a pleasure to represent all 58 members.

Kendric Dartis:

Thank you. Up next is Delorse Orlando. You have five minutes to comment. Please proceed. Delorse Orlando? Jason Hodge? You have up to five minutes to comment. Please proceed. Jason Hodge?

Jason Hodge:

Hello. Can you hear me?

Kendric Dartis:

Yes, we can.

Jason Hodge:

Thank you for the invitation. My name is Jason Hodge. I'm a private e-cigarette user. I was a combustible tobacco product user for 25 years. Somewhere near 2010, I discovered nicotine vaping. I was a dual user of combustible tobacco and vapor products until six months ago when I completely stopped smoking combustible tobacco. I have been 100 percent smoke-free since that time.

I've been an Oklahoma state board licensed funeral director and embalmer for 23 years. During my career, I've helped thousands of families deal with the death of a loved one. Statistics now show that Oklahoma has the highest prevalence of combustible tobacco use per capita in the United States. The general public does not have to imagine that tobacco use contributes to a very high number of deaths in Oklahoma and moreover, U.S. and the world. Anecdotally, I've never seen a death attributed to nicotine vaping in my whole career. Tobacco, on the other hand, it has its own statistical section on a death certificate. A simple yes or no box as to whether tobacco contributed to the death. I see it every day. Nicotine vaping has no such box on the death certificate because it hasn't caused a death. Despite governmental overreach and artificially, technically, deeming nicotine vapes or e-cigarettes as tobacco products, nicotine vaping is not tobacco.

Though I am thankful for today's public hearing, the FDA appears to be doing everything it can to limit input from industry and consumers alike. This can be made more fair by encouraging the FDA representative of the general public to interact with informed adult nicotine vapors. You need to understand why these products are so important for adult smoking cessation. Reasonable evidence-based standard manufacturing regulations and consumer protections are things that users of vapes have been seeking since the early days of nicotine vaping. Yes, we all want safe products. Regulating vaping products like medical products as evidenced by some of these proposed manufacturing practices is not reasonable.

The nicotine vapor industry has been self-regulating since its inception. And so far, the industry has succeeded in moving millions of people away from combustible tobacco more than any government agency or billionaire philanthropist. Proof of less harm and efficacy are evidenced by the FDA’s authorization of 23 adult nicotine vaping products so far. Though, I want to express some concern that 100 percent of those products are made by big tobacco, most are basically model T antiques, few are used by adult vapors, and the only products authorized are tobacco flavored which most adults don't want. I'm not sure how authorizing products that none will use to quit smoking is appropriate for the protection of public health.

Today, we're discussing rules and regulations that are pure window dressing, as has been exposed by outlets like Filter magazine, trade organizations like the American Vapor Manufacturers, the U.S. appeals courts, and now the U.S. House oversight chair investigation. The FDA has continually bowed to politics and ignored the science so much so that only companies that will be impacted by this rule are brands owned by tobacco and pharmaceutical companies. The manufactured moral panic promulgated by confusing public messaging by the FDA, wittingly or otherwise, thrusts citizens back to combustible tobacco product use.

By action and inaction in public messaging, the FDA has exaggerated unfounded fears of nicotine vaping device safety. This brings into question the FDA's true urgencies to reduce combustible tobacco use. What it's really doing is denying safer tobacco harm reduction options to 31 million American consumers. Many people would agree that the Tobacco Product Scientific Advisory Committee should have been consulted before the CTP set out on its mission to rewrite its rules at the 11th hour in an attempt to ban 99.99 percent of vaping products that Americans -- American adults actually use.

In my view, all of this was done for the apparent benefit of a golden parachute in a pharmaceutical company advisory board seats for, among others, the former director of the FDA's Center for Tobacco Products. I would also like to express concern that in its 10 plus years of existence that Tobacco Products Scientific Advisory Committee, representative of the general public position, has never been held by an informed ex-smoker who uses safer --

Kendric Dartis:

Thank you. Up next is Joshua Habursky. Joshua Habursky? You have five minutes, please proceed.

Joshua Habursky:

Thank you. My name is Joshua Habursky and I'm the deputy executive director for the Premium Cigar Association. PCA is a trade association that represents over 3,000 brick-and-mortar retailers and 250 premium cigar manufacturers.

Today, I'm here to speak against the proposed rule. Because a Federal Court has held that the FDA acted arbitrarily and capriciously in deeming premium cigars subject to Chapter 9 of the Federal Food, Drug, and Cosmetic Act, it is the PCA's position that the FDA lacks jurisdiction to apply this rule to premium cigars. The PCA urges the agency to make it clear that the proposed rule should not, cannot, and will not reach premium cigars. This proposed rule seeks to find a problem where one does not exist. Where is the empirical evidence, consumer complaints, or documented harm relating to non-conforming premium cigars and pipe tobacco, which is the state of justification for this rule?

FDA must provide such data on each tobacco product category in order to make serious and meaningful rulemaking. What we know from the timing of this rule is that most of the background research was done at a time before FDA even deemed premium cigars or pipe tobacco to be FDA regulated tobacco products. Since then, the agency has shown limited interest in understanding the nuances of distinct tobacco product categories, even failing to acknowledge the recommendations made by the National Academies of Science on its commission study health effects and usage patterns of premium cigars.

Therefore, it should come as no surprise that this proposed rule has several fundamental flaws in it that demonstrates FDA's lack of understanding of the process and conditions under which premium cigars and pipe tobacco are manufacturing. This rule will place major environmental burdens on rural regions in South America, Africa, and Southeast Asia. It will strain local infrastructure where it exists and it will drain critical resources from the developing economies from where the artisanal products originate.

Furthermore, there has not been sufficient environmental impact analysis on the major construction work and transportation of materials to manufacturing facilities, which are predominantly in rural regions that compliance with this proposed rule would require. For example, it would be very difficult to put in an industrial HVAC system into a 30-person premium cigar factory in rural Honduras. Even if the unit was available, the transportation, installation, and energy consumptions and maintenance will have significant environmental costs when multiplied across the industry.

I would also like to highlight that this proposed rule would impose significant financial and administrative burdens disproportionately on small, family-owned premium cigar manufacturers. Many of the requirements modeled after pharmaceutical medical device and food regulations are not appropriate for tobacco products. Others simply will not work for premium cigars or pipe tobacco, specifically, because these are artisanal agricultural products produced in lesser developed countries that do not have the resources or existing infrastructure to comply with the proposed rule.

It is clear that the FDA has not consulted with coordinate agencies that manage U.S. trade and foreign policy interest in the countries where tobacco is a major economic resource. Implementation would ultimately have unintended consequences in these countries such as rural unemployment, irregular immigration, and black-market activity. The FDA needs to perform a rigorous domestic and international economic impact study and explain enforcement processes and procedures with greater detail. The FDA is not equipped to handle this far-reaching rule. [inaudible] priorities have more important public policy to address.

Finally, implementing and maintaining lab-like procedures and conditions will require major capital investments and ongoing maintenance costs while being entirely unnecessary for products that have been manufactured in the same manner for hundreds of years. This would undoubtedly cause undue stress on small businesses, which are already struggling to main operations costs. The proposed rule is impractical given the state of infrastructure where these products are produced and the FDA's enforcement resources.

Earlier this month, Dr. Califf told the House Energy and Commerce Committee that the FDA needs to educate before it regulates. As it relates to this proposed rule, the FDA needs to educate itself a lot more before imposing a regulatory scheme with no value to the American public at high economic environmental costs. PCA looks forward to submitting a written, detailed comment.

Kendric Dartis:

Thank you. Up next, we have Taylor Melecio. Taylor Melecio? Up next, we have Meredith Berkman. Meredith Berkman?

Meredith Berkman:

Hi, I just want to make sure you can hear me?

Kendric Dartis:

Yes, ma'am. Five minutes for your comments. Please proceed.

Meredith Berkman:

Okay. Thank you so much. My name is Meredith Berkman. I am a co-founder of Parents Against Vaping E-cigarettes. I'm really appreciative of the opportunity to address you this morning and our organization is supportive of this very detailed and extensive rule. And we appreciate all of the hard work and thought that clearly has gone into drafting it. There are a few issues that I want to reiterate in broad strokes that we think are of particular importance and that we hope will be a focus on this rule as it is implemented.

The first is that we hope that in publicizing the rule when it is ultimately released and put into place that there is -- it is very clear and certainly in any public statements or comments or marketing by products that would be complying that compliance does not ensure safety. Meaning that there is no safe tobacco product. And as a national organization dedicated to educating parents about the dangers of youth tobacco use in fighting the predatory behavior of the tobacco industry towards kids, we, again, we want to reiterate and as we all know that absolutely no tobacco product is safe and certainly not for children. And we appreciate that this rule does address among many safety and security issues those that relate to protecting children.

And again, I think Laura Searcy on behalf of the pediatric nurses mentioned this as well, that childproof packaging is particularly vital with regards to ends products. And according to the National Poison Data System, we know that there has been an increase in recent years of incidents in which children had been harmed by exposure to e-cigarettes and e-liquids with just, in 2023 alone since the end of March, there have been almost 2,000 cases of exposure to these poisons.

And another thing is, we do have concerns about the viability of enforcement and we would just stress the importance for enforcement, particularly given the flood of e-cigarette products that are rushing into this country from outside through the borders, through the ports, particularly from China. Many of these products and the ones to which I refer are used in enormous numbers by kids, particularly disposable products coming from China that, you know, many of these products may have applied for PMTAs through FDA. We don't know because that list hasn't been made public, but many of them may just be among the many bad actors that we continue to see out there.

And so, we also would suggest that this law be put into effect immediately or as immediately as is possible under regulation because, as we know, in the youth vaping epidemic that products that are long periods of time without full regulation or implementation is particularly dangerous and damaging and can lead to youth initiation.

So, again, I want to be thankful for the opportunity and I am supportive of the regulation with the caveats that we hope you will focus on enforcement and not allowing any tobacco company to present its compliance as a way of saying that it is safe. No tobacco product is safe and certainly, no tobacco product would ever be safe for children. Thank you so much.

Kendric Dartis:

Thank you. Up next, we have Ray Edwan? Ray Edwan? Up next, we have Maham Akbar? Maham Akbar? You have five minutes to comment. Please proceed.

Maham Akbar:

Hello, good morning. Stacey Gagosian was unable to join today, so I will be speaking on her behalf. My name is Maham Akbar, and I'm a public policy director at Truth Initiative. Truth Initiative supports FDA's proposal of new requirements for tobacco product manufacturers regarding the manufacturer, design, packing, and storage of their tobacco products.

Tobacco use is still the leading cause of preventable death and disease in the country and leads to 540,000 deaths in the U.S. each year. The proposed rule will help to reduce unnecessary adverse health effects and minimize unintended contaminants of an inherently hazardous product class. It is important to establish such standards. However, even when these standards are met, these remain hazardous products and these standards do not render the product safer.

These proposed manufacturing practices are the bare minimum for what manufacturers should have to follow. Additionally, by following these manufacturing practices, manufacturers should in no way be able to imply or advertise that their tobacco products are quality products or safe products. Tobacco manufacturers must simply manufacture products to this minimum standard in order to do business. In no way should they be able to imply in packaging, labeling, or advertising, that by following these practices, their products are safe or safer, of higher quality, or in any way mislead consumers.

This must not become an advertising point for manufacturers of addictive products that so often lead to death and disease. Labeling must accurately reflect the nicotine content of tobacco products. For example, studies have found mislabeling to be a common issue for e-cigarettes, and labeling is not always a reliable indicator of nicotine content. FDA must also ensure that e-cigarette battery and device quality are sufficient to prevent explosions and overheating. Moreover, e-cigarettes and e-liquid in particular should come only in child-resistant packaging to prevent young people from ingesting these products, which causes sickness and, in some cases, can be fatal.

Finally, FDA must enforce these proposed manufacturing practices. FDA must inspect the factories in which tobacco products are made, often to check that manufacturers are following the plans in place. FDA has to ensure that the manufacturers of these inherently harmful products are held accountable when they do not follow these minimum standards laid out in the proposed rule.

Tobacco products made in factories that are not following the rules or are being made in subpar standards must be recalled. And FDA has to act quickly when it comes to recalled products. Tobacco products already cause much death and disease. It is even more important for FDA to remove products from the market, whose manufacturing has caused it to create even more unnecessary harm and risk. Again, Truth Initiative supports FDA's proposal of these tobacco product manufacturing practices and looks forward to submitting written comments to the docket.

Kendric Dartis:

Thank you. We're going to take a 32-minute break and resume back at 11:30 a.m. And we'll come back on at that time to pursue -- continue on in the Part 15 hearing. Thank you.

Tracy Galloway:

Good morning and welcome back. My name is Tracy Galloway, and I will serve as your moderator for this session of the call. Just as a reminder, each speaker has up to five minutes to speak. To assist commenters with timekeeping, we'll notify you at the one-minute remaining mark. If your remarks continue past the time limit, we'll need to move on to the next speaker so your line will be muted.

With that, we will start with Connor Fuchs. You are next to comment. You have five minutes to speak. Please unmute your mic.

Connor Fuchs:

Good morning. And thank you for the opportunity to speak today. My name is Connor Fuchs from the Campaign for Tobacco-Free Kids. And before turning to the specifics of the proposed rule, I want to begin by recognizing the proposal's importance, but also some of its limitations.

As FDA recognizes in the proposed rule, tobacco product manufacturing requirements have the potential to help mitigate the risk of health issues that are not normally associated with the use of a tobacco product. That includes, for example, requirements aimed at preventing the manufacture and distribution of adulterated tobacco products; products contaminated with foreign substances, such as metal, glass, dirt, and hair, all of which FDA says have been found in finished tobacco products.

However, it's also necessary to recognize the limits of the proposed rule. Compliance with these manufacturing practices will certainly not make a tobacco product safe, nor will it mean that the product benefits the public health in any way. As FDA and all of us know, these manufacturing practice requirements, once finalized, will not address the many serious and grave health issues that are normally associated with the use of a tobacco product, such as the fact that smoking causes 90 percent of all lung cancer deaths, 80 percent of all deaths from COPD, and leads to stroke and coronary heart diseases.

All tobacco products present inherent risk to the public health. And no tobacco product, even if manufactured in full compliance with this proposed rule, is safe for the individual. Nor will compliance with this rule establish that a tobacco product is beneficial to the public health in any way. Therefore, we caution FDA to be careful about how it describes the impact of this rule. The agency must avoid any implication that products manufactured in compliance with the rule are thereby safe or benefit the public health.

Turning now to some of the specifics, FDA proposes to require all tobacco products to have a unique identifier code that would help establish traceability for all that product's components, parts, ingredients, and additives, in which would aid in investigations related to complaints in nonconforming products. We remind FDA that section 920(B) of the Federal Food, Drug, and

Cosmetic Act creates a statutory obligation for the agency to implement a track and trace system to help prevent and enforce the law against the illegal market in tobacco products. As detailed in a 2013 Citizen Petition submitted by various public health officials and organizations urging FDA to adopt such a track and trace system, this system would help FDA to identify contraband products, including those not in compliance with tobacco product standards, and would also help establish at what point in distribution chain illegal tobacco products are unlawfully diverted into the legal market.

If, as the proposed manufacturing rule provides, FDA will require products to have these unique identifier codes, the agency should consider designing and implementing the codes in a manner that could also accommodate a track and trace system that gives the government meaningful and ready access to information needed to detect and investigate illegal diversion of tobacco products. Next, I want to touch on the implementation period. Under the proposed rule, manufacturers would not have to comply with the rule for the first two years after it's finalized. And small manufacturers would receive four additional years for a total of six years to comply with the rule.

Proposing two full years until the final rule becomes effective is too long. At the very most, FDA should give most manufacturers one year from when the rule is finalized to comply and five years for small manufacturers. That would reasonably align with the one-year default implementation period the Tobacco Control Act establishes for product standards. And indeed, compliance with the proposed manufacturing requirements should be less burdensome than compliance with the tobacco product standard, particularly because, as FDA notes, inspections have demonstrated that a number of manufacturers have already implemented many of the proposed measures here.

Moreover, many of the requirement's FDA proposes here are based on industry recommendations. Thus, manufacturers should not need two and, in some cases, six years to comply. Finally, enforcement will be critical to ensure that the public benefits from the standard set out in the proposed rule. In certain vitally important ways, FDA has failed to vigorously enforce the Tobacco Control Act. And that lack of enforcement has undermined the public health benefits of the statute and of FDA's tobacco regulations. For example, a plethora of products including youth-appealing flavored e-cigarettes remain readily available at stores across the country, even though they lacked the premarket authorization orders that are required by the Tobacco Control Act.

FDA must avoid making the same mistakes here and must actively enforce these manufacturing practice requirements from day one. And with that, I will conclude my remarks. Thank you again for the opportunity to speak.

Tracy Galloway:

Thank you. Up next, we have Patrick Murphy. Patrick Murphy? Up next, we'll hear from Mark Anton. Mark Anton?

Mark Anton:

Good morning. I would like to thank the FDA for the opportunity to speak on the proposed requirements for tobacco product manufacturing practice. My name is Mark Anton. My name is Mark Anton. I'm the CEO of What a Smoke, a small vape manufacturer.

I would like to address some of the points in the proposed regulations. While we agree it is important to provide consumers with consistent products that they can trust in quality and intended function, the proposed regulations of the -- as the FDA has stated, are an umbrella approach which allows for both a wide range of manufacturing processes, but also broadens the scope that the FDA can impose on the manufacturer. One of the concerns is that if the paperwork is deficient, the products, irrespective of their actual manufacturing, can be considered by the FDA as adulterated and subject to enforcement for a clerical error.

The intent may be to provide products that are appropriate for the protection of public health. Will the FDA provide the manufacturer an opportunity at corrective action? Will the FDA give recommendations for remediation, or will it immediately enforce? Redundancy adds to cost as well. Many of these regulations are already required in the PMTA filings that were due back in September of 2020. And if authorization is granted, many of these regulations are currently in post-market surveillance protocols as well.

The following statement whether software may be a component or part, the FDA states the manufacturer's subjective claims of intent are not controlling. Rather, FDA considers all relevant evidence, including direct or circumstantial objective evidence. In this fact, I believe intent is a critical factor, not reasonably expected to affect as the FDA states. If a manufacturer developed and designed technology that contains any tobacco and has other intents for its technology, the FDA can infer it to be a tobacco product, even if its intent is not so. How does the FDA plan to address this as the TCA expressly says, "Derived or for the consumption of tobacco products"?

The FDA is responsible for determining if something is appropriate for the protection of public health. The standard given by Congress puts the responsibility squarely within the agency. The agency is currently using the standard in which to determine whether a product may be authorized for sale to the public in the PMTA applications. Yet it looks as though the FDA may be inadvertently shifting this responsibility onto manufacturers. This is stated when assessing risks, proposed 1120.42(a)(1)(i) would require each finished and bulk tobacco product manufacturer to identify all known or reasonably foreseeable risks associated with the tobacco product.

This, in and of itself, is not an issue. However, further in the description, it says that a company would in determining the significance of the risk means evaluating whether the risk and its magnitude are acceptable, tolerable, or unacceptable. In determining the significance of the risk, manufacturers should develop criteria against which the risk and its magnitude can be evaluated. This implies the company is the determinant whether something is appropriate for the protection of public health, not the FDA. While these proposed regulations are vast, they leave companies individual latitude in how they approach the process of manufacturing. They also present a significant hurdle to smaller businesses, as the FDA is requiring additional staff to be employed to facilitate the FDA’s oversight of the products.

These regulations are significant and provide a disproportional burden on small businesses as the FDA notes in its own comments. I thank you for hearing me. I will also provide written comments at a future date. Thank you.

Tracy Galloway:

Thank you. Up next, we'll hear from Patrick Murphy. You have up to five minutes for your comment. Please proceed.

Patrick Murphy:

Good morning. And thank you for the opportunity to discuss FDA's proposed tobacco product manufacturing practice requirements. My name is Patrick Murphy. And I currently serve as the vice president, Scientific and Regulatory Affairs at RAI Services Company, a subsidiary of Reynolds American. We share FDA's interest to minimize or prevent certain risks associated with tobacco products beyond those inherent with their use. Indeed, various industry stakeholders, including Reynolds, submitted proposed TPMP regulations in 2013, and then amended the proposal in 2017 to cover newly deemed products.

To begin a dialogue with FDA on the development of TPMPs that meet FDA statutory requirements and are appropriate for tobacco products, we acknowledge and appreciate the agency's review and incorporation of various provisions of the industry's proposals. However, as we continue to review FDA's proposed TPMPs, Reynolds believes that certain changes are necessary to provide regulations that are appropriate for the manufacture of tobacco products, and that also provide clarity to the industry. First, and importantly, any TPMPs must provide the flexibility to manufacture, label, pack, and store tobacco products to account for different categories of tobacco products, different manufacturing processes, and the inherent variability of tobacco, while assuring all such activities are conducted in a controlled manner.

As such, we believe that it's important for FDA to reconsider their proposed design and development controls included in the proposed rule. We recognized FDA's statutory requirements include pre-production design validation. However, we believe there is more flexible and appropriate way to provide for the pre-production design requirements that continue to allow a manufacturer to ensure that development and manufacturing activities are conducted in a controlled manner. FDA should provide the specifications in the master manufacturing record, beginning when the regulation takes effect should be based upon the fine tobacco product development and manufacturing scale up processes.

The regulation should then provide that the controls, as developed by the manufacturer, that are utilized in the tobacco product development and manufacturing scale up processes, are appropriate to ensure tobacco product specifications are met. In addition, and importantly, TPMPs must allow for certain changes to be made to the product design that did not require a premarket submission to FDA, similar to FDA's regulation of medical devices. To ensure manufacturers are appropriately evaluating changes to product design, FDA should provide guidance to the industry, like its deciding when to submit a 510(K) for a change to an existing device, and FDA can review such determinations during inspections.

FDA should also consider certain changes to the design validation and verification requirements included in the proposed rule. For example, the agency should provide more clarity around validation and verification in the context of tobacco product manufacturing. Indeed, there is little difference in definitions of validation and verification. Further, in the *Federal Register* notice, there are no less than three definitions of validation, and the definitions are not harmonized.

Moreover, the proposed regulation appears to suggest that FDA expects validation activities for tobacco products to be similar to medical devices. While this may be appropriate for ENDS products, we do not believe that it is appropriate for other tobacco products like cigarettes. And FDA should provide clarity in what it considers to be adequate evidence that a process has been validated, specifically as FDA reviews such process validation in its premarket reviews.

Lastly, we have identified some areas that would be helpful for the agency to provide additional clarity, such as the transition periods of the proposed rule, the definition of a small manufacturer with respect to an overarching global entity, compliance of foreign manufacturers including contract manufacturers, given that FDA has yet to promulgate regulations requiring foreign tobacco product manufacturers to register with the agency, the requirements for specification developers including if specifications are developed at a global level, and lastly, FDA's interpretation of "trace" amounts of nicotine. Reynolds is committed to working with the agency to establish appropriate TPMP regulations for tobacco product manufacturers. And we look forward to submitting additional comments to the docket. Again, thank you for the opportunity to comment.

Tracy Galloway:

Thank you. Up next, we have Michelle Page. You have up to five minutes for your comment. Please proceed.

Michelle Page:

Hello. My name is Michelle Page. And I am a tobacco research chemist at Roswell Park Comprehensive Cancer Center in Buffalo, New York. I'm speaking today on my behalf. My work examines the chemical characteristics of various tobacco products, including combustible cigarettes and cigars, ENDS, heated tobacco and oral nicotine products. My work includes identifying the stability of various chemical constituents in tobacco products when exposed to different storage conditions over time.

Through this work, I've identified certain conditions which lead to decreased stability of chemical ingredients such as nicotine and commonly added flavoring chemicals, for example, vanillin and menthol. Specifically, my studies have found that nicotine-containing refill solutions for ENDS products that are exposed to light and ambient temperatures lead to substantial degradation of nicotine content. I also found that nicotine in ENDS refill solutions was more stable when those products remained in the dark and were stored in colder temperatures such as 4 degrees Celsius.

I've also completed a two-year study evaluating the stability of 20 flavoring chemicals used in ENDS liquids. I found that 85 percent of these flavoring chemicals were not stable over the two

years where their concentrations decreased by at least half of their initial content. Importantly, even during a relatively short time, over half of these flavoring chemicals degraded in just three months when products were exposed to ambient light and temperatures. However, when I kept ENDS liquids at ambient temperatures, but prevented exposure to ambient light, I was able to significantly reduce the degradation rates of those chemicals. The degradation rates are even more reduced when products were placed in a refrigerator with temperatures of 4 degrees Celsius.

Correspondingly, a decrease in nicotine in flavoring chemicals among ENDS liquids stored at ambient temperatures and exposed to ambient light was associated with the formation of byproducts from chemical reactions such as oxidation. For example, the oxidation of benzaldehyde, which is a common fruit flavoring use in cherry-flavored products, leads to the formation of benzoic acid. This is concerning as benzoic acid is a known precursor to benzene formation. These findings build upon previous scientific work that establishes the instability of flavoring chemicals, including the formation of hemiacetals. Prior work has suggested that those hemiacetals are more harmful than their parent aldehydes.

My comments today are to emphasize the importance of establishing product standards for ENDS liquids that would include requirements for their proper packaging and storage. This would ensure limited deterioration of these tobacco products. And such changes, as highlighted throughout the proposed rule, could render the product nonconforming and could potentially expose users to more significant harm. Much is unknown regarding the instability of flavoring chemicals across tobacco products, and in ENDS liquids particularly.

I believe consideration should be made in the finalized rule for storage and packaging during and after the manufacturing of products. Additionally, expiration date requirements should be included, which are to be informed by scientific stability studies performed under storage and packaging conditions that are reasonably expected by manufacturers, retailers, and users. Such dates should be based on acceptable thresholds to which known chemical constituents remain stable, and thus would help improve protection of public health. Thank you.

Tracy Galloway:

Thank you. Up next is Samy Hamdouche. You have up to five minutes for your comment. Please proceed.

Samy Hamdouche:

My name is Samy Hamdouche. I'm the co-founder and chief operating officer at Lucy Goods, a small tobacco product manufacturer engaged in the production and sale of oral nicotine products. Our customers are adult tobacco consumers who use our products to switch from combustible or smokeless tobacco. We support sensible regulation of tobacco and nicotine products and believe that such regulation should be flexible to the realities of operating a small business.

Lucy is fully committed to making quality products that are appropriate for the protection of public health. The establishment of TPMP is an important step for our industry. We appreciate the opportunity to comment. Upon review of the proposed TPMPs, we agree in principle with

many of the required controls, particularly those concerning master manufacturing records, production process control, and direct assurances that product fits the needs of our customers.

And while we appreciate that the proposed TPMPs include a longer compliance period for small entities, our concern is that the regulations themselves, once in effect, will be extremely onerous for those other than large tobacco companies. As an example, the proposed rule states that, "If a tobacco product manufacturer establishes and maintains documents and records in an electronic format, they are subject to the requirements of 21 CFR Part 11, including use of secure, computer-generated, time-stamped audit trails." This is a significant burden for Lucy and its toll manufacturers on which we rely to produce and package finished goods. It will require additional labor and a restructuring of the software architecture at each of these third parties, several of whom are themselves small businesses, and may result in their refusal to continue making our products.

Furthermore, it would have little to no benefit on production quality or risk to the consumer. FDA estimates the one-time cost for small entities to establish and maintain procedures is 0.1 percent of annual revenue, but this value is acknowledged as lacking in data. Even a single new hire at mean wage scale would be closer to 10x this estimate. We believe it would be helpful for the agency to set up a process in the coming years to provide support specifically for small business compliance and address how we can remain in business in light of such higher costs.

FDA is also soliciting comments on whether the scope of this regulation should be expanded to reach more than finished and bulk tobacco products, including potentially components or parts. Increasing the scope in this way would cripple our ability to source materials. We can set acceptance criteria for raw materials and packaging, and require food contact certifications, but are in no position to impose TPMPs on these partner entities for whom we are a small share of their overall business. Such a requirement would have little to no benefit on production quality or risk to the consumer, nor would it be consistent with the umbrella approach described in the proposed rule and may cause us to lose our ability to source raw materials.

A more flexible approach would be to allow manufacturers to set predetermined acceptance criteria, including a combination of grade standards and C of A and set AQL limits and confidence intervals ourselves while charting our compliance to ensure validation of the process. Small tobacco product manufacturers are critical to addressing the challenge of moving adult smokers down the continuum of risk. Historically, innovation in risk-reduced products hasn't come from big tobacco companies. And yet regulations, such as these proposed TPMPs, tend to advantage big tobacco companies that can subsidize the high cost of compliance with their immensely profitable sales of combustible tobacco.

By overburdening small companies like Lucy, whose business depends exclusively on the sale of the small but growing category of harm-reduced oral nicotine products, future innovation in the category will stall, if not regress. We feel that how Congress wrote the TCA has given FDA wide latitude in effecting regulations that are flexible to the realities of operating a small-scale business. However, given how FDA has chosen to implement the law, such small businesses are destined to become casualties in favor of companies that derive a majority of their sales from deadly cigarettes. We urge FDA to reconsider their approach and look forward to working with

FDA while continuing to provide our customers with oral alternatives to combustible tobacco. Thank you.

Tracy Galloway:

Thank you. Up next is Ron Tully. Ron Tully? Ron Tully, you have five minutes to provide your comment. Please proceed.

Ron Tully:

Oh, just check that you can hear me. Can you kindly confirm that you hear me?

Tracy Galloway:

Yes.

Ron Tully:

Okay. Thank you.

Tracy Galloway:

Yes, we can hear you.

Ron Tully:

My name is Ron Tully. I run a small consulting independent advisory service called TNV Ventures that provides advisory services to small tobacco product manufacturers, many of which make small volume on brand and private label toll manufacturing products for other small and mid-sized tobacco product manufacturers. There are numerous challenges presented with the manufacturer obligation proposed by the FDA rule, especially among the smaller tobacco product companies.

Firstly, some general observations, all obligations in requirements apply to all manufacturers equally, irrespective of their size and scale and irrespective of the complexity, quality, quantity of the product types produced by that manufacturer. Although consideration is given in the proposed rule for an extended implementation timeline for small companies, the extent of the control and reporting burdens for small manufacturers who produce large numbers of SKUs for multiple clients will surely overwhelm these industry players. For example, for every individual product produced from their facilities, small companies will need to develop complete product design and protocols for that product, ingredient and components, traceability, batch control procedures, as well as testing capabilities that are comprehensive enough to accommodate the many different types of tobacco products manufactured at that facility.

This is an extensive reshaping of functions for companies that are already under resourced, have few, if any, scientific capabilities, and who worked on marginal manufacturer profits across many hundreds of product SKUs. FDA suggests in its introduction to the proposed rule, and I quote, "Tobacco product manufacturers who have a complex manufacturing process would likely

need to establish more detailed procedures to comply with the rule, while tobacco product manufacturers who have a less complex manufacturing process may need less extensive procedures." While the above statement may well be true on its face, it does not reflect the levels of complexity and hidden costs and operating burdens that small industry players who manufacture multiple product types will endure through to lead up to the final implementation date.

Small companies foresee substantial new financial investments and buildings, processing equipment certification, IT systems, internal controls, training process validation, inline testing, inventory tracking, and the external lab testing that will ultimately drain opportunities for meaningful profitability and ability to compete against big tobacco. This will diminish choice for adult consumers and simply help consolidate the position and product offerings of larger industry players. FDA needs to prioritize and abridge the product manufacturing obligations that are set up by focusing on the essential product safety and stability requirements the agency has already identified from the following.

Firstly, only the critical learnings or processes from tobacco product manufacturer and importer facility inspections the agency has already undertaken. Secondly, from consumer self-reporting hazard complaints that have been directly notified to the agency and that have resulted in product defects. Thirdly, from experience the agency has had with the few manufacturer product recalls that have taken place over the last 14 years. And fourthly, from the millions of data points and testing data, ingredients, and components information that has been provided in substantial equivalence, or PMTA submissions over the last decade and a half.

While this rulemaking the agency is proposing is comprehensive to an extent that manufacturers -- sorry, with this ruling -- rulemaking, the agency is proposing a comprehensive set of manufacturing and regulatory requirements that cannot be justified on the basis of any immediate public health threat beyond the obvious and inherent dangers of regular tobacco use. FDA has provided no pressing rationale for the imposition of such sweeping product manufacturing and supply chain controls and across the manufacturers irrespective of their scale and capabilities to meet such requirements. It is proposed to FDA delay the rulemaking indefinitely or alternatively narrow the scope of the rulemaking to only those non-identifiable product process control requirements that present the most immediate product manufacturing hazards known to currently impact consumers. I appreciate your time. Thank you very much.

Tracy Galloway:

Thank you. Up next, we have Pamela Ling. You have five minutes to provide your comment. Please proceed.

Pamela Ling:

Can you hear me, Tracy?

Tracy Galloway:

Yes. Thank you.

Pamela Ling:

Thanks. Thank you for inviting me to speak today. I'm Dr. Pamela Ling, professor of medicine at the University of California, San Francisco, and director of our Center for Tobacco Control Research and Education. I'm the principal investigator of the UCSF Tobacco Center of Regulatory Science or TCORS, which focuses on integrated health, biological, behavioral, and economic research to inform tobacco product regulation. I have over 20 years of experience in tobacco research, particularly tobacco marketing and use behavior and interventions, with special interest in youth, young adults, and priority populations.

I've been an expert reviewer and adviser contributing to several Surgeon General reports on tobacco, CDC Office on Smoking and Health, and NIH scientific review committees. The UCSF TCORS has submitted a written public comment that generally supports the proposed tobacco product manufacturing requirements, because they will help protect public health. This written comment includes citations to the published literature, which support the recommendations that I will briefly discuss.

In general, the UCSF TCORS supports FDA's proposed requirements, because they will help minimize some of the risks inherent in tobacco products, ensure that products are made in conformance with established specifications and standards, and minimize the likelihood that nonconforming products will be distributed. Because of our UCSF TCORS particular interest and expertise in protecting the health of priority populations and youth, I would like to focus on two of the recommendations that are detailed in the written comment.

First, we strongly support the proposed section 1120.90, which requires manufacturers to establish and maintain procedures to control packaging and labeling to ensure they comply with FDA regulations, as well as with the manufacturers' established specifications. This is especially important to ensure that nicotine concentration labels on e-liquids and e-cigarettes accurately describe nicotine concentration levels that are contained in those products. There is considerable evidence that actual nicotine concentrations in e-liquids frequently vary considerably from the label concentrations.

Also, many studies show that young e-cigarette users are often unaware of the strength of nicotine in e-cigarettes, and many don't even realize that their e-liquids contain nicotine. Young people also have difficulty understanding often what is meant by nicotine concentrations on labeling described in milligrams per milliliter or percent nicotine. Inaccurate and ineffective labeling leads to misunderstanding, confusion, and possibly disregard of nicotine in e-cigarette products. This, in turn, may lead to inadvertent exposure to high nicotine levels, which may increase the likelihood of continued nicotine use and nicotine addiction. For these reasons, we strongly support FDA's proposed requirements to help ensure that e-liquids and e-cigarette labels accurately reflect the nicotine concentrations contained in the products.

To complement accurate labeling, education that's tailored to youth and priority populations to support proper interpretation of the labels is also important. Secondly, the UCSF TCORS also urges FDA to strengthen section 1120.102. This section requires manufacturers to establish procedures that ensure tobacco products are handled and stored under appropriate conditions. We recommend this section be strengthened to require manufacturers to set explicit

specifications addressing shelf life to clearly state the expiration date on product labels, and to require expired products to be removed from store shelves. This is important because, like other tobacco products, e-cigarettes have finite shelf life. They can become contaminated with bacteria and fungus that grow while the e-cigarettes sit on the shelf and become more toxic over time.

To protect public health, consumers should be warned not to consume products after a certain date, and the labels on the product should clearly state the expiration date. Outdated and deteriorated products must be removed from store shelves. Clear and accurate labels on tobacco products and public education to enhance awareness and accurate interpretation of labeling are important to achieve equity in tobacco use and to protect public health. Thank you for considering the UCSF TCORS' recommendations. And I'm happy to answer any questions.

Tracy Galloway:

Thank you. Up next, we'll hear from Pamela Granger. Pamela Granger? You have up to five minutes for your comment.

Pamela Granger:

Good morning.

Tracy Galloway:

Please proceed.

Pamela Granger:

I'm Pamela Granger. I'm a volunteer anti-tobacco coordinator for two coalitions in Northern California. It won't be a surprise, knowing where I am in the North Bay Area, that in California, actually, we're working towards the end game. The end game for us would mean ending the sale of all tobacco products by 2035. That being said, recognizing that not the -- that we're fortunate where science and political will have overlapped to allow us to pass preventive measures on the sale of tobacco products trying to reduce youth uptake.

One of our concerns along the way has been that with over 450 manufacturers, there's no consistency in manufacturing quality or labeling amongst ENDS products in particular. It looks like this will be, at the effort of the FDA, will go towards remedying at least part of that problem. I concur, on behalf of our two coalitions, that there is ignorance on the part of not just youth, but adult users of ENDS product as to what percentages of nicotine means to them. It is kind of humorous to us that we are talking about anything that would help assure public health are protected, when we look at making sure that there aren't contaminants. It's sort of like whether you jump off a 30-story building or a 20-story building in terms of what will help public health.

We also have concern about leaking nicotine during use and disposal since contact can be hazardous. It would be very helpful to have prominent disposal directions on packaging of ENDS products since they're considered a toxic hazardous waste. The risk is not normally associated with tobacco products. We could use a little bit of help on -- again on making sure --

it would be great if we could get the graphic warning labels that we've been working out for combustible products in particular.

So, while we're happy that the FDA is taking efforts to provide a consistency in ENDS products, we would be happier if the FDA helped us in reduce the use, and eventually end, manufacturing. Thank you so very much for your time.

Tracy Galloway:

Thank you. We are now able to accommodate additional commenters and will now provide all audience members and organizations that have not commented an opportunity to comment. If you would like to comment, please put your name and organization in the chat and we will proceed. Again, if you would like to comment on today's session, please feel free to put your name and organization in the chat, and you will be called according to your linage.

Jason Hodge, you are next to comment. Please unmute your phone. You will have five minutes to speak.

Jason Hodge:

All right. I'm back here. Just wanted to finish earlier. I didn't -- I got cut off earlier. I just wanted to express concern, in the last 10-plus years of existence, the Tobacco Products Scientific Advisory Committee representative of the general public position has never been held by an informed ex-smoker who uses safer nicotine alternatives that actually supports tobacco harm reduction. It would not be acceptable for any government HIV/AIDS policy committee to exclude persons living with HIV or AIDS. So, it should not be acceptable for you to exclude us vaping advocates either.

Please -- before finalization of these regulations, please consider actually visiting with an actual ENDS user, like myself, to get our thoughts about how well these products actually work. Thank you.

Tracy Galloway:

Thank you. As a reminder, if you have already provided a comment, we are unable to open your mic again. So, again, this is for all persons who have not provided a comment previously. If you're interested in providing a comment, please provide the -- your name and the organization in the chat, and we will proceed.

Delorse Orlando, you are up next to comment. You will have five minutes to provide your comment. Please unmute your mic. Delorse Orlando?

Delorse Orlando:

Can you hear?

Tracy Galloway:

Yes.

Delorse Orlando:

Yes.

Tracy Galloway:

We can.

Delorse Orlando:

Can you hear me?

Tracy Galloway:

Yes, we can.

Delorse Orlando:

Okay. All right. I just wanted to introduce -- first of all, thank you for coming back around to me. My -- I had missed my slot. But my name is Delorse Orlando. I am with the Florida Smoke Free Association. And I also own a retail -- actually, five retail shops in the state of Florida. We are a manufacturer -- we were a manufacturer up until the day of the deeming regs that they dropped, that was back in 2016. And we decided, based on the regulation that was presented, that we should shut down our mixing station. That has caused me a tremendous amount of lost revenue; however, we did continue on with pre-packaged e-liquid.

And for many years, responsible companies, such as mine, have asked the FDA to issue rules and regulations to ensure the quality of manufacturing and that products would be fit for purpose. Some even suggested that the FDA use the TPSAC in formulating these rules or in developing the PMTA process. Instead, the FDA, sat back for a decade, waiting and hoping that all the small- and medium-sized retailers and manufacturers and distributors, for that matter, would just fall off and die. They ignored calls for manufacturing rules that we had requested directly from small- and medium-sized manufacturers. They also ignored calls to get the TPSAC involved.

Now, the FDA is proposing manufacturing standards only after they illegally implemented a new standard to ban 99.99 percent of vaping products on the market, attempting to shut down my small business, despite no evidence that our products were getting into the hands of youth. And we're sued because the CTP director, Brian King, overruled the Office of Science when issuing PMTA denials. CTP leadership would rather dismiss its critics of social media armchair regulators than to acknowledge that there are real public health consequences of what they are doing.

Manufacturing rules for an industry fully dominated by large tobacco companies, as the FDA seems to have intended, were all irrelevant. But when we know that many adult vapers will never be willing to use substandard products, they are -- and they will either return to smoking or using illicit black-market products that rules won't -- that don't follow any rules whatsoever.

They're also ignoring the scientific studies of professionals in the science world, such as the Moffitt Cancer Center and also Dr. David Abrams, and many other doctors who have researched these products extensively.

I would be willing to provide those studies, if the FDA does not have them, at any moment you would deem appropriate. I'm also available for any questions that you might have. Thank you.

Tracy Galloway:

Thank you. This concludes our commenting session. I will now turn it back over to Necola Staples.

Necola Staples:

Thank you so much for your participation today in today's public hearing about the FDA's proposed requirements for tobacco product manufacturing practice. Gathering feedback from our stakeholders is such a critical part of the rulemaking process, and we truly value your perspective. So, thank you again. The comment period will remain open until September 6, 2023. And I encourage all interested stakeholders to please submit their comments to the docket. You can access the docket using the link on the screen.

As a reminder on May 18, CTP's Tobacco Products Scientific Advisory Committee will meet to discuss and provide recommendations on their proposed rule. The meeting will be open to the public. Finally, this hearing has been recorded. A transcript will be added to the docket of the proposed rule as well to the CTP website. The transcript will be available in the next few weeks. If you have any follow-up questions, please email us at AskCTP@fda.hhs.gov. Thank you for your time and have a good afternoon.

[end of transcript]