Remarks edited for brevity and clarity.

Thank you for having me and for this wonderful panel. I'm delighted to be with you today and share with you some thoughts about this topic.

First, as a company, our mission is all about harm reduction. Juul Labs exists to transition the world's one billion adult smokers away from combustible cigarettes. We realize that we cannot do that — we will not be able to accomplish that mission — while there is an underage use problem. We must actively combat underage use and do our best to be responsible stewards of our product. In fact, that is very consistent with the concept of the comprehensive framework that we are talking about today.

The Comprehensive Plan [for Nicotine and Tobacco Regulation] is really about nicotine, and the concept that -- while nicotine is addictive and can be harmful — it can be delivered on a continuum of risk. I think we can all agree that the best thing to do with respect to any nicotine-containing product is not to use it. Don't start. If you don't use nicotine, don't start using it. If you smoke cigarettes, which are the most harmful delivery mechanism that is known for nicotine, quit. The best thing you can do to reduce the risk of smoking cigarettes and the various harms is to quit using them. However, if you are unable to or unwilling to quit, you should switch to a less harmful alternative for nicotine delivery. This is the basic concept of the comprehensive framework that was adopted by the FDA in 2017.

This is reflected in the statement from Commissioner Scott Gottlieb and Director Mitch Zeller from 2017: “Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kills hundreds of thousands of Americans each year.”

The concept of this comprehensive plan is the idea that nicotine is delivered on a continuum of risk. I was very heartened to hear Director Zeller yesterday re-double the agency's commitment to this concept. In fact, I believe he said in response to a question that the agency remains absolutely committed to everything included in this plan. He also talked about the importance of a debate. And soon after coming up with this plan, we heard from Director Zeller and others on the idea of a debate around nicotine that was focused on some key questions.

I think that recently, that debate has focused on only one of those questions, and not others. I think that was what was meant yesterday by this idea of an “unproductive debate”. At some point, we are going to have to come back to this central idea: As a society, are we willing to adopt this risk continuum and it's corollary, which is the concept that nicotine is going to be available as a consumer product of *some* sort with appropriate regulation for *some* period of time? That is the underlying corollary of this

risk continuum. I look forward to a day when we can have that debate in a constructive fashion.

Now, the first part of the plan, as Barry Schaevitz pointed out, is a product standard, the aim of which would be to reduce the level of nicotine in cigarettes to minimally- or not-addictive levels. The second part of the plan is to support innovation and pathways to market an array of noncombustible products — that is, products that are farther down on the risk continuum, so that there is a robust marketplace of products that people can switch to. Landing places, if you will.

One of the tenets of this plan — and one of the issues that has come up since the statement of this plan — is the alarming rise of underage use, particularly of vapor products. FDA has made quite clear that none of this can come at the expense of underage use. We all understand that, we all appreciate that, and we all need to address that head-on.

As I said earlier, if we're going to make progress on this concept of a nicotine framework, we're going to have to deal with the misperceptions about nicotine.

A previous PATH study from 2016 (and it is still true today) showed that 80% of those interviewed in PATH incorrectly believed that nicotine causes cancer. We all know that nicotine is not the primary cause of tobacco-related death and disease. And yet there are these massive misperceptions.

In fact, the misperception even extends to physicians. Dr. Michael Steinberg and his colleagues have found that again, over 80% of specialists and physicians surveyed — a thousand of them — believe that nicotine directly contributes to cardiovascular disease, cancer, and COPD. That is a pervasive and ingrained misperception, which needs to be addressed if this comprehensive framework has a chance to succeed.

That misperception is not unique to this concept of nicotine. 47% of smokers were incorrect in concluding that smoking very low-nicotine cigarettes would reduce the risk, which of course it does not. For this comprehensive framework to work, misperceptions, with respect to relative risk — be they higher, lower, or about the same — need to be addressed.

We also know that misperceptions negatively impact switching. Dr. Alexander Persoskie and his colleagues very recently discussed the fact that smokers that were considering switching to a less risky product — in this case a vapor product — were three times more likely to switch if they properly placed the product on the risk perception scales. Non-combustibles were in the consideration set, but people with a better understanding or a correct understanding of the relative risk of them were three times more likely to switch.

So how do we advance the ball, and how do we encourage smokers down this continuum of risk? What are the ways that we can get people, if they can't, or won't quit completely, to go down this path -- down the path from combustibles to non-combustibles, which we know are a better landing place and part of this robust marketplace of alternatives that the FDA alluded to.

Dr. David Abrams and his colleagues have set up what I think is a very good rubric for thinking about this, and essentially it's the idea of the "sweet spot". The idea here is that a less harmful alternative must be acceptable to the target audience — to smokers. You need a product that is much lower in toxicity (let's equate that with harmfulness), high in appeal (that is, a product that can actually compete with a cigarette experience), and that has adequate dependence-inducing properties so that people can find it satisfying and effective in terms of nicotine delivery.

We have this idea of lower harm, sufficient appeal, and sufficiently-satisfying products. I think one of the reasons that we have seen limited success with nicotine replacement therapy in this country is the fact that they do not hit this "sweet spot". Smokers are used to the concept of a consumer product — not a medicine, not a drug — a consumer product with the trappings, the look, the feel, the value proposition, if you will, of their product. I think that is part of the appeal that David Abrams and colleagues are talking about.

This is a complicated issue with respect to the idea of dependence and nicotine delivery. Typically, for those of you who worked in the Drug center (sic), abuse liability is a negative term, which is meant to talk about something different than the way we talk about it in this category. I think the quote from the IQOS TPL memo gives you a good sense for how this fits in. "*The data indicate that the product has addictive potential and abuse liability similar to that of combustible cigarettes. This is important, as it signifies that the product can provide an adequate nicotine source for dependent populations, including combustible cigarette users.*"

This is a very crucial point, if you're going to have a landing place on this continuum of harm.

So, what does this mean for Juul Labs? While this is not a Juul-focused presentation or pitch, I'm very familiar with our data having just been through it, compiled it, and presented it in our Premarket Tobacco Product Application (PMTA). Take, for example, one of our pharmacokinetic studies that we have completed and submitted to the FDA. This consisted of about 144 smokers.

In the study, you have the JUUL System —Virginia Tobacco and Menthol at 5% — as well as nicotine gum as the negative control and cigarettes as a positive control. What you see is that the JUUL System has a very similar curve (nicotine delivery) to cigarettes,

reaching peak concentration at five minutes. Even though it delivered less nicotine than a cigarette, we think that this sort of curve, and certainly the data and the subjective effects data that go with it, suggest that smokers are able to use this product, to want to switch to this product, to give it a shot, if they're thinking about an alternative. Compare this to the nicotine gum, which didn't deliver peak concentration for 30 to 40 minutes, and even then was well below the nicotine delivery level of a cigarette.

So what does that mean for us? Using the switching data that we have presented in the PMTA, we can estimate that around 2 million smokers in the United States have switched completely — meaning not even a puff — from smoking cigarettes to JUUL products. We have been able to achieve this across a number of cohorts and types of smokers, from infrequent smokers to those who smoked cigarettes daily for more than five years. You also see that these things improve over time. A longitudinal study with up to 12 months of data shows that while smokers begin with dual-use of cigarettes and e-cigarettes, over time, this gets better, and better, and better. If you take the concept of the “sweet spot”, it is possible to completely switch a lot of smokers with a product that works.

The flip side is, should we limit nicotine in noncombustible products like vapor products? To use some real world examples — take data generated from the United States and Canada, where Juul Labs is able to sell it's 5% and 3% products, and compare that to data from the U.K., where the company has seen success, but is only able to sell the 18 mg/ml product, which contains far less nicotine.

What happens? This is a little bit complicated, because you're comparing apples with oranges, so Saul Schiffman and colleagues put together an odds ratio assessment. The odds of complete switching off of cigarettes among adult smokers is 1.5x higher in the U.S. and Canada than for the U.K., where we have a nicotine cap. Our data shows what many of us have believed, which is that nicotine restrictions for vapor products suppress switching rates — particularly among heavier smokers. We’re significantly higher in our ability to switch in countries where adult smokers have access to the JUUL products that have higher nicotine concentrations.

We are at the cusp of an era where the age of cigarettes could actually end. We have a significant opportunity before us, where noncombustible products potentially could completely replace cigarettes for those who can't or won't quit. No single product will work for every smoker, and a comprehensive plan that encourages people down the continuum of risk seems like a very opportune and thoughtful thing to do.

But the availability of products in this marketplace is not enough. We have got to address the misperceptions. I was encouraged to hear Kathy Crosby say that they're looking at, they're thinking about, and they're going to take a “cautious approach” to a possible category claim.

I understand that the office of communications has very big fish to fry with respect to real costs and the youth issue, and I appreciate that they're talking about targeting, or that they do try to target that media to youth-centered media versus adult-centered media.

But we don't want to lay this just on the hands or at the feet of our regulator. Everybody needs to work within our parameters to understand that tobacco smoke, not nicotine, is the cause of smoking-related mortality and morbidity. And when we have a situation where 80% of our doctors believe that nicotine causes disease, we're not going to make a lot of progress on the comprehensive framework.

The Comprehensive Plan presents a fundamental and important change to the nicotine market as we know it. Focused on driving down tobacco use and shifting demand, the Premarket Tobacco Product Application (PMTA) process that we're all in gives us the initial ability to prove our case on the opportunity.

I look forward to the rest of this panel and further discussion. And like Mitch Zeller, I really hope that we can get beyond unproductive disagreements and dialogue to more productive and constructive activity.

Thank you all.