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I first want to thank Imperial Brands for hosting the 74th TSRC. I also want to thank TSRC for organizing this event and encouraging today's exchange of perspectives.

It's wonderful to be here with you this morning.

In the next few minutes, I have the privilege of talking to you about the path forward on harm reduction. As I do that, you should know that my perspective on where we are, and how we make progress, is rooted not only in my passion as a scientist, but in my training and experience as a physician.

I have seen the devastating health effects of smoking up close and I know how critically important it is to reduce that harm.

As you listen this morning and as you attend sessions throughout this conference, I ask you to remember the over 33 million adult smokers in this country today, who so far have been unable or unwilling to quit.

Studies show that over half of these adult smokers may be interested in lower risk alternatives right now and any path forward on harm reduction should not – cannot – leave them behind.

A fully implemented harm reduction approach seems within reach – but many obstacles remain.

On one hand, as we gather today, there are some encouraging aspects:

- There is a near complete scientific consensus that an adult smoker who switches completely to a smoke free product will realize health benefits at the individual level.
- We have a science-based regulator who recognizes this fact.

Yet, on the other hand ...

- Misperceptions on the risk of nicotine and relative product harms are widespread among adult tobacco consumers.
- We have yet to see a stakeholder with the resources, willingness and credibility to work to meaningfully address these misperceptions.
- We believe that preventing underage access is essential to preserving the tobacco harm reduction opportunity for adults. We are encouraged that youth smoking is at an all-time low – but it is undeniable that the level of youth vaping reached alarming levels.
- And we continue to see policy fallout as state and local governments ban the sale some of the most promising harm reduction products – even including those that have satisfied FDA PMTA and MRTP scrutiny.

As researchers, it is in our nature at confusing times like these to lean on the core mechanisms of scientific research including engagement with peer scientists and public review of data and conclusions. Yet, I am concerned that this approach is falling short.

Congress placed the burden of demonstrating harm reduction science for specific products squarely on manufacturers. That's appropriate. As I will discuss, we have responded with substantial science investments and a comprehensive approach to product research.

But I am not sure how we meet this burden within a scientific community reluctant to even review our conclusions.

Instead of scientific engagement, we see:

- Scientific gatherings just like the one we are at today that have decided to block attendance by those of us who are seeking to share our science and receive external review of our work.
- Some academic journals are following suit.
- Peer reviewers asking for anonymity out of fear of reprisal for even having reviewed data from a tobacco manufacturer.
- And, researchers who engage with tobacco product manufacturers risk being penalized during grant considerations.

While these actions are disappointing, I think we have no choice but to continue to lean on core, well-accepted scientific principles and encourage all stakeholders to do the same.

I was encouraged when earlier this month 15 past presidents of SRNT published a valuable analysis of the risks and benefits of nicotine vaping – providing an example for the type of open-minded data review that will advance the harm reduction conversation.

As a scientist and researcher, I know there is a chance that the data will not support my hypothesis. I can accept if the data do not support a specific product application. What I do not believe any of us should accept is the refusal of foundational scientific institutions to fairly consider the science and evidence of harm reduction.

So, I am here today, to engage and discuss a path forward.

What does progress look like?

In my view, progress today is:

- Each stakeholder fulfilling their role
- In a system that fairly explores the science of tobacco harm reduction

I'll start with us. Let me share how we view our role and how we intend to contribute to harm reduction progress.

At Altria, there are both external and internal drivers of our scientific research.

First, as mentioned, Congress has given us – the manufacturers – the responsibility and obligation of delivering the science to support product and claim applications.

Second, the data make clear that adult tobacco consumers are seeking out products that may present reduced risk.

And finally, at Altria we have announced our vision to responsibly lead the transition of adult smokers to a smoke-free future. We believe we have the opportunity to make more progress on harm reduction in the next 10 years than we have in the past 50 years.

As a result of this alignment of external obligations and internal mission, our employees are committed to researching, developing, investing in and promoting products designed to reduce the harms of combustible tobacco products.

We follow a rigorous scientific framework for evaluating potentially reduced-risk tobacco products and supporting product applications to FDA. We evaluate tobacco products from all angles including:

- Product stewardship;
- Individual risk assessment; and
- Impact on the population as a whole.

We have seen others in the industry follow this approach to successfully receive product and claim authorizations.

We are confident in the data developed to support our submission for on! – an oral tobacco derived nicotine pouch.

FDA's premarket review must consider risks and benefits to both users and non-users, with a special focus on vulnerable populations including youth.

All stakeholders must be vigilant regarding the prevention of underage tobacco product access. To this end, in addition to our longstanding efforts to prevent underage tobacco use, Altria has launched the Underage Tobacco Use Survey, or UTUS. This study provides timely data covering more product categories as compared to other current survey tools to inform Altria's underage use prevention efforts and monitor underage behavior information. We share this data on a recurring basis on the Altria Sciences website, which I would encourage you all to visit.

We also support an updated approach to federal government underage use surveys to reflect emerging tobacco product categories and share information in a timely manner to facilitate nimble policymaking.

We believe that science- and evidence-based product standards are one way to accelerate review of reduced risk products and benefit public health. We have developed recommended product standards for potentially reduced risk product categories, including Oral Tobacco Derived Nicotine products, Heated Tobacco Products, and Electronic Nicotine Delivery Systems.

These proposed product standards are informed by product stewardship principles, emphasize product safety and should evolve with product innovation. We conducted an extensive review of existing voluntary standards for novel reduced risk products and considered products currently marketed in the United States. You can find more information about this project on the Altria Sciences website.

I would also invite you to the session and workshop on reduced risk product standards tomorrow morning at 8:30.

I also believe we are well-positioned to advance tobacco harm reduction as a result of our focus on the adult tobacco consumer. The adult smoker is at times forgotten or marginalized in the current scientific conversation.

The only products that will successfully transition those adults who can't or won't quit smoking to a smoke-free alternative are ones that are appealing and that adult smokers will want to use.

And what does that mean? I believe it starts with keeping an open mind to research regarding the product attributes that increase the likelihood of adult smoker product trial and adoption.

The data to date demonstrate that tobacco harm reduction will require products that meet adult smokers where they are – and that includes responsibly marketed products available with the product attributes shown to encourage adult smoker transition, including flavors demonstrated through science to appeal to adult smokers and nicotine levels that will meet adult consumer expectations.

Both FDA's premarket scientific scrutiny and the Agency's substantial postmarket authorities should provide us with confidence as the marketplace evolves. Products authorized by FDA as appropriate for the protection of public health have – and should – require extensive post-market monitoring of the marketplace by both the manufacturer and FDA as well as the ability for FDA to exercise its robust post-market enforcement authorities up to and including withdrawal of a market order if the Agency determines the product is no longer appropriate for the protection of public health.

And I believe that state and local policymakers should look to FDA on key harm reduction questions.

In one example, in April of 2019, FDA found the marketing of menthol Heatsticks used in the IQOS system to be appropriate for the protection of public health due to fewer or lower levels of some toxins than combustible cigarettes.

In our host city of Boston, though, and in many other jurisdictions around the country, this product is banned from store shelves as part of tobacco product sales restrictions, despite the Agency's review and conclusions.

Policy actions that prohibit adult smokers from accessing smoke-free alternatives, especially those that have gone through the extensive FDA scientific review processes, will undermine harm reduction efforts. As the Tobacco Control Act outlines, scientific evidence should drive the decision on if these products have a role in the marketplace.

I believe that FDA is well-positioned from a resource, expertise and authority perspective to shape the market nationwide.

Once authorized, adult consumers must understand the opportunity these products present. We know from PATH data that most adult smokers are interested in alternative products with the potential to reduce harm. But data also shows that consumers currently harbor misperceptions that may prevent them from recognizing harm reduction opportunities.

A 2016 study analyzing data from the Health Information National Trends Survey found that 73 percent of people “either incorrectly believed that nicotine is the main substance in cigarettes that causes cancer or were unsure about the relationship between nicotine and cancer.” This entrenched misperception is not limited to adult smokers. For example, a recent study found that more than 80% of surveyed physicians, an important source of health information for consumers, “strongly agreed” that nicotine directly contributes to the development of cardiovascular disease, COPD and cancer.

Collectively, these misperceptions could result in smokers rejecting smoke-free alternatives simply because they contain nicotine - and stakeholders must address this risk through a clear communication of scientific facts. Despite a commitment from FDA to “reframe the conversation around nicotine and harm reduction,” adult tobacco consumers and other important stakeholder groups, like physicians, remain uncertain about the role of nicotine in, and the differential risks of, smoke-free tobacco products.

Building on reported success in other targeted communication efforts, we urge FDA and CDC to conduct a communications campaign focused on correcting nicotine misperceptions among targeted audiences, particularly adult cigarette smokers.

For our part, we continue to invest in the science necessary to support MRTP submissions. We know the Tobacco Control Act provides us with a meaningful avenue to provide truthful and accurate information to adult consumers. We have submitted a proposed claim for a smokeless MST product and have announced intentions to do so for other products moving forward.

Finally, I would like to discuss the importance of equitable tobacco harm reduction. Emerging research shows demographic disparities in adoption of smoke-free products and accurate understanding of relative product harms and nicotine risks - perhaps resulting from negative messaging from policymakers or sensational media headlines

It is important for all adult smokers to understand harm reduction opportunities and have access to reduced risk products. The evidence shows that an individual adult smoker who can't or won't quit will benefit from switching to a smoke-free product. All stakeholders should work to ensure that the benefits of the harm reduction efforts are realized equitably.

I know there are some – perhaps even some in this room – who question the motives and science of industry actors. I can understand this perspective. What I can say is this: I stand by our work and I am confident that over time the strength of our science and harm reduction value of our products will earn trust. And, we invite your scrutiny of our science.

At the same time, I am a pragmatist - I know we must lead with the science and the rest will follow. I feel fortunate that federal tobacco regulatory actions must be based on scientific evidence – and we will continue to pursue the science to inform these decisions.

Finally, amid conversations about who can attend what conference, and what journals will consider which studies – it is always important to remember the more than 33 million smokers. They must remain at the center of our collective focus.

And, we must continue to work to understand what products and messages will convince these adult smokers who can't or won't quit combustible tobacco use to switch completely to smoke-free product use.

Gatherings like this are essential to making that happen. Thank you for having us.