



**Howard Willard, Chairman & CEO, Altria Group, Inc.**  
**Remarks at Global Tobacco & Nicotine Forum**  
**Wednesday, Sept. 25 | Washington, D.C.**

Thank you for the introduction, Patrick. And thank you to those responsible for putting together this forum and allowing me to speak with you today.

I also want to thank Senator Burr for his participation and leadership on harm reduction and important tobacco-related issues.

For those who were able to join us last night, we hope you enjoyed the welcome reception at the National Museum of Women in the Arts. We were honored to be able to host the event at such a fantastic location; and hope you had a chance to enjoy some good food, see some great art; and take advantage of the time to visit with friends and colleagues.

Today, I'd like to have a conversation on harm reduction and the important steps collectively we can take to make it a reality.

But before I do that, I want to first comment on some news. JUUL Labs, in which Altria is an investor, announced a leadership change. In case you missed it, named, as its new CEO, K.C. Crosthwaite. I've worked closely with KC at Altria for many years and am confident in his leadership and integrity and that he will help JUUL urgently confront and reduce underage vaping.

This is a pivotal moment for the industry and strong leadership and action are urgently needed.

Because we must acknowledge that a key component of harm reduction – vaping – is at an inflexion point.

Here's where we find ourselves...

- An epidemic of youth vaping.
- Restrictions on e-vapor products for adults.
- The public has legitimate concerns about marketing practices and flavored products.
- Vaping products – including those that are illegal --are at the center of a national investigation.
- Consumers are concerned and unclear about the health risks of these products.
- And, at all levels, policymakers are responding to the increased demand for action.

Given the tremendous progress made on harm reduction over the past 30 years, I find this very discouraging.

But I remain optimistic. Many of the leaders in this room – industry, public health, regulators, policy makers, scientists, and others -- have confronted significant challenges before and have the ability to change this trajectory.

The next steps we take are critically important.

It won't be easy and it requires us to think and act differently. But when it's put in the context of the 37 million adult smokers in the U.S., to me, it's an easy decision to take bold and compelling action.

- Like FDA's endorsement of a continuum of risk and setting a vision for future nicotine policy.
- Or changing a long-held industry position on the minimum age and putting full advocacy support behind raising it to 21.



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- And recently, proposals to remove flavored vapor products from the market until they've been properly reviewed through the PMTA process.

In our view, bold action requires thinking – not in weeks or months – but in terms of years as we try to change the current course and preserve the long-term potential of vaping and harm reduction.

Why is this so important?

With adult smoker demand for non-combustible alternatives, innovation and an appropriate regulatory framework, we have the opportunity to make more progress on reducing the harm caused by cigarettes in the next 10 years than we have in the past 50 years.

**Over the next decade, I believe we will see non-combustible products surpass combustible products as the preferred choice among adult tobacco consumers.**

**We, at Altria, are actively preparing for and embracing that future.**

In the past few years, we've seen substantial evidence that adult smokers are choosing new and innovative non-combustible products. We have also seen a scientific consensus take root that these products offer a huge potential for adult smokers and public health, and we've seen FDA set a vision for harm reduction and authorize products accordingly.

For example, just this past spring, the agency authorized the sale of IQOS, the first next generation-product to receive a PMTA. This signaled that, with careful review of the evidence and a thoughtful marketing approach, innovative products can be brought to market.

We are very excited about the opportunity to introduce U.S. adult smokers to Philip Morris International's leading heated tobacco product. IQOS is a global product, available in over 45 countries. More than 8 million adult smokers have fully switched to IQOS, and its market share continues to grow in every country where it is available.

At the state level, we've also seen some legislative bodies advance differential tax policies that encourage smokers to adopt nicotine containing products if found by FDA as presenting lower risk.

Let's not forget, that with more choices available and broad support, adult smokers are doing what we all hoped they would ultimately do. They are adopting non-combustible products and, increasingly, converting completely.

Tobacco harm reduction is no longer a theoretical exercise.

At Altria, we have come to understand adult tobacco consumers over many years. We know that conversion will only happen if adult smokers find the products to be satisfying and a fit for their lifestyle and preferences. No single product is likely to meet the preferences of all adult smokers.

According to the FDA PATH study, more than half of the 37 million U.S. smokers are interested in satisfying and less harmful nicotine products.

In fact, more adult smokers have switched to non-combustible products today than at any time in history.

- We estimate there are now 13.8 million adult vapers, a number that is steadily growing.



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Importantly, more than 7 million adult vapers report only vaping and not smoking, which is the highest level of exclusive use since the advent of vaping products.

- Retail sales of oral nicotine pouches in the U.S. grew 250% from 2017 to 2018.
- And, around the world, more than 8 million smokers have fully switched to the IQOS heated tobacco platform.

In fact, one size does not fit all. That's why at Altria, we have been investing in the platforms we believe present the most opportunity for adult smokers.

And today, our portfolio of products and investments includes leading products across:

- Heat-not-burn;
- Moist smokeless tobacco and oral nicotine pouches; and
- E-vapor.

Adult tobacco consumers are moving to these platforms. We need to support them.

As I said, our next steps will define the future of harm reduction in the U.S. Here's what I believe we must do to ensure this vision becomes a reality.

**First, we must confront youth e-vapor use with real solutions, while at the same time remaining focused on reducing underage use of all tobacco products.**

We all agree kids should not smoke, vape or use any nicotine product.

But we've all seen the headlines. The current levels of underage vapor use – reportedly 27.5% of high school students in the latest National Youth Tobacco Survey dataset – are unacceptable and alarming. As a result, the government plans to remove flavored vapor products from the market pending pre-market authorization. We support such decisive action and firmly believe that pre-market review is a critical process for evaluating whether and how these products should be made available to adults.

Reducing underage tobacco use has been and remains a top priority for Altria, as I know it is for everyone in this room. We recognize that the opportunity of harm reduction for adults is imperiled by the dramatic increase of underage use of vapor products.

Our underage tobacco prevention efforts began in the late 90s with the formation of a Youth Smoking Prevention department, which I oversaw earlier in my career.

At the time, youth smoking rates were on the decline, but we knew there was more work to be done and we were committed to being part of the solution. Now it didn't happen overnight and it took the efforts of many. But, we remained diligent and brought resources, partners and solutions to the issue. And with concerted efforts of public health, tobacco control, policy makers and retailers, it worked. Importantly, the latest NYTS data shows youth smoking at its lowest recorded levels in history. This is the model we must bring to bear regarding youth e-vapor use.

We continue to believe that raising the legal minimum age for purchase of all tobacco products to 21 at the state and federal levels is the most effective action to reverse rising underage e-vapor rates. There is strong momentum behind this policy change. Today, more than 50% of the US population is governed by these laws – we want to see it become the law of the land.

Data shows that youth under 18 get tobacco and e-vapor products primarily through social sources,



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including in-school peers who are of legal age. Approximately 80% of high school students in the U.S. turn 18 before they graduate. By raising the minimum age to 21, almost no high school student should be able to purchase tobacco products legally.

While this will help cut down on access, we know that more needs to be done. So, we've committed an additional \$100 million over the next two to three years to youth e-vapor prevention beyond our current investments.

Later today, my colleague Jennifer Hunter will appear on a panel to talk about other steps we are taking.

Driving down underage vaping rates won't happen overnight and will take the efforts of many.

It will also, for example, require tough FDA compliance checks that guard against underage sales, but also address the sale of illicit and adulterated products. Unlawful products skirt the law, harm legitimate manufacturers and will hinder our collective progress on youth vaping.

**Second, we must provide adult smokers accurate risk information about non-combustible products.**

Today, adult smokers and the general public remain unclear about the role of nicotine and the health risks associated with combustible versus non-combustible products.

According to research, we know:

- ✓ 72% of adult smokers think nicotine is just as a harmful or even more harmful than the smoke inhaled from the combustion of tobacco.
- ✓ 67% believe that smokeless tobacco poses the same or greater health risk than cigarette smoking.
- ✓ and 59% believe that e-vapor products pose the same or greater health risk than cigarette smoking.

And the flurry of alarming media headlines about lung illness and vaping reinforce these pre-existing beliefs.

When there is this kind of public confusion, we all fail to achieve our objectives around harm reduction. No one wins.

We can't allow misinformation and assumptions to drive policy and become accepted truths. We have an obligation to ensure the public and, most importantly, adult smokers have access to scientifically grounded information.

For the industry, we must pursue the necessary research to be able to justify modified risk claims.

Currently, FDA is reviewing PMI's MRTP application for IQOS, as well as our application for Copenhagen Snuff.

But the responsibility rests not only with the manufacturers. For those in public health and at FDA, adult smokers need your help in obtaining accurate and truthful information.



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From the confusion about the role of nicotine, to the misinformation regarding the relative risks of different products, you have a role to play in helping tobacco consumers make informed decisions. Imagine the benefits to adult smokers and public health by simply communicating about the role of combustion and relative benefits of smoke-free products.

We must not be negligent in our duty to accurately inform. We must empower adult smokers to make informed decisions based on science and evidence.

**Our third opportunity is to focus on conversion.**

We agree, for adult tobacco consumers concerned about the health effects of tobacco use, the best thing to do is to quit. And we agree that non-tobacco consumers should not start using tobacco products.

However, we know that many current adult tobacco consumers won't, or can't, simply quit.

For those, they now have another option: convert to non-combustible products.

At Altria, we are encouraging trial and conversion by using powerful tools like premier fixture space at retail, the adult tobacco consumer database, and inserts in cigarette packs.

And at our IQOS retail stores, we are taking adult smokers through guided trials, which we know is an important step toward conversion.

We know enough about adult tobacco consumer behavior to realize this won't likely be a quick one-for-one exchange. But, that can't stop us.

It's on manufacturers to continue innovating and creating better non-combustible products. What consumers prefer today will certainly change. We have to stay ahead of the curve and continue to create better, lower risk products.

Today, though, we question if our investment in the creation of new, innovative products will yield a PMTA authorization and if it will be timely enough so that the products are still what adult tobacco consumers want?

**This leads me to our fourth opportunity: optimizing the PMTA process.**

We must create a more fluid, predictable process that reviews and decides on applications in an appropriate time period and is transparent with the industry, adult tobacco consumers and public health.

Innovation and harm reduction unfortunately can't coexist within the process we have today. An unpredictable process discourages innovation and investment.

There must be clear rules of the road to encourage manufacturers to develop new products and invest in scientific research. To that end, it is encouraging that FDA started the process last week by issuing a proposed PMTA rule.

If a product offers the potential for reduced harm, we should all want that product to make it through the process in a timely manner and be delivered to adult smokers.

This includes an accelerated process for those products that have been previously found to be appropriate for the protection of public health and where enhancements have been made. In its proposed



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PMTA rule, FDA recognized this opportunity by including a key provision for “supplemental” PMTA applications for products that have already received a PMTA marketing order. This is an important step forward.

FDA should act quickly, using the blueprint created in its other centers, to establish a process that accounts for different levels of complexity, permits changes to allow products to improve, and gives manufacturers some certainty in what to expect for their efforts and investments. Moreover, to streamline the PMTA review process, FDA could set baseline performance standards for reduced risk products.

We believe the PMTA pathway creates an ideal opportunity for a manufacturer to provide the data and evidence to support its request for marketing authorization and for FDA to evaluate, in totality, whether to authorize the product in the context of its marketing.

We have long believed that science and evidence must be the foundation of good rulemaking. Doing so ensures confidence and creates consistency.

We are committed to generating high quality science and evidence to assess the risk reduction potential of new smoke-free products. Good science is at the foundation of progress in this area. And while we publish our research, speak at scientific forums and engage with the scientific community, we also know that decades old industry actions have led to a lack of trust and collaboration.

Our inability to come together to work on common goals like harm reduction limits the ability of public health and FDA to make decisions about nicotine product risks and educate adult smokers so they can make informed decisions.

The fact is...harm reduction is picking up speed and we want to work with stakeholders to continue this momentum.

I fundamentally believe we have the chance to make more progress on harm reduction in the next 10 years than we have the past 50. I believe taking the actions I’ve spelled out today will significantly advance harm reduction.

While 10 years can seem far away, with each PMTA authorization, MRTP claim and new non-combustible innovation, we get a little closer to making tobacco harm reduction a reality.

After talking about it for decades, the opportunity is right in front of us. And if we don’t seize it, it’s a loss for public health.

We must step forward and act because millions of adult smokers in the U.S. deserve and demand it.

Let’s not lose this opportunity.

Thank you.