Product Standards for Potentially Reduced Risk Tobacco Products

Smith, J.H.; Smith, R.T.; Smith, D.C.

Altria Client Services LLC, Richmond, VA 23219

Center for Research and Technology

74th Tobacco Science Research Conference
Boston, MA

August 29 – 31, 2021

Harm Reduction Through Innovative Products

In FDA's 2017 Comprehensive Plan, then-FDA Commissioner Gottlieb stated FDA policy should be used as a vehicle to "move addicted smokers down that continuum of risk to these less harmful [innovative] products." [1]

Adult Smokers, who cannot or will not quit, should have access to acceptable RRP alternatives that are substantiated through science and evidence[3]

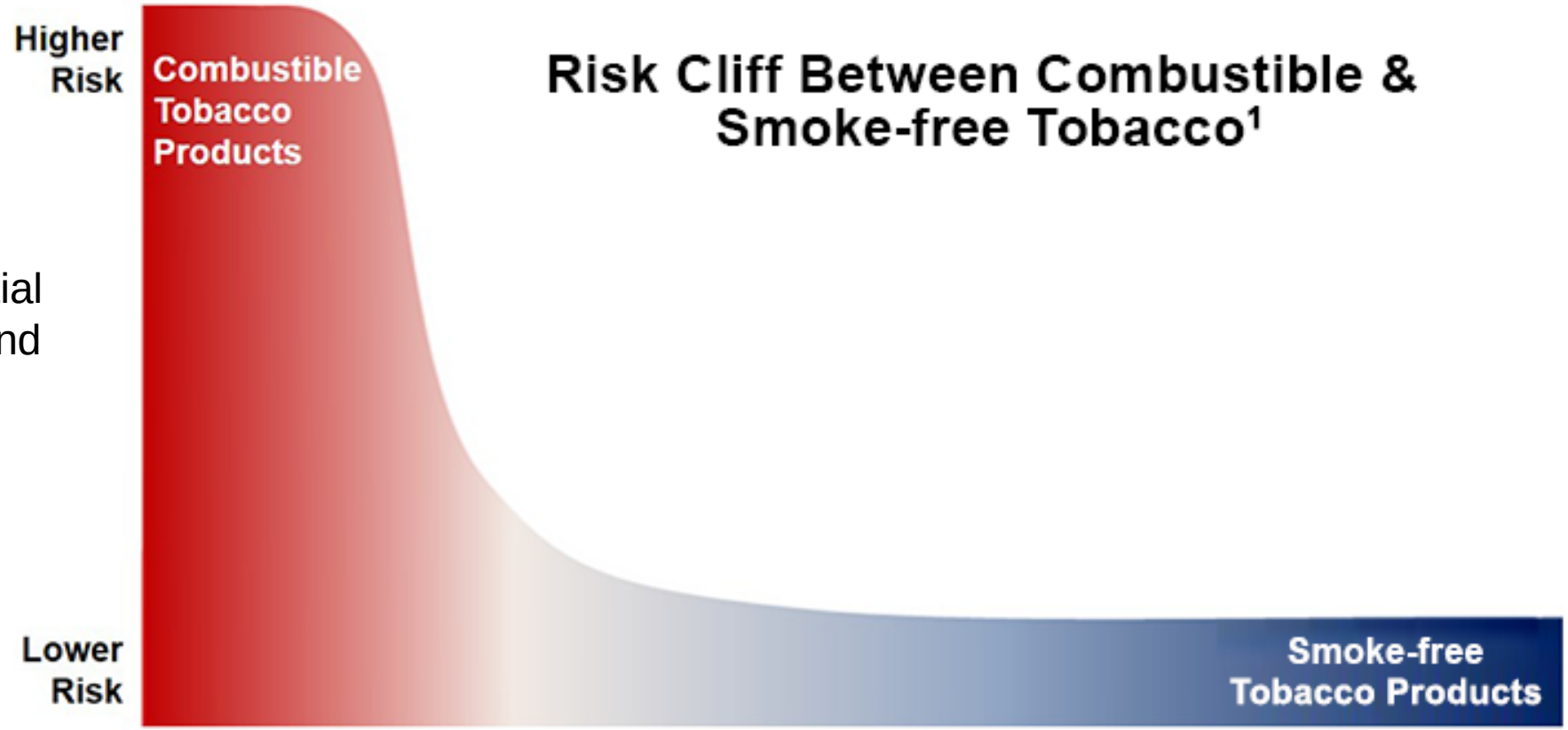
[1]"… we must acknowledge that there's a continuum of risk for nicotine delivery. That continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other." Remarks by Scott Gottlieb, M.D., Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (June 28, 2017), available at https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017.

[2]Adapted from Dorothy K. Hatsukami et al., Developing the Science Base for Reducing Tobacco Harm, Volume 9, Supplement 4, Nicotine & Tobacco Res. S537- S546 (2007).

[3]Press Release, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death (July 27, 2017), available at https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death (“Envision[] a world . . . where adults who still need or want nicotine could get it from alternative and less harmful sources. . .”).

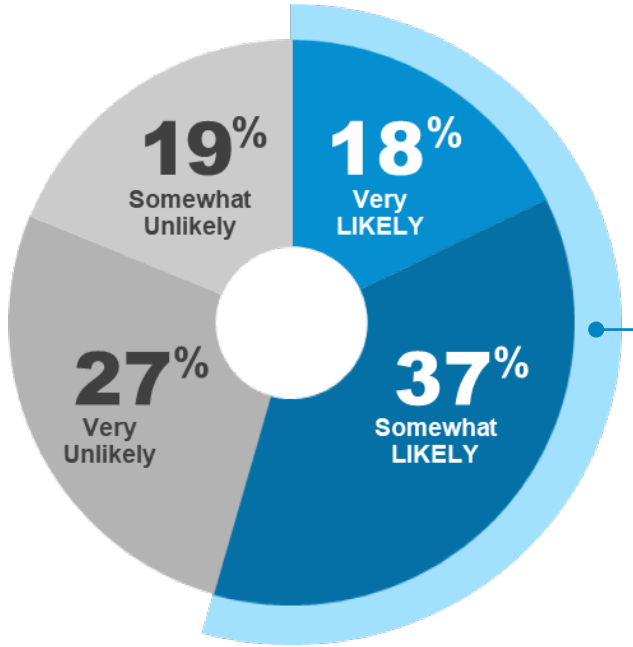
Supporting Potentially Reduced Risk Products (RRPs)

The body of evidence supports a risk differential between combustible and smoke-free categories.



[1] Adapted from Nutt, et. al Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur. Addict Res 2014; 20:218-225.

Adult Smoker Support for Reduced-Risk Tobacco Products



55%
Adult Smokers INTERESTED in Reduced-Risk Tobacco Products[1]

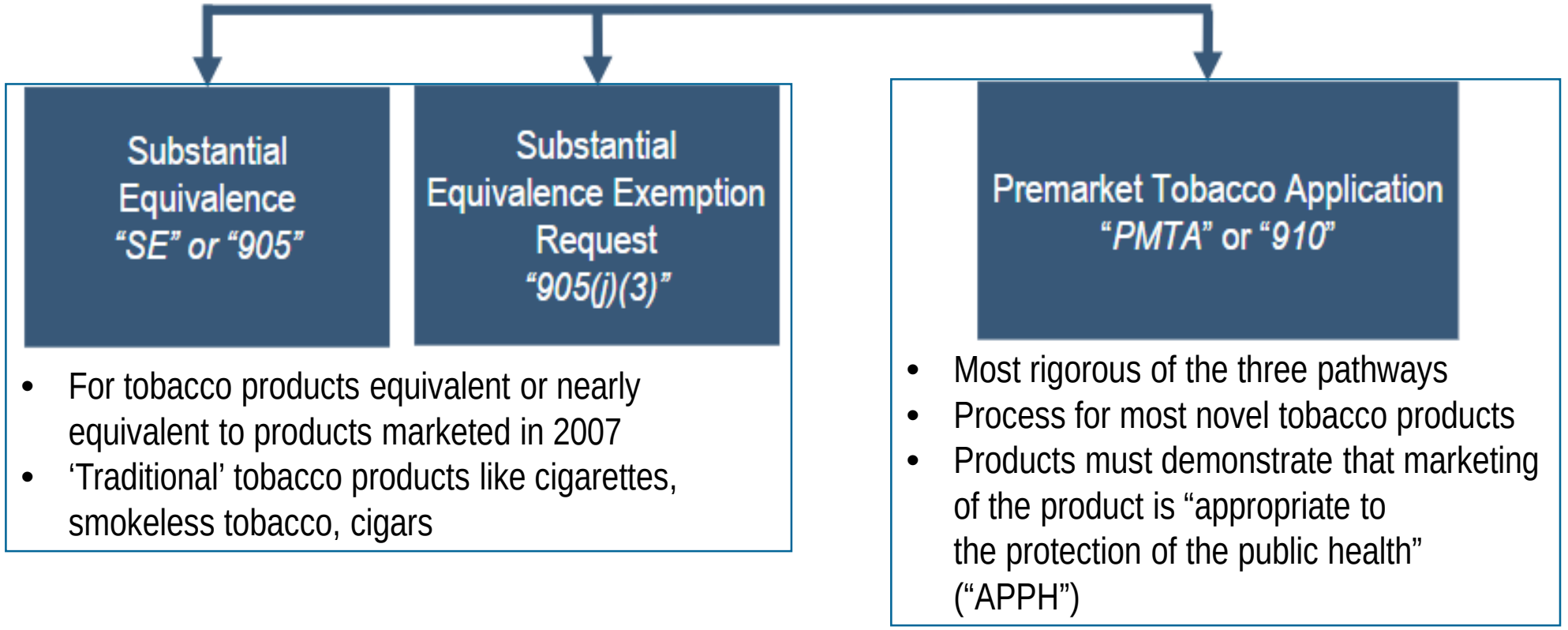
Adult Smokers, who cannot or will not quit, should have access to acceptable RRP alternatives that are substantiated through science and evidence[2]

[1]Based on ALCS analysis of PATH Wave 1 data Sept 12, 2013 – Dec 14, 2014. Response to question – "If a tobacco product made a claim that it was less harmful to health than other products, how likely would you be to use that product?" Numbers may not foot due to rounding.

[2]Press Release, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death (July 27, 2017), available at https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death ("Envision[] a world . . . where adults who still need or want nicotine could get it from alternative and less harmful sources. . .").

FDA Regulation of Tobacco Products

FDA Authorization Pathways



- For tobacco products equivalent or nearly equivalent to products marketed in 2007
- 'Traditional' tobacco products like cigarettes, smokeless tobacco, cigars

- Most rigorous of the three pathways
- Process for most novel tobacco products
- Products must demonstrate that marketing of the product is "appropriate to the protection of the public health" ("APPH")

FDA Regulation of Tobacco Products

It is easier, cheaper, and faster to put a new cigarette on the market than a reduced risk product

Reduced Risk Product Standards

- Proposed product standards
  - Provide a foundational baseline for safety and quality
  - Reduce the amount of product-specific information required in PMTA
  - Provide the basis for an abbreviated marketing authorization pathway
  - Do not alleviate the manufacturer from providing sufficient data to demonstrate APPH
  - Separate from Tobacco Product Manufacturing Practices (TPMPs)
- Proposal objectives
  - Facilitate discussion with tobacco product stakeholder

White Paper:
Product Standards for Potentially Reduced Risk Products in the United States

Proposed product categories

- Oral Tobacco Derived Nicotine (OTDN)
- Electronic Nicotine Delivery Systems (ENDS)
- Heated Tobacco Products (HTPs)

Potential Product Standards for RRPs

Product Design and Control

- Assessment of potential hazards
- Certification through industry standard, e.g., UL 8139[1]

Chemical and Physical Characterization

- Appropriate HPHC testing
- Extractables/Leachables for product components
- Appropriate stability testing for final product

Toxicology, Risk Assessment and Product Stewardship

- Full quantitative disclosures of ingredients from suppliers
- Ingredient and material risk assessment

[1]ANSI/CAN/UL 8139 – Electrical Systems of Electronic Cigarettes and Vaping Devices

Current Work and Next Steps

- Publish white paper
  - Available on sciences.altria.com
- Engage with stakeholders
  - Large and small industry
  - ISO technical committee 126
  - TSRC workshop
- Potential next steps
  - Webinar

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TECHNICAL COMMITTEES

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Tobacco and tobacco products

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Conclusions

- Product standards for RRPs should be class-specific and include science- and evidence-based product stewardship principles that evolve with product innovation
- Science- and evidence-based regulation, including product standards, may accelerate market authorization of RRPs and thereby benefit public health
- This proposal seeks to identify foundational product standards for each RRP category with a focus on product safety and quality

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Questions? Email us at altriascience@altria.com