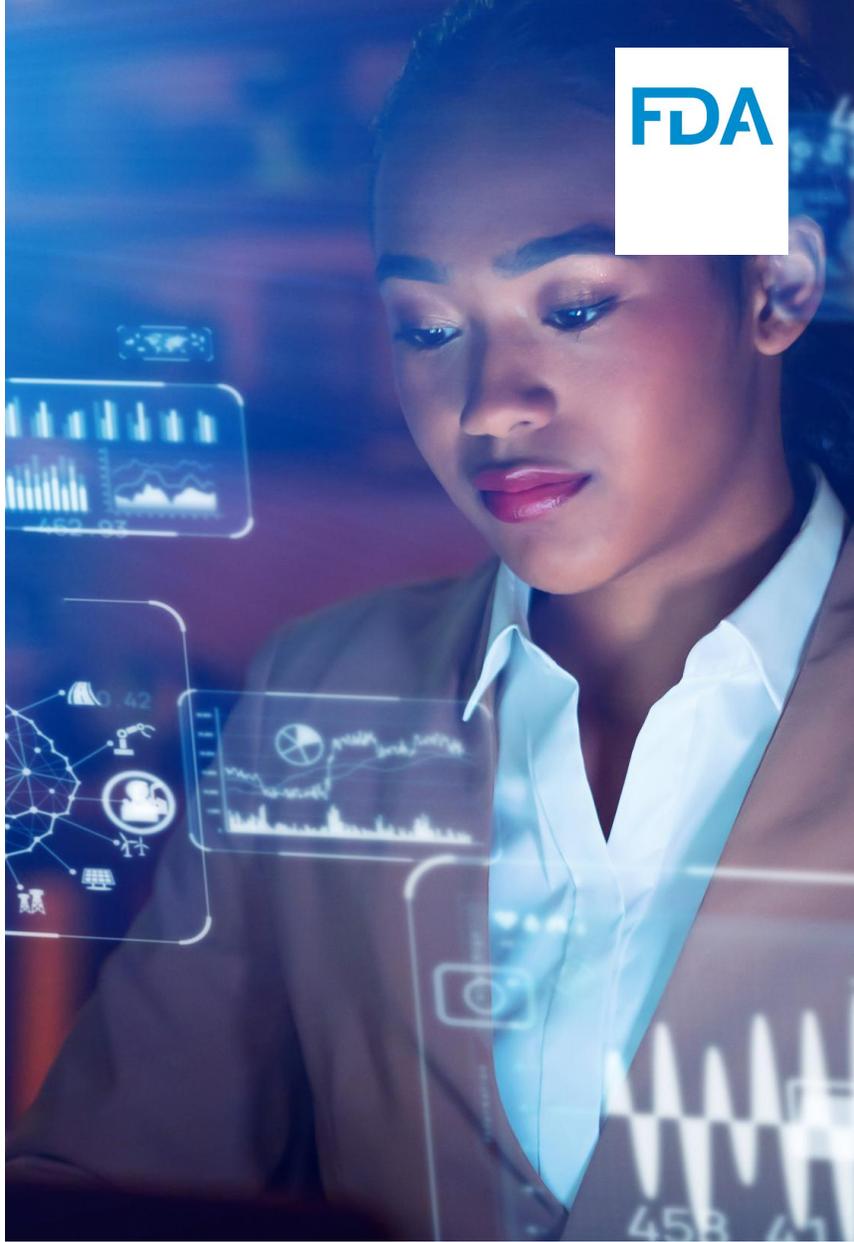


THE USE OF MODELING IN TOBACCO REGULATORY SCIENCE: INSIGHTS FROM CTP

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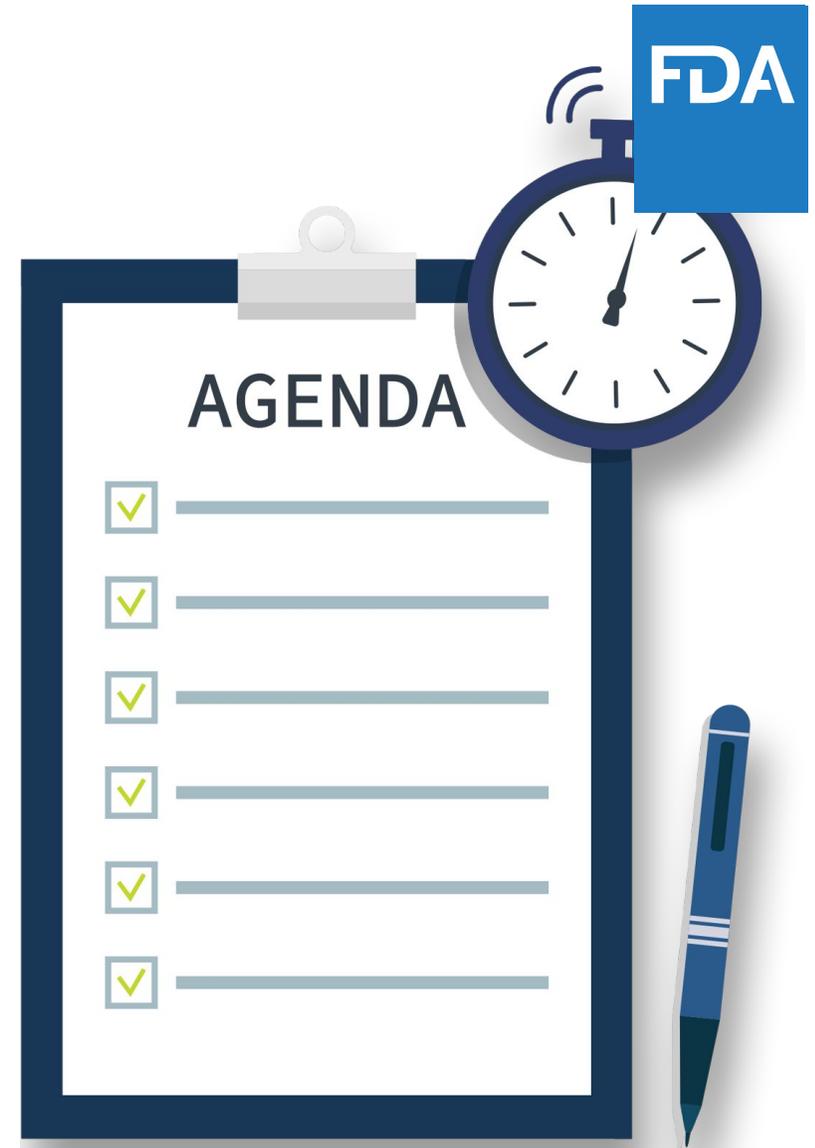
FDA

May 17, 2023

CENTER FOR TOBACCO PRODUCTS

AGENDA

- Computational Modeling & Population Health
- Modeling to Inform Product Standards
 - Menthol Cigarettes
 - Flavored Cigars
 - Nicotine
- Challenges & Opportunities
- Closing Thoughts



- Decisions about tobacco product regulation often include the integration of multiple lines of evidence
- Computational modeling can be a useful tool to integrate such evidence to assess new regulatory actions on short and long-term measures of tobacco product use, morbidity, and mortality





MODELING TO INFORM PRODUCT STANDARDS



Modeling estimated that if menthol cigarettes were no longer available in the U.S.:



Up to 650,000 smoking and vaping attributable deaths avoided over 40 years

15%

A 15% reduction in smoking in 5 years

Levy DT, Meza R, Yuan Z, et al. (2021). Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study. *Tobacco Control*, 32:e37–e44

Modeling estimated that prohibiting characterizing flavors would result in:



800 fewer deaths/year
due to increased cigar
cessation among adults

~~**112,000**~~

fewer cigar smokers
among each cohort
of 18-year-olds

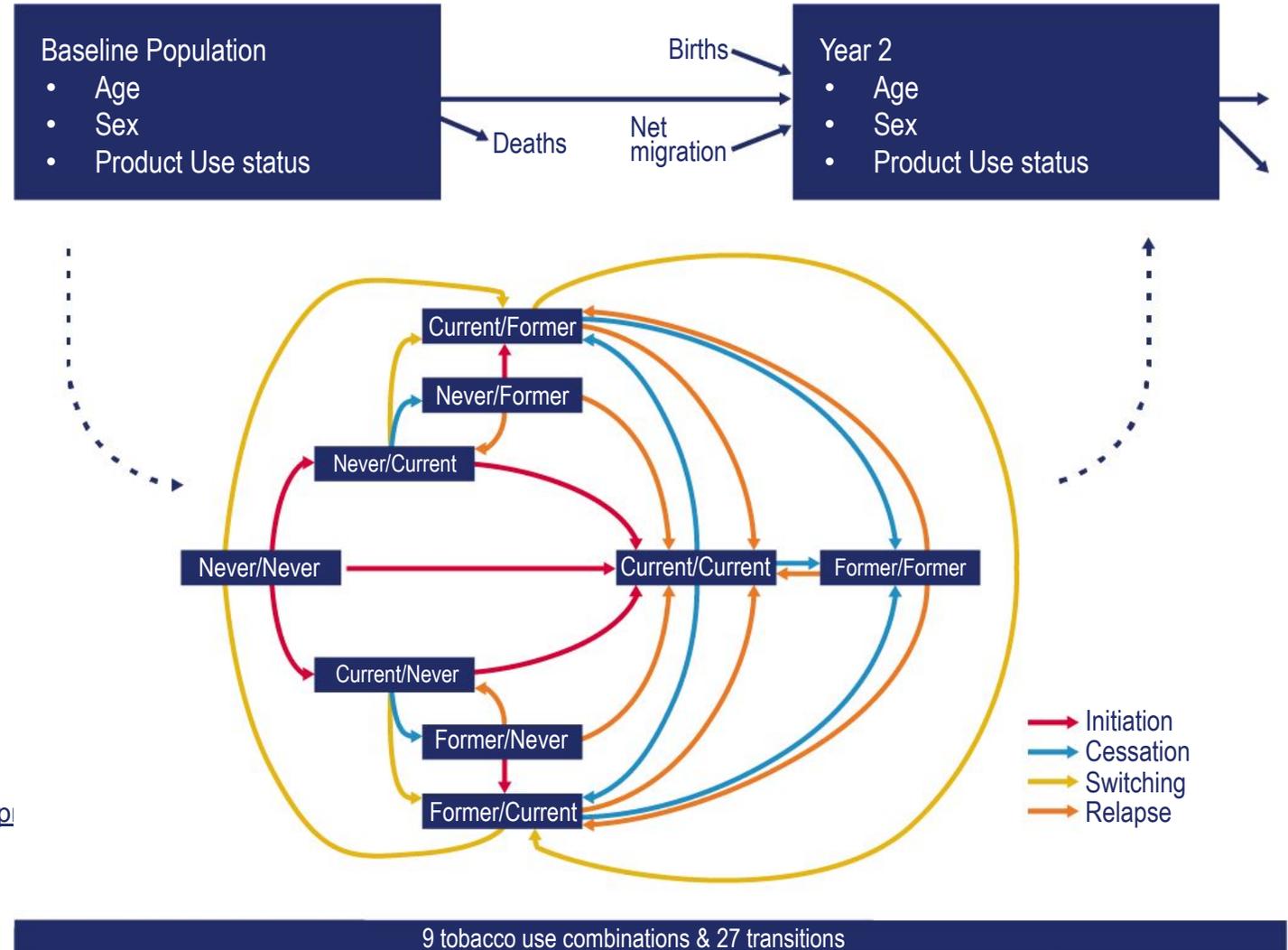
Rostron, B.; Corey, C.; Holder-Hayes, E.; Ambrose, B. Estimating the Potential Public Health Impact of Prohibiting Characterizing Flavors in Cigars throughout the US. *Int. J. Environ. Res. Public Health* **2019**, *16*, 3234. <https://doi.org/10.3390/ijerph16183234>

POTENTIAL NICOTINE PRODUCT STANDARD

Two-product model used to project impacts on tobacco use, morbidity, and mortality.^{1, 2}

Product 1: combustible products (including low nicotine cigarettes)

Product 2: non-combustible products (including e-cigarettes)



1

<https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes>

² Apelberg BJ, Feirman SP, Salazar E, et al.(2018). Potential public health effects of reducing nicotine levels in cigarettes in the United States. New England Journal of Medicine, 378(18), 1725-1733.

NICOTINE MODEL: 2018 STUDY RESULTS



About

5 million

adult smokers would quit smoking within just one year after implementation, compared to the baseline scenario



More than

134 million

years of life gained among the U.S. population by the year 2100



Only about

1.4%

of the U.S. adult population would smoke cigarettes by 2100



By the year 2100, more than

8 million

premature deaths from tobacco could be avoided

Sources of uncertainty may include:

- (1) structural assumptions of the model
- (2) parameter inputs
- (3) variability among individuals in the population



Institute of Medicine. 2015. Assessing the Use of Agent-Based Models for Tobacco Regulation. Washington, DC: The National Academies Press. <https://doi.org/10.17226/19018>.



Transparency and documentation of model inputs and assumptions



Comparisons of results across different modeling approaches



Quantifying how uncertainty in inputs translates into uncertainty in outputs

CLOSING THOUGHTS

- FDA regulates tobacco products using a population health standard considering risks to individuals as well as the impact of an action on the U.S. population
- Computational modeling can be a useful tool to inform regulatory actions by incorporating product risks and use behaviors to project the potential impacts of different regulatory decisions
- Useful features of models to inform tobacco product regulation include the relative impact of different regulatory options and potential countervailing effects, such as tobacco product substitution

