



Computational Modeling for Assessing Population Impact (COMPUTE)

Population Modeling: What Is It and Why Does It Matter?

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Background

- ✓ **Why We Use Models**
- ✓ **Application In Other Sectors**

Why Modeling in the Tobacco Space

Regulatory Application in the Tobacco Space

Modeling Requirements

Modeling Framework

Summary

Why do we use models?

“

If we had observations of the future, we would obviously trust them more than models, but unfortunately...

...observations of the future are not available at this time.

”

– Tom Knutson & Robert Tuleya



What is a Computational Model?

Computer code that is used to simulate a complex system and predicts outcomes based on specific changes to the system

Financial Industry



Academia

Insurance Industry



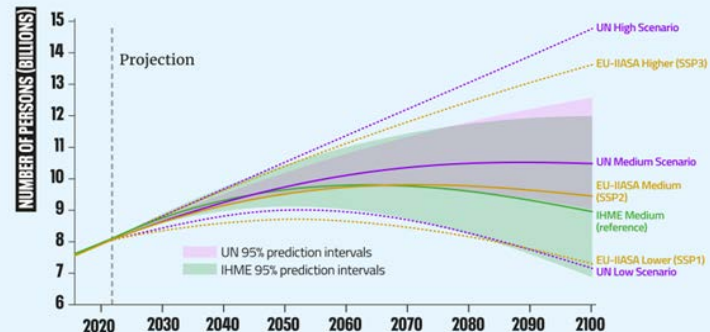
U.S. DEPARTMENT OF
ENERGY

Healthcare Industry

Public Health



POPULATION PROJECTIONS TO 2100 COMPARISONS



Source: United Nations Population Division, 2022

MRTPA/PMTA Requirements (§911/910)

Section 911(g)(1) – Modified Risk Tobacco Products (MRTTP) – Reduced Risk

Demonstrate that a MRTTP as used by the consumers will:

- A. Significantly **reduce the risk and harm of tobacco-related disease** to the tobacco user.
- B. Secondly it should benefit the **health of the population as a whole**, taking into account both users of tobacco products and persons who do not currently use tobacco products.

“**FDA encourages** the development and application of innovative analytical methods to make preliminary estimates of the potential effects of some change in the marketplace. Methods...include secondary data analyses and **computational modeling**.”

Section 910 – Premarket Tobacco Product Application (PMTA) – New Tobacco Products*

Demonstrate that [the product]”... “...is appropriate for the **protection of the public health** shall be determined with respect to the **risks and benefits to the population as a whole.**”

“**FDA recommends that...**The estimates should integrate all of the information in the PMTA regarding the product and its potential effects on health—to **provide an overall assessment** of the potential effect that the product’s marketing has or may have on **overall tobacco-related morbidity and mortality.**”

FDA PMTA Final Rule 2019

Source: Food and Drug Administration Center for Tobacco Products, 2012: Guidance for Industry - Modified Risk Tobacco Product Applications: Draft Guidance. Center for Tobacco Products.

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm262073.htm>

Population Modeling Framework Requirements

Risk
of using the
new tobacco
product relative
to smoking

An icon consisting of seven stylized human figures in green, arranged in a row. They are of varying heights and widths, representing a diverse population.

Benefit/Risk

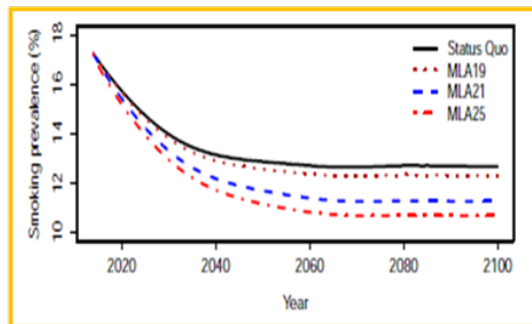
Changes
in product use
patterns due to
the introduction
of the product

Tobacco Product Standard Must be appropriate for the protection of public health

<https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/rules-and-regulations>

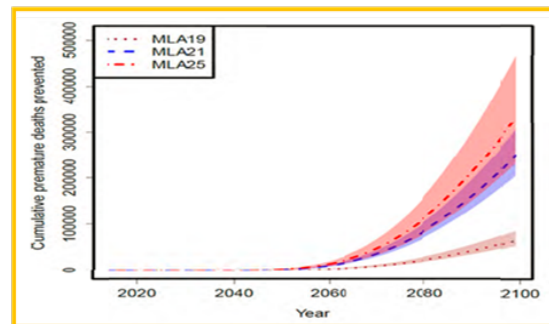
IOM's 2015 Report on Raising Minimum Age of Legal Access to Tobacco Products

Adult Smoking Prevalence – SimSmoke



IOM (Institute of Medicine). 2015. *Public health implications of raising the minimum age of legal access to tobacco products*. Washington, DC: The National Academies Press.

Premature Deaths Prevented – CISNET



^CISNET: The Cancer Intervention and Surveillance Modeling Network

Regulatory Modeling Best Practices

Models must undergo rigorous development, evaluation and ensure that the model development process is:

Transparent



Comprehensive



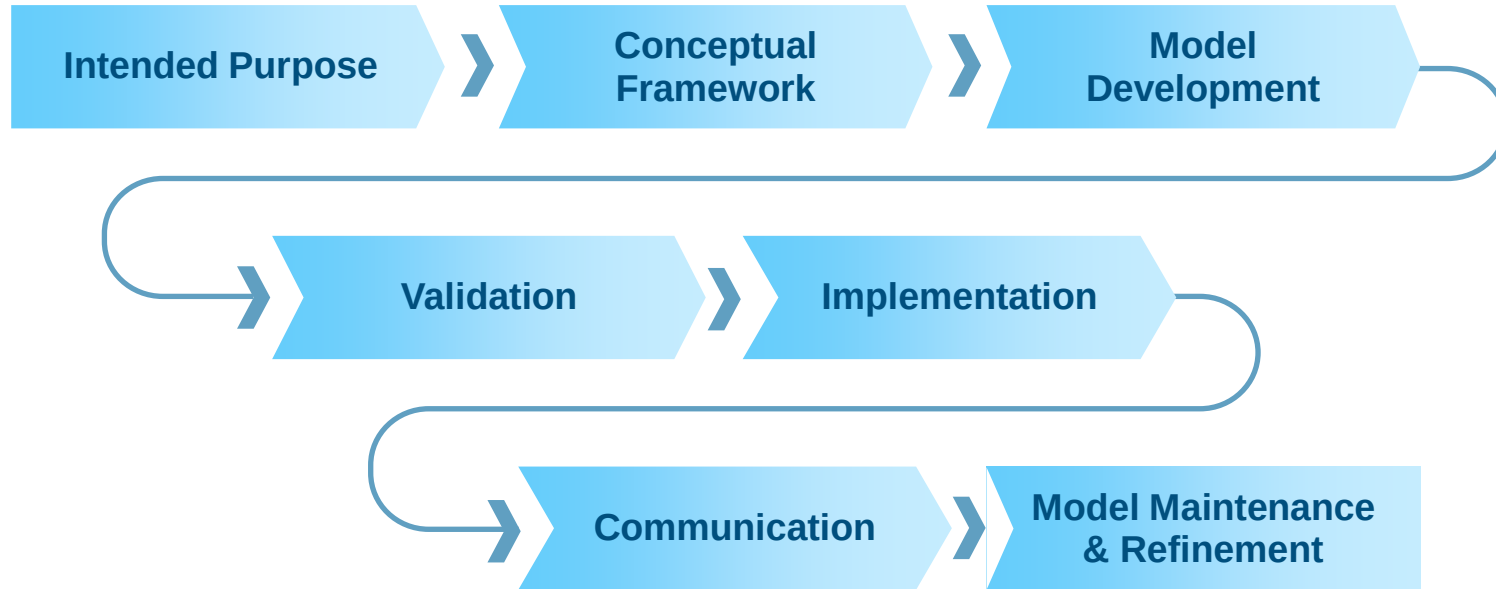
Well-documented



Modeling is an iterative process and should be updated as new information becomes available

George Rochester (CTP-FDA), Presentation at TPSAC, April, 2014.

Regulatory Modeling Best Practices

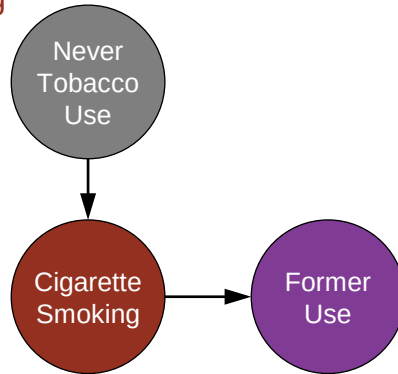


George Rochester (CTP-FDA), Presentation at TPSAC, April, 2014.

Conceptual Population Modeling Framework

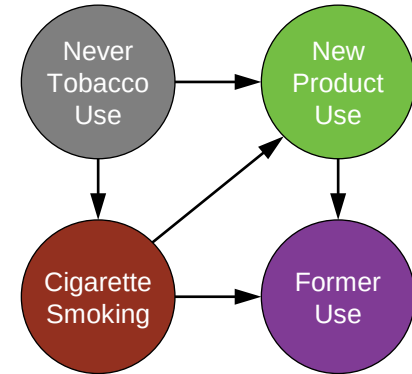
Base Case

Cigarette smoking is the most harmful tobacco product



Modified Case

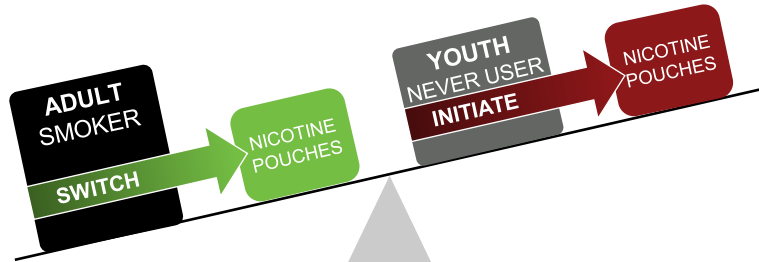
Introduction of a new nicotine delivery product has the potential to reduce harm to public health



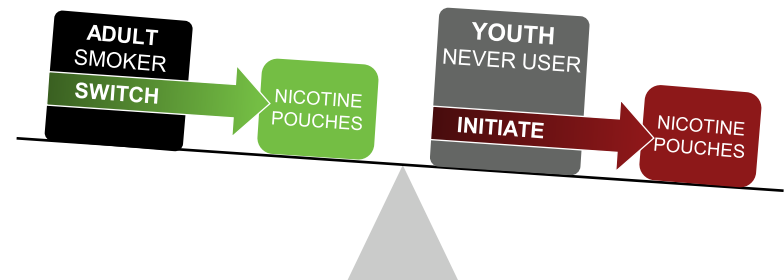
The difference between the Modified & Base Case determines whether the new product results in a net benefit to the population as a whole

Tipping Point Sensitivity Analyses

Public Health
BENEFIT



Public Health
RISK



Tipping point can be used to evaluate the
risk of initiation versus the benefit from adult smoker switching

MODELING is an important tool to answer questions regarding long-term population health impacts of a new product



Allows an integrated approach based on all the lines of evidence to determine the net benefit of marketing a new product



Provides the capability to test varying effects of Risk and Behavior (users and nonusers)



Is the best way to forecast numerous potential future scenarios