POPULATION HEALTH STANDARDS FOR MODIFIED RISK TOBACCO PRODUCTS

70TH TOBACCO SCIENCE RESEARCH CONFERENCE

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OVERVIEW

- Population health standards related to different pathways to market
- The role of social and behavioral sciences in understanding the population health impact of tobacco products
- Examples of studies used in the scientific literature to assess behavior and population health, including:
  - Consumer perception studies
  - Surveys of perceptions and tobacco use behaviors
  - Computational modeling

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FD&C) ACT

The Family Smoking Prevention and Tobacco Control Act, which amended the Federal Food Drug & Cosmetic (FD&C) Act, describes multiple pathways for introducing new products to the market, including Substantial Equivalence (SE) Reports and Premarket Tobacco Product Applications.

In addition, a manufacturer may submit a modified risk tobacco product application if seeking to market a product to reduce harm and the risk of tobacco-related disease.

In May 2016, FDA finalized a rule to extend its tobacco product regulatory authority over all products that meet the statutory definition of “tobacco products”, as well as their components and parts, except for accessories of newly deemed products.

POPULATION HEALTH STANDARDS

When assessing tobacco products, FDA is to consider:

- Impacts on users and non-users
  - In general, this includes an assessment of the health risks of the product and also the likelihood of initiation of tobacco use among non-users and likelihood of cessation among current users.

SUBSTANTIAL EQUIVALENCE (SE)

The SE pathway to market a tobacco product includes:

- A direct comparison of a new product with a valid predicate product
- FDA assessing whether the new and predicate products have different characteristics
- FDA determining whether differences in product characteristics "raise different questions of public health"

Some differences in characteristics between the new and predicate tobacco product, such as a change in flavor or portion size, may raise different questions of public health, as they could influence tobacco use behaviors.

PREMARKET TOBACCO PRODUCT APPLICATIONS (PMTA)

When evaluating a premarket tobacco product application, FDA is required to evaluate the risks and benefits to the population as a whole, including:

> "(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
>
> (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products."
>
> - Section 910(c)(4)

MODIFIED RISK TOBACCO PRODUCT APPLICATIONS (MRTPA)

FDA shall authorize the marketing of a tobacco product as an MRTP if it determines the product, as it is actually used by consumers, will:

> "(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
>
> (B) 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."

- Section 911(g)(1)

MODIFIED RISK TOBACCO PRODUCT APPLICATIONS (MRTPA)

An MRTP order may also be issued if, among other determinations, FDA finds that:

- "…such order would be appropriate to promote the public health…"
- "…the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies…"
- Such an order would be "…expected to 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."

- Section 911(g)(2)

THE ROLE OF SOCIAL AND BEHAVIORAL SCIENCES IN MRTPAS

- A broad range of scientific information is assessed in the regulatory evaluation of a tobacco product.

- A multi-faceted scientific review carefully considers the risks and benefits to the population as a whole including the health risk to the individual users of the products and the impacts on non-users, including the likely impact on initiation and cessation of tobacco use.

- Evidence from the social and behavioral sciences plays an important role in this evaluation.

POPULATION HEALTH IS IMPACTED BY THE LIKELIHOOD OF DIFFERENT PATTERNS OF UPTAKE AND CESSATION

In addition to the health risk profile of a modified risk tobacco product, the impact of a new product on population health depends, in part, on who ends up using these products.

Common research questions to be addressed include:

- How likely are current tobacco users to switch to and use modified risk tobacco products?
- Does the marketing of the product increase the likelihood that non-users will start using tobacco products?
- Does the marketing of the product decrease the likelihood that existing users will stop using tobacco products?

EXAMPLES OF TRANSITIONS IN TOBACCO PRODUCT USE

- Tobacco users may switch from other tobacco products to the new tobacco product;
- Non-users (including never and former tobacco users) may initiate the new tobacco product;
- Tobacco users and nonusers who, after adopting the new tobacco product, may switch to or switch back to other tobacco products that may present higher levels of individual health risk;
- Tobacco users may opt to use the new tobacco product rather than cease tobacco use altogether;
- Tobacco users who may use the new tobacco product in conjunction with other tobacco products.

EXAMPLES OF TYPES OF STUDIES TO EXAMINE THE POTENTIAL FOR PRODUCT UPTAKE OR CESSATION

Examples of studies that could provide information on the likelihood of changes in tobacco use behavior as a result of a modified risk tobacco product include, but are not limited to:

- Abuse liability studies
- Marketing research studies
- Experimental studies of upstream determinants of tobacco use uptake, such as consumer perceptions and behavioral intentions
- Observational studies of behavior (e.g., cross-sectional surveys, prospective studies)
- Randomized controlled trials of product switching among existing tobacco users

WHAT ARE CONSUMER PERCEPTIONS?

- Included in theories of consumer psychology and health behavior
  - Precursors to behavior
- Beliefs, attitudes, judgments or perceptions about the product:
  - Appeal
  - Health risk
  - Absolute and relative to other products and quitting all tobacco use
  - Sensory expectancies (e.g., flavor)
  - Other factors that may be deemed relevant to product uptake, use, and acceptance by consumers
- Intentions to purchase, try, discontinue use, or use the product
  - May be informed by the above perceptions

EXAMPLES OF PERCEPTIONS AND INTENTIONS

Appeal	Novelty of the product
	Beliefs about positive attributes of users of the product
	Beliefs about the quality of the product/positive attributes of the product
Health risk	Perceived health risk; overall and by disease outcome (absolute & compared to other products and to quitting all tobacco use)
	Perceived addiction risk
Intentions	Likelihood to purchase among non-users, users of other similar products, users of other types of tobacco products (e.g., cigarette smokers)
	Intention to try product in next XX months (among current users and non-users)
	Intention to use product instead of/in addition to another currently used tobacco product

EXPERIMENTAL CONSUMER PERCEPTIONS STUDIES

Some characteristics of experimental consumer perceptions studies:

- Tightly controlled, randomized assignment
- Manipulation of independent variable (e.g., presence or absence of a claim) to isolate the effect of those changes or interactions of those changes with other factors (e.g., tobacco use status)
- May use various kinds of stimuli including text or pictures
- Can examine range of potential outcomes, including:
  - Consumers' beliefs about the health risks of using the product
  - The ability of consumers to understand the modified risk information and the significance of the information in the context of one's health
  - Intentions to use the product

QUALITATIVE RESEARCH METHODS

- Are concerned with beliefs, perceptions, and experiences which cannot be expressed numerically
- Describes social phenomena as they occur naturally
- Often takes an inductive approach and is used to develop concepts and theories
- Examples include:
  - In-depth interviews – Intensive individual interviews with a small number of respondents to explore their perspectives. Findings could inform the development of a survey instrument.
  - Focus group – A small-group, focused discussion guided by a trained facilitator. Findings could be used to develop more generalizable research.

USING SURVEY DATA TO INFORM POPULATION HEALTH STANDARDS

- Surveys are often used as part of general or routine data collection; frequently used in observational settings

- Can provide insights on consumer attitudes, beliefs and behaviors related to tobacco products
  - Can assess behaviors, including current or previous use of tobacco products
  - Can assess detailed characteristics of users
  - May provide indirect information to make inferences about future behaviors

- Many considerations for conducting surveys to inform social/behavioral research, including:
  - **Cross-sectional** to assess behaviors at a point in time vs. **longitudinal studies** to understand trajectories within individuals over time
  - **Representative** vs. **convenience** samples – implications for external validity

STRENGTHS AND LIMITATIONS OF NATIONAL SURVEY DATA

Strengths of national survey data:

- Characterize current use status of a product category (e.g., e-cigarettes) at the population level (e.g., never, current, former)
- Describe the burden of use across different subgroups (e.g. by demographics, by current smoking status)
- Monitor secular trends in use or related behaviors over time

The utility of national estimates may be limited given:

- Questions focus on product categories generally, not specific products, brands, or subtypes
- Cross-sectional nature of most survey data

COMPUTATIONAL MODELING

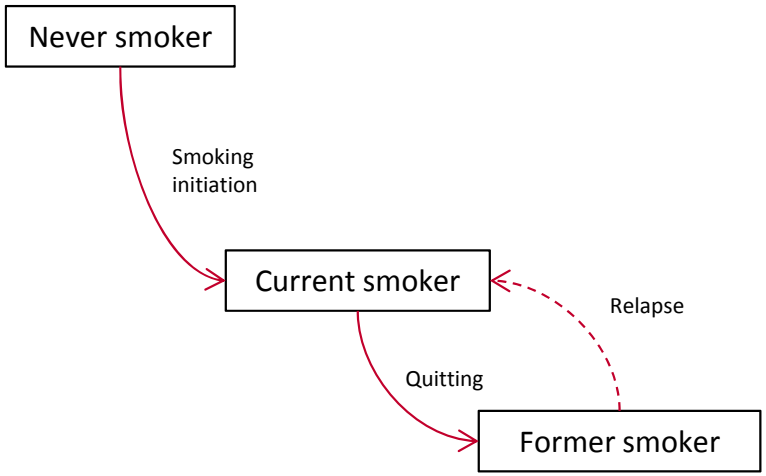
Computational modeling can be used to make preliminary estimates of the potential impacts of a new product on tobacco use behaviors and population health.

Several studies have modeled the potential impacts of new products or policies on population health. See, for example, Vugrin et al., (2015):

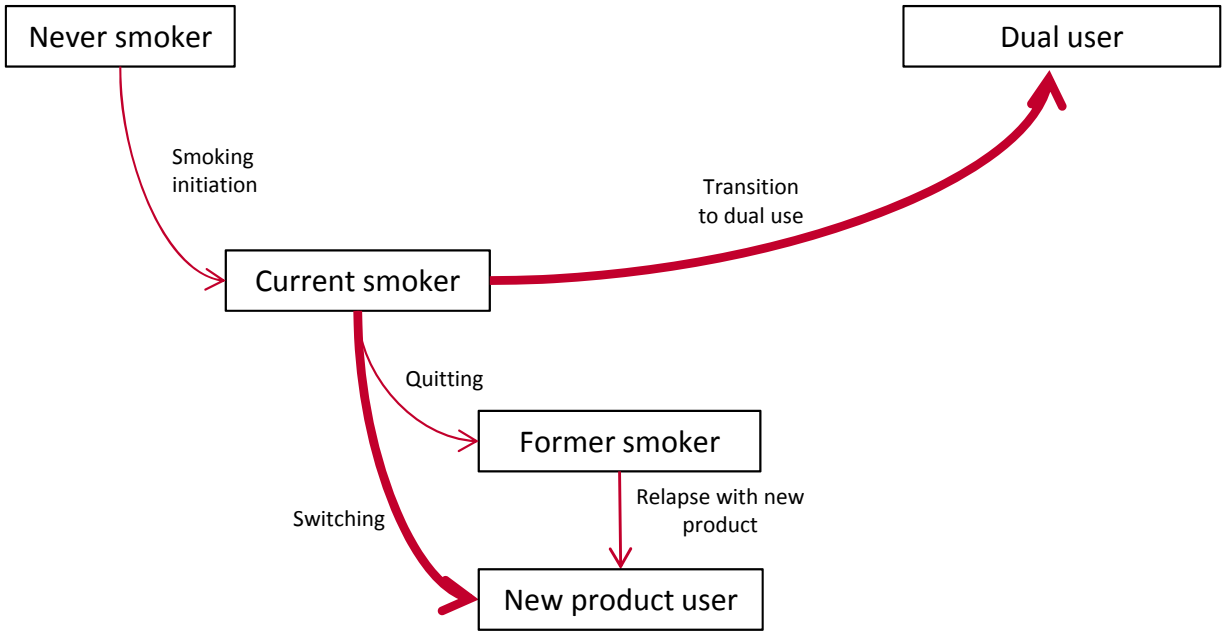
- "Model results show that population health benefits are particularly sensitive to product risks and initiation, switching, and dual use behaviors."

EXAMPLE OF THE POTENTIAL IMPACT OF A NEW PRODUCT ON SMOKERS AND NON-SMOKERS

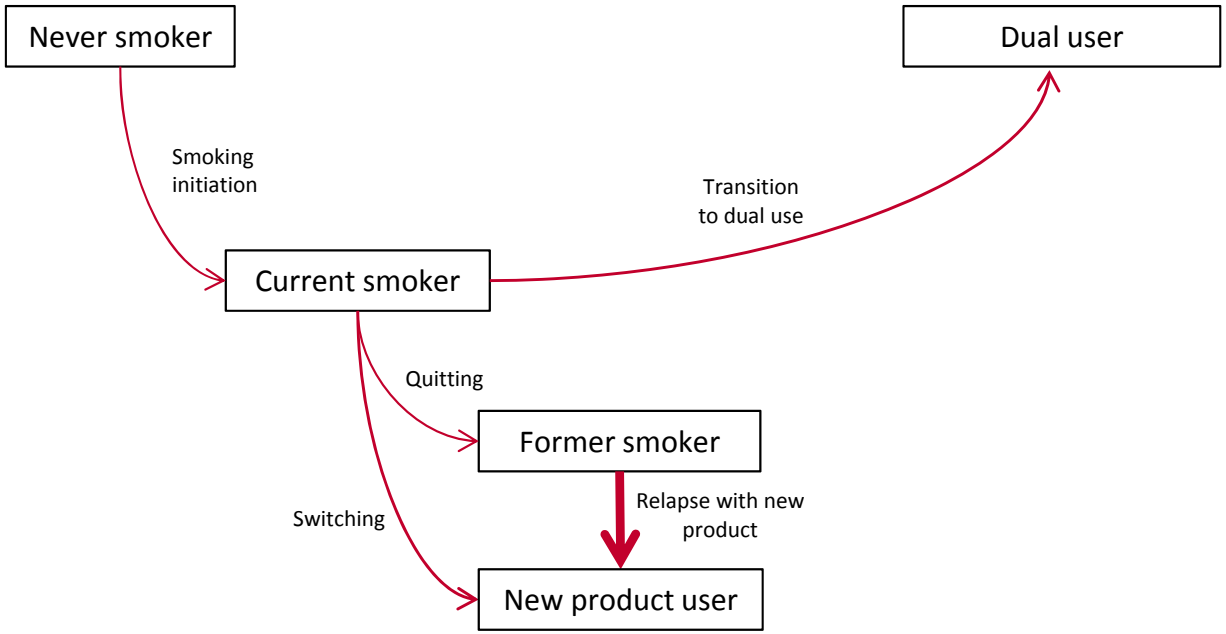
Cigarette smoking only



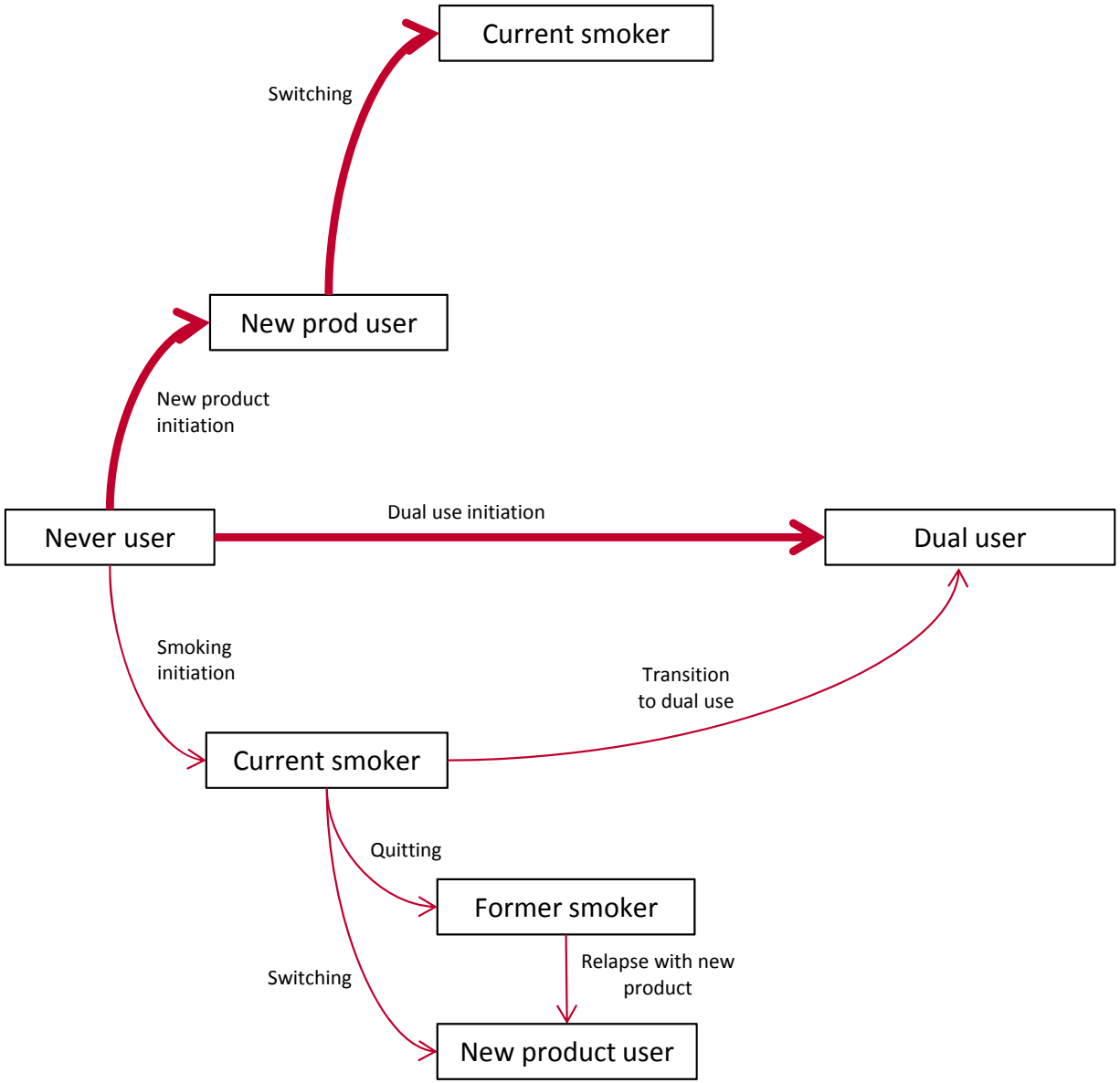
Impact on current smokers

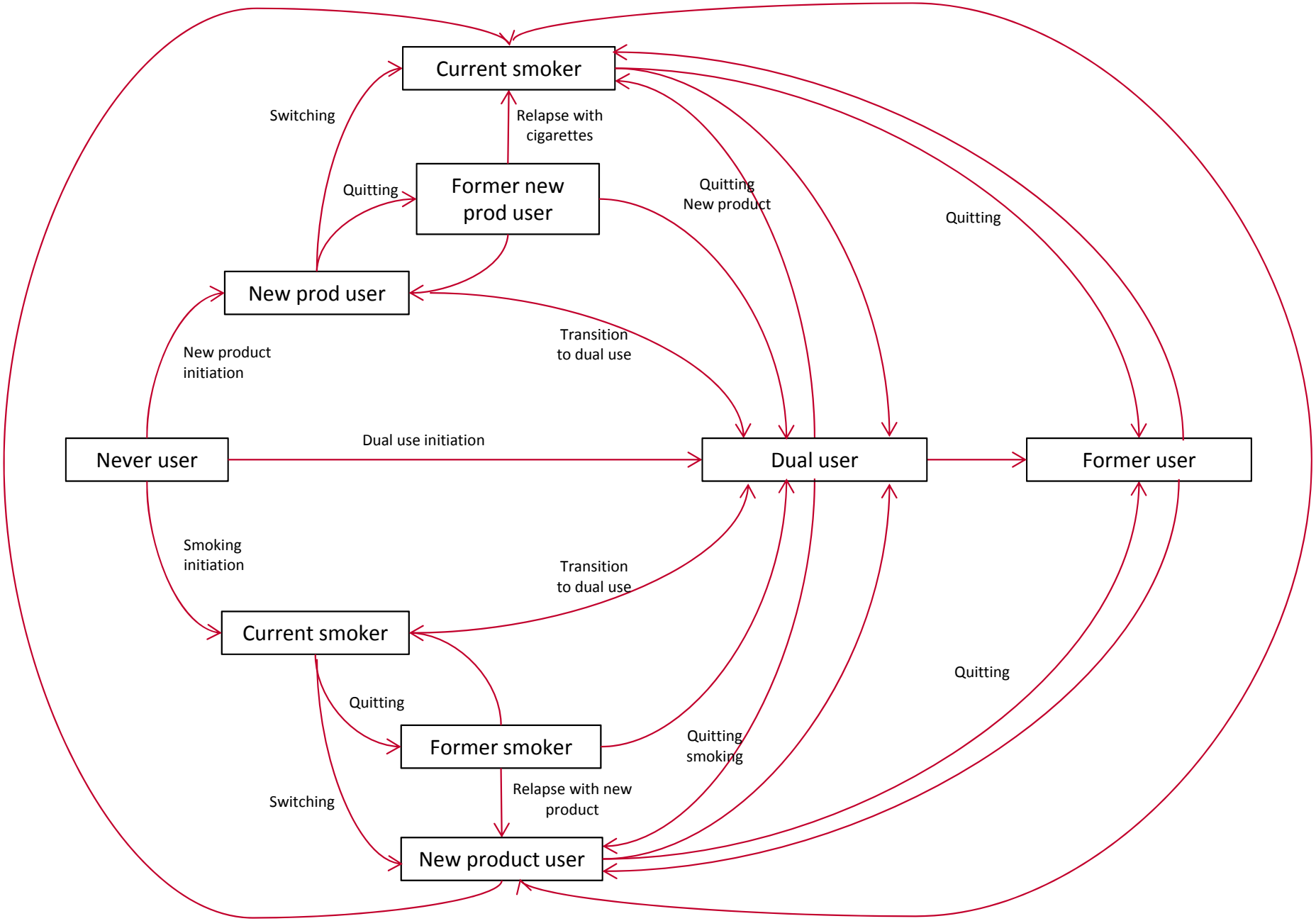


Impact on former smokers



Impact on never smokers





SUMMARY

Population health standards for tobacco regulation require FDA to consider impacts on the health of the population as a whole, including the impacts to tobacco users and non-users.

The population health impact depends on the health risks of the product to users and whether, how, and by whom, the modified risk products are used.

Social and behavioral scientific information can provide insight about the potential impacts of new and modified risk tobacco products prior to market.

THANK YOU