What the research says...

CAsToR Briefing

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The Center for the Assessment of Tobacco Regulations (CAsToR) aims to provide evidence-based and expert-informed modeling of the behavioral and public health impacts of FDA tobacco rules or other regulatory actions, focusing on Impact Analysis, Behavior and Health Effects as Scientific Domains.

How a nicotine product standard benefits public health

This brief summarizes key points from CAsToR's public comment to Docket No. FDA-2024-N-5471 in support of the proposed rule "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products." See full comment: regulations.gov/comment/FDA-2024-N-5471-4212

Background

On January 16, 2025, the FDA proposed a rule to regulate the nicotine yield of tobacco products and establish a maximum level of nicotine (0.70 mg of nicotine per gram of tobacco) in cigarettes and certain other combusted tobacco products.

In response, CAsToR researchers submitted a public comment in support of implementing a nicotine product standard by outlining its benefits to public health. This brief summarizes the contents of CAsToR's submitted public comment.

Key takeaways

Drawing on CAsToR research, we present evidence that a nicotine product standard would

- avert millions of premature deaths,
- directly benefit people with mental health conditions who smoke,
- improve maternal and infant health outcomes,
- lead to economic benefits due to life-years gained during working years,
- **not** lead to compensatory smoking, and
- yield minimal illict trade concerns.

In all, the evidence strongly **supports** the implementation of the nicotine product standard.

Millions of premature deaths attributed to smoking would be averted.

A recent US population micro-simulation modeling study estimated that if a nicotine product standard is implemented by 2027, smoking prevalence would be expected to decrease to <1% by 2040, with 1.7 million (1.3 to 1.7) premature deaths averted through 2100.[1]

Another macro-simulation model compares the projected mortality outcomes from 2025 to 2100 between two nicotine reduction scenarios starting in 2025. The results show that an **immediate** reduction of nicotine to non-addictive levels (consistent with the proposed standard) enacted in 2025 could avert between 1.2 and 2.3 million premature deaths by 2100. In comparison, a **gradual** nicotine reduction policy (over 10 years) would prevent 0.5 to 1.3 million premature deaths over 2025-2100.[2]

CAsToR researchers also estimated the human cost of not enacting a nicotine product standard earlier, starting from when tobacco companies first had the technical ability to implement such a standard. A nicotine product standard implemented in 1985 could have averted 16.3 million smoking attributable deaths from 1985 to 2084. If implemented 10 years earlier in 1975, the total deaths averted would increase to 18.9 million from 1975 to 2074. Yet another decade sooner could have averted 21 million from 1965 to 2064.[3]

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People with mental health conditions who smoke would benefit.

People with mental health conditions have much higher rates of cigarette smoking compared to the general population. A Cochrane systematic review of 106 studies found that smoking cessation does not lead to worse mental health symptoms[4] and may even improve mental health symptoms.[5]

CAsToR simulation modeling analysis evaluated the potential impact of a nicotine product standard on people with and without major depression. This model found that, if implemented in 2027, a nicotine product standard would result in 8.5 million fewer cases of depression by 2100, and ~200,000 premature deaths averted among people with major depression.[1]

Maternal and infant health outcomes would improve.

Smoking during pregnancy markedly increases adverse outcomes, including infant death. CAsToR investigators developed the Smoking, E-Cigarette Use, and Pregnancy (SEP) microsimulation model to project maternal and infant outcomes in the U.S. population. If a nicotine product standard takes effect in 2027, the model estimates ~63,000 infant deaths prevented by 2100 and ~$4.9 billion in direct healthcare savings from avoided pregnancy-related morbidity.[6]

Multiple strands of evidence refute claims about 'compensatory' smoking.

'Compensatory' smoking occurs when someone smokes more than they would have otherwise in an attempt to self-titrate their nicotine content.

Multiple trials have demonstrated that compensatory smoking to offset the reduction of nicotine as the result of a product standard is unlikely since, at the post-policy implementation nicotine levels, no compensatory behavior will be able to sustain a reinforcing effect to nicotine addiction.[7,8,9,10,11] It is also improbable because lower-risk alternatives, such as e-cigarettes, oral nicotine pouches, and nicotine replacement therapies, are now widely available.[12,13,14]

There are economic gains in worker productivity and consumer spending due to life-years gained.

With fewer people living with chronic diseases caused by smoking, workers will be able to contribute longer to the labor market. Modeling research estimates that if a nicotine product standard is implemented by 2027 as proposed, overall productivity will increase by $266 billion USD through 2100. The increased life-years gained across the population will also lead to an additional $1.2 trillion in consumer spending.[1]

Projected health and economic gains outweigh concerns about illicit trade.

Current estimates of U.S. illicit trade are based on evasion of state cigarette taxes. This type of tax evasion across state borders is largely irrelevant when considering a nicotine standard implemented at the federal level. The FDA also authorizes viable and legal nicotine substitute products that are widely available to consumers.

Even if an illicit market for nicotine cigarettes forms, it would only dampen the potential benefits of the standard; if illicit trade reduces the number of people who would quit smoking in response to the standard, this affects only the magnitude of health and economic gains, but not the direction of positive change for public health.[2]

Recommendation

The evidence strongly supports the implementation of a nicotine product standard. CAsToR recommends the FDA to finalize the nicotine product standard without delay, which would result in major public health gains by reducing combustible tobacco morbidity and mortality.

Conflicts of interest: None. None of the authors accepts funds from the tobacco or vaping industries.

Citations

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