

The Science of Decision Making: Connecting People and Policy

Enhancing the Economic Impact Analysis Used in FDA's Rules for Tobacco Products (Project 1)

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Abstract:

As part of its rulemaking process, the U.S. Food and Drug Administration (FDA) is required to conduct an economic impact analysis that assesses the costs and benefits of proposed regulations and to select the option that maximizes the net economic benefit. There are numerous challenges inherent in conducting this type of analysis, from fully assessing the various costs and benefits of proposed rules to quantifying these costs and benefits, often with incomplete data and evidence. The comments provided to FDA on the economic impact analysis contained in its proposed rule on required warnings for cigarette packages and advertisements highlight these challenges. The overarching aim of this project is to produce new evidence that will inform and refine the FDA's economic impact assessments of future proposed rules. This will be done through a combination of behavioral economics experiments with original data collection, acquisition of existing archival, survey, and commercial databases, and merged data analyses that address the issues discussed above, as well as others that emerge in coming years. To accomplish this, a variety of activities will be done to address three specific aims that together address most of the FDA's research priorities around understanding the role of economics and policies on tobacco use and perceptions: Aim 1 - assess the impact of FDA regulatory actions and other tobacco control policies on tobacco use and related outcomes, including the impact on trajectories of tobacco use among young people and adults, the differential impact of these actions on disparate populations, and the differential impact on the use of traditional and emerging tobacco products; Aim 2 - Assess the impact of FDA regulatory actions and other tobacco control policies on the consumer surplus obtained by tobacco users through a behavioral economics experiment that will quantify the extent of present bias, projection bias, and time inconsistencies in decisions about tobacco use and the implications of these biases for assessing changes in consumer surplus; Aim 3 - Extend the range of costs and benefits including in assessing the economic impact of FDA regulatory actions to include a broader set of health and economic benefits than that included in previous FDA assessments. This project will produce new evidence that addresses these challenges and better informs the FDA's economic impact assessments of future proposed rules concerning tobacco products.