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FDA underestimated net benefits of warning labels on cigarette packaging

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A paper released today by leading economists concludes that the Food and Drug Administration's controversial cost-benefit analysis of its graphic warning label regulation grossly underestimated the net benefits associated with implementing its own rule.

The authors, including Kenneth Warner from the U-M School of Public Health, stress that the FDA's approach, which counted the lost pleasure from smokers who quit as a cost of the graphic warning labels (GWLs), is a major flaw that severely undercuts the estimated benefits of the proposed rule. The authors urge the FDA to consider their findings in analyses of future proposed tobacco product regulations.

"The FDA estimate relies on standard economic models, but those don't apply well to cigarette smoking," said co-author Frank Chaloupka,

director of the Health Policy Center at University of Illinois-Chicago. "For example, if labels effectively move smokers to quit or cut back, the FDA's analysis actually considers this to be a cost attributed to lost pleasure, rather than a benefit—that's a serious mistake.

"Consumers choosing to quit shows that they are deriving more utility from quitting than from continuing to smoke. Hence, their quitting produces benefits to them that exceed any potential lost consumer surplus."

According to the authors, the FDA's reliance on lost consumer surplus, "lost pleasure," that would result from reduced tobacco use, is a critical concern. Consumer surplus reflects the difference between people's willingness to pay for a product and the actual price they pay in the marketplace.

The authors say for most smokers it's inappropriate for the FDA to reduce the estimated benefits of its proposed GWL rule due to lost consumer surplus or "lost pleasure" because it's likely that the vast majority of smokers do not find smoking pleasurable and derive little consumer surplus from smoking.

These findings are explained in part because starting to smoke can be an irrational decision. Most smokers start at a young age and aren't well-informed rational consumers who understand the addictive power of nicotine or the health and economic consequences of smoking.

The evaluation, which was supported by a grant to U-M from the Robert Wood Johnson Foundation, discusses other concerns about FDA's cost-benefit analysis of its proposed GWL rule, which also apply more broadly to other tobacco regulation.

—The FDA's evaluation of the impact of GWLs on smoking prevalence

underestimated the impact by a factor of 30 or more. The FDA estimated that the GWL rule would reduce smoking by 0.4 percent; more recent analysis indicates that the figure should be 12 percent or higher.

—The FDA omitted many potentially important benefits. The FDA failed to consider how GWLs would reduce exposure to second-hand smoke; this reduction could potentially prevent thousands of deaths and save $1.7 billion in lost productivity per year. Reductions in maternal smoking during pregnancy were ignored; the cost of several health care services needed to treat diseases caused by smoking were omitted; and the reduction in the number of cigarettes nonquitters will smoke each day was not considered in the FDA's analysis.

—The FDA further underestimated the benefits of its GWL rule by spreading the reduction in all benefits out uniformly over a period of decades. Discounting thereby diminishes the benefits. In fact, several benefits from quitting smoking are realized rapidly. For example, the risk of a heart attack or stroke is immediately reduced after quitting and most excess risk is gone within one to five years.

"It's critical for the FDA to fully understand the substantial health and economic benefits of graphic warning labels and of future tobacco product regulations," said co-author Warner, U-M professor of health management and policy. "Most of the concerns we raise apply to evaluating the costs and benefits of other tobacco rules, especially the inappropriate handling of lost consumer surplus. We believe the FDA should consider our concerns in future analyses."

The paper, "An Evaluation of FDA's Analysis of the Costs and Benefits of the Graphic Warning Label Regulation," was submitted as a public comment on the FDA's proposed rule to assert authority over all tobacco products, including e-cigarettes.

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