

# Cigarette graphic warning labels and smoking preference in Canada: A critical examination and reformulation of the FDA regulatory impact analysis

Huang, J., Chaloupka, F., Fong, G.T.

## **Abstract**

**BACKGROUND:** The estimated effect of cigarette graphic warning labels (GWL) on smoking rates is a key input to the Food and Drug Administration's (FDA) regulatory impact analysis (RIA), required by law as part of its rule-making process. However, evidence on the impact of GWLs on smoking prevalence is scarce.

**OBJECTIVE:** The goal of this paper is to critically analyse FDA's approach to estimating the impact of GWLs on smoking rates in its RIA, and to suggest a path forward to estimating the impact of the adoption of GWLs in Canada on Canadian national adult smoking prevalence.

**METHODS:** A quasi-experimental methodology was employed to examine the impact of adoption of GWLs in Canada in 2000, using the USA as a control.

**FINDINGS:** We found a statistically significant reduction in smoking rates after the adoption of GWLs in Canada in comparison with the USA. Our analyses show that implementation of GWLs in Canada reduced smoking rates by 2.87-4.68 percentage points, a relative reduction of 12.1-19.6%; 33-53 times larger than FDA's estimates of a 0.088 percentage point reduction. We also demonstrated that FDA's estimate of the impact was flawed because it is highly sensitive to the changes in variable selection, model specification, and the time period analysed.

**CONCLUSIONS:** Adopting GWLs on cigarette packages reduces smoking prevalence. Applying our analysis of the Canadian GWLs, we estimate that if the USA had adopted GWLs in 2012, the number of adult smokers in the USA would have decreased by 5.3-8.6 million in 2013. Our analysis demonstrates that FDA's approach to estimating the impact of GWLs on smoking rates is flawed. Rectifying these problems before this approach becomes the norm is critical for FDA's effective regulation of tobacco products.

## **Recommended Citation**

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