Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis

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Abstract

Background
The estimated effect of cigarette graphic warning labels (GWLs) on smoking rates is a key input to FDA's regulatory impact analysis (RIA), required by law as part of its rulemaking process. However, evidence on the impact of GWLs on smoking prevalence is scarce.

Objective
The goal of this paper is to critically analyze 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 U.S. as a control.

Findings
We found a statistically significant reduction in smoking rates after the adoption of GWLs in Canada in comparison to the U.S. Our analyses show that implementation of GWLs in Canada reduced smoking rates by 2.87 to 4.68 percentage points, a relative reduction of 12.1 to 19.6% — 33 to 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 analyzed.

Conclusions
Adopting GWLs on cigarette packages reduces smoking prevalence. Applying our analysis of the Canadian GWLs, we estimate that if the U.S. had adopted GWLs in 2012, the number of adult smokers in the U.S. would have decreased by 5.3 to 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.

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Background

The 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA) gave the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, and marketing of tobacco products. One key provision of the FSPTCA mandates more prominent warning labels for cigarettes and smokeless tobacco products. Specifically, FSPTCA requires pictorial or graphic warning labels (GWLs) covering the top 50 percent (the minimum percent recommended by the Article 11 of the World Health Organization's Framework Convention on Tobacco Control) of the front and rear panels of cigarette packages (Pub L No. 111-31 §201(a), 123 Stat 1776, 1842-45. 2009).

In June 2011, two years after FSPTCA became the law, FDA issued its first GWL regulations, which were later challenged by tobacco industry and subsequently struck down by the U.S. Court of Appeals (See Figure 1 for a timeline summarizing the events related to FDA's GWL regulations). One of the major reasons that the Court ruled against FDA was because FDA did not provide any "shred of evidence" that graphic warning images would "reduc[e] the number of Americans who smoke" (RJ Reynolds Tobacco Co v FDA, 696 F3d 1205, 1219, DC Cir 2012).

Despite the court ruling, the beneficial impact of warning labels, particularly large and prominent GWLs, has been well-documented.[1,2] Studies have shown that large GWLs on cigarette packages are an important source of health information for smokers and non-smokers.[3] Exposure to GWLs reduce cigarette packet appeal,[4] increase health knowledge, awareness and perception of risks associated with smoking,[5–11] strengthen intentions to quit,[5] encourage quit attempts,[4,7–9,12] increase use of quitlines,[13] prevent relapse,[14] discourage smoking initiation,[4,7,8] and decrease the odds of being a smoker.[12]

While the literature on the effectiveness of GWLs is substantial, the evidence to date is focused more on individual level impact than population impact, and the outcomes examined have been more distal indicators of smoking behavior than proximal indicators. And there is limited evidence on the impact of GWLs on smoking prevalence. The limited evidence for prevalence has critical implications for the ongoing legal and policy debates related to the proposed GWLs by FDA, particularly in light of recent failure by the Appeals Court in recognizing a large body of evidence on individual-level outcomes, and putting undue weight on population-level impact provided by FDA, which was not adequately prepared.

As part of its rulemaking process, FDA is required by law to assess all costs and benefits associated with its proposed regulations (known as the Regulatory Impact Analysis (RIA)), and to select the approach that maximizes net benefits when regulation is necessary. Accurately assessing the impact of adopting GWLs on smoking prevalence is a key input to FDA's RIA. In the economic analysis conducted for its graphic warning label regulations, FDA relied on the Canadian experience to estimate the effect of GWLs on U.S. smoking rates. FDA first compared trends in actual and estimated smoking prevalence in Canada and the U.S. from 1991 through 2009, projecting prevalence based on changes in inflation-adjusted cigarette taxes in the two countries in the period before Canada adopted GWLs in 2000. The difference between the projected prevalence rates and the actual prevalence rates for the two countries between 2001 and 2009 was then assumed to be the result of Canada's GWLs. FDA estimated that the reduction in smoking rates attributable to GWLs to be 0.088 percentage points, equivalent to a relative reduction of 0.4% of the U.S. smoking rate.

There are several major problems inherent in FDA's approach (See Table 1 for a summary of those problems). First, FDA used cigarette excise taxes rather than actual prices paid by smokers to quantify the changes in smoking rates attributable to cigarette prices. Cigarette excise taxes, official cigarette price indices, and actual prices paid by smokers may move in different directions. Controlling for cigarette taxes may attribute too much (little) of the differential decline in smoking rates to tax changes, and reduce (increase) the estimated impact of GWLs. Additionally, FDA's approach does not permit testing the statistical significance of changes in smoking rates resulting from the adoption of GWLs; as a result, it is impossible to ascertain whether the estimated impact of GWLs is statistically different from zero. More importantly, FDA's approach does not allow causal interpretations of the effect of GWLs.

Since those problems in FDA's approach may have profound impact on the estimates of the impact of GWLs on smoking prevalence, it warrants a careful and thoughtful re-examination. In this paper, we critically analyze FDA's approach to estimating the impact of GWLs on smoking rates in its RIA of the required graphic warnings. Employing a quasi-experimental methodology, this paper adds to the growing evidence on the impact of GWLs by examining the change in smoking rates in Canada after it implemented GWLs, compared to the U.S., where GWLs have not been implemented.

Methods

Difference-in-difference Model

To examine the impact of the implementation of GWLs on national adult smoking prevalence, we followed FDA's approach and used adult smoking prevalence data from the U.S. and Canada for 1991 - 2009, a period of 9 years before and after GWLs were introduced in 2000 in Canada. Comparing Canada as the treatment group (subject to GWLs after 2000) and the U.S. as the control group is an example of quasi-experimental methods that are widely used by economists and other policy researchers to estimate the causal impact of policy changes.[15] The validity of these methods and their advantages over randomization have been well-documented.[16–18,] Quasi-experimental methods are particularly appropriate in this case in that it is impractical to randomize persons or jurisdictions to GWLs before they are adopted.

The reason that FDA focused on Canadian GWL experiences lie in three aspects: first, culturally and geographically, Canada provides a closer comparison for the U.S. than any other country; second, Canada is one of the first countries to adopt GWLs, thus provides more data points for examination; last, Canada's GWL policy is much more similar to what was proposed in FDA's GWL regulations than similar policies adopted in other countries and regions (see FDA Final Rule 36712). To analyze FDA's approach, we also focus on analyzing Canadian's smoking prevalence data, as compared to that in the U.S.

In this paper, we use a specific quasi-experimental design, the difference-in-difference (DD) model, to assess, estimate, and test the impact of GWLs on national adult smoking prevalence. The general DD model has the following specification:

(1) Outcomes = β_1TreatmentGroup + β_2PostPolicyChange + β_3TreatmentGroup*PostPolicyChange + β_4X + e

"TreatmentGroup" is a dummy variable with a value of 1 for jurisdictions or individuals subject to the policy being examined (in this case GWLs). The estimated coefficient β_1 represents the difference between the treatment group (Canada) and the control group (the U.S.), which is not subject to the policy. "PostPolicyChange" is a dichotomous variable with a value of 1 for data observed after policy implementation. The estimated coefficient β_2 shows the difference between the pre- and post-policy periods. The key parameter is β_3, the interaction between the treatment group and the post policy change indicator, which reflects the estimated impact of the policy on the treatment group after implementation. Finally, X is a vector of control variables (cigarette prices in this case) and e is an idiosyncratic error term.

One of the advantages of DD model is that the existence of fixed differences in un-measured characteristics between the treatment and control groups does not affect the estimates. This is relevant to our analysis because the U.S. and Canada, despite their similarities, still have major differences.

Model Specification

To illustrate the differences between our approach and FDA's approach, we estimated the following equation based on the general DD model outlined above, using the same smoking prevalence data for the same time period used by FDA.

(2) ln(SmokingRate) = Intercept + β_1Canada + β_2PostGWL +β_3Canada*PostGWL + $\beta_4$ln(ExciseTax/PriceIndex) +$\beta_5$ln(Trend) + error

The dependent variable in equation (2) is the national smoking rate in log form. Canada's smoking rates came from Health Canada's multiple surveys (including General Social Survey, Survey on Smoking in Canada, National Population Health Survey, and Canadian Tobacco Use Monitoring Survey), for years 1991 to 2009, and for the population aged 15 and above. U.S. smoking rates were for the population aged 18 and above, for years 1994 to 2009, obtained from the National Health Interview Surveys. The smoking rates used in our analysis were obtained from Table 4 in FDA's Final Rule.

In equation (2), "Canada" is a dichotomous variable with the value of 1 indicating Canada, the treatment group, and the value of 0 for the U.S., the control group. "PostGWL" is a dichotomous variable with the value of 1 indicating the post-2000 time period and the value of 0 otherwise. "Canada*PostGWL" is the interaction between the treatment group (Canada) and the post-GWL time period. β_3 represents the impact of GWLs on the treatment group (Canada) after GWLs were implemented. "Trend" is a monthly trend variable used to capture the time trends in smoking rates, constructed based on the specific months in which key surveys were conducted in each country. This variable starts at 1 for January 1991, and increases by 1 each month. Data used in the analyses were presented in Appendix 1.

Controlling for Cigarette Tax/Price

Cigarette taxes/prices are one of the most important factors influencing smoking rates;[19,20] it is thus important to control for their impact on smoking rates when assessing the impact of GWLs. In our analysis, we use three alternative measures to capture the influence of cigarette taxes/prices. The first is the inflation-adjusted cigarette excise tax rate in Canada and the U.S. This variable is a population weighted average of the sum of federal and provincial/territory cigarette tax rates for Canada, and the sum of the federal and population weighted state cigarette excise tax rates for the U.S. It covers the entire study period 1991-2009.

Controlling for cigarette excise taxes rather than prices ignores the complex relationship between tax rates, retail prices, and the prices actually paid by consumers, and may bias estimates of GWLs. To account for these relationships, we use two alternative price measures. First, the official cigarette price index was used. The official U.S. cigarette price index was based on the monthly tobacco and smoking products price index compiled by the Bureau of Labor Statistics, adjusted by the overall consumer price index to account for general inflation, and constructed as the average tobacco price index over the months specific to the U.S. smoking surveys. Canada's official price index was constructed based on Canadian monthly consumer price index component for cigarettes, adjusted by Canada's general consumer price index, and averaged over the months covered by the Canadian smoking surveys. The official price indices also cover the entire study period 1991-2009. The tax and official price indices were both normalized and indexed to 1 in November 2002. The U.S. tax and price variables were normalized to a Canadian scale using the exchange rate between U.S. dollar and Canadian dollar.

Official statistics on cigarette prices may not reflect the actual prices paid by smokers given opportunities to obtain untaxed cigarettes and opportunities for substitution to discount brands. To address this, we modified the official price index to incorporate actual prices paid by smokers, constructed from the self-reported prices collected in multiple waves of the International Tobacco Control Policy Evaluation Project (ITC) surveys in Canada and U.S. for the 2002-2009 period. The ITC prices were adjusted for inflation, and constructed as the average price in the months specific to surveys of smoking rates in each country. Similar to the other two measures, it was also normalized and indexed to 1 in November 2002. In our analyses, the last price measure was constructed by combining office price indices (1991-2001) and the ITC prices (2002-2009).

One of the key underlying assumptions of our DD models is that the decline in Canadian smoking rates relative to the decline in the U.S. is due to the GWLs since we do not control for changes in other tobacco control policies and other time-variant factors that may influence smoking rates in both countries. Equation (2) also assumes that both countries had the same underlying trend in smoking, which may not be true. To relax this assumption, we re-estimated equation (2), adding an interaction between the trend and the "Canada" variable, allowing for differential trends in the two countries.

Results

Table 1 presents the estimated impact of GWLs on smoking prevalence. Model 1 controls for cigarette taxes, Model 2 controls for official cigarette prices, and Model 3 controls for actual prices paid by smokers. Models 4, 5, 6 are similar to Model 1, 2, 3, respectively, but allow for different trends in the two countries.

The first row of Table 1 shows estimates of β_3, the impact of GWLs implemented in Canada in 2000. They are statistically significant in all models, and range from -0.13 to -0.22. These estimates imply that GWLs reduced Canadian smoking prevalence between 12.1% (exp(-0.13)-1) and 19.6% (exp(-0.22)-1). These estimates imply that if US had adopted similar GWLs as did in Canada, the smoking rates in the U.S. would have declined by 2.87 to 4.68 percentage points, using the average pre-2001 smoking rates in the U.S. as the benchmark, which was 23.9 percentage points. Our estimated reduction in smoking rates in the U.S. is 33 to 53 times larger than the 0.088 percentage-point reduction estimated by FDA. Our estimates imply that if GWLs had been implemented in the U.S. in 2012, this would have led to a reduction of 5.3 to 8.6 million adult smokers in the U.S. in 2013, based on the number of adult smokers in the U.S. in 2011, which was 43.8 million.[21]

The weaknesses in FDA’s approach and sensitivity of its estimates are illustrated in Table 2. Starting with the replication of FDA's approach (Model A), subsequent models modify FDA's approach by substituting the official price index for the cigarette tax (Model B), substituting the actual price paid by smokers for the tax (Model C), and by using data from the entire 1991-2009 period for both countries (Models D-F), rather than using only pre-2001 data, as done by FDA. Results in Table 2 show that estimates based on FDA's approach vary considerably across models. Not only does the magnitude of the effect vary, but the direction also changes from model to model. More importantly, because FDA’s approach does not permit statistical testing, it is impossible to ascertain whether the estimated impact of GWLs is statistically different from zero, let alone to make causal interpretations. There are some minor differences between our replication of FDA's analysis (Model A) and the estimates in FDA's analysis, which may be attributed to three factors. First, Canadian federal excise tax rates differ across different provinces/territories, FDA did not specify how they constructed Canadian federal tax rates. We used the province/territory-population-weighted average as Canadian's federal tax rate. Second, when constructing the annual tax rates, we took into account the effective dates of tax rates. FDA's final rule did not provide information on how annual tax rates were constructed. Third, there was no information in the final rule on how the trend variable was constructed for observations from surveys that span 2 years. We used the mid-point method. Despite these minor differences, the magnitude of the estimated parameters and their standard errors from our replication (Model A) is very close to FDA's estimates (see Appendix 2 and 3).

Conclusion and Discussion

Since Canada adopted GWLs on cigarette packs in 2000, more than 40 countries have implemented similar prominent graphic health warning messages.[22] A growing body of research has demonstrated the impact of GWLs on a number of outcomes, including health knowledge, risk perceptions, intentions to quit, quit attempts, use of quitlines, cigarette consumption and smoking relapse.[1,2] This study adds to the growing body of evidence on the effectiveness of GWLs by examining their impact on smoking prevalence.

More importantly, our analyses exposed several serious methodological flaws in FDA's GWL RIA. Our analyses show that the GWLs adopted in Canada decreased adult smoking prevalence by 12 to 20%, 33 to 53 times larger than FDA's estimates. In addition, our estimates imply that if similar GWLs had been implemented in the U.S. in 2012, this would have led to a reduction of 5.3 to 8.6 million adult smokers in the U.S. in 2013. Our estimates are comparable to those found in recent studies that used individual level population survey data,[12] as well as simulation models that project the impact of GWLs.[23] Compared to studies that looked at intermediate outcomes such as risk perceptions or quit intentions, directly examining the impact of GWLs on smoking prevalence allows us to quantify the impact of GWLs on the number of smokers in a country, something that is critically important to policy-makers. More importantly, the quasi-experimental methodology used in this paper allows stronger inferences to be made on the possible causal impact of GWLs on smoking rates.

Our study has several limitations. First, we did not control for differences between Canada and the U.S. in other tobacco control measures, such as smoke-free air policies, marketing restrictions, and anti-smoking media campaigns. The impact of these other tobacco control policies on our estimates will depend on the strength and implementation of these policies in the two countries. If these policies were similar in Canada and the U.S. during our study period, our estimates of GWLs would not be affected. If policies were becoming stronger in one country relative to the other, our analysis could either overestimate, if policies were becoming stronger in Canada, or underestimate, if the opposite, the impact of GWLs. As a result, the estimated impact of GWLs from our DD models should be interpreted with caution.

Having said that, we believe the strength and implementation of these other policies in the U.S. were as strong as, if not stronger than, those in Canada during post-2000 period. For example, while Canada's Tobacco Act's prohibitions on advertising and promotion came into full effect after the introduction of the graphic cigarette labels, at least 41 states, plus the District of Columbia, enacted or substantially strengthened legislation regarding tobacco advertising and promotion, youth access or sampling and distribution between 2001 to 2008.[24] Similarly, while Canada launched a public education, outreach, and mass media campaign that had a goal of reducing tobacco-related death and disease among Canadians in 2001, the American Legacy Foundation launched the ''Truth'' Campaign, a nationwide advertising effort aimed at discouraging youth smoking, in 2000 and continued into the 2000s. Canada made significant progress with respect to second-hand smoke protection in the past decade, by 2009 all Canadian provinces and territories had legislated protection from second-hand smoke in enclosed public places and workplaces, up from five percent of Canadians at the beginning of 2000s. Meanwhile in the U.S., 26 states and more than 500 localities in the U.S. have adopted comprehensive smoke-free policies at bars, restaurants, and workplaces since early 1990s. Second, our estimated impact of GWLs on smoking rates is the average impact over the 2001-2009 period. The impact of GWLs may erode over time as smokers become inured to the labels and the novelty of the GWLs wear off.[25] Future studies could improve our analyses by accounting for other tobacco control policies and other factors that could influence smoking rates in Canada and the U.S., as well as by allowing the impact of GWLs to vary over time.

Despite these limitations, our study demonstrates that adopting large GWLs on cigarette packages reduces smoking prevalence. Our findings have direct relevance to and implications for the recent regulatory impact assessment conducted by FDA related to GWLs. The importance of these findings lies in their relevance to the status of GWLs in the U.S., where tobacco industry's challenges to implementation of GWLs have been upheld by the courts. In part, the courts' support of the industry's position derived from a lack of evidence that GWLs would reduce smoking prevalence. That conclusion was based in part on the FDA's own inadequate analysis of the impact of the GWLs in Canada.

Our analyses show that FDA's approach to estimating the impact of GWLs on smoking rates is flawed. FDA's estimates are highly sensitive to the changes in variable selection, model specifications, and time period used, and does not permit statistical testing of the impact of GWLs. This study demonstrates the inadequacy of the FDA's analysis and further shows that a more appropriate analysis indicates that the GWLs have had a statistically significant and practically important effect on actual adult smoking rates.

Compared to our estimates, and estimates from recent studies using individual level data and simulation methods, FDA's regulatory impact analysis significantly underestimate the likely impact of GWLs in reducing smoking rates in the U.S. To the extent that the assumptions and approach employed in FDA's analysis of GWLs becomes the agency's standard, continued use of this approach in FDA's economic analysis may lead to an underestimation of the impact of future proposed rules on tobacco products promulgated by FDA.

In addition, the fact that we were unable to replicate FDA's estimates indicates a significant problem with transparency and inadequacy of FDA's methods and rule-making process, which need better documentation, including more detailed descriptions of data sources, variable construction, and analytical models that are employed. Rectifying these problems before this approach becomes the norm is critical for FDA's effective regulation of tobacco products.

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Tables:

Table 1. Flaws in FDA's Regulatory Impact Analysis on Graphic Warning Labels (GWL)

<table>
<tr><td>1</td><td>FDA used cigarette excise taxes rather than actual prices paid by smokers, which reduced the estimated impact of GWLs on smoking prevalence.

<table>
<tr><td></td><td>Canada</td><td>USA</td></tr>
<tr><td>Inflation-adjusted average cigarette taxes (2001-2009)</td><td>increased by 123%</td><td>increased by 117%</td></tr>
<tr><td>Average inflation-adjusted official cigarette price indices (2001-2009)</td><td>increased by 64%</td><td>increased by 42%</td></tr>
<tr><td>Average cigarette prices actually paid by smokers (2002-2011)</td><td><u>decreased</u> by 4%</td><td>increased by 25%</td></tr>
</table>
</td></tr>
<tr><td>2</td><td>FDA did not utilize all available data points in the entire study period (1991-2009) in projecting smoking prevalence in the U.S. and Canada.</td></tr>
<tr><td>3</td><td>It is impossible to ascertain whether the estimated impact of GWLs on smoking prevalence from FDA's approach is statistically different from zero.</td></tr>
<tr><td>4</td><td>FDA's approach does not allow causal interpretations of the effect of GWLs on smoking prevalence.</td></tr>
</table>

Table 2. Estimated Impact of Graphic Health Warning Labels Using Difference-in-difference Models

Ln(Smoking Rate)	Model 1	Model 2	Model 3	Model 4	Model 5	Model 6
Canada & PostGWL Interaction	-0.145***	-0.163***	-0.181***	-0.129*	-0.181**	-0.219***
	(0.0367)	(0.0425)	(0.0455)	(0.0644)	(0.0722)	(0.0750)
Canada dummy	0.229***	0.137***	0.128***	0.319	0.0405	-0.0833
	(0.0389)	(0.0320)	(0.0343)	(0.290)	(0.317)	(0.332)
Post GWL dummy	0.00610	-0.0257	-0.0478	-0.00430	-0.0133	-0.0194
	(0.0332)	(0.0366)	(0.0385)	(0.0474)	(0.0550)	(0.0590)
ln(Monthly Trend)	-0.114***	-0.101***	-0.0994***	-0.0972	-0.120*	-0.142*
	(0.0175)	(0.0196)	(0.0216)	(0.0578)	(0.0667)	(0.0701)
ln(Index ExciseTax)	-0.172***			-0.178***		
	(0.0450)			(0.0491)		
ln(PriceIndex w/o ITC Price)		-0.135**			-0.130*	
		(0.0612)			(0.0649)	
ln(PriceIndex w ITC Price)			-0.0715			-0.0623
			(0.0709)			(0.0732)
Canada & trend interaction				-0.0197	0.0218	0.0479
				(0.0628)	(0.0711)	(0.0746)
Constant	3.511***	3.540***	3.573***	3.429***	3.631***	3.769***
	(0.0789)	(0.0913)	(0.0967)	(0.274)	(0.308)	(0.320)
Observations	29	29	29	29	29	29
R-squared	0.942	0.921	0.909	0.942	0.922	0.910
Estimated Relative Reduction in Smoking Rate in Canada	13.5%	15.0%	16.6%	12.1%	16.6%	19.6%
Estimated Percentage Point Reduction in U.S. Smoking Rate (Pre-2001 Benchmark = 23.9%)	3.11	3.59	3.97	2.87	3.97	4.68

Standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.10.

Table 3. Estimated Impact of Graphic Health Warning Labels: Analyzing FDA's Approach

Unexplained Smoking Rates in Canada

Canada[1]	*FDA's Approach*	*Model A Replication with cig taxes*	*Model B Replication with official price index*	*Model C Replication with actual paid price*	*Model D Using all obs with cig taxes*	*Model E Using all obs with official price index*	*Model F Using all obs with actual paid price*
Mean pre-2001 period	0.129	0.079	0.050	0.050	0.072	0.041	0.136
Mean post-2001 period	-0.501	-0.253	-0.116	-0.812	-1.777	-1.194	-1.574
Difference (Post - Pre)	-0.630	-0.332	-0.165	-0.861	-1.849	-1.234	-1.711

Unexplained Smoking Rates in the U.S.

United States[2]	*FDA*	*Model A*	*Model B*	*Model C*	*Model D*	*Model E*	*Model F*
Mean pre-2001 period	-0.010	0.001	0.000	0.000	0.085	0.112	0.125
Mean post-2001 period	-0.552	-0.475	-1.485	-1.686	-0.044	-0.061	-0.069
Difference (Post - Pre)	-0.541	-0.476	-1.485	-1.686	-0.130	-0.173	-0.194

Estimated Impact of Graphic Health Warning Label on Smoking Rate

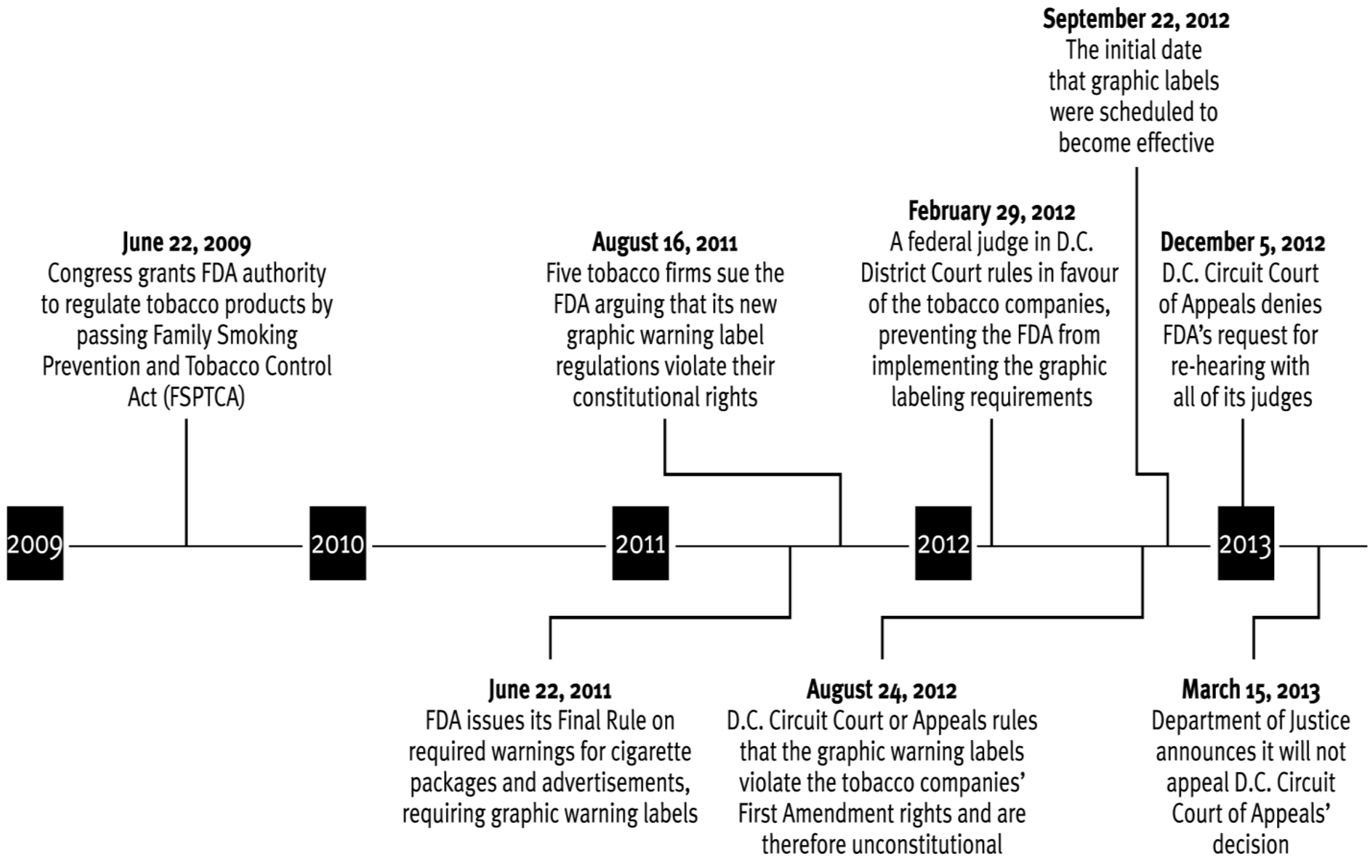
(Canada Difference – US Difference)	*FDA*	*Model A*	*Model B*	*Model C*	*Model D*	*Model E*	*Model F*
	-0.089	0.144	1.320	0.825	-1.719	-1.061	-1.516

1. The estimated/predicted smoking rates in Canada were presented in Appendix 4.

2. The estimated/predicted smoking rates in the U.S. were presented in Appendix 5.

Figures:

Figure 1: Timeline of FDA Graphic Warning Label Regulations and Relevant Court Decisions



What the paper adds:

- While the literature on the effectiveness of cigarette graphic warning label (GWLs) is substantial, there is limited evidence for their impact on smoking prevalence. This study adds to the growing body of evidence on the effectiveness of GWLs by examining their impact on smoking prevalence.

- This study demonstrates that adopting large GWLs on cigarette packages reduces smoking prevalence. In addition, our analyses show FDA's approach to estimating the impact of GWLs on smoking rates is inadequate.

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FJC, GTF and JH designed the study; GTF and JH collected data; JH conducted data analysis; FJC, GTF, and JH contributed to data interpretation; JH, FJC and GTF wrote the first draft; the final version of this paper has been reviewed and approved by all coauthors.

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Ethics Approval: The ITC Surveys in the United States and Canada were cleared for ethics by Research Ethics Boards or International Review Boards at the University of Waterloo (Canada) and Roswell Park Cancer Institute (US).

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Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis

Online-only Supplements:

Appendix 1. Data

Country	Smoking Survey Cycle	Year	Smoking Rate	Canada Dummy	Post GWL Dummy	Country PostGWL Interaction	Tax Rate Inflation Adjusted to July 2011	Price With ITC	Price W/O ITC	Normalized Tax Rate (Model 1 - 6)	Normalized Price With ITC (Model 1-6)	Normalized Price W/O ITC (Model 1-6)	Yearly Trend	Monthly Trend
US	Jan to Dec	1995	24.6	0	0	0	0.87	0.57	0.57	0.33	0.43	0.43	10	54.5
US	Jan to Dec	1997	24.6	0	0	0	0.85	0.59	0.59	0.33	0.45	0.45	12	78.5
US	Jan to Dec	1998	23.9	0	0	0	0.87	0.65	0.65	0.36	0.53	0.53	13	90.5
US	Jan to Dec	1999	23.3	0	0	0	0.94	0.82	0.82	0.39	0.68	0.68	14	102.5
US	Jan to Dec	2000	23.1	0	0	0	1.08	0.88	0.88	0.45	0.73	0.73	15	114.5
US	Jan to Dec	2001	22.6	0	1	0	1.06	0.93	0.93	0.46	0.79	0.79	16	126.5
US	Jan to Dec	2002	22.3	0	1	0	1.25	0.99	0.99	0.55	0.86	0.86	17	138.5
US	Jan to Dec	2003	21.3	0	1	0	1.38	0.94	0.98	0.54	0.73	0.76	18	150.5
US	Jan to Dec	2005	20.7	0	1	0	1.46	0.90	0.99	0.49	0.60	0.66	20	174.5
US	Jan to Dec	2006	20.6	0	1	0	1.46	0.93	1.00	0.46	0.58	0.62	21	186.5
US	Jan to Dec	2007	19.4	0	1	0	1.55	0.94	1.03	0.47	0.56	0.61	22	198.5
US	Jan to Dec	2008	20.4	0	1	0	1.61	0.99	1.06	0.48	0.58	0.62	23	210.5
US	Jan to Dec	2009	20.5	0	1	0	2.22	1.08	1.31	0.71	0.68	0.82	24	222.5
Canada	Jan to Dec	1991	31.1	1	0	0	5.85	0.90	0.90	1.31	0.90	0.90	6	6.5
Canada	May 1994	1994	31.0	1	0	0	2.81	0.57	0.57	0.63	0.57	0.57	9	41
Canada	June 1994 to May 1995	1994-1995	30.5	1	0	0	2.85	0.57	0.57	0.64	0.57	0.57	9.5	47.5
Canada	June 1996 to May 1997	1996-1997	28.6	1	0	0	2.91	0.58	0.58	0.65	0.58	0.58	11.5	71.5
Canada	June 1998 to May 1999	1998-1999	27.7	1	0	0	3.08	0.63	0.63	0.69	0.63	0.63	13.5	95.5
Canada	Feb to Dec	1999	25.2	1	0	0	3.10	0.63	0.63	0.69	0.63	0.63	14	103
Canada	Feb to Dec	2000	24.4	1	0	0	3.15	0.64	0.64	0.71	0.64	0.64	15	115
Canada	Feb to Dec	2001	21.7	1	1	1	3.49	0.71	0.71	0.78	0.71	0.71	16	127

Country	Smoking Survey Cycle	Year	Smoking Rate	Canada Dummy	Post GWL Dummy	Country PostGWL Interaction	Tax Rate Inflation Adjusted to July 2011	Price With ITC	Price W/O ITC	Normalized Tax Rate (Model 1 - 6)	Normalized Price With ITC (Model 1-6)	Normalized Price W/O ITC (Model 1-6)	Yearly Trend	Monthly Trend
Canada	Feb to Dec	2002	21.4	1	1	1	4.46	0.92	0.92	1	0.92	0.92	17	139
Canada	Feb to Dec	2003	20.9	1	1	1	6.15	1.03	1.04	1.38	1.03	1.04	18	151
Canada	Feb to Dec	2004	19.6	1	1	1	6.63	1.00	1.09	1.49	1.00	1.09	19	163
Canada	Feb to Dec	2005	18.7	1	1	1	6.55	0.98	1.10	1.47	0.98	1.10	20	175
Canada	Feb to Dec	2006	18.6	1	1	1	6.50	0.95	1.11	1.46	0.95	1.11	21	187
Canada	Feb to Dec	2007	19.2	1	1	1	6.53	0.92	1.13	1.46	0.92	1.13	22	199
Canada	Feb to Dec	2008	17.9	1	1	1	6.53	0.92	1.13	1.47	0.92	1.13	23	211
Canada	Feb to Dec	2009	17.3	1	1	1	6.59	0.93	1.16	1.48	0.93	1.16	24	223

Appendix 2 Estimated Models Using Only the Pre-2001 Observations

	FDA's Estimates		Model A(Replication)		Model B and C[i]	
	1	2	3	4	5	6
ln(Smoking Rate)	Canada	US	Canada	US	Canada	US
ln(Trend-1985)	-0.377	-0.115	-0.388***	-0.113	-0.353***	-0.0229
	(0.063)	(0.074)	(0.0588)	(0.0631)	(0.0525)	(0.0494)
ln(ExciseTax)	-0.215	-0.101	-0.225**	-0.122		
	(0.08)	(0.106)	(0.0733)	(0.0989)		
ln(PriceIndex)[i]					-0.322**	-0.129*
					(0.107)	(0.0388)
Constant	4.455	3.451	4.531***	3.450***	4.036***	3.184***
	-0.215	(0.202)	(0.210)	(0.167)	(0.106)	(0.138)
Observations	7	5	7	5	7	5
R-squared	N/A	N/A	0.922	0.896	0.920	0.972

i. estimated model parameters are the same for the selected periods with and without including the ITC prices since ITC prices only apply to post 2002 observations.
Standard errors in parentheses, *** p<0.01, ** p<0.05, * p<0.1

Appendix 3 Estimated Models Using All Available Observations

	Model D		Model E		Model F	
ln(Smoking Rate)	Canada	US	Canada	US	Canada	US
ln(MonthlyTrend)	-0.127***	-0.134**	-0.118***	-0.213***	-0.128***	-0.216***
	(0.0198)	(0.0468)	(0.0180)	(0.0551)	(0.0255)	(0.0421)
Post GWL Dummy	-0.0834		-0.0569		-0.0755	
	(0.0519)		(0.0532)		(0.0747)	
ln(ExciseTax)	-0.242***	-0.0647				
	(0.0545)	(0.0674)				
ln(PriceIndex w/o ITC)			-0.367***	0.0688		
			(0.0766)	(0.0951)		
ln(PriceIndex w/ITC)					-0.393**	0.0919
					(0.131)	(0.0860)
Constant	4.132***	3.759***	3.641***	4.139***	3.672***	4.161***
	(0.123)	(0.216)	(0.0691)	(0.280)	(0.0883)	(0.218)
Observations	16	13	16	13	16	13
R-squared	0.965	0.903	0.968	0.899	0.947	0.905

Standard errors in parentheses, *** p<0.01, ** p<0.05, * p<0.1

Appendix 4 Estimated/Predicted Smoking Rates in Canada

Year		Actual Smoking Rates	Estimated/Predicted Smoking Rates							Unexplained Smoking Rates						
			FDA Model	*Model A*	*Model B*	*Model C*	*Model D*	*Model E*	*Model F*	*FDA Model*	*Model A*	*Model B*	*Model C*	*Model D*	*Model E*	*Model F*
	1991	31.1	N/A	31.097	31.115	31.115	31.990	31.831	32.264	N/A	0.003	-0.015	-0.015	-0.890	-0.731	-1.164
N/U[1]	1994	31	N/A	31.344	31.176	31.176	30.216	30.242	30.408	N/A	-0.344	-0.176	-0.176	0.784	0.758	0.592
	1994-1995	30.5	30.391	30.601	30.693	30.693	29.559	29.841	29.965	0.109	-0.101	-0.193	-0.193	0.941	0.659	0.535
	1996-1997	28.6	28.172	28.277	28.389	28.389	27.914	28.103	28.072	0.428	0.323	0.211	0.211	0.686	0.497	0.528
Pre	1998-1999	27.7	26.237	26.232	26.172	26.172	26.536	26.412	26.248	1.463	1.468	1.528	1.528	1.164	1.288	1.452
	1999	25.2	25.855	25.834	25.842	25.842	26.249	26.183	25.999	-0.655	-0.634	-0.642	-0.642	-1.049	-0.983	-0.799
	2000	24.4	25.099	25.061	25.057	25.057	25.783	25.657	25.433	-0.699	-0.661	-0.657	-0.657	-1.383	-1.257	-1.033
	2001	21.7	24.088	23.874	23.686	23.686	24.825	24.413	24.108	-2.388	-2.174	-1.986	-1.986	-3.125	-2.713	-2.408
Post	2002	21.4	22.247	22.070	21.331	21.331	23.133	21.971	21.530	-0.847	-0.670	0.069	0.069	-1.733	-0.571	-0.130
	2003	20.9	20.274	20.071	20.141	20.182	21.170	20.857	20.408	0.626	0.829	0.759	0.718	-0.270	0.043	0.492
N/U[1]	2004	19.6	19.596	19.328	19.439	20.020	20.591	20.289	20.483	0.004	0.272	0.161	-0.420	-0.991	-0.689	-0.883
	2005	18.7	19.242	18.997	19.031	19.786	20.464	20.049	20.455	-0.542	-0.297	-0.331	-1.086	-1.764	-1.349	-1.755
	2006	18.6	18.950	18.670	18.653	19.651	20.326	19.830	20.541	-0.350	-0.070	-0.053	-1.051	-1.726	-1.230	-1.941
Post	2007	19.2	18.607	18.321	18.228	19.489	20.148	19.538	20.581	0.593	0.879	0.972	-0.289	-0.948	-0.338	-1.381
	2008	17.9	18.291	18.004	17.966	19.178	19.994	19.431	20.417	-0.391	-0.104	-0.066	-1.278	-2.094	-1.531	-2.517
	2009	17.25	17.957	17.671	17.540	18.839	19.808	19.110	20.203	-0.707	-0.421	-0.290	-1.589	-2.558	-1.860	-2.953

[1]N/U stands for Not Used. None of the models used the select years for mean difference in difference calculation because FDA model did not have those observations available for US.

Appendix 5 Estimated/Predicted Smoking Rates in the U.S.

Year		Actual Smoking Rates	Estimated/Predicted Smoking Rates							Unexplained Smoking Rate						
			FDA Model	*Model A*	*Model B*	*Model C*	*Model D*	*Model E*	*Model F*	*FDA Model*	*Model A*	*Model B*	*Model C*	*Model D*	*Model E*	*Model F*
Pre	1995	24.6	24.742	24.704	24.623	24.623	25.360	25.805	25.715	-0.142	-0.104	-0.023	-0.023	-0.760	-1.205	-1.115
	1997	24.6	24.213	24.276	24.444	24.444	24.191	23.918	23.822	0.344	0.324	0.156	0.156	0.409	0.682	0.778
	1998	23.9	23.971	23.979	24.071	24.071	23.694	23.373	23.325	-0.053	-0.079	-0.171	-0.171	0.206	0.527	0.575
	1999	23.3	23.564	23.562	23.305	23.305	23.190	23.136	23.206	-0.261	-0.262	-0.005	-0.005	0.110	0.164	0.094
	2000	23.1	23.005	22.974	23.055	23.055	22.638	22.708	22.807	0.060	0.126	0.045	0.045	0.462	0.392	0.293
Post	2001	22.6	22.869	22.857	22.884	22.884	22.364	22.302	22.417	-0.226	-0.257	-0.284	-0.284	0.236	0.298	0.183
	2002	22.3	22.141	22.259	22.658	22.659	21.865	21.976	22.116	0.121	0.041	-0.358	-0.359	0.435	0.324	0.184
	2003	21.3	21.945	21.854	22.647	22.765	21.487	21.582	21.631	-0.635	-0.554	-1.347	-1.465	-0.187	-0.282	-0.331
	2005	20.7	21.538	21.446	22.563	22.859	20.988	20.927	20.855	-0.814	-0.746	-1.863	-2.159	-0.288	-0.227	-0.155
	2006	20.6	21.447	21.319	22.533	22.727	20.798	20.636	20.626	-0.882	-0.719	-1.933	-2.127	-0.198	-0.036	-0.026
	2007	19.4	21.211	21.053	22.406	22.665	20.545	20.414	20.374	-1.762	-1.653	-3.006	-3.265	-1.145	-1.014	-0.974
	2008	20.4	20.948	20.853	22.316	22.494	20.336	20.193	20.212	-0.539	-0.453	-1.916	-2.094	0.064	0.207	0.188
	2009	20.5	21.190	19.961	21.674	22.233	19.773	20.258	20.124	0.323	0.539	-1.174	-1.733	0.727	0.242	0.376