Cigarette graphic warning labels and smoking prevalence in Canada: a critical examination and reformulation of the FDA regulatory impact analysis

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► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/tobaccocontrol-2013-051170).

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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.

BACKGROUND

The 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA) gave the US 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 (GWL) covering the top 50 percent (the minimum percent recommended by Article 11 of WHO 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, 2 years after FSPTCA became the law, FDA issued its first GWL regulations, which were later challenged by the tobacco industry, and subsequently struck down by the US Court of Appeals (see figure 1 for a timeline summarising 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 behaviour 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 recognising 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 rule-making 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 maximises 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 US smoking rates. FDA first compared trends in actual and estimated smoking prevalence in Canada and the USA from 1991 through 2009, projecting prevalence based
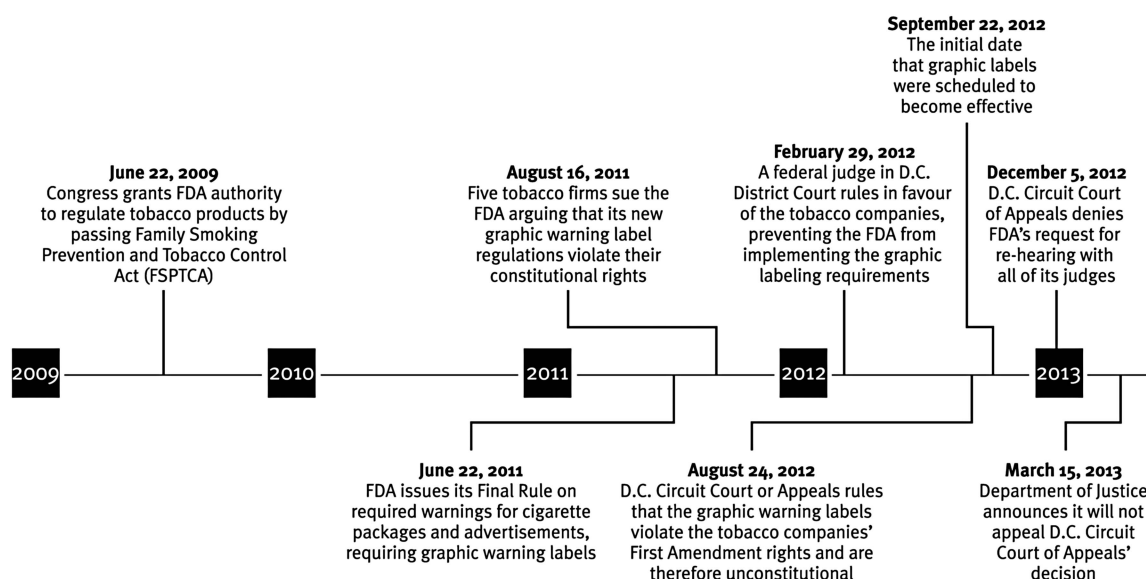
Figure 1 Timeline of Food and Drug Administration (FDA) graphic warning label regulations and relevant court decisions.

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 US 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 analyse 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 USA, 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 USA 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 USA 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 randomisation have been well documented.[16–18] Quasi-experimental methods are particularly appropriate in this case in that it is impractical to randomise 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 USA than any other country; second, Canada is one of the first countries to adopt GWLs, thus, it 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 analyse FDA's approach, we also focus on analysing Canadians' smoking prevalence data, as compared with that in the USA.

Table 1 Flaws in FDA's regulatory impact analysis on graphic warning labels (GWL)

		Canada	USA
1	FDA used cigarette excise taxes rather than actual prices paid by smokers, which reduced the estimated impact of GWLs on smoking prevalence		
	Inflation-adjusted average cigarette taxes (2001–2009)	Increased by 123%	Increased by 117%
	Average inflation-adjusted official cigarette price indices (2001–2009)	Increased by 64%	Increased by 42%
	Average cigarette prices actually paid by smokers (2002–2011)	*Decreased* by 4%	Increased by 25%
2	FDA did not utilise all available data points in the entire study period (1991–2009) in projecting smoking prevalence in the USA and Canada		
3	It is impossible to ascertain whether the estimated impact of GWLs on smoking prevalence from FDA's approach is statistically different from zero.		
4	FDA's approach does not allow causal interpretations of the effect of GWLs on smoking prevalence		

FDA, Food and Drug Administration.

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:

$$Outcomes = \beta_1 TreatmentGroup + \beta_2 PostPolicyChange$$
$$+ \beta_3 TreatmentGroup \times PostPolicyChange \quad (1)$$
$$+ \beta_4 X + e$$

'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 USA), 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 prepolicy and postpolicy periods. The key parameter is β_3, the interaction between the treatment group and the postpolicy 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 the DD model is that the existence of fixed differences in unmeasured characteristics between the treatment and control groups does not affect the estimates. This is relevant to our analysis because the USA 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.

$$(\ln(SmokingRate) = Intercept + \beta_1 Canada + \beta_2 PostGWL$$
$$+ \beta_3 Canada \times PostGWL$$
$$+ \beta_4 \ln(ExciseTax/PriceIndex) \quad (2)$$
$$+ \beta_5 \ln(Trend) + error$$

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 1991–2009, and for the population aged 15 years and above. US smoking rates were for the population aged 18 years and above, for years 1994–2009, 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 USA, 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 are presented in online supplementary 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 USA. 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 USA. 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 US 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 US smoking surveys. Canada's official price index was constructed based on the 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 normalised and indexed to 1 in November 2002. The US tax and price variables were normalised to a Canadian scale using the exchange rate between the US dollar and the 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 USA 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 normalised 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 USA 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 2 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 Models 1, 2, 3, respectively, but allow for different trends in the two countries.

The first row of table 2 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 the USA had adopted similar GWLs as done in Canada, the smoking rates in the USA would have declined by 2.87–4.68 percentage points, using the average pre-2001 smoking rates in the USA as the benchmark, which was 23.9 percentage points. Our estimated reduction in smoking rates in the USA is 33–53 times larger than the 0.088 percentage-point reduction estimated by FDA. Our estimates imply that if GWLs had been implemented in the USA in 2012, this would have led to a reduction of 5.3–8.6 million adult smokers in the USA in 2013, based on the number of adult smokers in the USA in 2011, which was 43.8 million.[21]

The weaknesses in FDA's approach and sensitivity of its estimates are illustrated in table 3. 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 Canada'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 SEs from our replication (Model A) is very close to FDA's estimates (see online supplementary 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 12–20%, 33–53 times larger than FDA's estimates. Additionally, our estimates imply that if similar GWLs had been implemented in the USA in 2012, this would have led to a reduction of 5.3–8.6 million adult smokers in the USA in 2013.

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 & Post-GWL interaction	−0.145*** (0.0367)	−0.163*** (0.0425)	−0.181*** (0.0455)	−0.129* (0.0644)	−0.181** (0.0722)	−0.219*** (0.0750)
Canada dummy	0.229*** (0.0389)	0.137*** (0.0320)	0.128*** (0.0343)	0.319 (0.290)	0.0405 (0.317)	−0.0833 (0.332)
Post-GWL dummy	0.00610 (0.0332)	−0.0257 (0.0366)	−0.0478 (0.0385)	−0.00430 (0.0474)	−0.0133 (0.0550)	−0.0194 (0.0590)
ln(Monthly Trend)	−0.114*** (0.0175)	−0.101*** (0.0196)	−0.0994*** (0.0216)	−0.0972 (0.0578)	−0.120* (0.0667)	−0.142* (0.0701)
ln(Index ExciseTax)	−0.172*** (0.0450)			−0.178*** (0.0491)		
ln(PriceIndex w/o ITC Price)		−0.135** (0.0612)			−0.130* (0.0649)	
ln(PriceIndex w ITC Price)			−0.0715 (0.0709)			−0.0623 (0.0732)
Canada & trend interaction				−0.0197 (0.0628)	0.0218 (0.0711)	0.0479 (0.0746)
Constant	3.511*** (0.0789)	3.540*** (0.0913)	3.573*** (0.0967)	3.429*** (0.274)	3.631*** (0.308)	3.769*** (0.320)
Observations	29	29	29	29	29	29
R^2	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 eeduction in US smoking rate (pre-2001 benchmark=23.9%)	3.11	3.59	3.97	2.87	3.97	4.68

SEs in parentheses.
*p<0.10, **p<0.05, ***p<0.01.
GWL, Graphic warning labels; ITC, International Tobacco Control.

Table 3 Estimated impact of graphic health warning labels: analysing FDA's approach

Canada*	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
Unexplained smoking rates in Canada							
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
USA†	FDA	Model A	Model B	Model C	Model D	Model E	Model F
Unexplained smoking rates in the USA							
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
(Canada Difference —USA difference)	FDA	Model A	Model B	Model C	Model D	Model E	Model F
Estimated impact of graphic health warning label on smoking rate							
	−0.089	0.144	1.320	0.825	−1.719	−1.061	−1.516

*The estimated/predicted smoking rates in Canada are presented in online supplementary appendix 4.
†The estimated/predicted smoking rates in the USA are presented in online supplementary appendix 5.
FDA, Food and Drug Administration

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 with 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 USA 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 USA 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 USA were as strong as, if not stronger than, those in Canada during the 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 and 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 5% of Canadians at the beginning of 2000s. Meanwhile in the USA, 26 states and more than 500 localities in the USA 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 USA, 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 USA, where the 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 RIA significantly underestimates the likely impact of GWLs in reducing smoking rates in the USA. 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.

Additionally, 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.

What this paper adds

► While the literature on the effectiveness of cigarette graphic warning labels (GWL) 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. Additionally, our analyses show the Food and Drug Administration's (FDA) approach to estimating the impact of GWLs on smoking rates is inadequate.

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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

ln(Smoking Rate)	FDA's Estimates		Model A(Replication)		Model B and C[i]	
	1	2	3	4	5	6
	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

ln(Smoking Rate)	Model D		Model E		Model F	
	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
N/U[1]	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
	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
Pre	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
	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
Post	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
	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
Post	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
	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

加拿大卷烟图形警示标识和吸烟率：批判性的审视和重构美国食品药品监督管理局所做的监管影响分析

Jidong Huang,[1] Frank J Chaloupka,[1] Geoffrey T Fong[2,3,4]

摘要

背景 评估卷烟图形警示标识（GWL）对吸烟率的影响是美国食品药品监督管理局（FDA）监管影响分析（RIA）的一项关键指标，也是制定监管细则过程中法律要求的一部分。然而，有关图形警示标识对吸烟率影响的证据却很稀缺。

目的 本文的目的是批判性分析在FDA监管影响分析中所采用的评估图形警示标识对吸烟率影响的方法，并推荐新的研究方法，评估加拿大在采用图形警示标识后，全国成人吸烟率所受到的影响。

方法 以美国为对照组，应用类实验研究方法测量加拿大在2000年后实行图形警示标识的影响。

结果 我们发现，与美国相比，加拿大在采用图形警示标识后吸烟率在统计上显著下降。我们的分析表明加拿大在采用图形警示标识后，吸烟率下降了2.87-4.68个百分点，相对降幅12.1-19.6%；其效果比FDA所评估的只是下降了0.088个百分点大33-53倍。此外，我们证明了FDA对此影响的评估是有缺陷的，因为该评估方法对变量选择、模型设定和分析时间段的变化高度敏感。

结论 在卷烟包装上采用图形警示标识可以降低吸烟率。应用我们对加拿大图形警示标识的分析，我们估计如果美国在2012年时实行了图形警示标识，到2013年美国的成人吸烟者将会减少530-860万人。我们的分析证明了FDA评估图形警示标识对吸烟率影响所采用的方法是有缺陷的。在该方法成为标准之前纠正这些问题，对FDA能有效监管烟草产品具有关键意义。

前言

2009年颁布的家庭吸烟预防和烟草控制法案（FSPTCA）赋予了美国食品药品监督管理局（FDA）监管烟草产品生产、分配、销售和市场营销的权利。该法案的关键条款之一是要求在卷烟和无烟烟草产品上采用更突出的警示标识。法案特别要求采用图形警示标识（GWL），而且标识要覆盖卷烟包装正反面的二分之一

（世界卫生组织《烟草控制框架公约》第11条所推荐的最低百分比）（出版号111-31 §201(a), 123 至 1776, 1842-45. 2009）

2011年6月，也就是在FSPTCA成为法律两年后，FDA发布了第一项有关图形警示标识的监管条例，但此条例被烟草业质疑并随后被美国上诉法院推翻（请参看图1，FDA之图形警示标识条例相关事件时间表）。法院否决FDA监管条例的主要原因之一是其未提供"丝毫证据"证明图形警示标识能"减少美国吸烟者数量"（RJ Reynolds Tobacco Co v FDA, 696 F3d 1205, 1219, DC Cir 2012）。

虽然法院作出了如此判决，但是事实上已经有许多文献详尽记载了警示标识，尤其是大而醒目的图形警示标识的有益影响[1,2]。有研究证实卷烟包装上大的图形警示标识对于吸烟者和非吸烟者都是一项重要的健康信息来源[3]。图形警示标识降低了卷烟包装的吸引力，使人们增加了对吸烟相关风险的健康知识、意识和认知[5-11]，强化了戒烟意愿[5]，鼓励戒烟[4,7-9,12]，增加了戒烟热线的应用[13]，预防复吸[14]，抑制了吸烟尝试[4,7,8]，并且降低了成为吸烟者的几率[12]。

虽然有关图形警示标识的有效性的研究成果很多，但至今这些证据更注重对个体而非群体水平的影响，而且对有效性的验证更多的是采用吸烟行为的远端而非近端指标。另外，有关图形警示标识对吸烟率影响的证据有限。这些有限的证据对于与FDA提出的图形警示标识有关的法律和政策的争论产生了关键影响，尤其是上诉法院没有认识到其自身所采用的大量证据来自个体水平的研究成果而轻视了来自于FDA的不充分的对群体水平研究的证据。

作为条例制定过程的一部分，法律要求FDA评估与其提出的条例有关的所有成本和收益（即监管影响分析），并且在需要监管手段时选择能产生最大净收益的方法。准确评估图形警示标识对吸烟率的影响是FDA监管影响分析的一项关键指标。在进行图形警示标识条例的经济分析时，FDA依赖于加拿大的经验来评估图形警示标识对美国吸烟率的影响。FDA首先比较了1991年到2009年加拿大和美国实际以及推算出来的吸烟率变动趋势，在估算吸烟率时考虑了加拿大在2000年实行图形警示标识之前两国经调整通货膨胀后卷烟税变化的影响。两国2001年到2009年推算吸烟率和实际吸

2012年9月22日
原定图形警示标识生效日期。

2009年6月22日
国会通过家庭预防吸烟和烟草控制法案（FSPTCA）授权FDA监管烟草产品。

2011年8月16日
5家烟草公司起诉FDA，认为其新颁布的图形警示标识条例触犯了宪法赋予他们的权利。

2012年2月29日
华盛顿特区地方法院的联邦法官作出有利于烟草公司的判决，阻止FDA实施图形警示标识条例的各项要求。

2012年12月5日
华盛顿特区巡回上诉法院驳回FDA的要求所有法官重新审理此案件的请求。

| 2009 | 2010 | 2011 | 2012 | 2013 |

2011年6月22日
FDA发布了卷烟包装和广告警示条例的最终版本，要求实施图形警示标识。

2012年8月24日
华盛顿特区巡回上诉法院裁定图形警示标识侵犯了烟草公司的第一修正案所赋予的权利，因此是违宪的。

2013年3月15日
司法部宣布其不会对特区巡回上诉法院的裁决提出上诉。
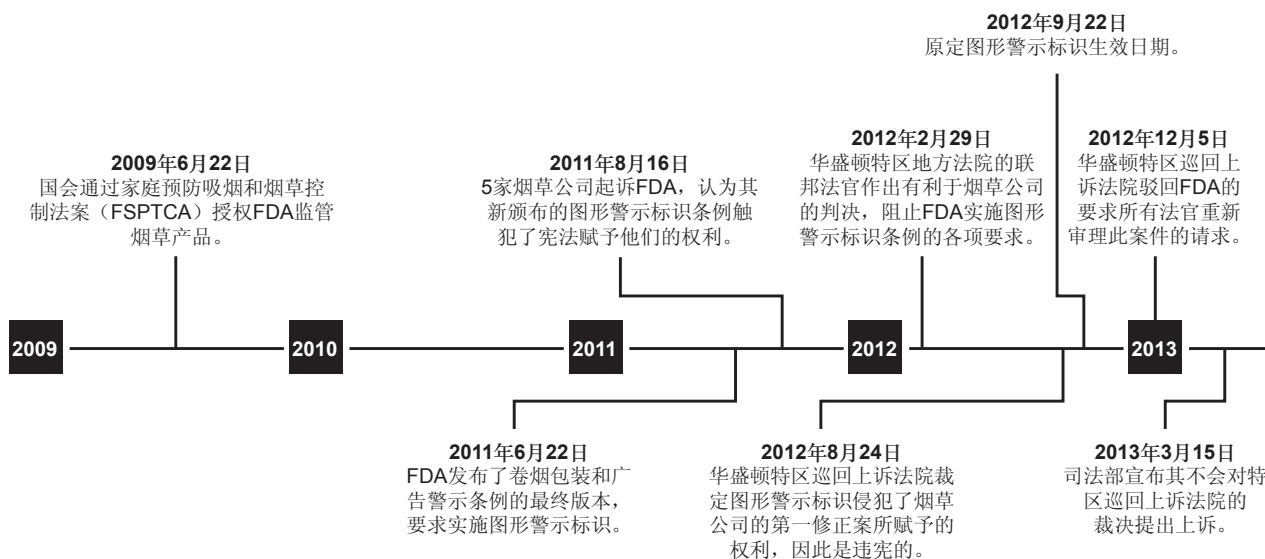
图1 FDA图形警示标识条例和相应法院裁决的时间表

烟率的差异假定为加拿大采用图形警示标识所致。FDA估算得出，图形警示标识对吸烟率下降的影响为0.088个百分点，相当于美国吸烟率相对降幅0.4%。

FDA的方法存在几个主要问题（参看表1对这些问题的总结）。首先，FDA使用了卷烟消费税而非吸烟者实际支付价格来量化卷烟价格对吸烟率产生的影响。卷烟消费税、官方卷烟价格指数和吸烟者实际支付价格可能变动的方向不同。控制卷烟税可能会导致过多（过少）的评估税收变化对吸烟率差异化下降的影响，从且减弱（增强）所估算的图形警示标识影响。另外，FDA的方法没有采用统计上的显著性检验来检验采用图形警示标识后造成的吸烟率变化的统计显著性；因此，所估算出的图形警示标识的影响是否与0有统计上的显著差异无法得到确认。最重要的是，FDA的方法不

允许采用因果关系解释图形警示标识影响。

FDA方法存在的这些问题可能已经严重影响了对图形警示标识对吸烟率的影响的估算，这就需要一次周密合理的复检。本文中，我们批判性地分析了FDA在估算图形警示标识对吸烟率的影响时所使用的图形警示监管影响分析中的方法。本文应用类实验研究方法，检验了加拿大在实施图形警示标识前后吸烟率的变化，并与仍未实施图形警示标识的美国的数据相比较，为不断增加的图形警示标识的影响的证据锦上添花。

方法

双重差分模型

为检验实施图形警示标识对全国成人吸烟率的影响，我们援用FDA的方法，使用1991-2009年美国和加拿大成人吸烟率的数据，即加拿大自2000年引入图形警示标识前后9年的时间。以加拿大为实验组（2000年后受图形警示标识影响）、美国为对照组进行比较，这是一个采用类实验方法的例子—经济学家和其他政策研究者普遍用该方法来评估导致政策改变的因果效应[15]。这些方法的有效性及其在随机化方面的优势已被很好的证明[16-18]。类实验方法在这种情形下尤为适用，因为在该案例中，人群样本和司法管辖区域在实行图形警示标识之前并不能被随机化。

FDA专注于加拿大实施图形警示标识的经验的原因有三方面：第一，与任何其他国家相比，加拿大与美国在文化和地理上都更具有可比性；第二，加拿大是首先实行图形警示标识的国家之一，因此能提供更多可供检验的数据点；最后，与其他国家和地区实行的类似政策相比，加拿大图形警示标识政策与FDA在图形警示标识条例里提出的监管规定更为相似（参考FDA最终条例）。为分析FDA的分析方法，我们也专注于分析加拿大的吸烟率数据，以便与美国的数据相比较。

表1 FDA图形警示标识（GWL）监管影响分析的缺陷

1	FDA使用了卷烟消费税而非吸烟者实际支付价格，这减弱了所估算的图形警示标识对吸烟率的影响		
		加拿大	美国
	调整通货膨胀后的平均卷烟税（2001-2009年）	上升123%	上升117%
	调整通货膨胀后的平均官方卷烟价格指数（2001-2009年）	上升64%	上升42%
	吸烟者实际支付的平均卷烟价格（2002-2011年）	下降4%	上升25%
2	在预测美国和加拿大吸烟率时，FDA没有利用整个研究时期（1991-2009年）所有能获得的数据点		
3	无法确认所估计出的图形警示标识的影响是否与0有统计上的显著差异		
4	FDA的方法不允许采用因果关系解释图形警示标识影响。		

FDA，食品药品监督管理局。

本文中，我们应用了一种特殊的类实验设计——双重差分（DD）模型，以评价、估计并检验图形警示标识对全国成人吸烟率的影响。一般的DD模型形式如下：

$$结果 = \beta_1实验组 + \beta_2政策改变后 + \beta_3实验组 \times 政策改变后 + \beta_4X + e$$

(1)

"实验组"为0-1变量，1代表服从于被检验政策的辖区或者个体（此例中为图形警示标识）。估计系数β_1代表实验组（加拿大）和未实施政策的对照组（美国）之间的区别。"政策改变后"是一个二分类变量，1代表实施政策后观测到的数据。估计系数β_2代表政策前和政策后时间段的区别。关键的参数为β_3，实验组和政策改变后指标间的交互项。它代表政策在实施后对实验组的估计影响。最后，X为控制变量的向量（此例中为卷烟价格），e为异质误差项。

双重差分模型的优势之一是实验组和对照组之间存在的不可观测的异质性不影响估计。这与我们的分析是相关的，因为尽管美国和加拿大有相似性，但他们仍存在主要区别。

模型说明

为说明我们的方法和FDA的方法的区别，我们依据以上陈列的一般双重差分模型评估了以下的方程，其中使用了FDA用过的同时期吸烟率数据。

$$\ln（吸烟率）= 截距+\beta_1加拿大+\beta_2图形警示标识后 +\beta_3加拿大 \times 图形警示标识后 +\beta_4\ln（消费税/价格指数） +\beta_5\ln（趋势）+误差$$

(2)

方程（2）的因变量是全国吸烟率的自然对数形式。加拿大的吸烟率取自加拿大卫生部的多项调查（包括一般社会调查、加拿大吸烟调查、全国人口健康调查和加拿大烟草使用监测调查），时间是从1991年-2009年，人口覆盖15岁及以上人群。美国的吸烟率数据来自1994年-2009年的全国健康调查，人口覆盖18岁及以上人群。我们的分析中使用的吸烟率取自FDA最终条例中的表4。

方程（2）中，"加拿大"为二分类变量，1代表加拿大，为实验组，0代表美国，为对照组。"图形警示标识后"为二分类变量，1代表2000年以后的时间段，0反之。"加拿大×图形警示标识后"是实验组（加拿大）和图形警示标识后时间段的交互项。β_3表示采用图形警示标识后图形警示标识对实验组（加拿大）的影响。"趋势"是月份趋势变量，用于衡量吸烟率的时间趋势，其建立基于在每个国家进行关键调查的特定月份。该变量自1991年1月开始取值为1，然后每个月增加1。该分析所用数据请参见在线发表的补充附录1.

卷烟税/价格的控制

卷烟税/价格是影响吸烟率的最重要因素之一[19,20]；因此在评价图形警示标识的影响时首先要控制它们对吸烟率的影响。在我们的分析中，我们使用了三种替代测量指标来测量卷烟税/价格的影响。第一种是美国和加拿大的经调整通货膨胀后的卷烟消费税。此变量是加拿大联邦和省/特区卷烟消费税率之和的人口加权平均值，及美国联邦和经人口加权的州卷烟消费税率之和的平均值。它覆盖了1991年-2009年整个研究时期。

控制卷烟消费税而非价格，忽略了税率、零售价格和消费者实付价格之间复杂的关系，可能导致在估计图形警示标识影响的过程中存在偏差。为了解释这些复杂关系，我们使用了两种替代价格指标。首先，运用了官方卷烟价格指数。美国官方卷烟价格指数来自劳工统计局汇编的每月烟草和烟草产品价格指数。该指数按总消费价格指数进行了校正以控制通货膨胀的影响，并且这是针对美国烟草调查的按月份所建立的平均烟草价格指数。加拿大官方卷烟价格指数的建立来自加拿大月度消费者价格指数中有关卷烟的部分。该指数根据加拿大总体消费者价格指数进行了校正，并平均到加拿大吸烟调查所覆盖的月份。官方价格指数也覆盖了1991年-2009年整个研究周期。卷烟税和官方价格指数在2002年1月都被正态化并指数化为1。美国卷烟税和价格变量按美国美元和加拿大加元之间的汇率正态化到加拿大水平。

考虑到吸烟者可能会获取未上税的卷烟，以及可以选择低价卷烟品牌，官方的卷烟价格数据可能不能反映吸烟者实际支付的价格。为了处理这个问题，我们修正了官方价格指数以体现吸烟者实际支付价格。该价格数据来源于国际烟草控制政策评价项目（ITC）2002年-2009年间在加拿大和美国的多轮调查所收集的自报价格。ITC项目的烟草价格经通货膨胀校正，成为调查每个国家吸烟率的月份期间的平均价格。与其他两个价格指标类似，它也在2002年11月正态化并指数化为1。在我们的分析中，最后一项测量指标是建立在结合官方价格指数（1991-2001）和ITC项目价格（2002-2009）的基础上的。

我们的双重差分模型的关键假设之一是加拿大吸烟率相对于美国的下降是由于图形警示标识的作用，因为我们并没有控制两国可能对吸烟率产生影响的其他因素，比如烟草控制政策的变化以及其他随时间产生变化的因素。方程（2）也假设两个国家在吸烟方面存在相同的发展趋势，但是该假设有可能是不确切的。为了放宽这个假设，我们重新估计了方程（2），加入了一个趋势和"加拿大"变量的交互项，以衡量两国不同的趋势影响。

研究结果

表2显示了图形警示标识对吸烟率的估计影响。模型1控制了卷烟税，模型2控制了官方卷烟价格，模型3控制了吸烟者实际支付价格。模型4、5、6与模型1、2、3相类似，但是考虑了两个国家的不同趋势。

表2的第一行显示了对β_3的估计值，即2000年在加拿大实施图形警示标识后的影响。在所有模型里它们都具有统计显著性，系数的取值范围从-0.13到-0.22。这些估计表明图形警示标识降低了加拿大的吸烟率，程度从12.1%（e-0.13-1）到19.6%（e-0.22-1）。模型结果显示：如果美国实行了类似加拿大的措施，推行了图形警示标识，以2001年前美国的吸烟率23.9个百分点为起点，美国的吸烟率有可能降低2.87-4.68个百分点。我们所估计的美国吸烟率下降程度比FDA所估计的下降0.088个百分点大了33-53倍。2011年美国成人吸烟者的人数为4380万，我们的模型结果显示：如果2012年美国实行了图形警示标识，2013年美国成人吸烟者将能减少580-860万人[21]。

表3说明了FDA方法的缺点及其估计结果的不稳健性。我们首先复制FDA的方法（模型A），接着我们以官方价格指数代替卷烟税以修正FDA的模型（模型B），以吸烟者实际支付价格代替卷烟税以修正模型（模型C），以及应用了两国从1991年-2009年整段时间的数据的模型（模型D-F），而非像FDA那样只用了2001年以前的数据。表2的结果显示，基于FDA方法的估计在各模型间差异相当大。各模型间不仅影响的数量级在变化，而且方向都在变化。更重要的是，由于FDA的方法不能进行统计上的检验，根本无法确定图形警示标识的估算影响是否与0有统计上的差异，更不能进行因果解释。我们对FDA的复制分析（模型A）与FDA的分析有少许不同，可归结于三个原因。第一，加拿大联邦消费税在不同省/特区间有所差异，FDA没有详细说明他们如何建构加拿大联邦税率。我们把省/特区人口加权平均数作为加拿大的联邦税率。第二，构建年度税率时，我们考虑了税率的生效日期。FDA最终条例没有提供有关年度税率如何构建的信息。第三，最终条例里没有关于样本的趋势变量是如何根据为期两年的调查进行构建的信息。我们运用了中点方法。尽管有这些小的差异，我们的复制模型（模型A）的估计参数的数量级以及它们的标准差十分接近FDA的估计（参看在线附录2和3）。

结论及讨论

自2000年加拿大在卷烟包装上采用图形警示标识以来，有超过40个国家已经采用了类似的醒目的图形健康警示信息[22]。越来越多的研究证实图形警示标识对吸烟者的一系列的影响，包括健康知识、风险认知、戒烟意向、戒烟尝试、戒烟热线的使用、卷烟消费和卷烟复吸[12]。此研究进一步补充了以上研究成果，即通过检验图形警示标识对吸烟率的影响证明其有效性。

更重要的是，我们的分析指出了FDA在图形警示标识监管影响中所采用的分析方法上的几个严重缺陷。我们的分析显示加拿大采纳图形警示标识使得成人吸烟率降低了12-20%，比FDA的估算大33-53倍。另外，我们的估算显示如果美国在2012年实施了类似的图形警示标识，2013年美国成人吸烟者将可减少530-680万人。我们的研究结果与最近个体水平调查数据的研究发现是有可比性的[12]，也与针对图形警示标识的影响的模拟模型预测的结果一致[23]。与那些关注中期结果的研究（比如风险认知或者戒烟意向）相比，直接检验图形警示标识对吸烟率的影响使得我们可以量化图形警示标识对一个国家吸烟者数量的影响，而这对政策制定者来说至关重要。更重要的是，本文所使用的类实验方法使得对于图形警示标识于吸烟率可能的因果影响的推论得以进行。

表2 用双重差分模型估计图形健康警示标识的影响

Ln(吸烟率)	模型 1	模型 2	模型 3	模型 4	模型 5	模型 6
加拿大 & GWL后交互项	-0.145***	-0.163***	-0.181***	-0.129*	-0.181**	-0.219***
	(0.0367)	(0.0425)	(0.0455)	(0.0644)	(0.0722)	(0.0750)
加拿大0-1变量	0.229***	0.137***	0.128***	0.319	0.0405	-0.0833
	(0.0389)	(0.0320)	(0.0343)	(0.290)	(0.317)	(0.332)
图形警示标识0-1变量	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(月趋势)	-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(消费税指数)	-0.172***			-0.178***		
	(0.0450)			(0.0491)		
ln(价格指数 不包含ITC价格)		-0.135**			-0.130*	
		(0.0612)			(0.0649)	
ln(价格指数 包含ITC价格)			-0.0715			-0.0623
			(0.0709)			(0.0732)
加拿大 & 趋势交互项				-0.0197	0.0218	0.0479
				(0.0628)	(0.0711)	(0.0746)
截距	3.511***	3.540***	3.573***	3.429***	3.631***	3.769***
	(0.0789)	(0.0913)	(0.0967)	(0.274)	(0.308)	(0.320)
观察值	29	29	29	29	29	29
R^2	0.942	0.921	0.909	0.942	0.922	0.910
估计的加拿大吸烟率相对下降值	13.5%	15.0%	16.6%	12.1%	16.6%	19.6%
估计的美国吸烟率百分点下降值 (2001年前 基准=23.9%)	3.11	3.59	3.97	2.87	3.97	4.68

括号内为标准差。
*p<0.10, **p<0.05, ***p<0.01。
GWL, 图形警示标识; ITC, 国际烟草控制政策评估项目。

表3 估计图形健康警示标识的影响：分析FDA的方法

加拿大*	FDA 的方法	模型 A 添加卷烟税的复检	模型 B 添加官方价格指数的复检	模型 C 添加实付价格的复检	模型 D 应用所有添加卷烟税的样本	模型E 应用所有添加官方价格指数的样本	模型 F 应用所有添加实付价格的样本
加拿大未能解释的吸烟率							
2001年以前时期均值	0.129	0.079	0.050	0.050	0.072	0.041	0.136
2001年以后时期均值	-0.501	-0.253	-0.116	-0.812	-1.777	-1.194	-1.574
差值（后 - 前）	-0.630	-0.332	-0.165	-0.861	-1.849	-1.234	-1.711
美国†	FDA	模型A	模型B	模型C	模型D	模型E	模型F
美国未能解释的吸烟率							
2001年以前时期均值	-0.010	0.001	0.000	0.000	0.085	0.112	0.125
2001年以后时期均值	-0.552	-0.475	-1.485	-1.686	-0.044	-0.061	-0.069
差值 (后 - 前)	-0.541	-0.476	-1.485	-1.686	-0.130	-0.173	-0.194
（加拿大差值 - 美国差值）	FDA	模型A	模型B	模型C	模型D	模型E	模型F
图形健康警示标识对吸烟率的估计影响							
	-0.089	0.144	1.320	0.825	-1.719	-1.061	-1.516

*加拿大估计/预测吸烟率见在线附录4。
†美国估计/预测吸烟率见在线附录5。
FDA, 食品药品监督管理局

我们的研究存在几点不足。第一，我们没有考虑到加拿大和美国在其它控制烟草措施上的不同，比如无烟环境政策、市场限制和反吸烟媒体运动。这些控制烟草政策对我们估算的影响取决于两国执行这些政策的力度和实施情况。如果在我们的研究期间，加拿大和美国所执行的政策类似，那么它们对我们的图形警示标识影响的估算结果没有影响。如果一个国家的政策相对于另外一个国家更强一些，比如加拿大的控烟政策变得更加强硬，我们的分析结果有可能高估了图形警示标识的影响效果；或者如果反过来，有可能低估了图形警示标识的影响效果。因此，我们应该谨慎地解释双重差分模型对图形警示标识影响的估算。

虽然存在高估的可能性，我们相信在2000年之后，美国推行的其它的控烟政策的强度和实施力度即使不比加拿大大，也与加拿大具有可比性。比如，加拿大烟草法案除了引入图形警示标识，还涉及广告和促销的禁令。2001年至2008年美国至少41个州，外加哥伦比亚特区，制定或者充分强化了关于烟草广告和促销、涉及青少年接触卷烟的途径或免费样品和配送的法令[24]。类似的，2001年加拿大开展了一项以减小烟草相关死亡及疾病为目标的公共教育、服务延伸和大众媒体宣传活动，而美国传统基金会在2000年开始开展了一项全国性广告宣传活动——"Truth"运动——并一直持续到21世纪，旨在劝阻青少年吸烟。在过去的十年里，加拿大在保护公众免受二手烟危害方面有了显著的进展，从21世纪伊始时的只有5%的加拿大人免受二手烟危害，到2009年加拿大所有的省和地区都建立了禁止室内公共场所和工作场所二手烟的保护性立法。在同一时期的美国，从20世纪90年代早期开始，美国的26个州和超过500个地区在酒吧、餐厅和工作场所实行了全面禁烟政策。另外，

我们估计的图形警示标识对吸烟率的影响是2001年-2009年这段时间的平均值。随着时间的推移，图形警示标识的影响可能会削弱，因为吸烟者习惯了该标识后，对图形警示标识的新鲜感逐渐消失[25]。考虑到加拿大和美国其它烟草控制政策和其它影响吸烟率的因素，以及图形警示标识随时间变化的影响，未来的研究可以改进我们的分析。

尽管存在这些局限，我们的研究证明在卷烟包装上采用大的图形警示标识能降低吸烟率。我们的调查结果对最近FDA进行的有关图形警示标识的监管影响分析有直接的关联和指导意义。这些调查结果的重要性在于它们涉及到美国图形警示标识的状况，而在美国法院支持烟草业对实施图形警示标识所提出的质疑。在某种程度上，法院对烟草业一方的观点的支持源自于缺乏科学证据来表明图形警示标识可以降低吸烟率，而法院的结论在某种程度上是基于FDA自身不完整的对图形警示标识在加拿大的影响的分析。

我们的分析显示FDA评价图形警示标识对吸烟率影响的方法是有缺陷的。FDA的估算对变量选择、模型设定和所用时间段的变化高度敏感，而且不能在统计上检验图形警示标识的影响。本研究证明了FDA分析的不足，而且表明如采用一个更恰当的分析方法就能够揭示图形警示标识对成年人吸烟率在统计上有显著的以及在实践上有重要的影响。

与我们的估计以及近期应用个体水平数据和模拟方法进行的估算相比，FDA的监管影响分析明显低估了美国在采用图形警示标识后对降低吸烟率的影响。如果FDA在图形警示标识分析中采用的假设和方法成为标准，继续采用FDA的这种经济分析方法可能导致低估FDA未来颁布的有关烟草产品法令的影响。

另外，我们无法复制FDA的结果这一事实，显示了FDA在研究方法和制定法规过程中严重缺乏透明度和完备性，这需要其更好的文献记录，包括对数据来源、变量构建和所使用的分析模型的更详细的描述。在该方法成为标准之前校正这些问题，对于FDA有效地监管烟草产品至关重要。

本文贡献

▶ 尽管有关卷烟图形警示标识（GWL）影响的论著很丰富，但是只有有限的证据涉及它们对吸烟率的影响。本文进一步补充了不断增多的此方面研究的证据，即通过检验图形警示标识对吸烟率的影响证明其有效性。

▶ 本研究证明卷烟包装采用大的图形警示标识降低了吸烟率。而且，我们的分析显示FDA估算图形警示标识对吸烟率影响的方法不完整。

利益冲突　无。

知情同意　已获得。

伦理审核　在美国和加拿大的ITC调查通过了University of Waterloo（加拿大）和Roswell Park Cancer Institute（美国）的研究伦理委员会/国际审查委员会的伦理审查。

出处和同行审查　未开展；外部同行已评审。

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