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Public health benefits from pictorial health warnings on US cigarette packs: a SimSmoke simulation

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ABSTRACT

Introduction While many countries have adopted prominent pictorial warning labels (PWLs) for cigarette packs, the USA still requires only small, text-only labels located on one side of the cigarette pack that have little effect on smoking-related outcomes. Tobacco industry litigation blocked implementation of a 2011 Food and Drug Administration's (FDA) rule requiring large PWLs. To inform FDA action on PWLs, this study provides research-based estimates of their public health impacts.
Methods Literature was reviewed to identify the impact of cigarette PWLs on smoking prevalence, cessation and initiation. Based on this analysis, the *SimSmoke* model was used to estimate the effect of requiring PWLs in the USA on smoking prevalence and, using standard attribution methods, on smoking-attributable deaths (SADs) and key maternal and child health outcomes.
Results Available research consistently shows a direct association between PWLs and increased cessation and reduced smoking initiation and prevalence. The *SimSmoke* model projects that PWLs would reduce smoking prevalence by 5% (2.5%–9%) relative to the status quo over the short term and by 10% (4%–19%) over the long term. Over the next 50 years, PWLs are projected to avert 652 800 (327 000–1 190 500) SADs, 46 600 (17 500–92 300) low-birth-weight cases, 73 600 (27 800–145 100) preterm births and 1000 (400–2000) cases of sudden infant death syndrome.
Conclusions Requiring PWLs on all US cigarette packs would be appropriate for the protection of the public health, because it would substantially reduce smoking prevalence and thereby reduce SADs and the morbidity and medical costs associated with adverse smoking-attributable birth outcomes.

INTRODUCTION

Despite recent declines in adult cigarette smoking prevalence in the USA, an estimated 45 million adults continue to smoke, and cigarette smoking accounts for nearly half a million preventable deaths and $300 billion annually in medical costs and productivity losses.[1] Cigarette companies, meanwhile, spend billions of dollars each year marketing their products[2] and cigarette packs continue to be an important marketing tool. The tobacco industry's brand imagery remains the most prominent feature of cigarette packs seen by consumers, since US regulations only require small, inconspicuous text-only warning labels on the side of the pack.[3 4]

Evidence consistently indicates that these text-only warnings are infrequently noticed by consumers.[5] A 2014–2015 survey of 2227 adult smokers in the USA found that only 11.8% reported noticing warning labels often or very often in the past month.[6] Recognising the limited effectiveness of text warnings, Article 11 of the WHO's Framework Convention for Tobacco Control has recommended pictorial warning labels (PWLs) that cover 50% or more of the front and back of the pack surface.[7]

Although globally more than 70 countries have adopted or are considering adopting PWLs for cigarette packs,[7 8] US regulations requiring text-only warnings have remained unchanged since 1985.[9] In 2009, the Family Smoking Prevention and Tobacco Control Act (the Act) was signed into law, authorising the US Food and Drug Administration (FDA) to regulate cigarettes and other tobacco products, including their packaging and labelling. The Act directed the FDA to issue a rule requiring new PWLs that cover 50% of cigarette packs.[10] The FDA issued a final rule to require the PWLs on all cigarettes on 22 June 2011,[11] but, pursuant to lawsuits by the tobacco industry, the D.C. Circuit Court of Appeals struck down the rule as violating the cigarette companies' First Amendment commercial speech rights.[12]

The US court decision to strike down FDA's PWL rule hinged in part on a concern that the PWLs might not produce any significant reduction in smoking.[12 13] Accumulating research, however, indicates that compared with text-only warnings, PWLs are more effective for capturing smokers' attention,[14–16] influencing perceived risks of smoking and attitudes towards smoking[17] and motivating quit attempts,[15 17–19] but also work directly to reduce smoking prevalence.[19 20] Moreover, FDA estimates of the likely impacts of PWLs in the USA were based on their findings that PWLs had little impact on smoking in Canada.[21] However, a subsequent analysis found that adopting PWLs in Canada actually led to relative reductions in smoking prevalence of 12–20%.[20]

Estimates of the impact of PWLs on smoking prevalence over time and the resulting impact on health outcomes would better inform FDA's future regulatory action relating to warning labels. To date, however, no such analysis of the public health impact of PWLs has been conducted. In light of this gap, the goal of this study is apply the well-established, peer-reviewed *SimSmoke* tobacco control policy model to estimate the impact of implementing PWLs on US smoking prevalence and smoking-attributable health outcomes. *SimSmoke* has been validated for over 20 nations, including the USA, and 6 states, and has been shown to predict well over time for a wide range of different policy changes.[22–30]

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METHODS

The *SimSmoke* tobacco control policy model

The US *SimSmoke* model begins in 1965 with the number of current, former and never smokers by age and gender, and projects forward through 2065.[30] Population growth evolves through births and deaths, adjusted each year to the actual population from the Census.[31] Smoking rates evolve through smoking initiation, cessation and relapse rates. A discrete time, first-order Markov process is employed to project future population growth and smoking rates from 1965 to future years.

Smoking rates are from the 1965 National Health Interview Survey (NHIS), as developed by Holford *et al*.[32] Smoking prevalence is defined in terms of those who have smoked 100 cigarettes during their lifetime and currently smoke. Initiation rates are based on responses regarding initiation age. Cessation, tracked from age 16, is defined in terms of having quit for 2 years, which reflects a trade-off between higher cessation rates in the first year and relapse in later years, with relapse distinguished by years since quitting after the second year.[33 34]

Initiation and cessation rates change over time as a result of new policies (tax, smoke-free air laws, marketing restrictions, health warnings, media campaigns, cessation interventions and youth access policies). The original policy parameters are based on literature reviews[35] and the advice of an expert panel. Smoking rates are projected through 2014 allowing for actual changes in policy.[30]

Health warning effect sizes

US health warnings currently include only text covering ∼50% of one of the narrow sides of the cigarette pack. We consider the effect of adopting rotating PWLs covering at least 50% of the front and the back of the pack (as FDA is required by the Act to implement). Consequently, we focus on studies that consider PWLs.

Policies often have the largest effect in the first years after implementation and then smaller effects in later years if the policy is maintained. We apply a method used for other policies and consistent with evidence that the marginal effects of PWLs decline over time.[36] Larger effects are often found when the policy is first implemented, which are modelled through direct reductions in prevalence. The effects may grow or decline over time depending on the effects of the policy on future initiation and cessation rates.

To inform the model, we used prior systematic reviews[37–40] and searched PubMed for additional studies using combinations of key words: 'graphic', 'pictorial', 'health' and 'warnings' with the word 'cigarette'. We limited the studies considered to those with at least one smoking behaviour outcome: smoking initiation, cessation or prevalence. While we include experimental studies, we emphasised population-level studies to inform the model. In addition, we considered changes in smoking prevalence data for countries following the implementation of PWLs, focusing on high-income nations, such as Australia, Canada and the UK, which have implemented PWLs in recent years.

The effects of PWLs are separately considered in terms of the effects on smoking prevalence, initiation and cessation. We develop best estimates and lower and upper bounds based of the range of credible outcomes.

Public health effects of pictorial health warnings

The public health impact of pictorial health warnings (PHWs) depends on their effect on health outcomes. *SimSmoke* estimates smoking-attributable deaths (SADs) and maternal and child health outcomes.

SADs are defined in terms of the excess death rates of current smokers (ie, current smoker mortality rate−never smoker mortality rate) and of former smokers (ie, current smoker mortality rate−never smoker mortality rate). Age-specific and gender-specific current, former and never smoker mortality rates are based on the Cancer Prevention Studies and the Nutrition Follow-up Studies.[41] Based on the Cancer Prevention Study II,[42] mortality rates of former smokers decline with years quit. For current and former smokers, SADs are calculated each year by age and gender as the excess death risk×prevalence×projected population and then summed over ages for each gender.

SimSmoke also estimates smoking-attributable low-birth-weight (LBW), preterm births (PTBs) and sudden infant death syndrome (SIDS) cases.[43] The number of cases is determined by their smoking-attributable fraction multiplied by the number of each of the outcomes by age and gender.[44] The rates of LBW, PTB and SIDSs were obtained from CDC WONDER[45] for 2012, and assumed constant over time. Rates of smoking while pregnant are derived using birth certificate data and adjusted for failure to report using recent estimates.[46] Relative smoking risks are based on the 2004 Surgeon General's Report[47] for LBW (2.0) and SIDS (2.3) and on Anderka *et al*[48] and Aliyu *et al*[49] for PTB (1.3).

Impact of PWLs on public health

To estimate the impact of implementing PWLs, the *status quo* smoking rates are first projected from 2015 to 2065, assuming that policies remain at their 2014 levels. The model is then estimated for best, lower and upper estimates of prevalence, cessation and initiation effects. We assume that PWLs are enacted in 2016 and maintained over time with other policies held constant. The reduction in smoking prevalence is calculated relative to the status quo levels in the same year. Health outcomes (SADs, LBW, PTB and SIDS) averted are calculated as the difference between the status quo level in a particular year and the level with PWLs, and are summed over the period 2016–2065 as a gauge of the overall effect of the PWLs on current smokers.

RESULTS

Effect sizes for PHWs

While one study[50] found no effect on smoking prevalence soon after PWLs were implemented in Canada, another study[51] considered 6 years after implementation and found a 12% relative reduction in smoking prevalence. An FDA analysis estimated a 0.5% reduction in smoking prevalence following Canadian PWLs.[21] After correcting for errors in the FDA analysis, such as the real price consumers paid (instead of assuming that the industry passed on the tobacco tax), Huang *et al*[20] estimated 12–20% relative reduction in smoking prevalence over 8 years.

Suggestive evidence is also indicated by changes in smoking prevalence trends following implementation of PWLs. After implementation in the UK in October 2008, smoking prevalence fell 10% relative to the 2008 level (from 20% in August 2008 to 18% in June 2009)[52] compared to a <5% decline in previous years.[53] With PWLs implemented in Australia in 2006, adult smoking prevalence fell 10.3% between 2004/2005 and 2007/2008 (from 21.3% to 19.1%)[54] compared to a 4.5% decline during the previous 3-year period.

In an auction experiment,[55] mean bids were $3.52 for packs with the current text-only warnings and $3.11 for packs with large PWLs, implying a 12.4% lower value for packs with PWLs than packs without PWLs. With adult prevalence declining by 2% for every 10% increase in price,[56] these findings indicate a 2.5% (0.124×−0.2) relative prevalence reduction with PWLs.

In summary, two of the better quality studies showed relative reductions in smoking prevalence of at least 12%[20 51] 6–8 years after implementing PWLs. Australia and the UK saw a 5% decline in smoking prevalence relative to the secular trend in the years following implementation of PWLs, and an experimental study suggests a relative reduction of 2.5%.[55] We estimate that, relative to text warnings, PWLs reduce smoking prevalence within a 3-year period by at least 2% and possibly by as much as 8%, with a best estimate of a 4% relative reduction (an approximate doubling of the US quit rate).

A Canadian study[51] found a 33% greater odds of making a quit attempt after PWLs were implemented. Other Canadian studies found that >40% of smokers reported that PWLs motivated them to try to quit smoking[5] and that 31% of ex-smokers reported that PWLs had motivated them to quit.[57] In Australia, 57% of smokers and 72% of recent quitters in 2008 reported that PWLs made them think about quitting and had helped them try to quit.[58] A recent experimental study[59] obtained an 18% ((40–34)/34) relative increase in quit attempts, and a meta-analysis obtained a 9% relative increase in quit attempts associated with PWLs.[39]

PWLs may also improve quit success. With Australian PWLs implemented in 2006,[58] previous year cessation lasting >1 month increases 34% (18% in 2000 vs 24% in 2008). Partos *et al*[60] found that the 55% of ex-smokers stating that PWLs make staying quit ‘a lot’ more likely had a 35% lower odds of relapse 1 year later, similar to an earlier study.[57]

Thus, studies indicate as much as 36% higher odds of a quit attempt following PWLs, and two studies indicated reduced relapse. However, studies also indicate that the effects of PWLs on quit attempts decline over time.[5 61–63] Taking into account the larger initial effects of cessation that we estimated through direct reductions in prevalence, PWLs are estimated to increase first-year cessation in later years by 10% after the initial effect on prevalence, with a range of 5–20%.

Evidence also indicates that PWLs affect attitudes, intentions and behaviours related to smoking initiation among adolescents and young adults. Between one-fifth and two-thirds of youth reported that PWLs helped prevent them from taking up smoking in Canada[64] and Australia.[58] About 30% of non-smokers in 28 European nations reported that health warnings were effective in preventing them from smoking.[65] A Canadian study of PWLs[66] found that about 30% of young adults said that they were less likely to start smoking. Similar results have been found in experimental studies.[40] Compared to text-only warnings, a US[67] study of young adults found almost a five times higher odds of perceived effectiveness of PWLs for preventing smoking and a 3.5 times higher odds of motivation not to start smoking, and an online survey of young adults[19] found that PWLs reduced the intent to start smoking and increased the intention to quit.

While previous studies relate PWLs to smoking initiation attitudes and intentions, more direct evidence initiation effects is found from survey data on youth and young adult smoking prevalence. With PWLs implemented in Canada in 2000–2001, smoking prevalence between 1999 and 2002 dropped 21% (28% vs 22%) for those aged 15–19 and 14% for those aged 20 and above.[68] Smoking prevalence dropped 18% for those aged 18–24 years in Australia after implementation of PWLs.[54] With PWLs implemented in 2008, a study of 11–15 years in England[69] found a 45% reduction in those who had smoked in the last week between 2006 and 2010 compared to a reduction of ~15% between 1998 and 2006. We estimate that implementation of PWLs reduces initiation in relative terms by 6% with a range of 2–12%.

Table 1 Estimated effect sizes of PWLs on smoking prevalence, cessation and initiation*

Type of effect	Best estimate	Lower bound	Upper bound	Primary studies/data used to derive estimates
Initial effect on prevalence rates	4% reduction	2% reduction	8% reduction	Azagba and Sharaf,[51] Huang *et al*,[20] Thrasher *et al*,[55] prevalence data from the UK[52] and Australia[54]
Effect on future cessation rates	10% increase	5% increase	20% increase	Azagba and Sharaf,[51] Hammond *et al*,[5] Hammond *et al*,[57] Brewer *et al*,[59] Noar *et al*,[39] Shanahan and Elliott,[58] Partos *et al*,[60] Li *et al*[57]
Effect on future initiation rates	6% reduction	2% reduction	12% reduction	Shanahan and Elliott,[58] Environics Research Group Limited,[64] EC,[65] Koval *et al*,[66] Noar *et al*,[40] O'Hegarty *et al*,[67] Villanti *et al*,[19] prevalence data from Canada,[68] Australia[54] and England[69]

*All effect sizes are measured relative to the current levels of the respective rates.
PWLs, pictorial warning labels.

The estimated effects and credible ranges are summarised in table 1.

SimSmoke projections

Table 2 presents the predicted smoking prevalence for males and females aged 18 and above and impact of PWLs on those rates. In 2015, the smoking prevalence under the status quo is 19.0% for males and 15.0% for females and declines slowly to 14.4% for males and 10.8% for females in 2065. After implementing PWLs, male and female smoking prevalence are both projected to decline by ~5%, relative to the status quo by 2020 with a lower bound of 2.5% and an upper bound of 9% (indicated as (2.5%, 9%)) increasing to a 10% (4%, 19%) decline by 2065.

Table 3 lists estimated SADs and the number of these deaths averted due to PWLs. Under the status quo, SADs are an estimated 447 756 (274 147 males 173 609 females) in 2015 declining to 262 085 by 2065. With PWLs implemented, 2843 (1428, 5075) SADs (including males and females) are averted in 2020 increasing to 16 199 (8664, 29 531) in 2045 and to 18 078 (8664, 3387) in 2065. From 2016 to 2065, a cumulative total of 652 769 (327 048, 1 119 529) SADs are predicted to be averted as a result of PWLs.

The effects of PWLs on adverse maternal and child health outcomes are presented in table 4. In terms of smoking-attributable cases, 14 488 LBW, 20 636 PTB and 320 SIDS cases are estimated under the status quo in 2015 increasing to 19 635 LBW, 27 974 PTB and 434 SIDS cases by 2065, generating a cumulative total of 849 900 LBW, 1 211 104 PTB and 18 788 SIDS cases between 2015 and 2065. After requiring PWLs, LBW cases are projected to decline by 648 (281, 1220) in 2020, increasing to 1155 (420, 2313) in 2065. A total of 46 585 (17 493, 92 344) LBW cases are estimated to be averted between 2015 and 2065. For PTBs, *SimSmoke* projected a

Table 2 The effects of PWLs on smoking prevalence, US SimSmoke model, ages 18 and above

	Male					Female				
	2015	2016	2020	2045	2065	2015	2016	2020	2045	2065
Smoking prevalence, %										
Status quo*	19.0	18.7	17.7	14.8	14.4	15.0	14.8	13.9	11.1	10.8
Best estimate	19.0	18.0	16.8	13.5	13.0	15.0	14.2	13.2	10.2	9.8
Lower bound	19.0	18.3	17.2	14.2	13.8	15.0	14.5	13.5	10.7	10.4
Upper bound	19.0	17.4	16.0	12.3	11.7	15.0	13.7	12.6	9.3	8.8
Relative change from status quo, %†										
Best estimate	–	−4.0	−5.2	−8.9	−9.7	–	−4.0	−5.1	−8.8	−9.6
Lower bound	–	−2.0	−2.5	−3.9	−4.1	–	−2.0	−2.5	−3.8	−4.1
Upper bound	–	−7.0	−9.4	−17.1	−18.7	–	−7.0	−9.2	−16.7	−18.5

*Status quo holds policies constant at their 2015 level in future years, whereas other estimates show the effect with strong graphic warnings implemented.
†Relative changes are from the status quo estimates measured as the difference in the smoking prevalence with warnings from the status quo prevalence in a particular year relative to the status quo prevalence in that year.
PWLs, pictorial warning labels.

Table 3 The effects of PWLs on smoking-attributable deaths, US SimSmoke model, ages 18 and above

Gender/year	Annual reduction					Cumulative impact
Male	2015	2016	2020	2045	2065	2016–2065
Status quo*	274 147	272 386	265 138	204 926	160 124	11 113 438
Best estimate†	–	149	1793	9662	11 460	396 752
Lower bound†	–	74	900	4876	5433	197 437
Upper bound†	–	261	3197	17 657	21 236	725 189
Female	2015	2016	2020	2045	2065	2016–2065
Status quo*	173 609	172 585	169 144	141 303	101 961	7 374 748
Best estimate†	–	86	1050	6536	6619	256 017
Lower bound†	–	43	527	3349	3231	129 611
Upper bound†	–	150	1878	11 874	12 151	465 340
Total	2015	2016	2020	2045	2065	2016–2065
Status quo*	447 756	444 971	434 282	346 229	262 085	18 488 186
Best estimate†	–	235	2843	16 199	18 078	652 769
Lower bound†	–	117	1428	8225	8664	327 048
Upper bound†	–	411	5075	29 531	33 387	1 190 529

*Status quo represents the predicted number of smoking-attributable deaths holding all policies constant at their 2015 level in future years.
†Best, lower bound and upper bound estimates represent the predicted number of smoking-attributable maternal and child health outcomes averted with PWLs compared to the status quo (ie, status quo attributable outcomes−outcomes with PWLs).
PWLs, pictorial warning labels.

Table 4 The effects of PWLs on LBW PTBs and SIDS for mothers aged 15–49, US SimSmoke model

Gender/year	Annual reduction					Cumulative impact
LBW	2015	2016	2020	2045	2065	2016–2065
Status quo*	14 488	14 532	14 692	17 361	19 635	849 900
Best estimate†	–	497	648	1020	1155	46 585
Lower bound†	–	248	281	371	420	17 493
Upper bound†	–	873	1220	2042	2313	92 344
PTB	2015	2016	2020	2045	2065	2016–2065
Status quo*	20 636	20 715	20 958	24 725	27 974	1 211 104
Best estimate†	–	787	1024	1612	1826	73 637
Lower bound†	–	393	446	589	667	27 774
Upper bound†	–	1380	1919	3208	3633	145 072
SIDS	2015	2016	2020	2045	2065	2016–2065
Status quo*	320	321	325	384	434	18 788
Best estimate†	–	11	14	22	25	996
Lower bound†	–	5	6	8	9	371
Upper bound†	–	19	27	44	49	1979

*Status quo represents the total number of predicted smoking-attributable maternal and child health outcome deaths holding all policies constant at their 2015 level in future years.
†Best, lower bound and upper bound estimates represent the predicted number of smoking-attributable maternal and child health outcomes averted with PWLs compared to the status quo (ie, status quo attributable outcomes−outcomes with PWLs).
LBW, low birth weight; PWLs, pictorial warning labels; PTBs, preterm births; SIDS, sudden infant death syndrome.

reduction of 1826 (667, 3633) cases in 2065, yielding 73 637 (27 774, 145 072) cases averted from 2015 to 2065. With 25 (9, 49) of the ~430 cases avoided in 2065, a total of 996 (371, 1979) SIDS cases are averted by 2065.

DISCUSSION

We estimate that implementing PWLs in the USA would directly reduce smoking prevalence in relative terms by 5% in the first few years. The effects would increase to 10% over the long-term through their effects on initiation and cessation. If implemented in 2016, PWLs are estimated to reduce the number of SADs by an estimated 652 800 by 2065 and to prevent more than 46 600 cases of LBW, 73 600 cases of PTB and 1000 SIDS deaths. Even the model's lower-bound estimates project that introducing PWLs in the USA would reduce the number of deaths by over 327 000, the number of LBW by over 17 000 and PTB births by over 27 000 each by 2065. While not considered here, the effects on smoking prevalence through PWLs can also be expected to reduce other smoking-related morbidity and disability, as well as to reduce associated healthcare and productivity loss. In particular, the morbidity and increased medical costs[44 70] associated with PTBs and LBW would be substantially reduced.

The results are based on a model that was previously validated by comparing smoking prevalence from *SimSmoke* against NHIS rates for four age groups (18–24, 25–44, 45–64 and 65+) over the period 1965–2012, and were found to validate well overall by age group.[30] Nevertheless, the results depend on the data and assumptions inherent in the *SimSmoke* model and effect sizes for PWLs.

While we have attempted to be conservative in our estimates of PWL effect sizes, our results depend on the effect sizes developed from our review of the literature. We reviewed evidence from diverse sources, including population-level and individual-level studies, data on trends in nations that have implemented PWLs and recent meta-analyses.[39 40] Our best estimate of a 10% relative reduction in long-term smoking prevalence is lower than the 13% relative reduction obtained in a recent meta-analysis.[39]

While estimation of the effects of PWLs on cessation is based on studies that specifically examine cessation behaviours, studies also indicate that PWLs increase calls to quitlines,[39] which have been found to improve quit success.[71] In addition, studies[5 39 72] find that PWLs have reduced the quantity smoked per smoker, which may contribute to quit success. Nevertheless, the evidence on initiation effects is more limited, since no previous studies have specifically examined initiation following the implementation of PWLs. In addition, the results for cessation and prevalence effects depend on the ability to isolate the effects of PWLs from other policies that may have been implemented around the same period of time. However, some of the better studies included controls for other policies,[20] and there were limited policy changes around the time that PWLs were implemented in the UK[53] and Australia.[39]

The effect sizes used in the model also depend on evaluations of PWLs from other nations, and the effects may vary in the USA depending on how PWLs are implemented. The court ruling that struck down FDA's original PWLs expressed concerns over warnings that evoked emotional responses. Consequently, PWLs in the USA may be less graphic than those studied in other countries, making them less effective at reducing smoking prevalence. However, the contrast between the existing small US text warnings and new PWLs may still be greater than that between the PWLs implemented in other countries compared to their prior warning labels. In addition, the FDA could bolster the impact by regularly refreshing them with new sets of PWLs and requiring package inserts[73] that provide further information about smoking health harms and smoking cessation. For example, quit line information on warnings[17 74 75] and integrating warning label and tobacco control media campaign messaging[76–78] may produce synergistic effects for promoting public health.

The results are also subject to assumptions inherent in the model. The model did not distinguish by socioeconomic status (SES) or racial/ethnic groups, but studies find that PWLs are equally or more effective for lower SES than for higher SES groups.[79–83] With the less rapid decline in smoking prevalence among low SES groups in the USA, PWLs may provide an important opportunity to reduce tobacco-associated disparities.[84]

We also did not model uncertainty in future smoking prevalence. Future trends in smoking prevalence will depend on whether new tobacco control policies are implemented and whether current policies are abandoned. In addition, the model did not incorporate the use of alternative nicotine delivery products, including smokeless tobacco, cigars and electronic cigarettes, all of which have increased in recent years.[85 86] Through changes in initiation and cessation, the use of these products could lead to changes in smoking prevalence not predicted by our model. In the absence of strong warnings on these other products, PWLs on cigarettes could lead to substitution of other tobacco products.[19 87]

In summary, the Tobacco Control Act generally requires that FDA's regulatory actions relating to tobacco products be 'appropriate for the protection of public health'.[10 88] Based on available research, we find that implementing PWLs for US cigarette packs would substantially reduce smoking prevalence and thereby reduce tobacco-attributable maternal and child health outcomes and deaths due to SIDS, heart disease, lung cancer and chronic obstructive pulmonary disease. Thus, implementing PWLs in the USA would substantially reduce the public health burden incurred by cigarette smoking and are therefore 'appropriate for the protection of the public health'.

What this paper adds

- Recent studies indicate important effects of PHWs on smoking prevalence and smoking cessation, but the public health impact of PHWs on smoking prevalence and health outcomes has not been estimated.
- Requiring large PWLs on US cigarette packs would substantially reduce smoking prevalence, avert SADs and reduce adverse smoking-attributable birth outcomes, and is, therefore, appropriate for the protection of public health.

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