A TOBACCO ENDGAME FOR CANADA

SUMMIT

Queen's University
September 30 to October 1, 2016

BACKGROUND PAPER

This document, which describes a potential endgame for commercial tobacco, was prepared with contributions from members of the Steering Committee and Action Groups. It does not necessarily reflect the views of any of the individuals who participated in its development, nor of the organizations with which they are affiliated.

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INTRODUCTION

WHY DOES CANADA NEED A TOBACCO ENDGAME?

THE BURDEN OF SMOKING RELATED DISEASE CONTINUES TO INCREASE.

Great strides have been made in tobacco control in Canada and globally over the past few decades through implementation of measures, including those endorsed by the international Framework Convention for Tobacco Control [FCTC].¹

Nevertheless, smoking prevalence remains substantial – 18.1% of Canadians over 12 years of age, representing 5.4 million Canadians). The overall burden of smoking related illness and death from cancer and from respiratory and cardiovascular diseases continues to be devastating. In 2002, 37,000 Canadians died from tobacco associated illnesses – the size of a small town being wiped off the map each year. Canadians lose an estimated 515,607 person years of life every year as a result of premature mortality from tobacco smoking.³

This burden of mortality and morbidity comes with substantial direct and indirect *financial costs* for Canada. The calculation of the costs of tobacco associated illness usually assesses the impact of illness from a macroeconomic perspective by aggregating costs across all economic agents. This approach derives a societal cost of the illness divided into direct costs (expenses incurred because of the illness (health costs, enforcement, etc.), and indirect costs (e. g. lost wages due to diminished productivity). It does not include welfare and leisure time costs or benefits and does not account for long term changes in demographic composition. Intangible costs such as pain and suffering are also not considered.

These costs are substantial: For the 2013 year, Krueger et al. estimated that tobacco smoking resulted in total costs of \$18.7 billion in Canada. ⁴ Direct health care costs alone totaled \$6.4 billion. These results are similar to those from 2002 where the estimates were \$17 billion per year with \$4.4 billion in direct health care costs.⁵

The future burden of disease (and associated costs and lost productivity) does not look brighter - even with implementation of all the MPOWER measures found within the FCTC*. For example, in Ontario, the absolute numbers of deaths are predicted to *increase* year over year for the next 2 decades [figure 1] and smoking rates will decline only by less than half over the same period [figure 2]. Figures 1

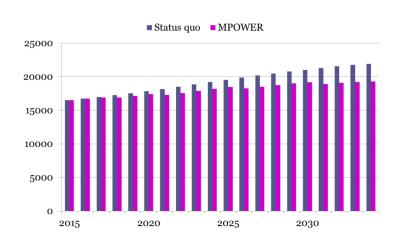


Figure 1: Predicted numbers of deaths in Ontario over time under the scenario of status quo policy environment, and one in which the recommendations of the WHO MPOWER framework are fully implemented.

^{*} The WHO Framework Convention on Tobacco Control (WHO FCTC) and its guidelines provide the foundation for countries to implement and manage tobacco control. To help make this a reality, WHO introduced the MPOWER measures. These measures are intended to assist in the country-level implementation of effective interventions to reduce the demand for tobacco, contained in the WHO FCTC.

and 2 incorporate MPOWER measures implemented in Ontario in 2012, but do not factor in implementation of MPOWER measures subsequent to 2012, nor measures going beyond the MPOWER package of measures.^{6†}

There is no justification for continuing with incremental declines in commercial tobacco use, given the overwhelming evidence about the devastation that it causes. Complaisance cannot be tolerated when we know that transformative action now will prevent hundreds of thousands of people from becoming sick and dying.

This recognition is becoming more widespread and is increasingly leading to the view that a strategy for an "endgame" for commercial tobacco is required.

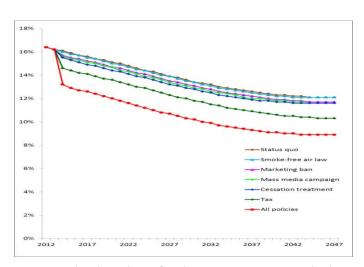


Figure 2: predicted prevalence of smoking in Ontario over time under the scenario of status quo policy environment, and one in which the recommendations of the WHO MPOWER framework are fully implemented.

TOBACCO ENDGAME DISCOURSE IS GROWING

The idea of a "Tobacco Endgame" is based on the perspective that "control" of tobacco will never be enough to deal with the epidemic of tobacco related diseases and that the focus must be shifted to develop strategies to reach a future that is free of commercial tobacco. This notion of Endgame, is qualitatively different from tobacco control strategies currently in place, perhaps best conveyed through the words of Ruth Malone in a recent publication:

"An endgame addresses tobacco as a systems issue, rather than an individual behaviour; addresses health and political implications; reframes strategic debates; advances social justice; and is fundamentally transformative in changing how tobacco use and the tobacco industry are regarded. An endgame is not merely more of the same, in that it requires an authentic public policy commitment to achieving a true endgame, as opposed to continuing to envision the public health challenge as an ongoing war of attrition"

Incremental change cannot fix this public health emergency, at least not absent a vision of an endpoint when the threat will be eradicated. Thus vision and goals are in some ways more important than specific tactics. What remains astonishing is the degree to which the social construction of tobacco as normal and desirable, accomplished over the last century by a savvy industry, still blinds many to the urgency of our task and the contradictions inherent in our own messages about tobacco." ⁷

[†] These graphs seek to illustrate the impact of the implementation of MPOWER measures in Ontario based on the Simsmoke model, a model developed outside Canada. The graphs do not seek to illustrate the impact of all measures implemented in Canada, or where Canada has implemented measures that go beyond the MPOWER standard.

This is not a view espoused by only a few academics, indeed the idea of Endgame for tobacco is gaining support in the global public health community.⁸

For example: In 2011, The Canadian Public Health Association in a paper entitled "The Winnable Battle: Ending Tobacco Use in Canada" called for a fall in pan-Canadian smoking prevalence rate of less than 1% by 2035.9 The 2014 US Surgeon General's Report on 50 years of Progress in Tobacco Control described the need for a vision for ending the tobacco epidemic "this nation must create a society free of tobacco related death and disease". Onfidence in implementing innovative measures to reduce smoking is further bolstered by the recent victory of Uruguay against a trade challenge by Philip Morris International. The World-Bank dispute resolution tribunal was clear that governments can move "in advance of international practice" and "innovate to protect health."

A "Tobacco Endgame" defines a desired target for the *rate* of smoking prevalence (e.g. 0% or less than 5%) and a *date* by which it is to be met (e.g. 2025). *Strategies* for Endgames are comprised of public health and policy measures through which these ambitious targets are believed to be achievable. No country has, as yet, both developed <u>and</u> achieved a tobacco Endgame – but in four countries documents with an Endgame goal have been published. These include:

- Ireland less than 5% by 2025¹¹
- Scotland less than 5% by 2034.¹²
- Finland 0% by 2040 or earlier¹³
- New Zealand "minimal levels" (or 5%) by 2025¹⁴

Published information within these documents vis-à-vis Endgame Measures vary in their detail, content and the amount of evidence available to support them (indeed this is by definition the case for *truly* novel measures – if never before deployed, evidence of effectiveness will not yet exist).

A TOBACCO ENDGAME INITIATIVE FOR CANADA — DEVELOPMENT OF PROPOSALS FOR THE SUMMIT

Canada has not yet articulated an Endgame Goal or strategy - but in recent months interest has been growing across numerous groups in creating a Canadian Tobacco Endgame. Furthermore, the Federal Tobacco Control Strategy is scheduled for renewal in 2017 – thus there is a unique opportunity to bring an Endgame initiative forward.

In early 2015, a small group of experts met to discuss a local proposal for Queen's University to host a Summit on the topic of a Tobacco Endgame Strategy for Canada. Such an event would coincide with the 175th anniversary of the University and inspire development of bold new ideas for moving from tobacco control towards tobacco elimination.

The individuals engaged felt that the time was right for such discussion. However, they indicated that firstly more widespread engagement was needed in planning and secondly, the Summit itself should not simply be a series of speakers, but rather an opportunity to debate potential options for Endgame measures that would be suitable in a Canadian context. This would require work developed by a series of action groups in advance of the Summit.

In short order, a Steering Committee was formed, which first met on July 8, 2015 to discuss the vision for the creation of a set of truly innovative proposals that could be implemented as Canada's Tobacco Endgame. The

agreed goal of the Committee and the "definition" of Endgame proposed was to achieve *less than 5% tobacco prevalence by 2035* ("Less than 5 by 35"). If this were to be achieved hundreds of thousands of Canadian lives would be saved in this century, this work could serve as a model for other countries, once more putting Canada at the forefront internationally in its efforts to stem the Tobacco epidemic.

Subsequently, a series of "Action Groups" were populated with a wide array of experts drawn from cancer control, health policy, law, tobacco control, academia, medicine, economics, social activism, NGOs, mental health and addiction, professional organizations and more. As shown in Table 1, some Action groups were tasked to discuss and document the potential endgame measures that could be brought to the Summit, and others to reflect on how best to engage with stakeholders, communicate and evaluate the Summit work in the months that followed.

Table 1 – Action Groups and Their Topics

Action Group	Questions to address
Economics/Business case	What are the short and long term impacts on the Canadian economy of achieving an Endgame (e.g. reduced taxation revenue but increased health and longevity of workforc increases income tax revenue)
Regulation and Law	What are the potential changes to regulation around tobacco that could substantially limit its availability and use?
Cessation and Prevention	What are options available to substantially enhance cessation efforts and to prevent tobacco uptake by non-smokers?
Product	What changes to commercial tobacco can be made to substantially reduce its addictiveness/appeal and are appropriate to implement in the Canadian context?
Litigation	What are the opportunities to maximize the impact of litigation on the tobacco industry
Engagement of "Actors" (political and otherwise)	Who will need to be engaged before and after Summit and how if the Endgame implementation is to be successful?
Communication and Public/Professional Engagement	What strategy will be needed to create the public and professional engagement before and after the Summit to ensure the Endgame is implemented?
Evaluation and Research	What types of questions and funding opportunities will need to be in place to evaluate the work and success of the Endgame?

The work of these Action Groups, and the ideas they brought forward, are reflected in the papers that follow in this document. Not surprisingly, proposals from different Action Groups showed some overlap (for example – measures to enhance prevention of smoking behaviour identified by the Cessation and Prevention Action Group overlapped substantially with some measures brought forward by the Regulation and Law Action Group). To address this, efforts were made to consolidate the proposals into thematic topics reflected in the papers that follow. Where appropriate, each paper identified potential Endgame recommendations for discussion. These will be the topics for discussion and debate and the summit.

CONSIDERATIONS AND CONTEXT

E-Cigarettes – the promise and the challenge

While no Action Group was specifically tasked to discuss E-Cigarettes, this topic arose in both the Cessation/Prevention and Regulation/Law Action Groups. Comments on this technology and similar electronic nicotine delivery devices as "Endgame" enabling (or not) are separately presented.

Dispelling Myths.

The notion of a Tobacco Endgame may raise the specter of one or more topics seen by some as immediately meaning an Endgame is impossible. A few words are needed to dispel the following myths:

• Smuggling and contraband

It is often argued that any measure to restrict/reduce commercial tobacco product access (historically taxation increases) *inevitably* lead to an increase in illegal smuggling and rise in contraband product availability *negating* the impact of those tobacco control measures. The evidence does not support this. A summary of data outlined in a 2015 report from the Ontario Tobacco Research Unit found that tobacco tax increases have an overall impact in *reducing* tobacco use (and increasing tobacco tax revenues), *even when* there is some small amount of accompanied contraband tobacco use. Many of the small proportion of smokers who move to contraband tobacco return to legal tobacco within a short period of time. Furthermore, accompanying increased tobacco taxes with anti-contraband measures are effective in minimizing leakage to contraband tobacco.¹⁵

• Governments will not be able to withstand loss of taxation revenue

As tobacco sales fall, it is sometimes argued that governments' loss of revenue from taxation will be a show-stopper. The Economics Action Group has undertaken a review of the literature and developed a model to address the questions around loss of tobacco taxation revenue as a frequently cited potential barrier to substantial reduction in tobacco consumption. Their findings are described in detail in this background paper, and will be important context for the Endgame discussion.

Isn't Endgame just another word for Prohibition?
 In a word, no. The Endgame is about a strategic process and series of measures that gradually decrease smoking prevalence, demand and supply to extremely low levels. This is quite different from an outright

ban on tobacco products where demand remains high.

These myths cannot stand in the way of the need to address the enormous public health burden that the tobacco smoking epidemic has and will continue to cause.

WHERE MORE WORK IS NEEDED

It is clear that a single Summit and a one-year process will not be able to address all the ideas, issues and opportunities the discussion of a Tobacco Endgame brings to the fore. Two needing more work are highlighted here:

Tobacco use by First Nations, Inuit and Métis Peoples

There is a need as well to highlight the particular circumstances of Indigenous Nations with respect to tobacco. For many First Nations people, tobacco historically has been and is used in traditional and spiritual ceremonies, for prayer and thanks. While tobacco is viewed as sacred among Indigenous Nations, the recreational use of commercial tobacco is addictive and harmful. Recreational smoking rates in Canada's First Nations, Inuit and Métis (FNIM) peoples are extremely high. Statistics Canada estimates that daily smoking rates among First Nations on or off reserve, Métis and Inuit are more than twice as high as for non-Aboriginal Canadians. In parallel, the health burden of smoking related illnesses is also extremely high. A recent report from the Canadian Partnership Against Cancer summarizing programs available for First Nations, Inuit and Metis people in Canada identified that many are in place across Canada but noted

that relatively few smoking cessation programs developed by, with, and for First Nations, Inuit, or Métis exist in Canada, highlighting an opportunity for improvement. ¹⁷ It is clear that engagement and consultation within FNIM organizations and communities will be extremely important to undertake as a strategy for a (commercial) tobacco free future is developed and implemented, including strategies developed within and by FNIM communities are essential to maximize the reduction in smoking prevalence. It is equally important to distinguish between traditional tobacco and commercial tobacco in the development of any strategy going forward.

Poverty, equity and disadvantaged populations

There is strong evidence that smoking prevalence rates are higher amongst Canadians with the lowest incomes and those with mental health diagnoses. The disproportionately high rate of smoking in these groups tracks with their increased burden of tobacco-related illnesses, adding substantially to the disparities in health that they experience. While an Endgame strategy cannot be expected to address the root causes of higher smoking rates in each of these groups, programs and policies emanating from Endgame work must reflect, where appropriate, differing community needs and practices. It is important to note that some of the recommendations found within sections of this paper directly reflect on challenges facing some of these groups, such as access and affordability of treatment for cessation and other measures.

The sections that follow document the ideas for Endgame measures that were discussed by many individuals who volunteered their time, their vision and their spirit over the past year. We go with open minds into the Summit to debate, discuss and improve these ideas further. We strongly believe that now is the time to commit to a Tobacco Endgame Strategy in Canada. The status quo is simply not an option. The hundreds of thousands of Canadians who, in the decades ahead, will otherwise be destined to suffer the ill health and premature deaths that tobacco smoking will bring, need action and leadership now.

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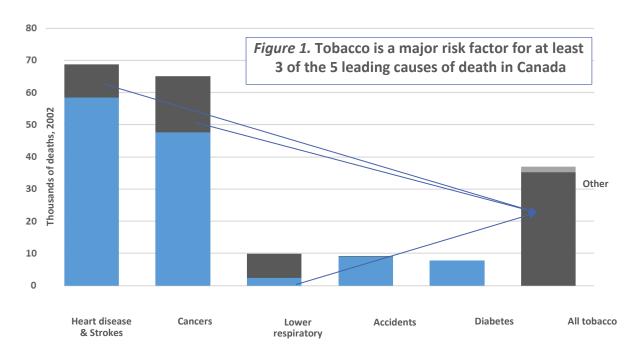
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1. THE ECONOMICS OF SMOKING

DISPELLING THE MYTHS THAT MAY STAND IN THE WAY OF AN ENDGAME

The burden of tobacco use in Canada is enormous. Few people are aware of the magnitude and the full range of health risks of smoking. While many people are aware that tobacco has long been a recognized cause of lung cancer, fewer are aware of the other cancers as well as cancers of the lip, oral cavity, nose, paranasal sinus, pharynx, larynx and esophagus, urinary bladder and ureter, kidney, liver, colorectal, pancreas, uterine cervix, stomach, bone marrow (myeloid leukemia) and is a suggestive cause of breast cancer. Other than cancer, tobacco causes ischemic heart disease, stroke, aortic aneurysm, and type 2 diabetes. Smoking also causes respiratory diseases including chronic obstructive lung disease, and impaired lung function in children and adults. It also causally contributes to the burden of pneumonia, asthma, and tuberculosis. Other diseases include fetal deaths and still births, SIDS, ectopic pregnancy, low birth weight, periodontal diseases, and erectile dysfunction. Each year, the list of diseases suspected or known to be caused by tobacco grows longer – Figure 1 illustrates some of this graphically.



Modeled on graphic used by WHO and available at: http://www.who.int/nmh/publications/fact sheet tobacco en.pdf

As a result of these tobacco related diseases, *in 2002, 37,000 Canadian died from tobacco use,* and this burden is expected to remain very high for years to come as described in the Introduction section. The cumulative burden of tobacco related diseases leads to 23,766 deaths among males and 13,443 among females each year.³ Canadians lose an estimated 515,607 person years of life every year as a result of premature mortality resulting

from tobacco smoking. This burden does not only fall upon the very old. These estimates include 58 boys and 33 girls under the age of one who died as a result of tobacco-attributable causes, and approximately 1,000 non-smokers who died as a result of second hand smoke exposure. Jha et al. (2013) estimated that a male non-smoker in the United States has an 81% chance to live to 70, but a smoker only a 55% chance.⁴

FINANCIAL BURDEN

This incredible burden of morbidity and mortality has direct financial costs for Canada. The primary method of calculating the societal costs of tobacco associated illness has been to assess the impact of illness from a macroeconomic perspective by aggregating costs across all economic agents. This approach derives a societal cost of the illness divided into direct costs (expenses incurred because of the illness (health care costs, medical products costs, etc.)), and indirect costs (e. g. lost wages due to diminished productivity). It does not include welfare and leisure time costs or benefits and does not account for long term changes in demographic composition. Intangible costs such as pain and suffering, or the negative impact of odours are also not considered.⁵

For the 2013 year, Krueger et al. (2015) estimated that tobacco smoking resulted in total costs of \$18.7 billion dollars in Canada⁶. *Direct health care costs alone totalled \$6.4 billion*. This compares to the estimate of \$17 billion dollars in costs per year with \$4.4 billion in direct health care costs estimated for the year 2002 by the Canadian Centre for Substance Abuse (Rehm, Baliunas, Brochu et al. 2006). ⁷ Krueger et al. also calculated that if the prevalence of smoking across Canada were reduced to the levels in British Columbia (12.7%), Canada would save \$2.8 billion per year in direct and indirect costs. Similarly, Popova, Patra, and Rehm (2009) estimated that modest interventions aimed at reducing smoking prevalence (implementing a 10% price increase and increasing coverage of behavioural counselling, nicotine replacement products and physician's advice) would lead to a savings of 33,307 hospital days and \$37 million dollars per year across Canada.³

Canada has already started to see some benefits from reductions in smoking prevalence over the last decades. For example, Manuel et al. (2016) measured the direct health care costs and change in costs between 2003 and 2014 of health care utilization of smokers and ex-smokers compared to non-smokers adjusted for age and SES using health administrative data. They found that 9.9% of Ontario health care costs could be directly attributed to smoking (\$880 million). Over 10 years, the cumulative cost savings attributed to a small decline in tobacco use were \$4.3 billion, accounting for 88% of the total health cost savings realized by the province's interventions against unhealthy behaviours. Recent estimates from the United States suggest that a 10% reduction in smoking prevalence would generate \$63 billion in savings the following year.

COSTS ESTIMATES FROM ENDGAME INITIATIVES AROUND THE WORLD

While reducing death and disease is the primary purpose of Endgame initiatives, there has long been recognition that a benefit of reducing smoking prevalence is a reduction in the financial costs associated with tobacco use.

While different countries have different ways of accounting for these costs, it is clear that the magnitude of the cost of tobacco related illness is large.

1. Tobacco Free Finland 2040

The Tobacco Free Finland 2040 action plan does not include direct cost estimates. The report describes tobacco control as an "investment and positive action". Next steps include the development of an investment plan and the identification of cost effective interventions. The government report further suggests need to estimate costs but this has not been done.¹⁰

Summary of from Tobacc Endgame in	co
Country	Per Capita Direct costs
New Zealand Canada Ireland Scotland United Kingdom	463 \$183 \$160 \$96 \$57

2. Smokefree Aotearoa 2025 (New Zealand)

The New Zealand initiative was developed with focus on selecting "cost effective" or "cost efficient" rather than cost saving interventions. However, they calculated health care costs attributable to smoking by comparing the costs of health care in those who smoked to never smokers in health administrative databases, either identified through hospital coding or through linkage with a population survey.¹¹

Findings: Direct excess health care costs of smoking over never smoking were estimated to be in the range of \$1.9 billion NZD up to \$2.34 billion annually.

3. Tobacco Free UK

Action on Smoking and Health (ASH) UK estimate of the cost of smoking provided a 2014 estimate of the overall cost of smoking to the UK for policy purposes. The ASH UK model includes health care, loss of productivity, cost of the cigarette package, absenteeism, loss of productive output (human capital), environmental costs, and fire costs. This method used additive attributable risk to estimate health care costs. 12,13

Findings: 13.9 billion pounds per year, 2 billion pounds in direct health care costs attributed to smoking.

4. Scotland 2034

The Scottish Endgame initiative used the Global Burden of Disease Project attributable fractions to estimate direct financial costs. ¹⁴ They subsequently applied the percentage of costs attributable to tobacco to actual health care costs in each region of Scotland to calculate tobacco related health care expenditures.

Findings: Direct costs up to 509 million pounds per year

5. Ireland 2025

The Tobacco Free Ireland report¹⁵ refers to a number of external costs studies, including "A study on liability and the health costs of smoking" commissioned by the EU.¹⁶ This report calculated direct costs, productivity costs (absenteeism), premature mortality in monetary terms using smoking attributable fractions. The report also calculated the cost of mortality using a willingness to pay model.

Findings: Direct costs of 500 million Euros, productivity losses of 160 million Euros and premature mortality cost valued at 3.5 billion Euros.

TAXATION AND LOST REVENUE - A MYTH WORTH DISPELLING

Cigarette taxes bring in significant revenue to governments at the national and provincial level.

In 2014-2015 Canadian Federal and Provincial governments received \$8.2 billion from the sale of tobacco.¹⁷ There is concern expressed by those opposed to tobacco elimination that reducing the number of smokers would decrease government revenue and that this would be of such a magnitude that it would not happen. However, there is overwhelming Canadian and international evidence that increases in tobacco taxes can reduce tobacco use and increase government tax revenue. ¹⁸⁻²⁵ At current taxation and tobacco use rates, taxes on tobacco products have the dual effect of decreasing the demand for tobacco and increasing government revenue. In fiscal year 2014-15, the federal government collected more than \$3 billion in cigarette taxes. ²⁶ In Ontario and Québec, Canada's largest provinces, the provincial governments collected more than \$1 billion each.

If Canada achieves 'less than 5 by 35' through non-tax interventions, total taxes collected on the sale of tobacco products would dwindle substantially. Given that in 2014, 18.1% of Canadians aged 12 and older smoked either daily or occasionally, ²⁷ it could be expected that annual tobacco tax receipts decrease by as much as 75% from 2035. Moreover, during the period of transitioning from 18% to 5% smoking prevalence, the cumulative amount of tax losses year over year would be far from negligible. Achieving 'less than 5 by 35', however, need not be achieved solely on the back of non-tax interventions. In the case, albeit extreme, that 'less than 5 by 35' is achieved solely through tax and price increases, the cumulative tax revenue gains during the transition period could be considerable. Irrespective, then, of the substantial cost savings gained from reductions in health care spending and reductions in indirect costs to society detailed above, it may be that during the period of transition to "less than 5" there may be minimal changes in government revenue, assuming that increased tax rates are a component of an Endgame strategy.

Our objective is to simulate the effect on tax revenue of achieving 'less than 5 by 35' in Canada.

METHODS

Full details for the simulation model appear in the Supplement. This model simulates the impact of tax and price increases required to achieve 'less than 5 by '35' by examining the impact on taxation revenues under three different scenarios: 1) 'less than 5 by 35' is achieved through non-tax interventions and excise taxes are increased only to keep up with inflation; 2)'less than 5 by 35' is achieved solely through excise tax increases; and 3) 'less than 5 by 35' is achieved through non tax intervention and excise tax increases that raise prices by 5% in real terms annually. We used accepted estimates of elasticity for changes in tobacco prices for adults (-0.4) and twice that for youth. The model accounts for population growth and inflation. We used data for the province of Ontario to simulate the impact of tax and price increases required to achieve 'less than 5 by 35' on tax revenue. At current tax rates, it is expected that Ontario will collect about \$1.5 billion in 2016. All monetary figures below are in constant \$2016.

RESULTS:

Scenario 1: 'Less than 5 by 35' achieved solely through <u>non-tax</u> interventions (excise taxes assumed to keep up with inflation):

- Tax revenue, 2035: \$163 million
- Tax revenue, 2016 2035: \$12,605 million
- Tax revenue, annual average, 2016 2035: \$630 million

Scenario 2: 'Less than 5 by 35' achieved solely through excise tax increases (assuming an underlying annual downward trend in smoking prevalence and consumption of 2.5%). Note that such a scenario requires that taxes increase annually by more than 20%:

- Tax revenue, 2035: \$5,054 million
- Tax revenue, 2016 2035: \$ 68,884 million
- Tax revenue, annual average, 2016 2035: \$3,444 million

Scenario 3: 'Less than 5 by 35' achieved through non-tax interventions <u>and</u> excise tax increases that raise prices by 5% in real terms, annually:

- Tax revenue, 2035: \$673 million
- Tax revenue, 2016 2035: \$24,261 million
- Tax revenue, annual average, 2016 2035: \$1,213 million

SUMMARY:

If Canada achieves 'less than 5 by 35' through non-tax interventions, annual tobacco tax receipts would decrease from about \$1.5 billion to about \$160 million in 2035. However, if tax rates increase such that prices increase by 5% annually (in excess of inflation) — a policy pursued by France from 1991 to the early 2000's — average annual tax revenue would amount to about \$1.2 billion and the cumulative taxes collected between 2016 and 2035 would be near \$25 billion.

Scenario 2 of the model, which shows that extremely high cigarette prices would be needed to achieve the 'less than 5 by 35' goal through taxation *alone*, underscores the need for a comprehensive policy for the Tobacco Endgame that relies on both tax and non-tax interventions.

Allowing for a portion of the effect of tax and price increases on tobacco use and consumption to be directed towards contraband cigarettes would reduce tax receipts, as expected, but does not invalidate any of the key findings. Similarly, our results are not sensitive to the use of a more conservative own-price elasticity estimate of -0.3.

Lost taxation revenue should not be a barrier to the Endgame. The analysis shows that with a sensible taxation policy, revenue impact over the period of implementation is minimal irrespective of the health care and social savings. Ultimately, however, it is important to recognize that the massive health and mortality burden due to tobacco is not worth sustaining for any amount of profit or revenue.

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SUPPLEMENT TO CHAPTER 1 - Data and Methods for Tax and Price Increase Simulation Model

Baseline data:

- Smoking prevalence and daily number of cigarettes consumed per smoker, by age: we used the most recent cycle (2014) of a large national survey, the Canadian Community Health Survey (CCHS) and obtained point estimates for smoking prevalence and intensity.
- Projected population: we used Statistics Canada medium growth population projection scenario (M1: medium-growth, 1991/1992 to 2010/2011 trend, CANSIM Table 052-0005).*
- Excise tax rate and revenue: we obtained current tobacco excise tax rates and more recent estimates of tobacco excise tobacco tax revenue from provincial Ministries of Finance
- Total cigarette tax paid sales: as a measure of tax-paid sales we used cigarette wholesale data as reported by tobacco manufacturers to Health Canada.

Baseline model parameters and assumptions:

- Own-price elasticity: there is overwhelming evidence that individuals respond to changes in tobacco prices. In high-income countries such as Canada and the United States, it is generally accepted that a 10% increase in prices would reduce total consumption by about 4%; and that half of the reduction comes from a reduction in the number of smokers and half from a reduction in consumption among continuing smokers.[1] It is also generally accepted that youth respond more to changes in prices about twice as much as older adults.[1] Consequently, as a baseline assumption for own-price elasticity for cigarettes, we used -0.4 for adults (20 years of age and above) (-0.2 for own-price prevalence elasticity and -0.2 for own-price consumption elasticity), and twice that for youth (12 to 19 years of age).
- Pass-through rate: tax changes do not necessarily lead to price changes as manufacturers are rarely required to pass on the full extent of tax increases to consumers. Manufacturers often under- or over-shift tax changes. In mature cigarette markets such as Canada, manufacturers typically over-shift tax increases. As a baseline assumption, we assumed that tobacco manufacturers over-shift tax increases by 10%.
- Prices: in order to estimate the effect of tax changes on smoking, it is necessary to estimate first the effect of tax changes on current prices. We used \$0.40 per cigarette stick.
- Underlying trend: smoking prevalence in Canada has steadily decreased since the mid-1960s. In 1965 about half of all Canadians aged 15 and above smoked. By the early 2010s, only about 20% did.[2] This steady decline was due to many factors such as information on the harmful effects of active smoking and secondhand smoke, tobacco control policies such as smoke free policies, advertising bans and taxation and changes in anti-smoking sentiment. Although it is difficult to disentangle the effects of each of these factors, it seems reasonable to assume that the downward trend in smoking prevalence observed between the early 2000s and the present would not abruptly end in the near future. In the last decade for which data are available, smoking prevalence, on average, declined annually by about 2 and 3% depending on the province. We assumed an underlying trend of 2.5% in annual decrease in both smoking prevalence and daily number of cigarettes consumed per smoker.
- Expected inflation: as a measure of expected inflation we used 2% annual increases to reflect the Bank of Canada's 2% inflation-control target.
- Cigarette tax evasion: although cigarette tax evasion has many causes, high taxes undeniably create an incentive for tobacco users and manufacturers to elaborate ways to evade tobacco taxes. Although the illegal nature of cigarette tax evasion makes it intrinsically difficult to measure accurately, cigarette tax evasion in some Canadian regions such as southern Ontario is not negligible. While recognizing this, our model does allow for a portion of the effect of tax and price increases on tobacco use and consumption to be directed towards contraband cigarettes.

Model Limitations

- A reduction in smoking prevalence and consumption in excess of current trends would inevitably lead to future populations that are larger than projected by Statistics Canada's medium growth population projections.
- There is strong evidence than higher incomes increase the demand for tobacco products.[1] However, income growth in Canada is projected to be relatively low. Consequently, income effects are unlikely to affect the above results.
- Our approach examines the effect of changes in tobacco excise rates on tobacco excise revenue and not on harmonized sales tax (HST) as ex-smokers and continuing smokers that reduce their consumption will very likely divert their spending towards goods and services that are also subject to HST.
- Our approach does not address the issue of tax avoidance such as brand switching. However, because governments in Canada rely entirely on tobacco specific excise taxes and not on specific ad valorem taxes, tax avoidance is a lesser concern.

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2. BUILDING ON SUCCESS.

SCALING UP INTERVENTIONS THAT WORK

Canada has implemented an impressive array of regulatory interventions, but at their current levels, they are not sufficient for advancing smoking rates to less than 5 percent by 2035. However sufficient scaling up[‡] of some of these measures has the potential to make a substantial impact on the prevalence of tobacco use.

Five areas of existing regulatory activity with proven effectiveness should be scaled up as part of Canada's Tobacco Endgame Strategy: 1) tax and price measures, 2) tobacco advertising and promotion bans (including plain packaging); 3) banning smoking in additional settings; 4) anti-contraband measures and 5) new funding streams.

1. TAX AND PRICE MEASURES

A. Increase tobacco taxes substantially:

Price has been one of the most effective tobacco reduction measures. There is strong evidence of high quality indicating that for every 10% increase in price of tobacco, consumption will decrease by around 4%. Jha and Peto¹ recommend tripling taxes to double price and decrease consumption by 50% - a course of action successfully undertaken in both France and New Zealand. The impact of tax increases on achieving the Endgame target is explored in more detail in the section addressing economic aspects.

B. Curtail price-based marketing incentives:

Federal legislation prohibits most marketing incentives, but not three-tier pricing model (premium, mi-tier and budget). Evidence shows that smokers who switch to discount brands less are likely to quit. Prohibitive (high) pricing could serve as a motivator to reduce consumption and as a market entry barrier.² Twenty five U.S. states have minimum price laws, but these are weakened by loopholes allowing trade discounts and promotional incentive programs New York State has have disallowed such incentive programs.³ Minimum price laws may risk increasing tobacco industry profits and reducing the pricing room available to governments to increase taxes.

2. BAN ALL TOBACCO PROMOTION, INCLUDING THROUGH IMPLEMENTATION OF PLAIN AND STANDARDIZED PACKAGING

A. Plain & Standardized Packaging (PSP)

PSP regulations remove graphics, logos and brand colours from tobacco packages and standardize pack shape and size. Plain packs have drab colors and maintain health warnings. The Canadian Cancer Society suggests that plain packaging would:

- eliminate promotional aspects of packaging;
- curb deceptive messages conveyed through packaging;

Various measures might be considered as "scaling up" existing interventions. Though some measures are included in this section entitled "scaling up", some measures in other sections of the paper might also be considered "scaling up".

- enhance the effectiveness of health warnings; and
- reduce tobacco use.⁴

Studies using experimental subjects show that plain packaging reduces the appeal of tobacco products and makes them less attention-grabbing, by reducing perceived attractiveness of the package, and by alleviating positive associations between specific brands and a smoker's identity. Studies using post-market data conducted in Australia following the implementation of plain packaging regulations provide a real-world understanding about the various impacts of plain packaging. The Single Source Survey Data conducted by Roy Morgan (an Australian market research company) found that the implementation of plain packaging (combined with enhanced graphic health warnings) resulted in a significant decline (0.55 percentage points) in smoking prevalence (among Australians 14 years of age or older) post-implementation compared to the anticipated prevalence without the implementation of plain packaging.

Plain and standardized packaging could be accompanied by a single presentation requirement, that is one brand variant per brand family, as Uruguay has implemented.

Zacher and colleagues, using an observational study, compared the change in the prevalence of pack display and smoking outdoors, before and after implementation of plain packaging legislation. ⁷ They concluded that following the full introduction of cigarette plain packaging legislation, smoking in outdoor areas of cafés, restaurants and bars declined by 23%.

B. Enhance package health warnings

Package health warnings are recognized to be cost-effective and are at present the most extensive communication in Canada to discourage tobacco use. Warnings can be enhanced by increasing their size, by improving content, and by increasing the frequency with which they are changed/refreshed.

C. Close holes in laws banning tobacco advertising and promotion

The remaining advertising in Canada is comparatively small and does not have nearly as large an effect as in the past. Nevertheless, advertising on matches/lighters, direct mail, bars, price signs at retail, online advertising and within the tobacco trade continues to encourage initiation and to make it more difficult for some smokers to quit. Young Canadians are still exposed to these promotions despite the intent of the *Tobacco Act* to reduce tobacco promotions to young people.

D. Retail advertising & promotion

With retail display bans in effect across Canada, there is evidence that the tobacco industry continues to promote its products at retail outlets by way of incentive payments to retailers for pushing their products mainly by offering discounts and extra payments to retailers. Quebec's Bill 44 will ban this practice effective November 2016 and other Canadian jurisdictions could do the same. In most provinces, total display bans have tobacco products sold from closed spaces that are clearly visible to customers. Under-counter storage is also feasible and should be considered.

E. Smoke-free movies (18A classification)

Movies are a powerful vehicle for promoting tobacco use. A substantial body of scientific evidence indicates that exposure to smoking in movies is a significant cause of smoking initiation and progression to regular smoking among youth. Higher exposure to onscreen tobacco increases the uptake of smoking among youth and undermines tobacco prevention efforts. 37% or more of youth who start smoking do so

as a result of seeing smoking in movies. Establishing an 18A classification (adult accompaniment) for movies that depict smoking would decrease initiation and gradually prevalence.

3. BAN SMOKING/TOBACCO USE IN MORE PLACES

While smoking is banned in almost all indoor places and some public places there are still some gaps that could be closed as part of Canada's tobacco endgame. By not closing these gaps, substantial parts of the population continue to be subjected to physical and social exposure to smoking. The social acceptability of smoking in these places contributes to initiation and impedes the success of quit attempts. Modelling is an essential element of childhood development and substantial evidence shows that increased youth exposure to tobacco use increases tobacco initiation among youth. Places where smoking is yet to banned in many Canadian jurisdictions include post-secondary school campuses, public spaces/workplaces on First Nation reserves, social and other multi-unit housing, and some outdoor public places. Also, in many jurisdictions, waterpipe smoking is not included in smoking bans.

4. Prevent contraband

Contraband tobacco trafficking undermines tobacco control efforts by curbing the effectiveness of tax increases and by causing government to be reluctant to adopt many policies out of fear that smokers will turn to the contraband market.⁸ In Canada, anti-contraband measures that have been implemented include the following: (1) licencing; (2) marking/labeling; (3) record keeping/control measures: (4) enforcement; (5) export taxation: (6) tax harmonization; (7) aboriginal tax agreements/compacts; and (8) Memoranda of Understanding and legal agreements.⁹ Yet, contraband activity continues to be a problem and as other tobacco endgame measures are implemented, it poses a risk of potentially increasing proportion.

Evidence from Quebec has shown that anti-contraband efforts can be successfully implemented. In 2008-09 the Quebec government increased efforts to control contraband tobacco through the Actions Concertées pour Contrer les Économies Souterraines (ACCES) tobacco committee which aimed to dismantle smuggling networks and to recover the tax losses linked to the illicit trade in tobacco. The actions that were taken since 2008 have led to a reduction in illegal tobacco trade and smuggling as well as increased revenue from taxes on tobacco products (from \$654 million in 2008-2009 to \$1,026 million in 2013-2014 without an appreciable increase in smoking rates in Quebec). There are a series of contraband prevention measures that have not yet been implemented by federal and provincial governments.

We are cognizant of the possibility that unless appropriate measures are taken, contraband could become a challenge of a different order of magnitude, the farther down the road we go toward constraining and transforming the existing commercial industry and the price/tax structure. There is a need to consider what anti-contraband measures might be needed to prevent the illicit tobacco supply from both the tobacco industry and illegal manufacturers from increasing in parallel with increasingly strong measures to curtail demand and supply of commercial production.

5. New Funding Streams

To encourage, support and supplement tobacco endgame interventions it is necessary to maintain and strengthen tobacco control activities carried out by a variety of actors at the national, provincial and regional levels. Funding for tobacco control activities has been unstable and low in comparison to CDC recommended

levels. To enable the other endgame measures, it is suggested that that the polluter pay principal be applied; and money so raised be used to support tobacco control activities:

A. Tobacco manufacturer license fee:

Since 2009, the US FDA has required a tobacco manufacturer license fee to recover the annual cost of the FDA's tobacco activities (in fiscal year 2016-17, FDA tobacco budget is US\$635 million). In Canada, between 1998 and 2001, the Senate on three occasions adopted bills that would have required a tobacco manufacturer license fee but these bills were not considered by the House of Commons. In B. C., legislation to require a tobacco manufacturer license fee was adopted in 1998 but was never proclaimed and was later repealed by a new government following an election. Many provinces have levies/license fees on industry sectors to pay for a particular initiative (e.g. levies on hotel rooms, such as 4% per stay with funds raised used to cover the cost of tourism promotion for the city/province; levies on potato growers to pay for the promotion of potatoes from the province.) Also many industries are subject to a "polluter pays" system of cost-recovery for damages resulting from harmful activities or events. For example, the costs associated with oil spills and train derailments are often paid by the companies involved. Tobacco companies should not be excused from the polluter pays principle, especially since Canadian governments are seeking significant damages for healthcare costs resulting from tobacco industry negligence and deception. Governments could require the tobacco industry to pay at least a portion of tobacco-related health care damages up-front through license fees rather than waiting for an unpredictable decision by the Courts.

B. Registration fee for every product:

Manufacturers can also be required to pay fees based on a per product basis (e.g. federally for approval of drugs, or medical devices). These are sometimes referred to as "user fees".

OPTIONS FOR SUBSTANTIAL SCALE-UP

- Increase tobacco taxes substantially
- Curtail price-based marketing incentives
- Implement plain and standardized packaging
- Enhance package health warnings
- Implement a full ban on tobacco advertising and promotion, including at retail
- Require movies that depict smoking to have an 18A classification, or equivalent
- Ban smoking in additional places, and ensure smoking restrictions apply to herbal water pipe products and to any product that is smoked
- Implement additional measures to reduce contraband
- Implement an annual tobacco manufacturer license fee to recover the annual cost of federal/provincial/territorial government tobacco control strategies
- Require tobacco manufacturers to pay an annual registration fee for each product

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3. NO SMOKER LEFT BEHIND.

TRANSFORMING ACCESS TO TOBACCO CESSATION

To reduce smoking prevalence in Canada to under 5% of the estimated population of 37 million Canadians in 2035, the absolute number of smokers in Canada will need to fall from today's estimated 5.4 million people to under 2 million. While prevention strategies will be central to achieving this, they alone will be insufficient to achieve the goals of less than 5% prevalence and to stem the excess deaths expected from tobacco use. This means we will have to introduce new approaches to increasing the proportion of smokers who are successful in quitting from today's two in three to at least four in five within the next two decades.

Evidence suggests this is possible: many Canadians have successfully stopped smoking, especially those who are more affluent and educated.³ *The Endgame challenge will be to make quitting a reality for all Canadians who want to quit, and to ensure that no smoker is left behind.*

Smoking behavior and related illnesses cross all social groups but are particularly prevalent in the least well educated in society. The prevalence rate of current smoking is significantly higher for Canadians with lower levels of education compared to those with higher levels of education. In 2012, Schwartz et al⁴ described that Canadians aged 18 years or over who had less than a high school education, completed high school, or completed some post-secondary education reported a higher prevalence rate of current smoking (29%, 24%, and 23%, respectively) than those who had completed post-secondary education (17%). Nevertheless, the greatest absolute number of current smokers is observed among Canadians who had completed post-secondary education, representing 2.6 million of the (then) 5.4 million smokers aged 18 years or over in Canada (or 49% of all smokers).

SMOKING CESSATION AND INEQUITIES

There is also strong evidence that smoking prevalence rates are higher in some Canadian communities than others – and these higher rates of tobacco use add substantially to health inequities .

In terms of individual smoking/tobacco cessation programs, improving access to tools that are known to help people quit (i. e. counselling, quitting medications and behavioural interventions) may represent the most promising approach for reducing smoking rates in disadvantaged groups. However, many authors conclude that more research is needed to establish the most effective interventions for some vulnerable high-risk groups (e. g. prisoners, homeless).

Furthermore, a recent report from the Canadian Partnership Against Cancer summarizing programs available for First Nations, Inuit and Metis people in Canada identified that many are in place across Canada but noted that relatively few smoking cessation programs developed by, with, and for First Nations, Inuit, or Métis exist in Canada, highlighting an opportunity for improvement.⁵

It is clear: In addition to interventions aimed at the general population where the greatest numbers of smokers are, new strategies are needed to specifically target and meet the needs of the populations where smoking rates are highest, and to find interventions that have a relatively greater impact in these groups.

EVIDENCE TO SUPPORT CESSATION ACTIVITIES

Cessation of smoking and other tobacco use will be greatly supported by the variety of Endgame actions which have been proposed for new regulations, product and marketing changes, etc. Putting these measures in place, however, will not remove the need for increasing support for new and existing programs targeted at helping *individual* smokers to quit.

For over 50 years, governments and health systems have recognized the risks of tobacco use and the importance to individual and public health of reducing smoking rates. Unfortunately, this recognition has not yet translated into a commitment to scale-up efforts and provide a sufficient dose of effective treatments to achieve a more substantial population-level change. Doing so in a framework that includes accountability for action will be a necessary step to achieving an Endgame for tobacco.

The foundation for such programs, and the evidence to support them, has been solidly built. Recent reviews have been undertaken by CAN-ADAPTT (the Canadian Action Network for the Advancement, Dissemination and Adoption of Practice-informed Tobacco Treatment), the U. S. CDC (Centers for Disease Control and Prevention), the Cochrane Collaboration and others. The measures validated by these reviews have been endorsed by the World Health Organization and other health authorities, and are among the obligations of countries which are party to the Framework Convention on Tobacco Control (FCTC).

A wide range of clinical and social interventions have been demonstrated to increase the number of quit attempts and the chances of a smoker successfully quitting. Even low intensity methods, like the brief provision of physician advice or self-help materials, will lead to fewer smokers. The most successful cessation programs are those which provide smokers with both behavioural support and stop smoking medications.⁶

Yet most smokers do not receive any support at all when they try to quit, even though doing so would likely increase the likelihood of their succeeding. The province of Ontario, for example, has implemented several interventions to support quitting, but these have reached fewer than 7% of the smokers in that province.⁷

To put these effective supports within the reach of smokers, they must be implemented in a number of settings in ways that ensure their use. For this reason, the FCTC recommends that governments "strengthen or create a sustainable infrastructure which motivates attempts to quit, ensures wide access to support for tobacco users who wish to quit, and provides sustainable resources to ensure that such support is available." The U. S. Centres for Disease Control and Prevention recommends a budget of US\$4.05 per capita for cessation interventions. No Canadian jurisdiction meets this level of investment.

Other population-wide and community interventions, such as advertising campaigns, taxation and price increases, social marketing and communications, health warning labels, Quit and Win competitions, news stories and other earned media, or even pharmaceutical advertisements, can increase the likelihood of a smoker making a quit attempt. These programs can be directed at the general population, or delivered to specific communities. The U. S. FDA, for example, recently launched a "This Free Life" campaign aiming to prevent and reduce smoking among lesbian, gay, bisexual and transgender young adults, who are twice as likely to use tobacco as other people their age. The CDC recommends an average expenditure of US\$1.69 per capita in for such mass-reach activities.

As health care systems are under the jurisdictional authority of the provinces, smoking cessation supports have primarily been the responsibility of provincial governments. Collaboration among governments has resulted in

the provision of some pan-Canadian services, such as Quit Lines. The Ottawa Model for Smoking Cessation is available in hospital and primary care locations in 48 cities. 12

The ability of a smoker to gain access to clinical or community services to support cessation varies greatly depending on the part of Canada in which they live. ¹³ Some, but not all, provinces cover the costs of stop smoking medications. The province currently providing the greatest access is British Columbia, where in 4 years more than one-quarter of smokers have been provided with no-cost cessation medications to help their quit attempts. ¹⁴

Today, there is no health system in Canada which is committed and resourced to provide a smoker with the same level of treatment for nicotine dependence as would be provided to treat the diseases caused by addiction to other substances. This must change.

TRANSFORMING CESSATION EFFORTS TO ACHIEVE THE ENDGAME GOAL

Transformation in the delivery and accountability of cessation efforts are required to achieve the endgame goal. The recommendations that follow are primarily focused on achieving this transformation through increasing the *scale* of the policy interventions, the *accountability* imposed on those who design and deliver cessation programs within the system, and finally through *embedding* the majority of the interventions within our universal health care system, as well as workplaces and community organizations. Beyond scaling up, transformation will occur through *scoping out* cessation with recommendations regarding novel interventions to overcome tobacco addiction and as well, actions that could specifically address the high smoking rates in disadvantaged and impoverished populations.

1. OPPORTUNITIES FOR SCALING UP.

A. Treatments that are universal, comprehensive and accessible.

Smoking cessation program access should be available through <u>all</u> health care settings. Institutions, clinicians *and* health care professionals should be accountable for screening, documenting, providing cessation programs, and be appropriately funded to provide smoking cessation counselling and treatment as they would for any other medically necessary treatment. Quit lines should be sustained with increased promotion.

Health care institutions should be responsible and accountable for screening for smoking and delivering smoking cessation programs to the smokers in their care; inpatients should have standard NRT orders provided, and electronic medical records should include mandatory fields for smoking and discussion of cessation. In recognition of its importance, access to smoking cessation, documentation of screening rates, and prescription of smoking cessation medication and counseling should be included as a *Required Organizational Practice*¹⁵ in the accreditation of hospitals and clinics. This metric should also be included in the Health *System Performance indicator list* developed by the Canadian Institute for Health Information. ¹⁶ Funding support that follows patients from inpatient to outpatient settings could ensure cessation begun in hospital could be sustained after discharge without interruption.

- B. Expanded settings and new partnerships for access to cessation services:
 - Supportive and pro-active workplaces
 Programs and policies should be developed and implemented at the workplace to promote cessation.
 These could include a ban on smoking in all workplace settings, indoor and outdoors, incentives for

employers to support cessation, better engagement of workplace health and safety systems and workplace benefit programs. Coverage for cessation treatments must be included in benefits packages and must be mandatory for all employers.

Supportive and enabling communities

Many smokers are recipients of community and social support and can be reached through housing shelters, community centres, and access points for social service supports. This social infrastructure should be engaged to reach smokers and to make support for quitting a standard offering.

• Residential and Ambulatory Addiction Programs

Individuals admitted to such programs for drug and alcohol addiction treatments should also receive treatment for any addiction to tobacco. The treatment of this addiction should be an integrated within these programs and all programs should be accredited to provide integrated tobacco addiction treatment as part of the service offering. People requesting specific services to address severe tobacco use disorder should be admitted residentially as well if appropriate.

The work in specific communities to transform access to appropriate cessation services, tools, and programs should also identify opportunities to collaborate with initiatives which address improving the health of the overall community.

C. Increased health professional expertise

At the core of this recommendation is the strong conviction that as a risk factor for disease, smoking must be screened for <u>and</u> managed just as other risk factors, such as hypertension or hyperlipidemia, are addressed in clinical practice. All health professionals should be capable of screening for and delivering smoking cessation treatment. Training should be included in the competency based curricula, for all regulated health professions.

D. Access to essential medicines and treatments

Behavioural counselling and access to evidence based pharmacotherapy for smoking cessation should be easily and freely available, with no restrictions on duration. This will require changes in policy for drug coverage in both the private and public sectors. Further steps to reduce cost can be taken, such as removing sales taxes (e.g. HST, PST, GST) from NRT and prescription smoking cessation products.

E. NRT – indicated use for as long as is needed

Some consumers use nicotine replacement products (e.g. nicotine gum) on a long-term basis as a substitute for smoking. Some physicians advise their patients to do so. However in Canada on the labelling for NRT, there is no indicated use for NRT to be used on a long-term basis. For example, the insert inside a package of nicotine gum states "Consult your doctor if you are finding it difficult to reduce your intake of nicotine gums or after using the product for 6 months" and "Do not use for more than 6 months without consulting a doctor". The indicated use on the label should be modified to indicate that NRT could be used as long as is needed. One country, the United Kingdom, has implemented this measure.

F. E-Cigarettes and similar electronic nicotine delivery systems (ENDs)

The role of e-cigarettes in a Tobacco Endgame is discussed elsewhere. With respect to smoking cessation, although ENDS may be useful tools to lead to successful quit attempts in some tobacco smokers (see, for example, April 2016 report by Royal College of Physicians¹⁷), e-cigarettes as currently marketed and used

will not likely move prevalence of smoking very far toward achieving endgame targets. This may, however, change in the future. Caution is advised in promoting e-cigarettes as long-term substitutes for cigarettes as the health effects of regular long-term use are not known. Data are currently evolving on the impact and effectiveness of these devices as cessation aids and should be monitored to determine how best to frame their use in the Endgame discourse. Regardless of their value as Cessation aids, in Canada regulation is required that, at a minimum should include: product content (including nicotine levels, other additives); and they should not be marketed in a way that will promote their use by non-smokers or by youth. Notwithstanding uncertainty surrounding e-cigarettes as smoking cessation devices, they may in the future have potential as a tool in helping phase out tobacco and achieve the endgame, as discussed later

G. Respect and inclusion

The right of all smokers to cessation support should be recognized by ensuring that services and programs are offered in ways that are culturally-appropriate, respectful and adapted by and for the communities and cultures they serve.

2. OPPORTUNITIES FOR SCOPING OUT

The impact of fully implementing the proven measures identified above can be strengthened by the development of novel cessation supports and by fostering innovation within the systems that provide them to reach more smokers and groups of high smoking prevalence.

A. Novel approaches targeted at individuals

The Action Group recommends further development of novel approaches for cessation approaches, and offers the following as ideas that could be considered:

- Financial or other gift incentives for smokers to quit.¹⁸
- Free NRT coupon and cessation program information mandatory inclusions in packages of tobacco products.
- Proactive recruitment of smokers into cessation programs using novel technologies, text messaging services, apps, mobile/outreach services

B. Novel approaches to address disadvantaged populations

While it is expected that the scaled up interventions noted above will have substantial impact for Canadians in all circumstances, specific strategies to promote cessation in populations with circumstances that are associated with higher smoking rates must also be developed. A variety of approaches will be required to address the many social, economic, personal, cultural and political factors which contribute to inequities in tobacco use.

C. Novel wide-reach media campaigns that are hard-hitting and sustained

Mass media campaigns can be effective at reducing smoking rates if they are well-designed, high-impact and sustained.¹⁹ Campaigns which focus on tobacco industry denormalization have been singled out as being particularly effective and a number of U.S. states, including California, Massachusetts and Florida, have demonstrated the impact that such programs can have.²⁰ No Canadian jurisdiction has yet attempted to launch comparable campaigns.

A key goal of comprehensive tobacco control is to increase the population cessation rate. The Ontario Tobacco Research Unit has estimated Ontario's cessation rate, that is, the proportion of smokers who remain quit for twelve months, to be only 1.9% ²¹. This cessation rate has remained unchanged for many years. The OTRU has estimated that the provincial smoking cessation rate would need to double in order to achieve a five percentage point reduction in smoking prevalence, a five-year target set in 2010 by the provincial Tobacco Strategy Advisory Group. ²² This five percentage point reduction is equivalent to 490,000 fewer smokers in Ontario ²³.

Public Education and mass media campaigns have been shown to increase quit attempts and increase population cessation rates.²⁴ Evidence has shown that messages that communicate the negative health effects of smoking and elicit a strong emotional response through the use of testimonials and graphic imagery are more effective at promoting recall and in motivating quitting behavior. A recent mass media campaign conducted by the Centres for Disease Control (CDC) in the United States featuring testimonials from former smokers about the serious harms they experienced from smoking was found to be effective, resulting in over 1.6 million quit attempts and over 100,000 quit attempts lasting at least six months.²⁵ There are many opportunities for local communities to use paid and earned media to extend the messages of larger campaigns that may be implemented at a provincial level. State-wide and local partnerships were critical to securing additional media coverage, both paid and earned, for the CDC campaign, contributing to the overall success of the campaign.

THE CHALLENGES AHEAD AND HOW TO OVERCOME THEM

Escalating community and health system support for smoking cessation to an Endgame scale is a complex endeavour that will require the active engagement of a multitude of systems and actors.

Policy and administrative changes will be required at the federal, provincial, regional, municipal and institutional levels. Training, regulatory and accreditation systems will have to be enhanced, and supportive infrastructures with accountability frameworks must be put in place. The necessary human and financial resources will have to be secured in sufficient quantity and sustained over time.

Such challenges are not unique to tobacco control. Other disease prevention measures - food safety, clean water, mass immunization, mental health - have similarly required a multi-tiered system change. Oversight mechanisms and accountability frameworks are a necessary component of such programs.

Catalyzing this engagement and accountability for its success is a "must do" Endgame action.

RECOMMENDATIONS

Short term

- Federal and provincial ministries of health, through the Tobacco Control Liaison Committee or other mechanism, should collaborate in the development of a roadmap to expand and adequately fund community, workplace and clinical smoking cessation programs to Endgame scale.
- Each ministry of health should create a smoking cessation accountability framework for its healthcare system and related transfer payment agencies as part of the cessation program framework.
- Pan-Canadian research funding agencies together with the Federal Tobacco Control Liaison
 Committee should collaborate in the development of a research road map as well as a strategy
 for the funding required to support the required research in support of the End Game

Medium term

- Implementation of the expanded cessation programs will begin alongside the accountability framework
- In collaboration with the ministry of health, ministries of labour and social services should integrate smoking cessation supports within their service delivery systems.
- Organizations which train, regulate, accredit or fund health care professionals or institutions should be required to report on the measures they have taken to respect the right of smokers to receive effective cessation support.
- The federal minister of health should provide bi-annual reports to parliament on the status of smoking cessation across Canada.

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4. ALIGNING TOBACCO SUPPLY WITH PUBLIC HEALTH GOALS

For more than half a century, governments have tried to discourage people from smoking by increasing public knowledge about the dangers of smoking and by seeking to influence behaviours in directions away from smoking. This demand-reduction approach has worked only modestly well: Canada still has 5.4 million smokers (18% of adults) and smoking is still the largest preventable cause of disease and death. But even with implementation of a series of new measures, this will not be sufficient to take us where we need to go as long as the tobacco industry is working the other side of the street.

Tobacco companies work diligently to drive up product sales, the direct consequence of which is continued tobacco use, recruitment of new tobacco users and substantial amounts of avoidable morbidity and mortality. The impetus for tobacco companies to act so harmfully is entrenched in Canadian commercial law: as business corporations, tobacco manufacturers have a legal obligation to maximize profits and shareholder value. ¹ This requirement conflicts with the public health objective of eliminating tobacco use, and with health regulations and other laws. ²

The conflict between laws which encourage tobacco supply and those which discourage tobacco demand can be resolved in ways which favour health. Doing so can increase the impact of existing tobacco control measures and can contribute to achieving an endgame for tobacco. Failing to do so will leave unaddressed some structural impediments that will continue to slow our progress and will make it unlikely if not impossible to reach the Endgame target.

In recent years, several proposals have been made to complement this demand-side approach with measures to control the supply of tobacco products. These suggestions address the central dilemma of tobacco control – how the industry's drive for profits harms health. All seek to reduce both the supply and demand for tobacco and all intervene in some way on the profit-maximization goal of tobacco companies. Some would place restrictions on tobacco supply while others aim to would reduce tobacco's harms. Still others envision a phase-out of tobacco, some at a faster rate than others.

Some of these ideas closely resemble each other, while others are distinct to the point of being incompatible with others. Some are more clearly intended to end tobacco use than others. Some contemplate that it is the marketplace that will guide the outcome, while others see that as a role for the regulator. (Both marketplace and regulator have in the past successfully phased out harmful products. No one has banned straight razors, but they have been largely replaced by electric razors and safety razors. Government has demanded a ban or phased-out end to other unwanted goods, including hydrochlorofluorocarbon refrigerants, lawn darts, baby walkers and incandescent light bulbs.³

NEXT GENERATION INTERVENTIONS FOR TOBACCO SUPPLY

Transformative next-generation regulatory interventions can be considered under four sub-themes: 1) limiting retail tobacco availability, 2) aligning industry behaviour to public health goals 3) limiting the supply of tobacco products available for sale; 4) other.

1. LIMIT RETAIL AVAILABILITY

Many jurisdictions restrict the retail availability of products less harmful than tobacco, such as alcohol, to designated, licensed and highly regulated outlets. Yet tobacco products are now available at just about every corner store. Alcohol research demonstrates that restricting retail availability is a highly effective policy at reducing use. Tobacco research indicates that high outlet density is associated with increased initiation and impeded quitting. Three retail availability reduction policies - higher cost retail licensing, zoning and tobacco only stores - aim to reduce smoking-related harms through the same general mechanisms. The theory of change for decreasing retail availability is that it would decrease access to tobacco by reducing overall availability and decreasing exposure to marketing. These would help reduce social cues for smoking which may reduce initiation of smoking by youth, decrease cigarette consumption for those who continue to smoke and decrease relapse during quit attempts by current smokers. The ultimate goals of these interventions, within a comprehensive tobacco control strategy, are to decrease initiation, increase long-term cessation, and contribute to the denormalization of tobacco retail marketing--resulting in an overall decrease in tobacco use.

Secondary or indirect evidence includes cross-sectional studies which do not allow the inference of causality. Evidence summarized by Tilson⁴ and from several cross-sectional studies suggests that higher tobacco retail density is associated with smoking-related outcomes in youth, including initiation;⁵ increased risk or prevalence of smoking;⁶ number of cigarettes consumed;⁷ purchasing cigarettes from retailers;⁸ and attitudes and intentions towards smoking.⁹ In a recent Ontario study, Chaiton et al¹⁰ found that higher tobacco retail density was associated with higher smoking at the public health unit level. Among current adult smokers, proximity of tobacco retail outlets, rather than outlet density, has been shown to be related to relapse during cessation attempts in two cohort studies.¹¹

A. Higher cost retail licensing

Licencing-associated strategies could be used to reduce the retail availability of tobacco products by:

- limiting the number of licenses that can be issued (and perhaps reducing this limit over time);
- increasing the licensing fee;
- not renewing licenses to existing license holders;
- not granting licenses to particular retailers; and
- holding an auction or lottery for a limited number of available licenses.¹²

In addition, certain conditions of license such as limiting the hours and/or days during which tobacco can be sold could also aid in reducing tobacco retail availability.¹³ An Australian study showed that a 15-fold increase in retail license fees (from \$12.90 AUD to \$200 AUD per annum) could be an effective method for reducing the number of active tobacco licenses (purchased or renewed).¹⁴ They found that the total number of tobacco licenses significantly decreased by 23.7% from one year to two years after the first of

four fee increases. 15 The fee change did not appear to be a sufficient disincentive for venues such as tobacconists and convenience stores, for which tobacco accounts for a large proportion of revenue.

B. Zoning

Potential zoning restrictions to reduce tobacco retail availability include:

- capping the number of retailers in a specific geographical area;
- prohibiting retailers within certain distances of schools or other youth-oriented facilities;
- prohibiting retailers along access routes to schools;
- stipulating a minimum distance between tobacco retailers; and
- restricting the location of tobacco retailers to certain areas.

Private liquor stores in Alberta are subject to municipal zoning restrictions such as prohibiting retailers within certain distances of schools or other youth-oriented facilities and establishing minimum the distances between retailers. It is anticipated that cannabis retailers will be subject to municipal zoning restrictions once the sale of marijuana is legalized.

C. Tobacco-only stores

Government-controlled or licensed outlets could offer cessation, and volume purchases could reduce wholesale prices while allowing high net prices via taxation. This has not been implemented in any jurisdiction.

Another approach that has been suggested is to transform retail supply and directly align retail behaviour with public health goals, including by incentivizing them to support cessation efforts and provide passive and/or active cessation advice. Tobacco companies, through a combination of financial carrots and sticks, have turned retailers into promoters of tobacco products. Under any of the proposed retail reforms, retailer behaviour could be realigned to reduce smoking.

2. CHANGING TOBACCO SUPPLY

Measures in this category seek to modify the behaviour of tobacco suppliers by re-directing their motivation, incentives or obligations towards the achievement of tobacco reduction.

A. Performance-based regulations

Traditional regulation imposes behavioural requirements on a regulated industry, but does not oblige it to achieve the regulatory objective. In a performance-based regulation (PBR) the onus is placed squarely on the regulated companies to achieve the objective while granting some flexibility in how that is done. PBR could be used to hold companies responsible for achieving annual targets for reductions in smoking prevalence, with financial incentives and penalties to motivate compliance.¹⁷

B. Regulated market model

The regulated market model would create a state-controlled tobacco distribution monopsony with a public health mandate. This new middle link in the distribution chain would seek to reduce harm from tobacco. 18

C. Non-profit enterprise with public health mandate

The problem of profit-maximization in the tobacco business could be squarely addressed by converting the tobacco industry into a non-profit enterprise with a public health mandate. Under this scenario, the entire supply of tobacco products would be directed towards an accelerated and steep decline in use. One way to achieve this would be by expropriating the existing Canadian operations. The estimated cost, about \$15 billion, is somewhat less than the amount of tobacco excise taxes collected in two years and is a fraction of the amount claimed in damages in provincial health care cost recovery suits. ¹⁹ A strong argument can be made that it would be financially prudent for governments to secure these assets while awaiting the outcome of the lawsuits to ensure at least partial recovery of any healthcare damages that are awarded

D. Market conditions could be changed to advantage "clean nicotine" over tobacco products. Advertising and price advantages could be given to pharmaceutical nicotine²⁰.

3. LIMIT SUPPLY OF TOBACCO PRODUCTS AVAILABLE FOR SALE

Measures in this category aim to decrease the supply of tobacco products as the specific regulatory focus. These measures, while differing in their structure, would all substantially change the way the tobacco companies do business, make tobacco suppliers responsible for achieving reductions in tobacco use, and would fundamentally change the motivation of tobacco companies. By reducing supply, there is an expectation that price would increase and availability would decrease leading to both less initiation and decreased consumption. These interventions also address the often rapidly evolving nature of tobacco products as the industry adapts to changing demand patterns. Supply limitation measures can be implemented so at to affect more or less rapid change. Related ideas not included here are proposals to abolish the commercial sale of tobacco products²¹ or to prohibit smoked tobacco products.²²

A. Sinking Lid

It has been proposed that an ever-declining cap (sinking lid) be placed on tobacco available for sale each year. Predictable annual declines in tobacco supply would occur towards a fixed target, likely within two decades.²³ A variation of sinking lid would be to phase out both conventional cigarettes and e-cigarettes in a coordinated fashion, with e-cigarettes getting a marketplace advantage of a slower phase-out^{24§}.

B. Cap and Trade

Under a cap and trade system a firm and ever-declining cap is placed on supply. Producers who go over their cap could trade their overage, for a fee to other suppliers who were under their cap. In this way, the cap would be achieved for the entire industry. Such a cap-and-trade system has found currency in programming reductions in carbon emissions. Currently, Ontario, Quebec and California operate a joint system to achieve declines in carbon emissions. Alberta has maintained a cap-and-trade system on carbon emissions from large emitters for almost a decade. The acid rain problem in Canada and the U. S. was large solved through a joint cap and trade program that was implemented in 1990 through amendments to the *Clean Air Act*. Under a new cap and trade system, it may be possible to enlist participation from manufactures that are currently operating illegally or quasi-legally through participation incentives. Increased legal participation would help to limit contraband activity.

C. Moratorium on new tobacco products

All new tobacco products and all new packaging for existing products could be banned with the potential long-term result of reducing tobacco product supply as demand for existing products would decrease. This idea has gained currency in Quebec.²⁶ A quasi moratorium is in effect in the United States, where current USA FDA premarket approval regulations make it difficult, but not impossible to introduce new tobacco products.²⁷

4. OTHER PROPOSALS.

A. Capping tobacco wholesale prices

Capping tobacco wholesale prices would decrease tobacco industry profitability. Lower wholesale prices would decrease the excessive profits generated by the tobacco companies through many of their brands. Lower profitability reduces the incentive of tobacco companies to maintain their sales, and to defend activities (such as promotion) that contribute to sustaining sales.

B. Tobacco supplier profits surtax

A manufacturers' tobacco income surtax was implemented in Canada in 1994. Corporate restructuring has allowed some multinational tobacco companies operating in Canada to largely avoid this surtax and their income tax responsibility while continuing to transfer most of their \$1 billion per year profits to their overseas owners. The surtax should be extended to ensure it applies to all tobacco manufacturers and importers, including through application to corporate dividends as necessary.

The World Oncology Forum that met in Lugano Switzerland in 2012 had as its recommendation number one: "Wage

	ements of proposals to form tobacco supply	Diminish profitability	Influence Market availability	New supply infrastructure	New Accountability	Framework	Continued use anticipated	Phase out anticipated	Market-driven outcome	Regulator-driven outcome
1. L	imit Retail Availability									
A. B. C.	Higher cost licensing Zoning Tobacco-only stores	•	•	•	•		•		0	• •
2. <i>A</i>	Align Supply to Public Health Goals									
A.	Performance-based Regulations				•			•	0	0
В.	Regulated Market Model		•	•			•			•
C.	Non-profit enterprise with a public health mandate			•	•			•		•
D.	Market conditions could be changed to advantage "clean nicotine" over tobacco products			0			•		•	0
3. L	imit Supply									
A.	Sinking lid				•			•	0	0
В.	Cap and trade				•			•	0	0
C.	Moratorium on new tobacco products		•				•			•
4. C	Other									
A.	Capping wholesale prices	•					•			•
В.	Tobacco supplier profits surtax	•	0				•		0	•
C.	Permit to purchase tobacco products						•			•

war on tobacco, by far the biggest cause of cancer death across the globe. Extend to all countries the antitobacco measures already found to be effective and tax the profits made from tobacco"²⁸

C. Permit to purchase tobacco products

A permit for individuals to purchase tobacco products is seen as a way to encourage smokers to quit (cessation) and reduce smoking onset (prevention), as it would establish a disincentive to smoke, as well as a mechanism for potential tobacco users to receive targeted information and support.²⁹ Mandatory permits have the potential to decrease demand for tobacco products and thus eventually to decrease profitability. In terms of prevention, requiring a permit to purchase tobacco products would also enable assurance that the individual's age meets the minimum age for legal sales and would facilitate the retailer's role in avoiding sales to minors.

OPTIONS FOR ALIGNING SUPPLY WITH PUBLIC HEALTH GOALS

No single supply-side measure discussed above would be certain to produce, by itself, an Endgame result. All of them can be considered in the context of expanding current tobacco control strategies simultaneously shrinking both supply and demand for cigarettes.

There are many details that remain to be worked out with any of the ideas proposed to date. More ideas will hopefully emerge. The absence of this information is no reason to stall policy development at this stage.

Governments, civil society organizations and individuals with responsibilities for public health should:

- Adopt in principle that tobacco supply must be aligned with public health goals.
- Identify, develop and implement supply-side tobacco control measures suitable for a Canadian Endgame for tobacco use with potential measures for consideration including:
 - Limiting retail availability through high cost retail licensing, zoning or potentially tobacco only-stores;
 - Changing tobacco supply through: performance-based regulations, a regulated market model, non-profit enterprise with public health mandate;
 - Limiting tobacco supply through: sinking lid, cap and trade, moratorium on new tobacco products,
- Conduct policy audits and ensure that all laws, regulations, policies and programs, are aligned with the public health goal of eliminating tobacco use.

In addition:

• Approaches should be studied to control tobacco wholesale prices

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5. PRODUCT REGULATION

Regulating tobacco products themselves has the potential to reduce prevalence and to contribute to the Endgame objective of less than 5% prevalence by 2035. The tobacco industry has a long history of marketing products that have had the effect of increasing prevalence, thus product regulation has the potential to do the opposite.

Historically, many efforts regarding product regulation have sought to reduce the harmfulness of cigarettes. Approaches that at first seemed to many to be promising turned out to be failures. Filter cigarettes increased in popularity in the 1950s, with marketing that associated filters with reduced harm. Cigarettes with lower machine-based tar yields were marketed in Canada in the 1950s, but marketing of "light", "extra light" cigarettes etc. really accelerated in the 1970s. Many consumers would perceive "light" and "mild" cigarettes to be less harmful, and thus would switch to these products instead of quitting altogether. It is now understood that the experience with "light" and "mild" cigarettes has proved to be a public health disaster. Lower tar and nicotine numbers from machine-based test methods are not representative of human smoking behaviour.

The tobacco industry has spent billions of dollars over decades in seeking to develop and market less harmful cigarettes, but to date has not been successful in marketing a less harmful cigarette that has had sustained consumer acceptability. The tobacco industry has far greater product knowledge than do regulators and the public health community, knowledge that the industry has gone to great effort to conceal.

Product regulation can be a difficult area. The tobacco industry can use its extensive product knowledge to get around or reduce the impact of regulatory measures. For the most part, there is almost no successful international regulatory experience to draw upon in terms of regulating the product itself.

Nevertheless, governments are taking increasing action regarding the product, and considering potential regulatory measures. In Canada, there are existing measures to reduce cigarette flammability (ignition propensity), ¹ to restrict flavours and additives, ² and to require reporting to Health Canada of additives/ingredients and other product characteristics.³

Consistent with the Endgame, this paper only considers potential measures to reduce prevalence to help achieve the Endgame objective of less than 5% prevalence by 2035. Thus measures seeking to reduce the harm of tobacco products – such as reducing the level of specific harmful emissions in cigarette smoke – are not covered by this paper.

The potential role of e-cigarettes in contributing to a reduction in smoking prevalence is covered elsewhere.

1. MARKET SURVEILLANCE AND RESEARCH

It is essential to have knowledge of tobacco products in the marketplace, including characteristics of tobacco products and product trends. Canada, through the federal *Tobacco Reporting Regulations*, ⁴ has relatively extensive reporting requirements for the tobacco industry, but these requirements are insufficient. The

tobacco industry is required to report to Health Canada information on a brand by brand basis for sales, additives/ingredients, constituents in tobacco, toxic emissions, marketing expenditures and research. However, much of the brand specific information (sales, additives/ingredients, marketing expenditures) as well as research information is not publicly disclosed. There are gaps in the reporting regulations: for example, there is no requirement to report information for water pipe tobacco as this was not an issue in 2000 when the regulations were adopted. British Columbia previously required public disclosure of additives on a brand by brand basis (1998-2007),⁵ but this is no longer the case, and has never been done federally.

The US FDA has a far more extensive research and surveillance initiative than Canada, the cost of which in the US is part of the US\$635 million annual FDA tobacco control budget (fiscal year 2016-17). The entire cost of the FDA's US\$635 million tobacco control budget is recovered through a license fee on tobacco manufacturers that is paid based on market share.⁶ Guidelines under the WHO Framework Convention on Tobacco Control (FCTC) recommend that governments recover the cost of product regulation initiatives and provide a number of cost recovery options to consider⁷ – one such option is the licensing fee on the tobacco industry that has been implemented by the FDA.

The federal government in Canada could enhance its market surveillance and research activities, including through more extensive reporting regulations on the tobacco industry, through public disclosure of reported information, and by fully recovering the cost from the tobacco industry.

2. BANNING FLAVOURS/ADDITIVES

Flavours in tobacco products make tobacco use more attractive and palatable, among both adults and youth. The national Youth Smoking Survey for 2012-13 found that of high school students in Canada who use tobacco, 50% use flavoured tobacco, and of high school students who smoke, 29% smoke menthol.⁸ A report prepared for the US FDA provides an evidentiary summary of how menthol contributes to increased smoking initiation and reduced smoking cessation.⁹

Canada has taken steps to restrict flavours. The federal government has banned flavours in cigarettes, most cigars, and blunt wraps, with an exception for menthol. ¹⁰ The federal government now has plans to remove this menthol exemption, and thus to ban menthol in cigarettes, most cigars and blunt wraps. ¹¹ Six provinces (Alberta, Ontario, Quebec, New Brunswick, Nova Scotia, Newfoundland) have banned flavours in tobacco products including menthol (Ontario and Nova Scotia exempt some cigars and traditional pipe tobacco; Alberta exempts traditional pipe tobacco, water pipe tobacco and some

Bans on flavours	Flavours, excl. menthol	Menthol	Implementation date
Newfoundland		0	01-07-17
Prince Edward Island			
Nova Scotia		•	31-05-15
New Brunswick		•	1-01-16
Quebec		0	26-08-16
Ontario		0	1-01-17
Manitoba			
Saskatchewan			20 00 15
Alberta British Columbia		•	30-09-15
Yukon			
Northwest Territories			
Nunavut			
110110101			05-07-10
Government of Canada	•		15-12-15
○ = legislation adopted; • = in force			

cigars). These menthol bans include bans on menthol capsules in filters. Provincial legislation bans "characterizing" flavours (though wording of provincial legislation varies) while federal legislation bans flavours and additives that enhance flavours in any quantity. Certain additives are exempt from the federal ban, typically where the additives have a functional role in the cigarette such as affecting burn rate.¹²

There are further federal restrictions on additives beyond flavours. Federal legislation bans amino acids, caffeine, essential fatty acids, probiotics, vitamins, glucuronolactone, taurine, and most mineral nutrients in cigarettes, most cigars, and blunt wraps.¹³

Legislation should ban all flavours including menthol in all tobacco products; flavour bans should apply to flavours in any quantity and should not be limited to just "characterizing" flavours. There should also be a ban on all additives in all tobacco products except those additives that are specifically permitted; the role of justifying any permitted additives should be with the tobacco industry, not with government. Some additives currently permitted in cigarettes should be prohibited (footnote 12 lists a series of permitted additives). An extensive flavouring/additive ban has been adopted in Brazil, although it has not yet been implemented pending a court challenge, and an expert evidence review has supported this regulation.¹⁴

3. CIGARETTE ATTRACTIVENESS

There are several potential measures regarding standardizing the appearance and attractiveness of cigarettes, including width and length, appearance of cigarette filters and paper, and having a health warning on the filter overwrap.

A. Size:

Slim and superslim cigarettes target females and associate smoking with glamour and weight loss; many consumers perceive slim and superslim cigarettes as less harmful.¹⁵ In recent years, the tobacco industry globally has placed emphasis on marketing slim and superslim cigarettes, with tremendous success. Global slim/superslim cigarette sales increased from 221 billion in 2008 to 347 billion in 2012, representing an increase in market share of global cigarette sales from 7% to 11%. ¹⁶ In the EU, the Tobacco Products Directive initially proposed by the European Commission in 2012 contained a ban on slim cigarettes, i.e. cigarettes with a dimension of less than 7.5 mm.¹⁷ However, due to tobacco industry lobbying, this provision was not in the final version of the Directive that was approved. The EU Directive does ban slim pack formats, ¹⁸ as does Australia and Quebec ²⁰ legislation, but the EU, Australia and Quebec do not ban slim cigarettes themselves. A typical cigarette diameter is 7.55 mm. In the US, Camel Wides are sold with a diameter of 9mm. A typical length for cigarettes in Canada is 72 mm for regular length, with King Size at 85mm, and some cigarettes with a length of 100 mm or 120 mm. Thus a product standard could specify that the cigarette diameter must be within 7.5 mm to 7.7 mm, and that the length must be a specified dimension or must not be longer than 85 mm.

B. Appearance

Federal legislation bans colouring of cigarette paper and filters, with an exception for imitation cork filter overwraps, and an exception that allows trademarks to appear on cigarettes. ²¹ Further measures should be taken to make cigarettes less visually appealing by standardizing the appearance of the filter, prohibiting additives that make paper whiter, and considering other measures. By prohibiting additives that make paper whiter, the appearance of cigarette paper would be more like the appearance of unbleached recycled paper. Standardizing the appearance of filters would help prevent the tobacco industry from conveying perceptions of reduced health risk because of the filter. Prohibiting tobacco industry trademarks on cigarettes could be included as part of plain packaging requirements, as Australia has done.

C. Warnings on cigarettes

Health warnings have long been required on tobacco packaging, but to date no country has required a health warning on the cigarette itself. Tobacco companies know the communications value of the cigarette, and have placed tobacco company brand names, logos and colour indications on the cigarette, normally on the filter overwrap part, or close to the filter on part of the cigarette that would normally not be burned. (Australia has prohibited tobacco companies from placing brand indications on cigarettes.) There were 29.5 billion cigarettes sold in Canada in 2014, meaning that warnings on cigarettes would receive substantial exposure. Placing warnings on the filter overwrap portion of cigarettes is a measure recommended for consideration in FCTC guidelines.²² No country has yet required health warnings on cigarettes themselves, though Singapore requires a tax-paid marking "SDPC" on cigarettes (SDPC stands for Singapore Duty Paid Cigarette).

D. Palatability

Over a period of decades cigarette chemistry has been progressively altered to make cigarettes feel better, taste better, smell better, be easy to inhale and deliver a satisfying smoke. It has been suggested that cigarettes could be reverse engineered to slowly make them less attractive across these dimensions in ways that should be virtually imperceptible to smokers but would more quickly discourage young people from taking up smoking. Cigarettes can be made less inhalable, and nicotine can be made less bio-available, by raising the pH. The elasticity of cigarettes can be adjusted (an elastic cigarette is one where it is made easier for the smoker to obtain nicotine because nicotine delivery increases faster than the puff volume).

4. CIGARETTE ADDICTIVENESS

Nicotine is the addictive substance in tobacco products, and nicotine is highly addictive.²³ There have been a number of potential measures that have been raised regarding nicotine addictiveness.

One proposal is to reduce nicotine in cigarettes to levels that are not addictive. ²⁴ Most cigarettes have 10-15mg of nicotine in the tobacco portion of the cigarette. It has been proposed to reduce nicotine content to 0.5mg, with a level of 0.5mg essentially representing a 95% reduction in nicotine (caffeine can be removed from coffee, but there may still be some caffeine in decaffeinated coffee; regular beer may have 5% alcohol, while non-alcoholic beer may have 0.5% alcohol). The objective and expectation with this approach is that cigarettes would no longer contain enough nicotine to addict new users, and would no longer contain enough nicotine to sustain use by smokers generally. Studies are being conducted in this regard. ²⁵ To date, however, no country has implemented a regulation to reduce nicotine content. And issues have been raised about factors that may make this proposal not workable/effective, especially in the Canadian context. Those issues include contraband and potential compensatory behaviour by smokers to adjust for reduced nicotine. In the US, Quest brand cigarettes with such low nicotine content were introduced in the market, but the cigarettes were a market failure and were removed from the market. Herbal cigarettes, which contain no nicotine, have been on the Canadian market for decades but have never had any material sales volume. Research is ongoing regarding the potential for reduced nicotine content cigarettes.

Another potential approach has been taken in the European Union in the new Tobacco Products Directive, prohibiting additives in quantities that would increase addictiveness to a significant or measurable degree. It is not clear yet the extent of the impact that this measure will have.²⁶ Given the addictiveness of nicotine,

approaches should be studied for the Canadian context to prevent tobacco products from being made more addictive, and to provide for tobacco products to be less addictive.

5. FILTERS

It has not been demonstrated that filters have reduced the health consequences of smoking. Filters, however, may make it easier to smoke. Tobacco companies have increasingly introduced types of filters that create the perception that the filter reduces health risks. Examples include having carbon in filters, or du Maurier's "duPlus" filter that contains a recessed opening. Many filters have ventilation holes that reduce machine-measured tar and nicotine yields (though machine test methods are not representative of human smoking behaviour). Approaches that could be studied would be to ban ventilation holes in filters or to ban filters altogether. Among the aspects to be examined would be deceptiveness related to filters.

RECOMMENDATIONS

Canada should adopt product regulation standards to reduce tobacco use:

- Implement a well-financed surveillance and research initiative paid for by companies through a license fee on tobacco manufacturers
- Ban all flavours including menthol in any quantity (not just "characterizing" quantities) in all tobacco products
- Ban all additives except those that are specifically allowed, with the tobacco industry to justify any permitted additives; ban some additives currently permitted for cigarettes
- Standardize the appearance of cigarettes by specifying width and length dimensions, by standardizing the appearance of cigarette filters and paper, and by requiring a health warning on cigarette filter overwraps.

In addition:

- Approaches should be studied to prevent tobacco products from being made more addictive,
 and to provide for tobacco products to be less addictive, including by reducing nicotine content
- A measure should be studied regarding a ban on ventilation holes in filters or a ban on filters altogether
- Approaches should be studied to reduce the palatability of tobacco products

- 1 Cigarette Ignition Propensity Regulations, SOR/2005-178 (Canada).
- 2 Tobacco Act (Canada), sections 5. 1, 5. 2, Schedule, and provincial legislation.
- 3 Tobacco Reporting Regulations, SOR/2000-273 (Canada).
- 4 Tobacco Reporting Regulations, SOR/2000-273 (Canada).
- 5 Tobacco Testing and Disclosure Regulation, B. C. Regulation 282/98, repealed by B. C. Regulation 393/2007 (British Columbia).
- Family Smoking Prevention and Tobacco Control Act (US, 2009), enacting section 919 of the Food, Drug and Cosmetic Act (US)
- Conference of the Parties to the WHO Framework Convention on Tobacco Control, *Partial guidelines for implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and regulation of tobacco product disclosures)*, Appendix 1.

- 8 Manske SR, Rynard VL, Minaker LM. 2014 (September). Flavoured Tobacco Use among Canadian Youth: Evidence from Canada's 2012/2013 Youth Smoking Survey. Waterloo: Propel Centre for Population Health Impact, September 10, 2014.
- 9 US Food and Drug Administration, "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes" 2013.
- 10 Tobacco Act (Canada), sections 5. 1, 5. 2, Schedule.
- Health Canada, Notice to interested parties Proposed order to amend the schedule to the Tobacco Act (menthol), Canada Gazedtte Part I, April 30, 2016.
- Pursuant to the Schedule to the *Tobacco Act*, the flavours ban for cigarettes, most cigars, and blunt wraps includes a ban on Fruits, vegetables or any product obtained from the processing of a fruit or vegetable (excluding activated charcoal and starch); spices, seasonings and herbs; sugars and sweeteners (excluding starch); mineral nutrients (excluding those necessary to manufacture the tobacco product).

 The additives exempt from the ban on flavours and additives that enhance flavours are: benzoic acid (CAS 65-85-0) and its salts; butylated hydroxytoluene (CAS 128-37-0); carboxy methyl cellulose (CAS 9000-11-7); citric acid (CAS 77-92-9) and its salts; ethanol (CAS 64-17-5); ethoxylated sorbitan monolaurate (CAS 9005-64-5); fumaric acid (CAS 110-17-8); glycerol (CAS 56-81-5); guar gum (CAS 9000-30-0); menthol (CAS 89-78-1); l-menthol (CAS 2216-51-5); l-menthone (CAS 14073-97-3); n-propyl acetate (CAS 109-60-4); paraffin wax (CAS 8002-74-2) propylene glycol (CAS 57-55-6); rosin glycerol ester (CAS 8050-31-5); sodium acetate anhydrous (CAS 127-09-3); sodium alginate (CAS 9005-38-3); sorbic acid (CAS 110-44-1) and its salts; triacetin (CAS 102-76-1); tributyl acetylcitrate (CAS 77-90-7).
 - For cigars weighing between 1.4g and 6g, there is an exemption for rum, wine, whiskey and port flavours.
- 13 Tobacco Act, Schedule (Canada).
- 14 Working Group on Tobacco Additives, Report submitted to ANVISA, Brazil, August 2014.
- Mutti S. , Hammond D. , Borland R. , Cummings K. M. , O'Connor R. J. , Fong G. T. "Beyond light and mild: cigarette brand descriptors and perceptions of risk in the International Tobacco Control (ITC) Four Country Survey" *Addiction* 2011; 106(6):1166-75; Doxey J. , Hammond D. "Deadly in pink: The impact of female-oriented cigarette packaging among young women" *Tobacco Control* 2011; 20:353-360.
- André Calantzopoulos, Chief Executive Officer, Philip Morris International, presentation at Morgan Stanley Global Consumer Conference, New York, Nov. 20, 2013, slide 17. The sales volume for slims include extra slim and superslims. The sales volume and market share excludes China, USA and duty-free.
- European Commission, "Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products" December 19, 2012.
- 18 Tobacco Products Directive 2014/40/EU, Art.9. 3, 10. 1(g) (European Union).
- 19 Tobacco Plain Packaging Regulations 2011, SLI 2011 No. 263 (Australia), regulation 2. 1. 1.
- 20 Regulation under the Tobacco Act (Quebec), section 6. 1, as enacted by An Act to bolster tobacco control (Quebec, 2015), section 72.
- 21 Tobacco Act, Schedule (Canada).
- 22 Conference of the Parties to the WHO Framework Convention on Tobacco Control, *Guidelines for implementation of Article 11 (Packaging and labelling of tobacco products)*, para. 11.
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- 26 Tobacco Products Directive 2014/40/EU, Art. 7(9) (European Union), requires that EU countries "shall, on the basis of scientific evidence, prohibit the placing on the market of tobacco products containing additives in quantities that increase the [...] addictive effect [...] of a tobacco product at the stage of consumption to a significant or measureable degree."

6. ELECTRONIC CIGARETTES

Electronic cigarettes (e-cigarettes; also referred to as Electronic Nicotine Delivery Systems [ENDS]) are battery powered devices that are used to heat and aerosolize a solution containing propylene glycol, vegetable glycerin, flavourings and sometimes nicotine. There is a vast range of e-cigarette products available and a wide range of use patterns, including e-liquids, device components, and heating mechanisms. E-cigarettes vary in look (from cigarette look alike to large tank devices), power and temperature of heating mechanisms and efficiency and effectiveness in delivering aerosol into the lungs. E-liquids vary in use of propylene glycol and vegetable glycerin, flavouring additives (with thousands of flavours) and nicotine content (ranging from zero to levels higher than contained in tobacco cigarettes).

E-cigarettes present as a both potentially contributing as a solution to the tobacco epidemic and as a health problem, which complicates policy development.

Widespread use of e-cigarettes risks posing a new public health problem. A recent systematic review of e-cigarette health effects research concluded that the evidence of potential health effects is sufficient to suggest that anybody who is not a current smoker of tobacco cigarettes should not vape electronic cigarettes.² Moreover, the health effects of long-term regular use of e-cigarettes have not yet been studied. The review found that carbonyls, tobacco specific nitrosamines (TSNAs), and impurities were frequently detected in e-liquids at low levels. Low levels of carbonyls, VOCs, TSNAs, metals, impurities, and particulate matter have been found in e-cigarette aerosol. E-cigarette use may result in low levels of passive exposure to nicotine, organic compounds, metals, and particulate matter. Air quality measurements have found high levels of particulate matter in indoor vaping by a large number of people. In addition, the strengthening of evidence about the effects of nicotine on brain development suggests that people should not vape nicotine e-cigarettes until they are in their 20s.³ The Surgeon General's conclusion that there is sufficient evidence about the effects of nicotine on the development of the fetus suggests that pregnant women should not be exposed to nicotine e-cigarette aerosol.⁴

While in absolute terms, e-cigarettes pose health risks, there is widespread consensus that they are less harmful, and many say very greatly less harmful than smoking tobacco cigarettes thus offering a potential solution to the tobacco epidemic. Large numbers of smokers quitting via vaping and then quitting vaping as well or even just switching to vaping could help move tobacco use prevalence down. As the tobacco endgame is about decreasing tobacco smoking prevalence, not about decreasing ingestion of nicotine through e-cigarettes or other ways, e-cigarettes may have a legitimate place in a tobacco endgame strategy. However, systematic reviews of research on e-cigarettes as a cessation aid indicate that while some smokers successfully quit by vaping e-cigarettes, they make up only a small proportion of smokers both who have tried vaping and who have not tried vaping. While some smokers using certain kinds of e-cigarettes in certain ways may quit smoking, some smokers may become dual users which may or may not lead to cessation. By far, most smokers who try e-cigarettes, do not become vapers and do not quit. The state of the evidence about the effectiveness of e-cigarettes as a smoking cessation aid is currently assessed as very low to low, due primarily to methodological weaknesses of current studies.

Possible reasons why large proportions of smokers are not quitting through vaping include: inadequate nicotine delivery stemming from mechanics of the device and from difficulty in using the device properly; ecigarettes being unsatisfying for smokers for other reasons (not same feel...); lack of knowledge about harms; not wanting to switch from one bad thing to another, but preferring to quit altogether; clinicians unwilling and unable to help smokers quit via e-cigarettes.

Policy environments for e-cigarettes are evolving in divergent ways in the United Kingdom and the United States. Each approach is supported by a growing and sometimes conflicting evidence base. The U.K. Royal College of Physicians recently recommended that regulation "should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers" and that "in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK". In contrast to this, the United States government is taking a more cautious approach. In May, 2016, the United States Food and Drug Administration extended its jurisdiction to regulate e-cigarettes and all other tobacco and nicotine products, including those not yet on the market. All existing and new products will be subject to significant regulatory requirements, including premarket review and authorization. The US Preventive Services Task Force has concluded that current evidence is insufficient to recommend e-cigarettes for tobacco cessation among adults.

Into this complex area, an approach has been suggested which may provide guidance for Canada. "From a public health perspective, VNP (vaporized nicotine products) policies should aim to discourage experimental and regular use of VNPs by never smokers who would not have smoked otherwise while encouraging innovations in VNP products that promote smoking cessation". ⁹

In future, there may be potential for e-cigarettes to bring large proportions of smokers to quit or switch to vaping by addressing these obstacles. Research and development to explore this possibility might be part of an Endgame Strategy with the possibility that down the road, e-cigarettes could become an important part of the solution so long as policies are put in place to prevent them from becoming a problem for non-smokers, or for deterring cessation.

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7. PREVENTING A NEW GENERATION OF SMOKERS

Tobacco addiction has been called the major pediatric disease of our time.¹ It is during adolescence and young adulthood that tobacco use begins and that addiction to smoking is established. Although the chronic diseases caused by tobacco use may not be noticed by the smoker until later in life, they are rooted in that first youthful smoking experience.

Efforts to prevent young people from smoking have been a key element of tobacco control programs for decades. But only in recent years, following the implementation of measures designed to reduce smoking initiation (tax increases, bans on advertising and retail displays and large health warnings), has there been a large increase in the proportion of teenagers and young adults who never try smoking.²

But even with many of these measures in place, tobacco companies are still able to recruit new customers. Over the past 10 years, about 1 million young Canadians have become smokers. At present in fact, by the time they turn 20, one in five Canadians identify themselves as smokers.³

Tobacco companies benefit from and exploit the social and environmental factors that influence young people to smoke. Their brands are sold as image-laden "badge products" to young people who are seeking to establish an identity and to gain social acceptance. The presence of smoking in movies and videogames, and in the community that surrounds them, helps signal to youth that smoking is a social norm.

All young people are at risk of smoking, but some are especially vulnerable. Family circumstances (such as living with a parent who smokes), personal circumstances (such as having used other drugs, being depressed or having difficulties at school), and public policy circumstances (such as having easy access to affordable tobacco products, not receiving adequate information about the risks of smoking or being exposed to marketing) can increase the likelihood of a young person beginning to use tobacco. The first smoking experience of the post-millennial generation does not necessarily resemble that of their parents. The range of inhalable products that are available to them — including cigarettes, e-cigarettes, shisha, marijuana — provide many gateways through which regular smoking and addiction may follow. The changing regulatory environment around e-cigarettes and marijuana, and the development of novel products will present new challenges.

Public health measures to prevent youth smoking have evolved considerably, as evidence on effectiveness and political support for stronger measures have grown.⁵ The comprehensive set of demand-reduction measures promoted by the World Health Organization and included as obligations in the Framework Convention on Tobacco Control (FCTC), reflect a scientific and policy consensus on effectiveness for smoking prevention. These measures include higher tobacco taxes and prices, elimination of all promotions for smoking, smokefree laws and policies, public education, high impact mass media campaigns, community programming, among others.

Many of the regulatory measures are already in place in Canada, including some – such as display bans in retail stores and graphic health warnings – that were pioneered here. Others, such as plain packaging and comprehensive flavour bans, are imminent. But there remain several ways in which smoking prevention measures in Canada do not meet international best practices. These include the absence of a price strategy and the low-tax policies of the two most populous provinces. Only a limited number of public awareness activities, such as De Facto, 6 have been sustained over time.

Tobacco control is a shared responsibility of governments at all levels, and there is a wide variety of approaches taken by different jurisdictions, yielding a patchwork approach to tobacco control. Youth access laws restrict

sales of cigarettes to people over 18 in some provinces, and to those over 19 in others. Surveillance systems to monitor youth tobacco use are in place nationally, with additional systems in some provinces but compliance monitoring and enforcement vary substantially across provinces and territories.

Several innovative programs which engage young people in peer-to-peer efforts to support prevention and cessation have been put in place in some provinces. These include programs at universities, such as 'Leave the Pack Behind',⁷ and Exposé,⁸ as well as programs in high schools and youth centres or in the community.⁹

Achieving Canada's Endgame target of less than 5% smoking prevalence by 2035 will have at its heart policy and regulatory measures that will substantially reduce the proportion of young Canadians reaching their 20th year who smoke from 19% down to 0%. A broad array of novel regulatory changes will be required to achieve this – many of these are described in detail earlier in this paper.

ENDGAME OPTIONS FOR PREVENTION

There are additional novel measures that could *provide a transformative leap forward* in preventing a new generation of smokers or could *substantially strengthen existing prevention approaches*. Interventions from both these categories will be required to achieve the endgame goal of "less than 5 by '35".

1. AGE-BASED RESTRICTION ON LEGAL SALES OF TOBACCO.

- A. Stage I: Increasing the minimum age for sales to minors to 21 and potentially 25 years. About 20 years ago, the federal government raised the minimum age for buying cigarettes from 16 to 18, which was subsequently raised to 19 by some provincial governments. Evidence of the benefits of increasing the minimum age to 21 has recently encouraged legislators in California and Hawaii and many US municipalities to adopt this change. ^{10 11}
- B. Stage II: A Canadian Tobacco-Free Generation

 The Tobacco Free Generation proposes to phase-in an end to tobacco use via prevention of new smokers by prohibiting tobacco sales to all persons born after a specific date (the year 2000 in the cited reference)¹²

 Legislation to implement this measure has been proposed in Tasmania, Australia but there is no evidence to date of the success of this approach. This proposal is clearly transformative and merits discussion within a Canadian Endgame Strategy.

2. STRENGTHEN / DEVELOP FINANCIAL PENALTIES TO REDUCE YOUTH TOBACCO USE

- A. Youth Purchase-Use-Possession laws
 - Currently young Canadians who are in possession of tobacco products are liable for sanctions under law in Alberta and Nova Scotia, although such measures are rarely enforced. The youth possession features of the federal law were rescinded in 1994. Several U. S. states have adopted such measures. ¹³ Youth possession laws have generally not been recommended by health organizations in Canada.
- **B.** Make tobacco manufacturers responsible for youth tobacco use

 A "strict liability" standard is already used with respect to tobacco retailers, who face consequences if they sell cigarettes to under-age customers even if there was no intent to commit a crime. ¹⁴ These penalties can be increased and made more powerful as a deterrent to youth smoking.

Tobacco manufacturers do not face similar responsibility for youth smoking or any repercussions for young people using their products. To the contrary, they benefit from the additional sales and the future revenues. Proposals for ways to reverse these incentives were made over 20 years ago, ¹⁵ and were reflected as a "look-back" obligation of the 1997 draft Global Settlement negotiated with U. S. tobacco companies. As part of an endgame strategy, Canada could develop a requirement for tobacco manufacturers to "pay" for the costs of under-age smoking through a levy based on an assessment of their anticipated future sales revenues to this group thus reversing the economic incentives of manufacturers to recruit new smokers. The intent would be to not only remove any incentive to stimulate youth smoking but impose a penalty to remove incentives for tobacco companies to promote youth smoking.

OPTIONS FOR PREVENTION STRATEGIES

The following could be included in an Endgame for Tobacco in Canada.

- A pan-Canadian change to minimum age for legal purchase of tobacco products to age 21.
- Consideration of further age-based restrictions on sale, such as a minimum age of 25 or a maximum birth year of 2000.
- Improvements in accountability and deterrence for smoking onset.

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 In 2014, the "never smoking" prevalence of non-immigrant Canadians born between 1956 and 1970 was 27%; for those born between 1985 and 1994 it was 46%. In 2000, one-third (33%) of children aged 12-19 had smoked one cigarette; in 2013-2014, only one-sixth had done so (16%).
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8. LITIGATION AND THE ENDGAME

LITIGATION IS PART OF A COMPREHENSIVE APPROACH TOBACCO CONTROL.

In recent years, governments and citizens' groups have looked to the justice system for support in strengthening tobacco control. Courts are seen as a way of both holding the industry accountable for past wrongdoing and helping change the way they behave in the future. Litigation is acknowledged as "an important part of comprehensive tobacco control" in the Framework Convention on Tobacco Control (FCTC).

The negligent behaviour of tobacco companies has already been proven in a Canadian court. After a lengthy trial and a review of a 50-year history of tobacco industry actions, the Quebec Superior Court ruled in 2015 that the industry's "ruthless disregard for the health of their customers" was an "egregious fault" under Quebec law. By promoting their brands while misleading smokers about the harmfulness of their products and impeding the efforts of others to provide this information, the companies broke four Quebec laws, including by unlawfully interfering with the right to life, security and integrity of the person guaranteed by the Quebec Charter of Rights and Freedoms. ³

Trials like these can be a forward-looking tool to improve public health.

- Legal actions can result in the release of documents, increased media attention and enhanced public awareness of the harmfulness of smoking, the tobacco market, and tobacco company behaviour. This will increase public and political support for stronger measures in response.
- Large financial awards can support health objectives by leading to an increase in the price of cigarettes, which will reduce tobacco consumption and internalize some of the costs of tobacco use in the market ("market deterrence").
- The actual or potential financial consequences of large lawsuits may destabilize and change the tobacco market in other ways that could benefit health, by driving down profitability and attractiveness to investors. Weakening the economic situation of companies may make structural reforms to the industry more feasible.
- Litigation against tobacco companies could deter future wrongdoing. Companies can be forced by legal
 proceedings to change their behaviour, or may be encouraged to do so by the consequences or threat of
 litigation.

Canada is one of the few countries where governments have turned to the courts to reclaim the costs of treating the diseases caused by the wrongful actions of this industry, or where the companies are facing large damages from class action suits initiated by consumers. To date, court actions have not been prominent within the context of tobacco Endgame discussions.

1. THE CHALLENGE OF SUING BIG TOBACCO

Tobacco litigation has a long history, particularly in the United States. For decades, tobacco companies emerged virtually unscathed from any lawsuit filed against them by individual smokers. They used their wealth to deploy a legendary "scorched earth" strategy of outspending, intimidating and defeating claims, and used legal strategies to create winning conditions in courts.

The situation changed in the 1990s, when a new "third wave" of large class actions and state government health care cost recovery lawsuits was launched in the United States. In 1998, the tobacco industry entered settlements first with four state governments individually (Mississippi, Florida, Texas and Minnesota), followed by the remaining 46 states in the historic Master Settlement Agreement in which the companies agreed to pay US\$246.5 billion over 25 years, as well as agreeing to other measures, such as some marketing restrictions. The settlement has been used to fund the Truth Foundation (previously called the American Legacy Foundation), among other measures.⁴

These events were seen as a turning point in tobacco litigation, and inspired action in Canada and elsewhere. Within a decade, more than a dozen lawsuits against tobacco companies were filed in Canadian courts on behalf of smokers, including class actions⁵ individual suits⁶ and small claims cases.⁷ In 1998, the first Canadian provincial government initiated a health care cost recovery suit, and by 2015 each of the provinces had done so. Federal and provincial governments also filed suits to recover tobacco tax revenues which had been lost when the companies engaged in illegal contraband sales.⁸ The federal government has also initiated criminal investigations and laid charges against the companies under federal tax laws.⁹

All three of the major tobacco companies operating in Canada entered into settlement agreements with the federal and provincial governments concerning civil claims related to contraband. The three companies were also convicted of contraband on guilty pleas. Total fines and civil payments reached \$1.7 billion, though for two companies the civil payments were payable over roughly 12 years thus substantially diminishing their real value.¹⁰

In comparison with litigation in other countries, tobacco lawsuits in Canada have gone poorly for the companies. Two of the class actions resulted in a decisive judgment against them and damages 15 times their annual profits. They agreed to settle federal and provincial claims for lost tax revenues. Tobacco companies have also been unable to prevent the filing of provincial health care cost recovery suits, although company actions have contributed to delays in any of these getting to trial.

Beyond the U. S., the industry has continued to defeat many, but not all, lawsuits against them. ¹² In 2016, Philip Morris International reported that of the 442 claims filed against it since 1995, it had ultimately won all but three cases, and these are still under appeal. Two of those losses are in Canada. ¹³

2. THE CHALLENGE OF TRANSLATING LAWSUITS INTO HEALTH OUTCOMES

Winning litigation against the tobacco industry does not automatically reduce the number of people who smoke. Translating successful court actions into effective tobacco control measures (let alone game-changing Endgame measures) has proven challenging, prompting concerns with the management of tobacco litigation by some governments.

In the United States, the Master Settlement Agreement included provisions to reduce tobacco advertising, finance the American Legacy Foundation (now the Truth Initiative) and release industry documents. These measures, and the impact of the cigarette price-increase used to finance the payments, were considered to have contributed to a reduction in smoking. ¹⁴ ¹⁵ Settlement provisions and implementation have been criticized for various reasons, including the long-term payment schedule ties state interests to continued smoking, and the failure to use settlement funds to help reduce smoking. ¹⁶

Political actors can also impede the impact of litigation. For example, a lawsuit filed in 1999 (during the Clinton administration) by the U. S. Department of Justice under the *Racketeer-Influenced and Corrupt Organizations Act* was considered to have been undermined by subsequent administration's decision to reduce financial claims against the industry. Ultimately, the ruling by Justice Gladys Kessler excoriated the industry¹⁷ but did not result in any financial award or successful injunctive measures.¹⁸

In Canada, the contraband settlements in 2008 and 2010 were reached through secret negotiations between provincial and federal governments and the industry, and ultimately were found to have done little to address the harm to public health caused by the deliberate undermining of tobacco tax policies. These agreements were considered to have been "tobacco-friendly" because of the relatively small amount of the payments agreed to, the abandonment of criminal charges and the resulting acquisition of direct control over tobacco growing by the companies.¹⁹

The overall impact of private lawsuits is difficult to measure. The health impact of the Quebec class actions is yet to be fully felt. They do, however, illustrate the importance of the legal reforms adopted by Quebec to assist tobacco litigation, and that the historic procedural barriers and systemic use of procedural delaying and obstructing tactics. Although the Court articulated standards for health warnings which exceed those currently on the package, the companies have made no discernable changes to the packaging or marketing of their brands since the ruling. The \$15 billion award of damages is under appeal, although two of the three defendants have been required to put in trust a large portion of their annual profits until a final ruling is made. The financial and health impacts of these cases and any ripple effects are still unknown. The final outcome of these cases may prove to be game-changers: upholding the lower court award of \$15 billion would likely bankrupt the companies.

The approach that the companies will take to the provincial lawsuits as they move forward is a matter for speculation. It can be expected that, as in other lawsuits, tobacco companies will seek to delay as much as possible provincial government lawsuits from going to trial.

The approach that the provinces will take in furthering these suits is also unknown, and there has been no invitation for public health input into these processes to date. More than a decade after the first provincial lawsuit was filed, the public remains largely unaware of these important proceedings.²⁰ There is a desire for these suits to go to trial and be resolved in a way that is transparent to the public and which improves the health of Canadians. If provincial governments follow the example of their American counterparts and resolve their suits through settlements, the benefits of a public and transparent trial will be lost.

The government medicare cost recovery lawsuits provide a major, historic opportunity to benefit public health and tobacco control. The extent of public health outcomes will largely depend on priority that is given to health outcomes in the government's management of these cost recovery suits.

3. THE OPPORTUNITIES FOR NEW APPROACHES

In addition to civil liability suits, the legal system may offer other opportunities to alter the behaviour of tobacco companies and to improve public policy, as illustrated by experience in Canada and elsewhere (see box).

The behaviour of the companies has been found negligent under Quebec civil law, but has not yet been assessed under the federal Criminal Code. (David Doherty, currently a Justice of the Ontario Court of Appeal, once offered an opinion that criminal charges against the companies might succeed.²¹) The scope of harm caused by this industry's products justifies such a reflection, and could contribute to realigning the behaviour of the companies and the individuals who work within it to less harmful outcomes.

Courts can be asked to correct industry behaviour or to change government policy. Currently, government enforcement actions do not typically go beyond specific infractions of tobacco-specific laws, like sales to minors, smoking restrictions, promotion restrictions, and contraband. Other harmful aspects of tobacco product marketing could be addressed through legal actions under consumer protection legislation, human rights and other laws. Citizens can ask the courts to review whether government actions are consistent with established policy or with rights established under law.

RECOMMENDATIONS

Litigation can contribute to an Endgame for tobacco and can facilitate the implementation of Endgame measures. The following are ways to maximize the health benefits of tobacco litigation.

- Provincial governments should bring health care cost recovery lawsuits to trial.
- There should be transparency in any settlement negotiations, such that public health voices are actively included.
- Health care cost recovery lawsuits must have effective public health outcomes, including investing part of proceeds in tobacco control.
- Governments should not agree to litigation outcomes that would see tobacco industry payments directly or indirectly tied to continued tobacco industry sales.
- Tobacco control laws should include enforcement mechanisms which allow injunctions to be sought by private citizens or civil society organizations.
- Funding should be available to help provide access to courts for those seeking injunctions in support of tobacco control.
- Efforts should be made to explore legal mechanisms to advance tobacco control including mechanisms to catalyze government action.
- Governments and nongovernment organizations should be ready to identify action measures should the outcomes of the Quebec class actions provide opportunities for significant change.

Types of Legal Action

Health care providers can sue for the costs of treating tobacco-related disease. Following the U. S. example, governments in a handful of countries filed health care cost recovery claims. Health care cost recovery claims are active in Canada, Brazil, Nigeria and South Korea.²²

Individuals can sue for compensation. Personal injury claims by individuals have succeeded in some U. S. states, where tobacco companies now face thousands of such claims.²³ Outside the USA, they are less common and rarely successful: Philip Morris International reports that it is currently facing 69 such suits outside the U. S. A, including 2 in Canada.

Class action suits can be filed on behalf of individuals. Class action suits are not permitted in many countries, but they are allowed in Canada, and there are currently nine such claims. Of these, only three have been authorized to proceed as class actions, two of which – the Quebec *CQTS/Blais* and *Létourneau* class actions – reached a successful trial judgment. Outside the USA and Canada, Brazil is the only other country outside the United States and Canada where tobacco class actions are known to be under way.

Courts can be used to trigger changes in government policy. Citizens groups in countries with such diverse legal systems as Argentina, Belgium, India, the Netherlands, New Zealand, Pakistan and Venezuela have sued their governments for failure to apply tobacco control measures. In other areas of health policy (assisted dying, medical marijuana, private health care services), legal actions have been used by citizens' groups to force change. In Canada to date, there has been little in the way of such "offensive" litigation in terms of tobacco control, though there have been some related to exposure to tobacco smoke with human rights claims for discrimination of the basis of disability, ²⁴ occupational claims for unsafe workplaces, ²⁵ and worker compensation. ²⁶ Proceedings have also been attempted to place tobacco under the *Hazardous Products Act*. ²⁷ and to have the federal government ban misleading descriptors "light" and "mild". ²⁸

Citizens' groups can ask courts to enforcement tobacco laws. In France non-governmental organizations have the right to sue tobacco companies for violation of tobacco control laws, and have done so successfully on multiple occasions. ²⁹ [They are able to retain a portion of any fines levied against the companies for infractions of the law]. Quebec consumer groups have a similar right to ask the court to enforce that province's *Consumer Protection Act*, but no such attempts have yet been made with respect to tobacco products. At least once, a private prosecution in Ontario resulted in a fine against a retailer for selling cigarettes to children.³⁰

Criminal charges can be laid. Just as tobacco companies have been held liable under civil law for wrongdoing, the companies and the individuals directing them can face charges under the *Criminal Code*. Private prosecutions can be filed for criminal offences, although government prosecutors have the right to take over the prosecution or to required that the charges be discontinued. 32

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LOOKING TO THE FUTURE

An authentic commitment to an Endgame strategy for Canada will require the development of enabling measures and structures. These will include funding to support strategy development and implementation and the creation of new structures (or revision of old structures) to oversee it and to report on its success.

It will also require a culture of openness to consider new and at times what may appear to be bold ideas that Canada may be the first to implement. There is no recipe that currently exists for achieving a tobacco-free future and thus those in leadership roles from the fields of policy, charity, professional organizations, research and advocacy who embrace a vision for Canada's Endgame will need to pull together to reach success.

The following specific actions are recommended:

1. CREATION OF AN ENDGAME STEERING COMMITTEE OR "CABINET"

To ensure continued development of an Endgame initiative it is recommended that a broad consortium of organizations coalesce to form a Cabinet whose role will be to ensure ongoing engagement of the charitable, public, research and professional sectors in the initiative. One (or two) key organizations will need to embrace this as an activity they will lead – and house a secretariat to organize meetings, develop communication strategies and ensure this initiative gains momentum at all levels of government in Canada. It is proposed that Cabinet roles would include:

- a. <u>Communication</u>: Public communication and education about the Endgame initiative including within special populations
- b. <u>Advocacy:</u> to encourage Endgame discourse and ideas are embraced by policy makers and government
- c. Ensuring accountability of those in leadership to pursue Endgame measures
- d. Engage with relevant federal government and FPT structures
- e. Report to public on progress

2. ENABLING RESOURCES:

A. Enhanced Funding Support:

To encourage, support and supplement tobacco endgame interventions it will be necessary to maintain and strengthen tobacco control/elimination activities carried out by a variety of actors at the national, provincial and regional levels. New funds are required not only for ramping up some activities (e.g. surveillance) in the short term, but as investment in the Endgame strategy *development and implementation*.

Recently, funding for tobacco control in Canada has been unstable and low in comparison to the U. S. Centers for Disease Control (CDC) recommended levels. CDC recommends governments invest about US\$10.50 per capita in interventions designed to promote quitting, reduce exposure to second hand smoke

and reduce smoking onset.¹ The recent budget of the federal health portfolio (including Health Canada and the Public Health Agency of Canada) has been \$37.6 million per year. In 2014-205, the most recent year for which information is available, \$28.3 million in expenditures on tobacco control by the health portfolio were identified.²

Funding is required to enhance tobacco control investments at all levels of government if Endgame initiatives are to be considered. In the main, tobacco control and achieving the endgame will be self-financing activities. The costs of implementing the measures will be mitigated by increased revenue from new tobacco taxes, reduced health care costs and general improvements to the economy that will result from more people living longer, happier and more productive lives. Some of the measures proposed here will even generate new revenues. These include raising excise taxes, imposing licensing fees and a revived surtax on tobacco company profits. Sources of funding include a number of opportunities to extract additional funds from manufacturers as was outlined in detail in the paper section "Building on Success".

3. New Structures, Consultations and Accountabilities

A. Strengthen tobacco industry surveillance

Canada already requires tobacco companies to report on a wide array of activity, including sales, manufacturing, ingredients, toxic constituents and emissions and research and promotional activities.³ Although these data have been used in government reports and academic research, there are still difficulties in accessing information and limitations in the material itself. Publicly available data is limited. The problem encountered over the years is the difficulty to access from the government the information required. More extensive reporting requirements and more publicly available information is required.

- B. Creation of a Foundation to lead tobacco reduction programming:
 - An independent foundation that engages in non-regulatory tobacco control activity would add value to the Endgame goals and could grow from the Endgame Cabinet activity. If properly set-up, the benefits of an independent foundation (which could be funded by funds extracted from Tobacco industry) are that it could engage in effective initiatives that governments would be unwilling to do on their own and allow for long-term sustainable funding for tobacco control activities. The foundation could do hard hitting ads, public communication and information dissemination that the governments may be unwilling to do. As an example, in the United States, the American Legacy Foundation (now called the Truth Initiative) was created through a tobacco industry litigation settlement the 1998 Master Settlement Agreement involving state medicare cost recovery lawsuits. The Truth Initiative is focused on achieving a culture where all youth and young adults reject tobacco.
- C. Government and Organizational Accountability for the Endgame
 - As an Endgame strategy is created, it must embed within it clarity around which organizations and/or levels of government are accountable for undertaking and achieving the interventions and targets described. Without overt descriptions of accountability, and reporting, tracking success and mitigating challenges will not be possible. Achieving the ambitious target of less than 5% by 2035 will require that accountabilities be clear and that Canadians be informed about progress towards the Endgame goal on a regular basis.
- D. Consult and Collaborate with First Nations, Inuit and Metis (FNIM) Peoples

As described in the Introductory Section of this document, engagement and consultation within FNIM organizations and communities will be extremely important to undertake as a strategy for a (commercial) tobacco free future is developed. Collaboration and partnership with Indigenous organizations will be required for the advancement and delivery of endgame initiatives, including policies and legislative changes.

E. Industry Accountability

In various sections this paper describes numerous approaches to pushing the Tobacco Industry towards greater accountability – these include around novel approaches to reducing youth smoking, increasing their contribution to tobacco control and surveillance, paying for health costs, and eliminating practices that induce sales by retailers, and changing the product and its packaging. Through continued litigation, the tobacco industry could be held accountable for the millions of lives it has foreshortened in the past, and could be required by law to achieve a reduction in tobacco use.

THE BEGINNING OF THE END(GAME)

The Steering Committee for the Summit believes that this work, and the Summit itself, will be the beginning of a new discourse on tobacco control in Canada – with a shift from "control" of tobacco to the unwavering belief that we must achieve a tobacco free future for our citizens. Those who are suffering, who have died prematurely or are too young to speak for themselves, deserve our focus and courage in working together to realize this vision.

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