CONSTRAINING ALTERNATIVES TO CIGARETTE SMOKING

A Submission to Health Canada

On the Notice of Intent – Potential Measures to Reduce the Impact of Vaping Products Advertising on Youth and Non-users of Tobacco Products

March 20, 2019

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Statement of Conflicts: *I have no financial conflicts of interest related to the tobacco, pharmaceutical, vaping or other commercial interests, nor do I have financial conflicts of interest related to entities that embrace an abstinence-only position on tobacco or nicotine issues. My work on this topic is self-financed. I also fund work by others on various public health measures including measures aimed at reducing the carnage due to cigarette smoking.*

My comments in response to the solicitation received on February 26, 2019 follows. I have sought to keep this readable rather than technical. I also request an opportunity to meet with Health Canada's Tobacco Directorate to discuss this issue in more detail, to provide additional information on this submission and to provide insights based on my decades of experience working in Canada and elsewhere to reduce the extraordinary carnage caused by cigarette smoking.

1) REMEMBER THE GOAL

Tobacco control efforts should be directly and rationally aimed at improving public health through measures consistent with good public health principles. This includes measures articulated in the iconic Ottawa Charter for Health Promotion. The best way to solve many health problems is by empowering those most affected.

It appears that Health Canada is confused about priorities. To begin, this solicitation for comments makes the same error that has repeatedly occurred in Health Canada documents: "Tobacco use is the leading preventable cause of disease and premature death in Canada." In fact, and has been repeatedly pointed out, it is not 'tobacco use' but the repeated inhalation of the products of combustion, primarily from cigarettes, that is the cause of the carnage. Tobacco is used in many ways, including genetic research, extraction of nicotine for pharmaceutical products and in low risk non-combustible consumer products. To continue to confuse the plant and the inhalation of the smoke from burning the plant is deeply problematic. Would Health Canada feel any better if all tobacco use ceased but those seeking nicotine simply switched to smoking some new genetically modified plant that was otherwise identical?

Since at least the 1970s it has been known that it is the smoke that is the cause of the epidemic of diseases associated with cigarette use. That is a rational starting point for policy considerations.

2) RATIONALITY AND PROPORTIONALITY

Aside from the confusion on what causes the disease, the consultation document does a good job of summarizing the impact of cigarette smoking in Canada:

> It is a known or probable cause of more than 40 debilitating and often fatal diseases of the lungs, heart, and other organs, responsible for the loss of over 45,000 lives every year in Canada. Direct health care costs are estimated at 16.2 billion dollars annually.

This succinctly states the magnitude of the health tragedy we face. It is mind-numbingly enormous, tragic, and preventable. That it has never been treated with the seriousness the carnage demands, and the ease of resolution science allows, is akin to Canadian infrastructure still incorporating open sewers.

These deaths are not a theoretical construct of a potential worst-case scenario decades from now. The deaths are current. At roughly 128 a day, dwarfing our other preventable causes of deaths.

Failure to address the tragedy of ongoing widespread inhalation of the products of combustible tobacco products is a singular failure of public policy. We know the cause, and we know from vast experience not just with nicotine products but a myriad of other goods and services that substitution of safer alternative products promotes better health.

Good public policy should be based on the concept of proportionality; making decisions that are proportionate to the issues involved. In this case we have the ongoing, preventable epidemic of death, disease and suffering due to a widely used but immensely and unnecessarily toxic delivery system for nicotine. We also have a massively less toxic delivery system that has huge potential in signalling a rational way to end, or at least greatly reduce, the cigarette epidemic. There is also some evidence that, as with virtually any intervention, there are potential unintended consequences associated with the emergence of these vaping products. So, what is a rational, proportional, response?

Policy making is about trade-offs. To address the epidemic of diseases caused by cigarette smoking through the availability of massively lower risk alternatives we have the risk of potential novel users of those alternative products; including young people. But to limit the possibility of young people vaping we invariably do things that can limit the likelihood that cigarette smokers will be empowered to save their lives.

This is not an unusual situation. Auto safety features can encourage more driving, condoms more sexual encounters, clean needles more drug use, legalized marijuana more pot smoking, etc.

What should be the trade-off? A rational, proportionate, response would be to consider relative harms and the ability to control potential unintended consequences with less intrusive, less counter-productive, measures.

3) WHAT ARE THE TRADE-OFFS?

As stated above, in quoting Health Canada's statements on cigarettes, we have a catastrophe of enormous proportions. Those 45,000 annual deaths, over 120 a day, or one every 12 minutes, are real and immediate. It is happening now. Roughly one and a third million Canadians have died since a harm reduction provision (s.17(a)) was passed in 1988 in our federal Tobacco Products Control Act (I drafted the relevant section) only to have the law struck down by cigarette company legal challenges on other aspects of the law, and the concept not being reintroduced in subsequent legislation. That failure to maintain a public health risk reduction standard on tobacco products could very well be the biggest single health tragedy in Canadian history. Many of those dying today from smoking-caused diseases only started smoking after the loss of that risk reduction provision, and failure to focus laser-like on risk reduction now will perpetuate the tragedy.

It is important to emphasize that these deaths are entirely preventable, as they are caused by an unnecessarily dramatically toxic delivery system. Non-combustible products, as we are now seeing in Canada but see beyond doubt in the US, UK, Japan, South Korea, Sweden, Norway and Iceland, can replace cigarettes. Technology can speed that transition if regulatory regimes encourage the transition and empower the public. Again, not unlike the history of public health breakthroughs that came from measures such as facilitating sanitary foods, science-based pharmaceuticals, cleaner water, vaccinations, fire-resistant building materials, refrigeration, etc., etc.

The health gains to Canadian who smoke from measures that transition them from cigarettes to non-combustibles start almost immediately. Indeed, gains to others, such as reduced exposure to second-hand smoke, reduced fire risks and reduction in modelling and cigarette availability to youth are immediate.

By comparison, what are the risks from vaping that has led to this proposed measure from Health Canada? The concern focuses on youth who report having tried vaping products. But much of this concern is based on questionable assumptions, poor interpretations of data, and fear of something that might happen (transitioning to smoking) for which there is little evidence, and for which the timeline for taking corrective policy measures is much longer term than it is for millions of current cigarette smokers.

Compared to the undisputed fact of the 45,000 deaths annually from cigarette smoking, the science on nicotine significantly and negatively impacting the human brain is decidedly weak. There are a couple of rodent studies, but rodent studies are a poor indication of applicability to humans. The world has well over a billion long-term nicotine users, the substance has been used in various forms for centuries, and the 'brain damage' accusation only emerged when some people were looking for ways to denigrate vaping. So, maybe there is an issue, albeit a minor one that has been non-measurable in humans to date. But maybe it is more akin to the arguments abstinence-only advocates make about the potential risks of every other non-abstinence-focused intervention throughout the history of public health. Regardless, it is a massively lower risk than the same nicotine delivered by cigarettes, and orders of magnitude less than the risks faced by the millions of current smokers in Canada.

The reported rates of vaping among young people are apparently a significant part of the basis for the current Health Canada proposals. We can examine the basis of this concern by looking at the data, the science, and the concept of proportionality. The vast majority of the reported vaping is very occasional use. As has been said, this infrequent use among teens is not a sign of addiction so much as of having friends. Young people try many things, at least several of the more common ones (alcohol consumption, unsafe use of motor vehicles, smoking marijuana) are decidedly more hazardous than occasional vaping.

A sensible goal should be to limit the risks to youth (or anyone else) in ways that do not cause significant negative consequences to them or others. But with reputable health bodies pointing out that nicotine itself is no more dangerous than caffeine, why the moral panic about youth occasionally trying vaping (which may or may not involve nicotine) but not on the level of youth caffeine use? Why are we not overly concerned about a similar but much more widely used drug with similar impacts on the adolescent brain? Is the concern about nicotine founded in science or morality? Is it based on principles of proportionality?

The issue of young never-smokers (who would not have otherwise become smokers) becoming addicted to nicotine and transitioning to lethal cigarettes appears to be another major concern behind these

proposed measures. Again, facts matter. Nicotine addiction is measured by the Fagerstrom Test for Nicotine Dependence. By this accepted scientific measure, it does not appear that there is a significant and pressing concern about nicotine dependence among young people experimenting with vaping. The reports of youth vaping used in the Health Canada consultation simply do not meet the test for nicotine dependence. Virtually all use is merely 'past 30 days', a criterion which when used as a sign of nicotine addiction, or alcohol or analgesic addiction, makes a mockery of the concept.

The highest-usage data from the surveys is 15+ times in the past 30 days. One assumes because daily use is too infrequent to measure. Evidently the fear is that this rate of use is a sign of addiction and that these are never-smokers who would not have otherwise started smoking, and that they will transition to smoking. Compared to the certainty of cigarette smoking presently killing 5 Canadians per hour, this is pretty tangential reasoning.

The reported rate of vaping 15+ of the past 30 days among never smoking youth in Canada, as reported in Table 3 of the yet-to-be-published ITC study, is 0.6%. Given that only a subset of this group would be daily vapers and, in turn, a subset of that group being such regular vapers to qualify as even at the low end of the Fagerstrom Test, we are currently looking at an 'at risk' population that is a fraction of a fraction of 1% of youth. That is not to say that one should ignore such data, that there is not a risk of increasing rates of dependence, or that issues of joint liability tell us most of them are the sort of risk-takers who would have otherwise been smoking anyway. But proportionality requires us to look at this data in relation to the measures proposed to deal with it, and the consequences that will have on the ongoing epidemic of cigarette-caused death.

To the extent this is addiction or could eventually become addiction, what are the less intrusive measures that can be taken to mitigate it? For instance, policy measures can make it exceedingly unlikely that anyone who vapes would transition to cigarettes, just as policy measures have facilitated moves to unleaded fuel, sanitary foods and so many other safer goods and services throughout our history.

4) DEALING WITH TRADE-OFFS

On the one hand we have an enormous cause of disability, disease and death. It is an immediate and pressing, but unnecessary. It is by far Canada's largest cause of preventable death. Millions of people who currently smoke cigarettes are modelling the behaviour to youth, and often directly or indirectly supplying youth with cigarettes. A large majority want to not be smoking but are nicotine dependent. As with the concern about youth, cigarette smokers lack agency – the power to act independently and to make their own free choices – due to addiction and to multiple other life challenges highly correlated with cigarette use. Issues of health equity should dissuade us from engaging in victim blaming, false attributions of agency, and other actions that result in further harm to so many of our most vulnerable citizens.

Nicotine can be delivered with massively lower risks through non-combustible alternatives such as vaping. The technology behind such products has been rapidly developing to meet the needs of ever more people who smoke. But these Canadians, often among our most marginalized, lack information on relative risks, lack knowledge of and access to products, lack encouragement to switch, are terribly

misinformed about nicotine, and are dying in large numbers not just from smoking but from policies that fail to empower them. The rest of the world might be paying attention to the principles of the Ottawa Charter for Health Promotion, but what about the federal health authorities based in Ottawa?

On the other side of this equation we have overwhelmingly irregular use of vaping products by a subset of youth. There is little sign of any significant level of addiction in this group, the risks of vaping are tiny compared to smoking cigarettes and we have years to monitor and to intervene to mitigate any identified problems before they could manifest as significant health risks.

Simply put, we are weighing the reality of 45,000 deaths a year against a small, speculative and containable problem that is unlikely to cause any significant harm and any such harm that might arise is likely decades away and can be addressed through rational interventions. Interventions that do not threaten to perpetuate the cigarette epidemic.

5) WHAT WOULD THE PROPOSED MEASURES DO?

Measures that further restrict the already-hugely-constrained promotion of life-saving products to millions of Canadian who smoke will reduce switching by making products less accessible, reducing awareness of them to smokers and those who care about them, reinforce the erroneous message that vaping is not a much safer alternative, and discourage innovation by stymieing the market.

The *Tobacco and Vaping Products Act* already addresses product promotion, with an enormous onus on anyone seeking to inform the public to carefully avoid attracting youth:

> **30.1** No person shall promote a vaping product, a vaping product-related brand element or a thing that displays a vaping product-related brand element by means of advertising if there are reasonable grounds to believe that the advertising could be appealing to young persons.

Health Canada has not addressed why such a statutory provision is insufficient to prevent any promotion that is a legitimate concern in terms of young people. The law was only recently passed and there is no indication that this subsection has proven inadequate as a means of regulating the market.

The proposed warnings on vaping products also need, at a minimum, to be focus tested with cigarette smokers before there is any consideration of implementing them. Messages that reinforce nicotine as a problem: "**Vaping products contain nicotine. Nicotine is highly addictive.",** and messages that focus on "**chemicals that can harm your health"** need to be seen in relation to whether they are informing or misleading Canadians; whether they are rational and proportionate measures or yet another example of policies that have the foreseeable consequence of perpetuating the cigarette epidemic. Among other issues, where is the evidence that nicotine itself, rather than via specific delivery systems at specific dosages, is "highly addictive"? Try getting addicted to a nicotine patch, or to eggplant or other nicotine-containing plants. Where is the evidence that no cigarette smokers will be dissuaded from switching to vaping by prominent warnings about "chemicals that can harm your health"?

Tobacco and nicotine products constitute a very broad spectrum of risks. If the goal is to reduce death and disease the clear target is cigarette smoking. It is, after all, the inhalation of smoke that is the overwhelming cause of the current carnage. Other products, including non-combustion tobacco and nicotine products, have been shown capable of substituting for cigarettes. Anything that conflates

vaping products with smoking is likely to misinform, and the onus should be on Health Canada to show that proposed messages, and overall policy directions, are facilitating rather than impeding a move to a healthier Canada.

6) ALTERNATIVE PRODUCTS TO CIGARETTES – AN OPPORTUNITY, NOT AN OBSTACLE

We have the ability, through regulatory measures Health Canada can enact, to empower Canadians who smoke cigarettes to add product substitution to the options available to them to improve their health. The substitution of lower risk products and behaviors are, of course, a key aspect of pragmatic public health interventions. We regularly practice it with respect to food manufacturing and preparation, pharmaceuticals, sexual health, automobile use, alcohol consumption, workplace standards, airline safety, and a very, very long list of other aspects of life. Nicotine use stands out as an area where such a reasonable approach has been widely ignored or opposed despite there being one of the greatest degrees of risk differentiation we have ever had between substitutable products. Dealing with this irrational inconsistency is among the greatest opportunities we have for improving the health of Canadians.

The lowest rate of smoking and of tobacco caused disease in the OECD is in Sweden, where substitution of the low-risk oral tobacco product called snus deserves much of the credit. Norway has recently replicated that success, halving cigarette smoking prevalence in a decade. Iceland, with a combination of snus and vaping, reduced smoking by 40% in just three years. Japan and South Korea have seen dramatic declines in cigarette sales with the availability of products that heat tobacco but do not result in lethal combustion. Substitution clearly works in practice as well as theory and should be embraced as life saving, empowering, cost effective and consistent with good public health practice.

Confusing ‘tobacco’ with ‘smoking’, in terms of policy, and in the minds of people who smoke cigarettes, should be avoided. So, too, perpetuating continued confusion about ‘smoking’ and ‘nicotine’, or cigarette smoking and vaping, by treating the promotion of vaping products like cigarettes or placing messages on vaping products that are likely to misinform on issues of relative risks. Such measures are akin to conflating smallpox and cowpox.

7) THE ROLE OF CONSUMER RESEARCH

We have long known that cigarette smokers, and users of other tobacco and nicotine products, are very poorly informed about relative risks, the risk of nicotine itself, the likelihood of various diseases, the prognosis for each, and of the actions they can take to reduce risk. This is in large part related to the confused and often inaccurate information made available to them, and regulations that shape the marketplace (and thus the environment of how products are perceived) and the information sources that could otherwise empower them.

Health Canada has promised, but not yet delivered, a series of permitted messages on the relative risks of vaping and cigarette smoking. This is necessitated by the *Tobacco and Vaping Products Act* having, almost certainly unconstitutionally, prohibited accurate speech that can save lives. The focus on concerns about youth vaping, despite the actual health problem apparently being small and otherwise

containable, appears to have delayed regulatory actions to tell Canadian who smoke truthful information. That is not just disproportionate policy, but a public health tragedy and a further erosion of the Charter rights of Canadians.

We need to tell Canadians the truth; to actively empower those people most at risk. We need policies that facilitate healthier behaviours. There should be attention paid to youth, but that attention should include concerns about their exposure to second-hand smoke from the adults around them. It should demonstrate to our youth that the Government of Canada respects individual rights, empowers consumers and pursues fundamental justice. It should also include protecting them from the ongoing tragedy, bereavement and loss of love and support caused by their parents, grandparents and other significant people in their lives prematurely dying in such huge numbers due to cigarette smoking. We need to think of our youth, but to do them justice and to create a healthier Canada, that thinking must be done in a context of informed and proportionate policy making.