Comments on Health Canada's proposal to limit the concentration of nicotine in e-liquids to 20mL/mg¹.

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¹ Government of Canada, Department of Health. (Dec 19, 2020). Canada Gazette, Part I, Volume 154, Number 51: Concentration of Nicotine in Vaping Products Regulations. https://gazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg3-eng.html

Introduction

I welcome the opportunity to comment on Health Canada's proposal to limit the concentration of nicotine in e-liquids to 20mg/mL.² I have chosen to divide my comments into two sections. In the first section, I write in my sole capacity as a citizen of Canada who stands to be harmed, and who knows people who will be harmed if the proposed Regulation goes into effect. In the second section, I write in my expert capacity as a PhD candidate in Sociology who studies vaping, the controversy surrounding it, and the state of evidence on the implications of vaping for public health.

PART I: My comments as a Canadian citizen who uses vaping products as harm reduction

I will begin with a personal disclosure: Vaping is how I stopped smoking after years of unsuccessful quit attempts. For the first year that I vaped, I was a "dual user," in large part because the available products at that time were simply not able to deliver an adequate amount of nicotine on a per puff basis. As the technology evolved, I was eventually able to switch completely using advanced generation vaping products. The products were cumbersome and finicky, but they delivered a lot of vapour, and as a result, were able to deliver the amount of nicotine that kept me from craving cigarettes.

When Canada's vaping regulations came into effect, effective, high-nicotine closed system e-cigarettes became available on the legal market for the first time (mostly in convenient stores). Having read numerous studies about reduced emissions in "high nicotine" vaping products, I decided to give these products a try myself, and found them preferable to what I had been using. Since I have used these smaller high nicotine "pod systems" I have had absolutely no residual desire to smoke (something I struggled with even when using very expensive, large vapes). Nicotine limits would render the products that work best for me entirely ineffective and force me to switch to products that are not only less effective, but are also more risky. And that is the best case scenario. In the worst case scenario, in the absence of effective alternatives I will start to smoke again. And I think it is perverse that an agency responsible for my health is proposing to hurt me, and people like me, without any robust evidence to support the claim of a benefit to youth.

If the products I use now are banned as a result of the proposed Regulation, I am relatively confident that I will not return to smoking, *so long as there are no further changes to the landscape of the current market.* That is to say, I can make due with affordable, effective open systems devices, a variety of non-tobacco e-liquid flavours. It will not be ideal. I am concerned that I will begin craving cigarettes again. I prefer my safer, easier, smaller and more effective JUUL, and my small, refillable pod devices which I use with high-nicotine fruit flavoured e-liquids (since the only remaining JUUL flavor I like is mint), to any other vaping product on the legal market right now.

² Government of Canada, Department of Health. (Dec 19, 2020). Canada Gazette, Part I, Volume 154, Number 51: Concentration of Nicotine in Vaping Products Regulations. https://gazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg3-eng.html

Importantly, Health Canada gives me no reason to believe that the less than ideal market that could keep me away from cigarettes is long for this world, regardless of nicotine limits. The affordability of vaping products is threatened by provincial and federal excise taxes and a regulatory environment that removes incentive for competitive pricing within the vaping products arena and between vaping products and cigarettes. The future availability of effective open systems hardware is also questionable in Canada, as most products face de facto prohibition with the introduction of "child proof" tank requirements. And it appears that the next target for prohibition by Health Canada is non-tobacco e-liquid flavours which the vast majority of adult vapers, including myself, use. Needless to say, as I write this, I am haunted by the increasing likelihood that soon, none of the products that work for me at all, let alone the ones that work well (threatened by the current proposed Regulations) will be legally available in the near future. I am afraid that my choices will be to take my chances on harm reduction products that come from a potentially dangerous unregulated black market, or return to smoking. This scares me.

What scares me more is what will happen to people who have recently switched to vaping specifically because of high nicotine e-cigarettes, whose current status as "former smokers" is far more precarious than my own.

Since I began vaping, and especially since I began examining vaping from an academic perspective, and familiarized myself with the research on relative risk, I have recommended to friends and family members who smoke that they switch if they are unable to quit. Before products like JUUL were on the market in Canada, it was often the case that my loved ones would tell me "I tried but it just didn't work." "I don't have the energy to learn this" "I want something that is as easy as cigarettes."

When JUUL arrived in Canada, and I had read enough research that convinced me it may be a better alternative for hardened smokers than open systems vapes, I began suggesting this type of product to smokers I knew. And I suggested it to all of my friends and family members who had failed to switch to vaping with earlier products. While I do understand the difference between anecdotal and systematic knowledge, I still find it remarkable that every single person who tried JUUL or an equivalent small pod system with high nicotine based on my recommendations, has now successfully switched to vaping. All of these people have told me "I would never have been able to do this without this kind of e-cigarette."

Health Canada absurdly assumes 100% of current vapers will switch to remaining products in the wake of nicotine limit regulations. This is 100% wrong. I know many people - people I love, people I care about - who absolutely will return to cigarettes if small pod systems are rendered less effective and/or more expensive (because people will be forced to buy more pods to get the same amount of nicotine) by the proposed Regulation. One of them already did when JUUL pulled her favourite flavour of pods off the market. A friend of mine in BC, who switched to Vuse after smoking for years, has started smoking again specifically due to the provinces nicotine limits. And I highly doubt that he is the only person in that province harmed by that regulation.

I am not normally open about my personal use of nicotine, due to the stigma and bias associated with smoking and now vaping. I am also sensitive to the fact that a great deal of "expert opinion" on vaping comes from stakeholder groups who are disrupted by vaping products much in the same way as the tobacco industry. Because of this, I have written many of my responses to consultations such as this from

the perspective of a sociologist studying the technologies and the controversy surrounding them. It allows me to speak from a detached position, (albeit one that is consciously and unabashedly pro harm reduction) about the evidence and politics of vaping.

I am breaking from that pattern today because my government is about to hurt me, and hurt people I know and love, and hurt Canadians who depend on vaping products in general, and high nicotine products specifically, to stay free from deadly, addictive cigarettes. Moreover, the rush to prevent youth vaping only makes it more difficult for youth who are going to experiment with nicotine regardless of how Health Canada feels about it, will be forced to do so with extremely harmful, addictive combustible tobacco products that are known to kill half of the people who use them, instead of relatively benign alternatives. Nicotine use is endemic among young people and the increase in youth vaping reflects a once dangerous behaviour becoming far safer.

The proposed Regulation treats vaping in general, and youth vaping in particular, as though it happens in a bubble. It doesn't. There are real and manifestly harmful unintended consequences to this proposal that Health Canada does not appear to have seriously considered.

Reducing the strength of nicotine will reduce the effectiveness of the most popular e-cigarettes, that are helping the most canadians stay smoke free. The evidence does not support Health Canada's belief that higher nicotine concentrations make vaping more attractive to young people. However, if youth were vaping for (high) nicotine, they would still be able to get the same effect from low nicotine concentrations and high power devices. But the easiest way to get a nicotine buzz remains cigarettes. And Health Canada should think twice before it creates an entirely unnecessary generation of new smokers by eliminating effective vapes.

The stated aim of Canada's Tobacco Strategy (CTS) is to "reduce the burden of disease and death from tobacco use and its consequential impact on the health care system and society."³ Robust tobacco control measures have only gotten us so far as a country, and have left many behind. A market for consumer-acceptable alternatives to smoking is absolutely essential to further reduce tobacco death and disease. Canada has this in vaping, and it is counterproductive to the CTS to enact regulations that limit access to effective, enjoyable substitutes to deadly legal products. Leadership from Health Canada is desperately needed. Canadians deserve a regulatory regime that is guided by sober consideration of the best available evidence, and not a knee-jerk reaction to panicked cries from stakeholders whose own relevance depends on the continuation of a cigarette problem in Canada.

Regulations that make vaping less able to compete with cigarettes on the level of satisfaction (including flavor, nicotine pharmacology, price) threatens the potential of these products to obsolete cigarettes, and as a result, impedes the country's ability to reduce death and disease caused by smoking.

I will conclude my personal remarks with a personal plea: Please do not harm me, please do not harm any Canadians, by enacting this arbitrary cap on nicotine in harm reduction products. There is no public health

³ Government of Canada, Department of Health. (2020). Canada Gazette, Part I, Volume 154, Number 51: Concentration of Nicotine in Vaping Products Regulations.

https://gazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg3-eng.html

justification for the proposed Regulation. None. There is no plausible benefit to youth overall, there is a clear risk of harm to youth at risk of smoking, and there will be undeniable harm done to people who depend on the products to stay free from smoke.

PART II: My comments as a sociologist who studies vaping, the controversy surrounding it, and the state of evidence on the implications of vaping for public health

As an expert in vaping technology and a sociologist studying the vaping controversy, I strongly recommend *against* this proposal for the following reasons:

1.1 Flawed analysis of the risks and benefits to youth

- A. The proposed Regulations (a) exaggerate the risk of nicotine dependence from experimental vaping and (b) are premised on the widely debunked proposition that vaping is a gateway to smoking (i.e. the assumption that vaping is but a first step in a transition to more hazardous forms of tobacco use).
- **B.** The proposed Regulations fail to consider the harms of limiting nicotine strength to young people, especially those who are at high risk of smoking harms.
- C. The proposed Regulations represent a reaction on the part of Health Canada to heightened concerns expressed by special interest groups who perceive higher strength nicotine concentrations as a threat in general, and specifically as a threat to youth. It appears that Health Canada has accepted at face value that the threat perceived by these stakeholders is (a) empirically real and (b) serious enough to warrant drastic regulatory actions. Moreover, Health Canada has not offered any indication of the scope of the problem, if it exists at all.

1.2 Discussion

There is little to no evidence supporting the assumption that the appeal of vaping products to youth is even correlated to the concentration of nicotine in these products, and absolutely no evidence suggesting that the given concentration of nicotine in vaping products plays a causal role in increasing or reducing the appeal of these products to young people.⁴ Therefore, the claim that the proposed Regulations will have any impact on the appeal of vaping products to youth is highly questionable. Moreover, the expectation that setting a limit on nicotine concentration will reduce "the number of [youth] experimenting with vaping products," presumes youth who engage in experimental use of nicotine are motivated by technicalities of nicotine concentrations in products, which is highly dubious. I expand on this in the discussion below.

⁴ Levy, D. T., Warner, K. E., Cummings, K. M., Hammond, D., Kuo, C., Fong, G. T., Thrasher, J. F., Goniewicz, M. L., & Borland, R. (2018). Examining the relationship of vaping to smoking initiation among US youth and young adults: A reality check. *Tobacco Control*, tobaccocontrol-2018-054446. https://doi.org/10.1136/tobaccocontrol-2018-054446

i) The proposed Regulation exaggerates the risk of nicotine addiction in experimental vaping

Health Canada does not have an evidence base to justify limiting the nicotine delivery capability or nicotine concentration of vaping products on public health grounds. Restrictions on nicotine delivery and/or concentration will realistically impede smoking reduction and cessation rates among Canadian adults. Effective nicotine delivery in devices that are accessible and relatively easy to use are extremely important for smokers, especially smokers trying e-cigarettes for the first time.

Nicotine use is reinforcing and can lead to dependence, though the likelihood of and degree of dependence varies with the rate, amount, and pattern of nicotine delivery, the biological and psychological characteristics of individual users, and the social and cultural contexts in which nicotine use takes place^{5 6}

The effects of nicotine varies between individuals. For some, nicotine has little effect, and can even be experienced as aversive, while others are highly susceptible to nicotine dependence and find the drug intensely appealing and for most, the effect of nicotine lies somewhere in between the extremes.⁷ Importantly, and contrary to what appears to be implicitly assumed by Health Canada in their justification for the proposed Regulation: **exposure to nicotine does not automatically result in addiction, and in fact, most people who try nicotine do not develop a dependence on the drug, even when they try it in its most addictive form: nicotine inhaled in tobacco smoke ⁸**

When delivered via tobacco smoke, nicotine is absorbed most efficiently and rapidly into the bloodstream. Combustible tobacco smoke is associated with high levels of addiction, and toxicity in human users, and prior to the advent of e-cigarettes, combustible tobacco smoke was also associated with the highest levels of user appeal.⁹ Recreational nicotine delivery products that can compete with cigarettes on the level of satisfaction (appeal and pharmacological effectiveness) can save the lives of adults who are most harmed by or most at rick of herm from cigarettes.

risk of harm from cigarettes.

ii) The proposed Regulation inappropriately relies on a discredited proposition that e-cigarettes are a gateway to smoking

⁵ Niaura, R. (2016). Re-thinking nicotine and its effects (p. 24). Truth Initiative.

http://vapit.it/wp-content/uploads/2016/12/ReThinking-Nicotine.pdf

⁶ Benowitz, N. L. (2009). Pharmacology of Nicotine: Addiction, Smoking-Induced Disease, and Therapeutics. Annual Review of Pharmacology and Toxicology, 49, 57–71.

https://doi.org/10.1146/annurev.pharmtox.48.113006.094742

⁷ Niaura, R. (2016). Re-thinking nicotine and its effects (p. 24). Truth Initiative.

http://vapit.it/wp-content/uploads/2016/12/ReThinking-Nicotine.pdf

⁸ibid ⁹ ibid

There is an absence of strong evidence that e-cigarettes act as a gateway to nicotine addiction and/or graduation to riskier forms of tobacco use does not exist. Moreover, the "gateway theory" of addiction has been widely debunked and its application to the case of vaping is questionable. A 2014 article by Bell & Keane highlights the problematic use of the gateway theme in discussions of e-cigarettes and the impossibility of empirically verifying the phenomenon which "is neither fixed nor stable" :

Although the concept of the gateway theory is often treated as a straightforward scientific theory, its emergence is rather more complicated. In effect, it is a hybrid of popular, academic and media accounts—a construct retroactively assembled rather than one initially articulated as a coherent theory. However, rather than detracting from its utility, this instability has been central to the continued productivity of the concept and its capacity to promote certain understandings of new forms of drug use structured around notions of harm, especially to young people. By producing a simple narrative of escalating drug use, the gateway theory allows for quite different and specific processes (biological, legal, social and cultural) to be collapsed into a unified discourse of risk and harm. These processes crystallize clearly in recent debates about e- cigarettes, where the gateway theory has been taken up in quite distinctive ways. Treated as a predictive rather than a descriptive model, concerns center on e-cigarettes as a 'gateway' or starter product for combustible cigarettes. Most intriguing about the deployment of the concept in this context is that the 'gateway' in question is from nicotine to nicotine. In this framing, nicotine is constituted as simultaneously 'soft' and 'hard' das both relatively innocuous and incontrovertibly harmful. We have suggested that this path demonstrates and reproduces the changed status of smoking from its earlier identity as a precursor of harmful drug use to a form of harmful drug use in itself. It also reveals the complexity of nicotine as an addictive substance which has been conceptually separated from the most prominent harms of smoking, but which is always seen to potentially spawn itself in new and more dangerous forms.¹⁰

While vaping and smoking are correlated (in all age groups), current available evidence suggests that in youth, this is explained by the common liabilities model.¹¹

iii) The proposed Regulation does not consider the evidence for a beneficial substitution effect in the population as a whole, and the particular benefits of this effect to young people if it results in the obsolescence or near obsolescence of cigarettes. It also ignores the benefits of high nicotine e-cigarettes to youth who already smoke cigarettes.

An arguably beneficial unintended consequence of a safer market for adults, is the protection of youth. This includes protecting youth from negative effects of parental smoking, and protecting the entire population of youth from paying the costs of a smoking crisis that can end if we allow it to. More urgently, vaping protects youth who experiment with nicotine, especially those who are most susceptible to nicotine dependence, from having to use deadly products.¹² Vaping also confers direct benefits to youth who smoke.¹³ For those who value public health measures that reduce harm to others, this is unquestionably a good thing. Among those who see acts of normative deviance, like smoking, as a threat

¹⁰ Bell, K., & Keane, H. (2014). All gates lead to smoking: The 'gateway theory', e-cigarettes and the remaking of nicotine. Social Science & Medicine, 119, 45–52. https://doi.org/10.1016/j.socscimed.2014.08.016

¹¹ Etter, J.-F. (n.d.). Gateway effects and electronic cigarettes. Addiction, n/a-n/a. https://doi.org/10.1111/add.13924

¹² Kozlowski, L. T. (n.d.). Younger individuals and their human right to harm reduction information should be considered in determining ethically appropriate public health actions. *Nicotine & Tobacco Research*. <u>https://doi.org/10.1093/ntr/ntz049</u>

to moral fabric of society, and view people who smoke as moral failures whose behaviour makes them deserving of negative consequences, the benefits of harm reduction measures are often feared precisely because they reduce the negative consequences of deviance.¹⁴

Nicotine use is endemic in the youth population.¹⁵ Concerns about youth vaping must not distract from the much more important public health goal of reducing known death and disease from smoking¹⁶. Youth experiment with recreational nicotine products which they appropriate from the adult marketplace, despite efforts of adults to dissuade them, and legal barriers to access enacted by legislators. Efforts to discourage nicotine use among young people must not be based on a fantasy that total abstinence from nicotine in the youth population is the natural state of affairs, or realistic outcome of any policy.

Whether or not cigarette obsolescence through vaping will protect young people who are susceptible to nicotine dependence from developing a nicotine addiction is up for debate. But a market dominated by appealing nicotine products that are dramatically safer than cigarettes will unquestionably protect many experimental youth from developing an addiction to nicotine delivery devices that will make them sick later in life, and/or kill them prematurely.

2.1 Flawed understanding of nicotine pharmacology and nicotine concentrations

- D. The proposed Regulations appear to be based on a fundamentally flawed notion that the "addictiveness" of a vaping product (or any nicotine/tobacco product) is primarily a function of the concentration of nicotine in that product, while the more relevant issue of nicotine pharmacokinetics/pharmacodynamics (pk/pd) has been all but ignored.
- E. While vaping any commercially available concentration of nicotine is considerably safer than smoking cigarettes, there is ample high quality evidence suggesting higher concentrations of nicotine reduce exposure to toxicants in people who vape. The proposed Regulation would remove what are currently understood to be the least risky products in the category from the legal marketplace, and forcing people to consume nicotine in variously more hazardous ways, either by consuming higher volumes of e-liquids, or by returning to smoking cigarettes.

¹⁴ Kozlowski, L. T. (2017). Minors, Moral Psychology, and the Harm Reduction Debate: The Case of Tobacco and Nicotine. Journal of Health Politics, Policy and Law, 4193642. https://doi.org/10.1215/03616878-4193642

¹⁵ Institute of Medicine. (2007). Ending the Tobacco Problem: A Blueprint for the Nation. The National Academies Press. https://doi.org/10.17226/11795

¹⁶ Kozlowski, L. T., & Abrams, D. B. (2016). Obsolete tobacco control themes can be hazardous to public health: The need for updating views on absolute product risks and harm reduction. *BMC Public Health*, *16*, 432. <u>https://doi.org/10.1186/s12889-016-3079-9</u>

2.2 Discussion

Nicotine self-titration, also known as compensatory smoking, is well documented among people who smoke, and it has been demonstrated that when given cigarettes with lower nicotine, smokers respond by increasing the amount of smoke they inhale either by taking more frequent/longer puffs, by increasing the intensity of puffs, or by smoking more cigarettes.^{17 18 19 20 21 22}

It is now overwhelmingly clear that people who vape self-titrate their nicotine consumption as well. Several laboratory and real-world studies demonstrate that lower nicotine concentrations in e-liquids are associated with compensatory vaping (e.g. consuming more e-liquids, more intense puffing) and as a result, *greater exposure to carcinogens*. ^{23 24 25} Plainly speaking, lowering the nicotine in vaping products does not result in reductions in the amount of nicotine consumed. People who vape, like people who smoke, will adjust how they puff and how much they consume in order to maintain the level of satisfaction from the drug that they are accustomed to.²⁶

The majority of people who vape concentrations of nicotine higher than 20mL/mg use small, low-wattage, low power devices that do not produce anywhere near the volume of aerosol as large "mods" and tanks. It is not the strength of nicotine that appeals to these users, but the device size, the

¹⁷ Ashton, H., Stepney, R., & Thompson, J. W. (1979). Self-titration by cigarette smokers. British Medical Journal, 2(6186), 357–360. https://doi.org/10.1136/bmj.2.6186.357

¹⁸ Ashton, H., & Watson, D. W. (1970). Puffing frequency and nicotine intake in cigarette smokers. British Medical Journal, 3(5724), 679–681. https://doi.org/10.1136/bmj.3.5724.679

¹⁹ Russell, M. A., Wilson, C., Patel, U. A., Feyerabend, C., & Cole, P. V. (1975). Plasma nicotine levels after smoking cigarettes with high, medium, and low nicotine yields. British Medical Journal, 2(5968), 414–416. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681802/

²⁰ Russell, M. A., Jarvis, M., Iyer, R., & Feyerabend, C. (1980). Relation of nicotine yield of cigarettes to blood nicotine concentrations in smokers. British Medical Journal, 280(6219), 972–976. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1601132/

²¹ Sutton, S. R., Russell, M. A., Iyer, R., Feyerabend, C., & Saloojee, Y. (1982). Relationship between cigarette yields, puffing patterns, and smoke intake: Evidence for tar compensation? BMJ, 285(6342), 600–603. https://doi.org/10.1136/bmj.285.6342.600

²² Woodward, M., & Tunstall-Pedoe, H. (1993). Self-titration of nicotine: Evidence from the Scottish Heart Health Study. Addiction (Abingdon, England), 88(6), 821–830.

https://doi.org/10.1111/j.1360-0443.1993.tb02096.x

²³ Dawkins, L. E., Kimber, C. F., Doig, M., Feyerabend, C., & Corcoran, O. (2016). Self-titration by experienced e-cigarette users: Blood nicotine delivery and subjective effects. Psychopharmacology, 233(15–16), 2933–2941. https://doi.org/10.1007/s00213-016-4338-2

²⁴ Dawkins, L., Cox, S., Goniewicz, M., McRobbie, H., Kimber, C., Doig, M., & Kośmider, L. (2018). 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: Subjective effects and nicotine, acrolein and formaldehyde exposure. *Addiction (Abingdon, England)*, *113*(10), 1874–1882. <u>https://doi.org/10.1111/add.14271</u>

²⁵ Smets, J., Baeyens, F., Chaumont, M., Adriaens, K., & Van Gucht, D. (2019). When Less is More: Vaping Low-Nicotine vs. High-Nicotine E-Liquid is Compensated by Increased Wattage and Higher Liquid Consumption. *International Journal of Environmental Research and Public Health*, *16*(5). <u>https://doi.org/10.3390/ijerph16050723</u>

²⁶ Dawkins, L. E., Kimber, C. F., Doig, M., Feyerabend, C., & Corcoran, O. (2016). Self-titration by experienced e-cigarette users: Blood nicotine delivery and subjective effects. Psychopharmacology, 233(15–16), 2933–2941. https://doi.org/10.1007/s00213-016-4338-2

relative simplicity compared to larger vapes, and the effectiveness of the product as a replacement for cigarettes. It is on the last point that the strength of nicotine is important. For small e-cigarettes (like JUUL, or Vuse) to work effectively for smokers, they need to be able to deliver a peak nicotine concentration that approaches that of smoking²⁷. While their simplicity and size may be what attracts consumers who would never enter a vape shop to switch to vaping, the success of the switch ultimately depends on whether or not a given product can deliver an appropriate amount of nicotine. While larger, more powerful vapes from vape shops do this by vaporizing high volumes of low strength e-liquid, small e-cigarettes do so by vaporizing low volumes of high concentrations of e-liquid.²⁸

Conclusion

It is imperative that decisions affecting the health of millions of Canadians are made on the basis of the best available evidence, and the proposed Regulations do not do this. The European Union enacted an arbitrary restriction on nicotine at 20mg/mL prematurely, and the current evidence strongly suggests that this decision was inappropriate for the protection of public health. Health Canada should respect the expertise of vapers, veteran nicotine and tobacco researchers, public health experts who understand both the risks *and benefits* of vaping products, including high nicotine products, to population health. While concerns about high nicotine vaping products are real, the presumed risk that has prompted these concerns is not. Given the absence of high quality empirical evidence of a genuine threat posed by high nicotine e-cigarettes to young Canadians, the overwhelming evidence that cigarettes remain the number one cause of preventable death and disease in this country, and the growing evidence based consensus that vaping products act as economic substitutes for cigarettes, it is inappropriate to enact arbitrary limits on nicotine concentrations at this time.

²⁷ For example, the original JUUL pod strength of 59mg/mL was meant to offer comparable peak nicotine plasma concentrations of nicotine on a puff by puff basis compared to cigarettes. (see Bowen, A., & XING, C. (2014). *Nicotine salt formulations for aerosol devices and methods there of.* Patent No. WO2014182736A1<u>https://patents.google.com/patent/WO2014182736A1/en?q=cartridge&q=storage+compartment&q=mouthpiece&q=device&q=heater&before=priority:20131223&num=100&scholar</u>) Notably, while there are some studies that show JUUL may approach similar dependence risks to cigarettes due to devices ability to rapidly deliver nicotine, there is no evidence or reason to believe that the dependence risk of JUUL exceeds that of cigarettes which are not affected by the proposed Regulations. At best, the high concentration in a JUUL pod allows it to deliver nicotine as effectively, but not moreso, than cigarettes.

²⁸ Farsalinos, K. E., Spyrou, A., Stefopoulos, C., Tsimopoulou, K., Kourkoveli, P., Tsiapras, D., Kyrzopoulos, S., Poulas, K., & Voudris, V. (2015). Nicotine absorption from electronic cigarette use: Comparison between experienced consumers (vapers) and naïve users (smokers). *Scientific Reports*, *5*. https://doi.org/10.1038/srep11269

About the Author

I am a PhD candidate in Sociology at the University of Waterloo, interested in the social, historical, and political dynamics of technological change, radical technologies, user-driven innovation, and disruptive markets.

My dissertation documents the history of vaping product innovation, and analyzes the processes, practices and events that led to the birth and rapid growth of the independent vaping sector. I further examine the conditions under which vaping came to disrupt the American tobacco and "tobacco problems" ecology. My study provides an empirically driven explanation of why hostility and fear towards vaping has overtaken contemporary media narratives and public opinion, and shows how the moral panic over vaping is linked to incumbents' strategic efforts to stop a disruptive threat.

I have applied my subject matter expertise in vaping issues outside of an academic setting, primarily as an advocate for nicotine policy reform in Canada and the United States. I have submitted written comments to the Canadian Senate, Health Canada and the Ontario Ministry of Health for consultations regarding vaping regulations, and testified as an expert witness in a successful preliminary injunction hearing for a lawsuit challenging the state of Michigan's "emergency" ban on e-cigarette flavors. I have done all of this in an independent capacity, and without compensation from any industry group or NGO.

I have written and co-authored published articles on vaping in a number of academic specialist and popular venues including The American Journal of Public Health, the Toronto Star, Policy Matters and the Philadelphia Inquirer, Vaping.com, Vaping360, and been a guest on a number of podcasts, including the acclaimed drug policy program Narcotica. I have assisted journalists at publications including the Philidalphia Inquirer, the New Yorker magazine, and Northwestern University's Changing the Narrative project with backgrounding research related to vaping, and have been interviewed by Buzzfeed, Vice, the Nation, and the Financial Post on issues pertaining to vaping and the politics surrounding it.

Recently, I have provided occasional paid consulting to Keller and Heckman LLP, a law firm representing several small and medium sized independent vapor firms in the United States on matters related Pre-Market Tobacco Applications submitted to the U.S. Food and Drug Administration.

The views reflected in this comment are my own and not those of the University of Waterloo, the organizations I have volunteered with, or Keller and Heckman LLP. I received no compensation for this comment.