Rethinking Nicotine: The Role of Public Health Law in Ending an Epidemic

David Sweanor and Adam R. Houston

CIGARETTE SMOKING IS THE leading cause of preventable death in wealthy countries, and rapidly replicating that status for the rest of the world. The World Health Organization (WHO) predicts that on current trends cigarette smoking will kill a billion people this century. Yet these deaths are almost exclusively caused by the inhalation of smoke rather than from the nicotine these consumers primarily seek. Cigarettes are an incredibly dirty, and particularly addictive, delivery system. It has been known in scientific circles for decades that people smoke for the nicotine but die from the tar, but it is through creative legal measures that we could ultimately prevent the current public health catastrophe.

Consumer acceptable ways to deliver nicotine without the inhalation of the products of combustion already exist, giving robust proof-of-concept for the dramatic role alternative delivery systems could play in fundamentally altering rates of disease and death. Legal measures such as replicating the constitutional challenges that have removed barriers to life saving harm reduction efforts for users of illicit drugs, and well-crafted regulatory reform that seeks the best risk-benefit tradeoff for products designed to make cigarettes obsolete, have enormous potential to rapidly transform the market. As Canada, like other countries, already has to adapt laws due to new nicotine products, the opportunity to target health gains is clear.

LA CONSOMMATION DE CIGARETTES est la principale cause de morts évitables dans les pays riches et le devient rapidement dans le reste du monde. L'Organisation mondiale de la santé (l'OMS) prédit que, si la tendance actuelle se poursuit, la consommation de cigarettes tuera un milliard de personnes au cours du siècle actuel. Cependant, ces morts découleront presque exclusivement de l'inhalation de la fumée plutôt que de la nicotine dont les consommateurs recherchent l'effet. Les cigarettes constituent un mode d'administration incroyablement nuisible et particulièrement toxicomanogène. Il est bien connu des cercles scientifiques, et ce depuis des décennies, que les gens fument pour la nicotine mais meurent à cause du goudron. Ce n'est que par des mesures législatives créatives que nous pourrions en fin de compte prévenir l'actuelle catastrophe en santé publique.

Il existe déjà des manières acceptables pour les consommateurs d'administrer la nicotine sans inhaler de produits de la combustion. Il s'agit là d'une solide preuve théorique du rôle remarquable que les modes d'administration de rechange pourraient jouer pour ce qui est de changer le taux de maladie et le taux de mortalité d'une façon fondamentale. Des mesures légales semblables à la reprise des défis constitutionnels qui ont permis d'abolir les obstacles aux efforts de réduction des risques et de sauver la vie des utilisateurs de drogues illégales ainsi qu'une réforme bien pensée de la réglementation en

Legal reform measures aimed at replacing the current unscientific abstinence-only approach to nicotine with a pragmatic policy aimed at reducing harm would continue a very long line of public health successes on such products as foods, pharmaceuticals, and automobiles, where regulations facilitating risk reduction initiatives have dramatically reduced deaths, injuries, and disease. Intelligent regulatory oversight, including differentiating taxation based on relative risks, could also enable harm reduction initiatives to act synergistically with current policies aimed at preventing smoking onset, encouraging cessation, and protecting third parties from environmental tobacco smoke.

Given the political, social, genetic, and neuroscientific challenges in continuing an abstinence-only approach to nicotine use, legal interventions facilitating harm reduction measures would appear to have the greatest potential for a global breakthrough in reducing cigarette-related mortality and morbidity. Through such legal interventions, Canada could lead the world in tobacco/nicotine policy, much as the country did in past decades on a wide range of other anti-smoking initiatives.

Using legal measures to apply harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.

vue d'un compromis entre les risques et les avantages à l'égard des produits visant à remplacer la cigarette disposent d'un énorme potentiel susceptible de transformer rapidement le marché. Étant donné que le Canada, tout comme d'autres pays, doit déjà adapter ses lois avec l'avènement de nouveaux produits contenant de la nicotine, il est évident que c'est une occasion de miser sur les gains en matière de santé.

Une réforme légale qui viserait à remplacer l'abstinence comme étant la seule méthode envers la nicotine, laquelle n'a pas été prouvée scientifiquement, par une politique pragmatique visant à réduire les risques et les méfaits s'enlignerait sur les très nombreux succès en matière de santé publique, sur des produits de consommation comme la nourriture, les produits pharmaceutiques et les automobiles, où la réglementation facilitant les mesures de réduction des risques ont permis une diminution marquée dans le nombre de décès, de blessures et de maladies. Un régime de surveillance réglementaire intelligent, y compris une taxation différentiée selon le risque, pourrait également permettre que des initiatives de réduction des méfaits aient une action synergétique avec les politiques actuelles visant à empêcher les jeunes de commencer à fumer, à encourager les fumeurs à arrêter et à protéger les tiers de la fumée secondaire.

À la lumière des défis politiques, sociaux, génétiques et neuroscientifiques que présente une approche à l'utilisation de la nicotine uniquement fondée sur l'abstinence, toute intervention juridique visant à faciliter les mesures de réduction des risques semblerait avoir de meilleures chances d'avoir une percée rapide globale pour ce qui est de réduire

les taux de mortalité et de morbidité liés à la cigarette. Grâce à de telles interventions, le Canada pourrait être un chef de file mondial en matière de politique sur le tabac et la nicotine, tout comme il l'a été au cours des dernières décennies pour un large éventail d'autres initiatives antitabac.

Recourir à des mesures légales pour appliquer des principes de réduction des risques aux politiques de santé publique sur le tabac et la nicotine va au-delà d'une politique simplement rationnelle et empreint de compassion. C'est là plus qu'une réponse pragmatique à un marché qui, de toute façon, subit déjà d'importants changements. Il est susceptible d'effectuer l'une des plus grandes percées de l'histoire de l'humanité en matière de santé publique en modifiant de façon marquée les pronostics d'un milliard de décès causés par la cigarette au cours de notre siècle.

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I. NICOTINE USE: THE PROBLEM

Cigarette smoking is the leading cause of preventable death in Canada. This remains the case despite decades of considerable progress in reducing its prevalence. Health Canada estimates that it causes roughly 40,000 deaths per year, representing 17% of total national deaths.[1] At a global level, it is estimated that cigarette smoking will result in 1 billion deaths this century.[2] By any measure, cigarette smoking remains one of the major public health challenges in Canada, and the world. Critically, this health catastrophe results not from the nicotine that smokers seek, but from the inhalation of smoke in order to obtain it. Replacing combustion-based nicotine delivery has the potential to rapidly resolve the smoking epidemic, just as the provision of clean water deals with cholera epidemics. But such a policy is, ironically, not supported by many of the protagonists in the global effort to reduce smoking. There is a barrier to actually dealing with the delivery system, and overcoming that barrier through a rethinking of overall nicotine policy has huge scope to improve health.

A key component of effective public health policy is the role of law in implementing and protecting health measures, and in balancing issues

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1 Health Canada, "Smoking and Mortality" (21 September 2011), online: <www.hc-sc.gc.ca>.

2 Prabhat Jha et al, "Tobacco Addiction" in Dean T Jamison et al, eds, *Disease Control Priorities in Developing Countries*, 2nd ed (Washington DC & New York: World Bank & Oxford University Press, 2006) 869 at 869.

of individual and collective rights. Determining what makes people sick is a medical-scientific challenge, but solving these issues at a population level once the cause has been identified is typically a social-legal-political endeavour. In the case of smoking and of nicotine, the science on what causes the harm is settled. Health policy measures, including law reform, are critical for applying this knowledge in order to achieve the societal changes necessary to make cigarettes obsolete.

In recent decades, Canada's achievement of a very significant reduction in both cigarette sales and reported prevalence of cigarette smoking has been very closely associated with law reform initiatives. These measures started gaining momentum in the mid-1980s.[3] But the measures that have been used in Canada to date have been limited to dealing with issues about the use of cigarettes, with very little effort directed towards dealing with the product itself (aside from relatively minor issues, such as seeking to ban menthol or reducing the fire risk of discarded cigarettes). Laws have been used to impact the price of cigarettes; govern where and to whom they can be sold; greatly limit any advertising and promotional efforts; dictate package health warnings; and restrict where they can be used.[4] But unlike efforts to deal with the risks caused by products such as automobiles, pharmaceuticals, industrial machinery, and a myriad of other products, there has been a dearth of action on regulating cigarettes or on seeking ways to replace the incumbent product with one that is less of a health risk.[5]

II. ALTERNATIVE NICOTINE DELIVERY METHOD AS A "SIMPLE IDEA" SOLUTION TO SMOKING'S HEALTH TOLL

The failure to use policy to alter the nature of products on the market is an intriguing situation. If we look at public health campaigns aimed at reducing any cause of death, injury, or disease, there are four broad areas of intervention. Measures are aimed at preventing the onset of the dan-

3 David Sweanor & Ken Kyle, "Legislation and Applied Economics in the Pursuit of Public Health" in Joy de Beyer & Linda Waverley Brigden, eds, *Tobacco Control Policy: Strategies, Successes, and Setbacks* (Washington DC & Ottawa: The World Bank & International Development Research Centre for Research International Tobacco Control Secretariat, 2003) 71 at 71.

4 *Ibid*.

5 See David T Sweanor, "Policy Options to Reduce Tobacco-Caused Mortality" (1999) 18:3 J Addictive Diseases 1; David Sweanor, "Legal Strategies to Reduce Tobacco-Caused Disease" (2003) 8:4 Respirology 413.

gerous behaviour; at achieving cessation of the behaviour among those already engaged in it; at protecting third parties from harm caused by the behaviour; and at reducing the risks faced by those who will persist in engaging in the behaviour.[6] Campaigns that refuse to countenance this fourth category are generally seen as based on moralist abstinence-only orientations; though they are common on issues such as illicit drugs, alcohol, and sex outside of marriage, they lack the pragmatism and respect for individual autonomy that are an accepted part of legitimate public health efforts. While paternalism plays a role in public health efforts (for example, seatbelt and milk pasteurisation laws) there are sparse grounds for the imposition of compulsory measures when less intrusive measures will suffice, and for abstinence campaigns that are inconsistent with science.

The science underlying health measures is critically important. In the case of nicotine use, the failure to focus on reducing the risks associated with cigarette smoking is disconcerting in that the harms from smoking are almost entirely due to the inhalation of smoke, rather than the nicotine that smokers desire. People smoke for the nicotine but die from the tar.[7] The resulting health problems are essentially due to a very dirty delivery system for a very widely used drug. As seen with non-combustion tobacco products—medicinal nicotine, various types of smokeless tobacco products, and now vapour products—the ability to effectively deliver nicotine without the inhalation of smoke is possible. Thus, shifting the market to non-combustion alternatives not only has the potential to achieve a public health breakthrough of truly historic significance, but is also a rather simple idea. The failure of the anti-tobacco movement and public health bodies to seize on this idea is an example of the concept of "zones of incomprehension," as described by Saul Bellow in *The Dean's December*: matters that are "so fully apparent that you couldn't see them."[8]

III. PUBLIC HEALTH BREAKTHROUGHS: A LONG HISTORY OF LONG DELAYS

It would be incorrect to see the failure to grasp the significance of nicotine harm reduction as an anomaly in public health that can be laid solely at

6 David Sweanor, Philip Alcabes & Ernest Drucker, "Tobacco Harm Reduction: How Rational Public Policy Could Transform a Pandemic" (2007) 18:2 Int J Drug Policy 70 at 70.

7 MAH Russell, "Low-Tar Medium-Nicotine Cigarettes: A New Approach to Safer Smoking" (1976) 1:6023 Brit Med J 1430 at 1431.

8 See Saul Bellow, *The Dean's December*, 1st ed (New York: Harper & Row, 1981) at 5.

the feet of the peculiar culture of some anti-tobacco advocates. Rather, it is just one in a long list of truly simple ideas that have historically had to overcome zones of incomprehension in order to yield tremendous public health breakthroughs.[9] As with replacing the outrageously harmful method of inhaling smoke into the lungs to facilitate the delivery of nicotine, the adoption of these other simple ideas typically took decades as they faced opposition from the recognized public health authorities of their day.

Dr. Edward Jenner is rightly honoured for the simple idea that cowpox could protect against smallpox, but his breakthrough in understanding the importance of vaccinations faced opposition. Such opposition came from those who saw such things as interfering with the will of God, and those opposed to the violation of autonomy and equality resulting from the manner of immunization drives.[10] As a result, widespread immunization took many decades to achieve. The history of sanitation is even more fraught. The ground-breaking work of Dr. Ignác Semmelweis, on the simple idea of doctors washing their hands between conducting autopsies and attending to childbirth, was not merely ignored for decades, but his sanitary procedures were actually abandoned on the orders of his superiors, who did so *after* his measures had proven exceedingly effective at preventing an epidemic of unnecessary maternal and child deaths.[11]

The zones of incomprehension also manifest themselves in the decades of delay in such things as scurvy prevention;[12] in sanitary food manufacturing;[13] in the move to science-based pharmaceuticals in place of snake oil;[14] in the transition to science-based and professionally licenced medicine in place of charlatans;[15] in removing lead from gasoline;[16] and in ongoing efforts to apply simple harm reduction policies in the realm of venereal dis-

9 *Ibid*.

10 See Michael Willrich, *Pox: An American History* (New York: Penguin Press, 2011) at 262, 270.

11 See Sherwin B Nuland, *The Doctors' Plague: Germs, Childbed Fever, and the Strange Story of Ignác Semmelweis*, 1st ed (New York: W W Norton and Company, 2003).

12 See Stephen R Bown, *Scurvy: How a Surgeon, a Mariner, and a Gentleman Solved the Greatest Medical Mystery of the Age of Sale* (New York: Thomas Dunn Books, 2003) (Dr. James Lind's successful experiment occurred in 1747, but citrus only became official issue to all Royal Navy ships in 1799) at 95–97, 225, 228.

13 See James Harvey Young, *Pure Food: Securing the Federal Food and Drugs Act of 1906* (Princeton, NJ: Princeton University Press, 1989).

14 See Philip J Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation* (Chapel Hill, NC: University of North Carolina Press, 2003).

15 See Pope Brock, *Charlatan: The Fraudulent Life of John Brinkley* (London: Weidenfeld & Nicolson, 2008).

16 See Needleman, *supra* note 8.

ease,[17] automobile safety,[18] and illicit drugs.[19] The pattern of the obstacles to changes in established thought and practice is well entrenched, and the challenges in dealing with nicotine delivery can be correctly seen as fitting Thomas Kuhn's work on paradigms: that fundamental changes in concepts and practices of scientific disciplines go through standard, and time consuming, transitions.[20]

Dealing with cigarettes is thus no exception to a distressingly common phenomenon. By the early 1940s, Dr. Lennox Johnston had demonstrated the ability to replace cigarette smoking with alternative nicotine delivery sources, and by the 1970s there was recognition that people were dying, not from the nicotine in cigarettes, but from the inhalation of smoke as a means of obtaining nicotine.[21] This is not theoretical, but based on a thorough understanding of the causes of the diseases associated with smoking. It is also backed by decades of Swedish experience with snus, a non-combustible form of tobacco with comparatively minimal health risks. Nevertheless, snus has been banned in the rest of the European Union, while cigarettes—despite being dramatically more harmful—remain widely available.[22] Nicotine, without inhalation of smoke, finds its place in a long line of simple ideas confronted by a zone of incomprehension.

IV. THE PROBLEM OF AN ABSTINENCE DEPENDENCE IN NICOTINE POLICY

Nicotine without inhalation of smoke might not be as clear an example of a zone of incomprehension if total nicotine abstinence was itself a viable strategy. Clearly, if it were possible in short order to get all nicotine users

17 See Allan M Brandt, *No Magic Bullet: A Social History of Venereal Disease in the United States Since 1880* (New York: Oxford University Press, 1985).

18 See Sean O Grady, "The Man who Saved a Million Lives: Nils Bohlin—Inventor of the Seatbelt", *The Independent* (18 August 2009), online: <www.independent.co.uk>.

19 See Gabor Maté, *In the Realm of Hungry Ghosts: Close Encounters with Addiction* (Toronto: Alfred A Knopf Canada, 2008); and Dan Baum, *Smoke and Mirrors: The War on Drugs and the Politics of Failure* (Boston: Little, Brown & Co, 1996).

20 Thomas S Kuhn, *The Structure of Scientific Revolutions*, 2nd ed (Chicago: University of Chicago Press, 1970) at 10–11, 15.

21 Christopher Snowden, *Velvet Glove, Iron Fist: A History of Anti-Smoking* (Ripon, North Yorkshire: Little Dice, 2009) at 86, 135.

22 See J Foulds et al, "Effect of Smokeless Tobacco (Snus) on Smoking and Public Health in Sweden" (2003) 12:4 Tobacco Control 349 at 358; and Letter from Martin Jarvis et al, to Rt Hon Jeremy Hunt MP (7 October 2013) *The Counterfactual* (blog), online: <www.clivebates.com>.

to collectively "just say no," harm reduction strategies would not be needed. However, a wide range of obstacles stand in the way of relying on abstinence. Not least among them is the importance of the principle of individual autonomy in public health efforts. As with the use of other drugs, there are people who will continue to use nicotine, despite admonitions to the contrary.

There is, of course, a dismal history of abstinence-only policies on issues including not only alcohol[23] and illicit drugs,[24] but also even coffee. In the 1700s, Sweden was among the countries that had banned coffee. King Gustav III was convinced it was a poison—he even ordered a convicted murderer to drink coffee every day until the man died (the convict outlived the king).[25] In addition, cigarettes deliver nicotine in a particularly addictive way, further limiting the ability for existing users to "just say no."[26] As a result, the success of unaided attempts to quit smoking cigarettes is in the low single digits.[27] Importantly, the addictiveness of a drug is related to the delivery system rather than a feature of the drug itself; in contrast to inhalation via smoking, nicotine patches are not prone to creating dependence.[28] So, with a focus on re-thinking the delivery system, it is important to know that nicotine use need not be either particularly harmful to health or particularly addictive.

But the hold of nicotine goes deeper than addiction. There are strong genetic links involved in smoking. For example, research has shown that people with certain genes do not reduce cigarette consumption in the face of otherwise powerful anti-smoking policy tools, such as tax increases.[29] In addition, nicotine has positive impacts and, equally important in terms of ongoing use, is perceived as having positive impacts by consumers. Much of nicotine use can be ascribed to self-medication,[30] which is particularly

23 See Daniel Okrent, *Last Call: The Rise and Fall of Prohibition* (New York: Scribner, 2010).

24 Baum, *supra* note 19.

25 Bennett Alan Weinberg & Bonnie K Bealer, *The World of Caffeine: The Science and Culture of the World's Most Popular Drug* (New York: Routledge, 2002) at 92–93.

26 Karl Fagerström & Thomas Eissenberg, "Dependence on Tobacco and Nicotine Products: A Case for Product-Specific Assessment" (2012) 14:11 Nicotine & Tobacco Research 1382 at 1385–86.

27 American Cancer Society, "A Word About Success Rates for Quitting Smoking" (6 February 2014), online: <www.cancer.org>.

28 Murray Laugesen, "Tobacco Far More Addictive than Nicotine—But Why?" (3 June 2011), *Health New Zealand*, online: <www.healthnz.co.nz>.

29 Jason M Fletcher, "Why Have Tobacco Control Policies Stalled? Using Genetic Moderation to Examine Policy Impacts" (2012) 7:12 Plos ONE e50576, online: <www.journals.plos.org>.

30 Jacques le Houzec, "The Positive Effects of Nicotine" (12 January 2012), *Nicotine Science and Policy* (blog), online: <nicotinepolicy.net>.

an issue for those with mental illness, among whom rates of smoking have not seen the sort of decline that has occurred elsewhere in the population.[31]

The use of drugs has often been associated with policies based more on moral panics than on public health pragmatism.[32] Yet, the altering of consciousness is actually a very consistent aspect of human behaviour, including seeking out the endorphins from physical activity, the dizziness from rolling down a hill, or the effects of a very wide range of substances we consume.[33] In the case of caffeine, drug use is so ingrained that it is now often not even seen as a drug, though it was once feared.[34] As with nicotine, caffeine can be addictive, yet it has significant benefits for many people, and there is no chance of it being eradicated in any foreseeable future.[35] And as caffeine is delivered without inhalation of the products of combustion, its negative health impacts are sufficiently minor as to attract very little attention from public health campaigners. Yet, in a world where caffeine was obtained by smoking and nicotine was obtained without combustion, public health priorities would surely be reversed.

By moving to non-combustion sources of nicotine for those who need or want the drug, the result might well be like the current caffeine market. There could be less use as consumers weened themselves off the drug through the use of less addictive delivery systems, or there could be a greater use than the risk-constrained market we see today. But the health impact of such nicotine use would be, as stated by the Royal Society of Public Health, comparable to caffeine.[36]

The opportunity non-combustion presents for solving one of our most longstanding and intractable health problems is hard to overstate. With 1 billion lives on the line this century, such a move would be comparable to the greatest historic public health breakthroughs. Abstinence-only ap-

31 See Karen Lasser et al, "Smoking and Mental Illness: A Population-Based Prevalence Study (2000) 284:20 J American Medical Assoc 2606 at 2608; and Benjamin Lê Cook et al, "Trends in Smoking Among Adults With Mental Illness and Association Between Mental Health Treatment and Smoking Cessation" (2014) 311:2 J American Medical Assoc 172 at 178.

32 PJ Giffen, Shirley Endicott & Sylvia Lambert, *Panic and Indifference: The Politics of Canada's Drug Laws* (Ottawa: Canadian Centre on Substance Abuse, 1991).

33 Gene M Heyman, *Addiction: A Disorder of Choice* (Cambridge: Harvard University Press, 2009).

34 Weinberg & Bealer, *supra* note 25 at 92–93. See also Stewart Lee Allen, *The Devil's Cup: Coffee, The Driving Force in History* (London: Canongate, 1999).

35 Bennett Alan Weinberg & Bonnie K Bealer, *The Caffeine Advantage: How to Sharpen Your Mind, Improve Your Physical Performance, and Achieve Your Goals—The Healthy Way* (New York: Free Press, 2002) at 9.

36 Royal Society for Public Health, News Release, "Nicotine 'No More Harmful to Health than Caffeine'" (13 August 2015), online: <www.rsph.org.uk>.

proaches to nicotine are fundamentally flawed due to what science tells us about the nature of nicotine and those who use it. The resulting abrogation of individual rights to public health through the restriction of viable options, and the resulting unnecessary public health burden, are major policy failures. What is more, the failure to think beyond abstinence has resulted in, and continues to perpetuate, the current massive public health catastrophe.

V. THE CULTURAL BARRIERS TO A HEALTH LAW BREAKTHROUGH

The barriers to changing public policy, and the laws necessary to effectively implement that policy, can be usefully seen in relation to what has come to be known as the field of moral psychology.[37] People tend to make rapid morals-based assessments of issues, then primarily use rationality to support their initial "gut" reaction. By way of example, among public health practitioners, feelings of justice and personal autonomy are typically dominant;[38] hence, the support for such interventions as sex education and needle exchange programs. By contrast, other people use operating principles such as deference to authority (hence looking to what authorities say about sex education and needle exchange programs), or a standard of purity/sanctity, wherein comes the opposition to measures such as sex education and needle exchange programs.

The role of moral psychology in the realm of tobacco/nicotine has been detailed very well in the case of smokeless tobacco.[39] The result is that those on different sides of the debate on harm reduction simply see the world in different ways, and "talk past" each other. Those who are centred on personal autonomy and justice get angry at those who will not accept, as an underlying principle, honestly and pragmatically working with those at risk. For example, witness the reaction to those who, for reasons of "purity" or "authority," actively mislead people in order to try to get them to adjust their behaviour, such as claiming that all tobacco products are equally hazardous.[40] Those deferring to authority/community standards evince

37 Jonathan Haidt, *The Righteous Mind: Why Good People are Divided by Politics and Religion* (New York: Pantheon Books, 2012).

38 Jess Alderman, Katherine M Dollar & Lynn T Kozlowski, "Understanding the Origins of Anger, Contempt, and Disgust in Public Health Policy Disputes: Applying Moral Psychology to Harm Reduction Debates" (2010) 31 J Public Health Policy 1.

39 *Ibid*.

40 Sally Satel & Brad Rodu, "Why Public Health Advocates Care More About Heroin Addicts Than Smokers", *Forbes* (9 September 2015), online: <www.forbes.com>.

contempt for others who will not accept such an orientation (such as the contempt shown for those disagreeing with the views of the World Health Organization or the Centres for Disease Control and Prevention (CDC)). Those with a purity/sanctity viewpoint feel disgust at those who see the issues differently (note the focus on "children" among people with this viewpoint, and their reaction to those who would countenance the use of a "drug").

Typically, public health campaigns battle against those with authority-based or purity/sanctity-based world views in trying to implement risk reduction strategies. But among the obstacles to implementing a health-based nicotine harm reduction strategy is the fact that much of the anti-smoking community in countries like Canada and the US, including major public health bodies, oppose it. The oppositional approach by major public health entities sticks out as an extraordinary anomaly. If one were to search risk reduction options for a very wide range of issues on the website of a leading public health entity such as the US CDC,[41] the autonomy/justice principles associated with public health, and the acceptance of risk reduction as a key component of an effective response, are plainly visible. The importance of risk reduction is readily apparent in the information outlining the benefits of seatbelts, life jackets, condom use, sun protection, and clean needles. But search for ways to reduce the truly horrendous, and almost totally avoidable, risks of smoking cigarettes, and the agency's abstinence-only orientation on tobacco/nicotine manifests itself. In fact, the website gives information on non-combustion alternatives to cigarettes, such as smokeless tobacco[42] and electronic cigarettes,[43] that is much like what we see in other abstinence-only campaigns: overstating risks and uncertainties, and dodging issues of relative risk. Hence, the website is far more likely to mislead than to inform.

This anomaly of how tobacco/nicotine is treated compared to other public health issues is a major impediment to overcoming the zone of incomprehension that stands in the way of measures that could realistically implement one of public health's revolutionary simple ideas. It is also likely a cultural artifact from the behaviour of cigarette companies that caused anti-smoking advocates to coalesce around a "war on tobacco," something

41 Centers for Disease Control and Prevention, online: <www.cdc.gov>.

42 Centers for Disease Control and Prevention, Office on Smoking and Health, "Smokeless Tobacco: Health Effects" (4 November 2014), online: <www.cdc.gov>.

43 Centers for Disease Control and Prevention, Office on Smoking and Health, "Electronic Cigarettes" (26 January 2016), online: <www.cdc.gov>.

that ultimately became an absolutist struggle against "evil." But this approach did not end with the fight against cigarette companies, in the manner that drug harm reduction campaigns, or risk reduction efforts with sex workers, can be tough on traffickers while simultaneously working with those at risk to find pragmatic interventions consistent with principles of autonomy and justice. Smoking itself came to be seen more as a "sin" than a public health issue. Smokers are treated much like fire and brimstone preachers treat sinners; there is a need to repent (feel awful about smoking), and do penance (one must truly struggle to give up smoking), or face perdition (an early and awful death). This culture leads to the seemingly absurd situation where typically socially liberal people working on tobacco control efforts take stances more readily identified with, say, those of religious conservatives on issues of sexual or illicit drug risk reduction. As a result, and very importantly as we look at ways to reduce smoking, the barriers to further reducing the harms of cigarette use thus include the self-limiting range of policy options that are acceptable to the culture of those running the campaigns.[44]

VI. THE REGULATORY BARRIERS TO ACHIEVING A BREAKTHROUGH

A further barrier is the existing regulatory structure for nicotine. In Canada, as elsewhere, since tobacco products predated drug regulation, such products were effectively grandfathered, thus avoiding oversight as drugs. But non-tobacco product-based nicotine comes within drug laws, creating a very uneven playing field.[45] The historical result has been that the less hazardous the form of nicotine delivery, the higher the regulatory burdens.[46]

In Canada, the *Tobacco Act* provides an exemption in section 2 that creates a legal distinction between tobacco products and a nicotine product covered by the *Food and Drugs Act*:

> "*tobacco product*" means a product composed in whole or in part of tobacco, including tobacco leaves and any extract of tobacco leaves. It includes

44 David Sweanor, "A Canadian's Perspective: Limits of Tobacco Regulation" (2008) 34:4 Wm L Rev 1595.

45 Joseph A Page, "Federal Regulation of Tobacco Products and Products that Treat Tobacco Dependence: Are the Playing Fields Level?" (1998) 53 Food & Drug LJ (Supp) 11.

46 Jack E Henningfield & John Slade, "Tobacco-Dependence Medications: Public Health and Regulatory Issues" (1998) 53 Food & Drug LJ (Supp) 75.

> cigarette papers, tubes and filters but does not include any food, drug or device that contains nicotine to which the *Food and Drugs Act* applies.[47]

Health Canada has also taken the position that electronic cigarettes containing nicotine come under the *Food and Drugs Act*, and are therefore illegal unless approved under medical devices regulation.[48] In addition, Health Canada discourages Canadian smokers from using them.[49] This approach to the regulation of potential replacements for cigarettes creates, at best, a confusing situation (those selling vapour products in the now ubiquitous "vape shops" typically claim that their nicotine products are not prohibited under Canadian law).[50] While there have been moves to develop a new regulatory structure, the current regulatory situation deters innovation and market entry by companies that understandably seek legal certainty.[51] It is also indicative of the wider challenge inherent in dealing with new technology that does not fit cleanly into established regulatory systems.

The resulting regulatory uncertainty deters actions that can facilitate making cigarettes obsolete. But an additional barrier to implementing effective measures to replace cigarettes is what are called "red flag rules",[52] named after the 19th century rules that required any motor car to be preceded by someone waving a red flag. The nature of such rules is that new products are held to a higher safety standard than the products they seek to replace, as demonstrated by the much higher regulatory standards placed on medicinal nicotine products,[53] and by the previously noted bans on snus, the Swedish product that has a tiny fraction of the risk associated with cigarette smoking.[54] New safety standards, including proposed FDA regulation in the US that would apply to electronic cigarettes produced

47 *Tobacco Act*, SC 1997, c 12 at s 2. See also, *Food and Drugs Act*, RSC 1985, c F-27.

48 Health Canada, "Notice—To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada", Policy No 09-108446-55 (27 March 2009), online: <www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/pol/notice_avis_e-cig-eng.pdf> [Health Canada, "Notice"].

49 Health Canada, "Health Canada Advises Canadians Not to use Electronic Cigarettes", Advisory RA-110003348 (27 March 2009), online: <www.healthycanadians.gc.ca>.

50 Electronic Cigarette Trade Association of Canada, "Frequently Asked Questions—General", online: <ectaofcanada.com>.

51 House of Commons, Standing Committee on Health, *Vaping: Toward a Regulatory Framework for E-Cigarettes* (March 2015) (Chair: Ben Lobb), online: <www.parl.gc.ca>.

52 Eric Schmidt & Jonathan Rosenberg, *How Google Works* (New York: Grand Central, 2014) at 359.

53 Health Canada, "Notice", *supra* note 48.

54 Foulds et al, *supra* note 22.

after 2007,[55] would not only limit the expansion of electronic cigarette usage, but would also reduce it from current levels, putting at risk the potential of innovative technology to facilitate a public health breakthrough.

VII. ABSTAINING FROM ABSTINENCE POLICIES

The failure to grasp the public health potential of nicotine harm reduction has left tobacco control policies hostage to an abstinence-only agenda. The problem is so acute that even major US governmental health bodies avoid telling the public of the huge differential in risk between smokeless tobacco and cigarettes.[56] Yet there is no question that the differential is extraordinary.[57] The result is the pursuit of a "tobacco free" agenda, rather than a goal of lower rates of death and disease by pursuit of a harm reduction approach. This problem becomes intensified with increasing efforts to define vapour products, which contain no tobacco, as "tobacco products."[58] So long as the goal is to be tobacco free and alternatives to cigarettes are deemed to be tobacco products, the prospects of a harm reduction orientation are dismal.

The result of this situation is, as Allan Brandt identifies in his history of venereal disease, a "persistent tension between a rational, scientific program and a behavioural, moralistic approach."[59] This presents serious obstacles to the implementation of pragmatic strategies. It is also one that, in addition to maintaining a zone of incomprehension about a simple idea to end the epidemic of smoking-caused diseases, actually undermines the

55 US Food and Drug Administration, "Deeming—Extending Authorities to Additional Tobacco Products" (13 October 2015), online: <www.fda.gov> [FDA, "Deeming"].

56 Lynn T Kozlowski & David Sweanor, "Withholding Differential Risk Information on Legal Consumer Nicotine/Tobacco Products: The Public Health Ethics of Health Information Quarantines" (2016) 32 Int J Drug Policy 17.

57 See Kathleen Stratton et al, eds, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* (Washington DC: National Academy Press, 2001) at 39; NL Benowitz, "Smokeless Tobacco as a Nicotine Delivery Device: Harm or Harm Reduction?" (2011) 90:4 Clinical Pharmacology & Therapeutics 491; European Commission, Scientific Committee on Emerging and Newly Identified Health Risks, *Scientific Opinion on the Health Effects of Smokeless Tobacco Products* (European Commission, 2008) at 12; online: <ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf>; and David T Levy et al, "The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts" (2004) 13:12 Cancer Epidemiol Biomarkers Prevention 2035.

58 FDA, "Deeming", *supra* note 55.

59 Brandt, *supra* note 17 at 182.

potential for other complementary strategies for tobacco control.[60] Because of the myriad of challenges faced in getting smokers to simultaneously cease use of cigarettes, tobacco, and nicotine (and to do so forever), we have resorted to policies that seek to force behavioural change without facilitating it. Since measures to prevent onset, facilitate cessation, protect third parties, and reduce risks for continuing users interact much like the four suits of cards in a game of poker, the failure to use all four in the pursuit of public health goals condemns consumers to a much less successful long-term outcome. It is akin to someone deciding to never play spades in a poker game, losing out on not only the potential winning hands with spades alone (for example, a flush), but also of all the other card combinations where spades would act in conjunction with other suits for a winning hand (four of a kind). Where smoking is concerned the stakes are high; adopting such a strategy is literally gambling, against the odds, with human lives.

For instance, Canada's graphic health warnings on cigarette packages are designed to frighten smokers into quitting (as can be readily seen, they are not merely informational).[61] Yet we know from social psychology that, to be effective, fear-based messages need to be combined with "clear, specific, effective means of reducing the danger."[62] In the absence of a policy that offers more viable harm reduction options to those unwilling, or unable, to quit using not only cigarettes, but also any alternative source of nicotine, an otherwise important intervention such as package warnings becomes less effective: "merely painting a gruesome picture of the impact of dangerous behaviours, such as smoking . . . may also be ineffective — or even backfire — if unaccompanied by a good plan of action."[63]

By not using harm reduction as the "fourth leg of the chair" in tobacco control policies, we do more than weaken the impact of information and warnings. We aggravate bigger problems, with recalcitrant smokers continuing to expose others to second-hand smoke, modelling smoking behaviour for youth, and creating more access points for cigarettes.[64] We

60 Sweanor, Alcabes & Drucker, *supra* note 6 at 71.

61 Health Canada, "Health Labels for Cigarettes and Little Cigars" (12 December 2012), online: <www.hc-sc.gc.ca>.

62 Noah J Goldstein, Steve J Martin & Robert B Cialdini, *Yes!: 50 Secrets from the Science of Persuasion* (London: Profile Books, 2007) at 35.

63 *Ibid* at 37.

64 Scott T Leatherdale et al, "Social Influences" in Health Canada, *2002 Youth Smoking Survey Technical Report*, Catalogue No H46-1-44-2002E (Ottawa: Health Canada, 2005) 103 at 104, online: <publications.gc.ca/collections/Collection/H46-1-44-2002E.pdf>.

also economically abuse citizens who are already typically marginalized by increasing tobacco taxes in order to motivate cessation, and then raise the bar too high (by broadly defining cessation to mean the drug rather than merely the harmful delivery system) for them to achieve that goal. This in itself is a violation of public health ethics, where coercive programs should be kept to a minimum and not be used where less autonomy-restricting measures could achieve similar goals.[65] The failure to use cross-elasticities to nudge smokers towards less hazardous alternatives is a particularly important missed opportunity for public health.[66]

VIII. THE ROLE OF ENLIGHTENED HEALTH LAW

There is at least one benefit arising from the delay experienced in addressing the zone of incomprehension on nicotine delivery, and in moving forward on the simple, but incredibly promising issue of health-focused policy reform on nicotine. It has allowed time to evaluate ever increasing examples of health and safety issues involving other topics where the role of appropriate regulatory interventions has been addressed and measures put in place. These precedents can guide efforts on nicotine policy.

Food policy is an obvious place to look. In the 1800s, there was an abstinence-only campaign against manufactured foodstuffs based on moralistic grounds, such as the role of manufactured foodstuffs in allowing urbanization and the perceived associated temptations to engage in sin.[67] Over time, it became clear that manufactured foodstuffs and the urbanization that was creating the demand for such products were not going to go away. At the same time, advancing scientific knowledge allowed for distinguishing degrees of risk of various products, and businesses came to see the opportunity for gaining a marketplace advantage by being recognized as selling safer products. Along with public outrage about the unsanitary conditions of such things as meatpacking plants,[68] and deaths from contaminated or toxic products,[69] the pressure was such that the US (like other countries) started regulating foods. The move in the US

65 Nancy E Kass, "An Ethics Framework for Public Health" (2001) 91:11 American J Public Health 1776.

66 Frank J Chaloupka, David Sweanor & Kenneth E Warner, "Differential Taxes for Differential Risks—Toward Reduced Harm for Nicotine Yielding Products" (2015) 373:7 New England J Medicine 594 at 595–96.

67 Young, *supra* note 13.

68 Upton Sinclair, *The Jungle* (Mineola, NY: Dover Publications, 2001).

69 Young, *supra* note 13.

towards science-based pharmaceuticals as a replacement for the exceedingly lucrative snake-oil market was again facilitated by a combination of advances in science and public outrage about deadly products such as sulfanilamide, resulting in comprehensive legislation in 1938.[70] This new regulatory framework created significant incentives to create and market products that were far safer and more effective than those existing at the time. The incentive was such that, "[i]n the 1920s the top two hundred drug companies in the United States had only a few thousand scientists on staff, and most of those concerned themselves with the processing of chemicals. But by the 1940s, there were 58,000 scientists in the industry engaged specifically in research."[71]

The drugs business was forced to adapt to the new reality of regulations that created a huge market for a fundamentally different type of product. It was not a matter of using less hazardous products as "gateways" to the old standbys, but a matter of a regulation-altered competitive landscape that fundamentally and rapidly changed the marketplace, as "[b]y the early 1950s, 90 percent of the prescriptions filled by patients were for drugs that did not even exist in 1938. And with the drugs came sharp drops in suffering and death."[72]

This process has been replicated in a myriad of policy areas, including the implementation of auto safety measures that, among other things, started to focus on reducing the risk inherent in the actual product rather than blaming individual behaviour,[73] and the tackling of diseases, such as HIV/AIDS, through regulatory change driven by science rather than moralistic admonitions to those at risk.[74] At a time when even the War on Drugs appears to be giving way to rational legal interventions aimed at the reduction of harm,[75] it is completely absurd to abandon tens of thousands of Canadians every year to a premature death simply due to a failure to bring

70 See James Harvey Young, *Toadstool Millionaires: A Social History of Patent Medicines in America Before Federal Regulation* (Princeton: Princeton University Press, 1961); Brock, *Charlatan*, *supra* note 15; and Hilts, *Protecting America's Health*, *supra* note 14 at 89.

71 Hilts, *supra* note 14 at 93.

72 *Ibid* at 105.

73 Roger White, "Auto Safety History", *National Museum of American History*, online: <amhistory.si.edu>.

74 Jonathan Engel, *The Epidemic: A Global History of AIDS* (New York: Smithsonian Books, 2006).

75 See e.g. *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44 at para 1, [2011] 3 SCR 134.

forward health-focused, regulatory policies concerning nicotine delivery products.

Regulatory measures could transform the nicotine market at a pace, and to a degree, surpassing the experience with food, pharmaceuticals, fuel, and automobiles. Indeed, it could possibly match the health gains from vaccinations[76] and access to clean water.[77] From a risk reduction perspective, it should handily eclipse the gains from improving safety standards for electrical goods, air travel, children's sleepwear, alcoholic beverages, industrial machinery, and a vast range of other products. The enormous potential for harm reduction in the realm of nicotine includes: the existence of viable alternative products; the ability to incentivize markets to deliver ever better alternatives to cigarettes; the transformation being self-financing (those at risk are already buying cigarettes, and typically for a much higher price than the safer alternatives); the extraordinarily large differential in risk between products;[78] and smokers already being receptive to quitting smoking (7 out of 10 US smokers say they want to quit,[79] and over 60% of Canadian smokers say they intend to within six months).[80] What keeps people smoking cigarettes is not the nicotine addiction, genetic predispositions, self-medication, or even the simple enjoyment of nicotine. It is, rather, a marketplace where regulatory policy has led to an absence of viable alternatives to cigarettes.

Policies ensuring consumers have access to alternatives, know the differentials in risk between these products, have price incentives to switch,[81] and could access less harmful products more readily than the deadly ones, would start to transform the market. Further constraints on the ability to market the lethal combustible products would assist this transformation, as would measures that make it more profitable to manufacture less toxic alternatives to cigarettes.[82] Naturally, these policies could be accompanied

76 Arthur Allen, *Vaccine: The Controversial Story of Medicine's Greatest Lifesaver* (New York: W W Norton & Company, 2007).

77 Rose George, *The Big Necessity: The Unmentionable World of Human Waste and Why it Matters* (New York: Metropolitan Books, 2008) at 72.

78 Royal College of Physicians, "The Risk Profile of Smokeless Tobaccos" in *Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit* (London: RCP, 2007) at 129.

79 Centers for Disease Control and Prevention, Office of Smoking and Health, "Quitting Smoking" (21 May 2015), online: <www.cdc.gov>.

80 Canadian Cancer Society, "Tobacco Facts", *Smoker's Helpline*, online: <quit.smokershelpline.ca>.

81 Chaloupka, Sweanor & Warner, *supra* note 66.

82 Anna B Gilmore, J Robert Branston & David Sweanor, "The Case for OFSMOKE: How Tobacco Price Regulation is Needed to Promote the Health of Markets, Government Rev-

by measures to discourage youth uptake of new products, and to raise product standards for alternatives as the market develops. There could also be an emphasis on segmenting the current nicotine market, since there are many different reasons people currently smoke. Seeking to find a range of better options for those currently using cigarettes for differing reasons could become a priority. For instance, for many of those who are currently self-medicating through smoking, there is potential for entirely different consumer or pharmaceutical products that better meet their needs with massively lower risk—products that, as happened with pharmaceuticals in the US in the 1940s, will be incentivized to come to market once laws are changed to facilitate such developments.

This transformation of the nicotine market to drastically reduce and potentially eliminate cigarette smoking has enormous potential to be one of the greatest ever public health breakthroughs. As with so many such breakthroughs, it is a simple idea, one that has been stymied to date by a zone of incomprehension. But with attention now focused on the potential of technology, such as electronic nicotine delivery systems, the time is right for some creative thinking on regulation to better meet public health goals. As has been seen with other products, the transformation can be swift. It is simply a matter of legal reform measures that allow this potential to be realized, to subsequently tailor the regulations as the market transforms, and to reap the benefits of saving 1 billion lives in the next century. We have known for over fifty years that cigarette smoking causes an epidemic of disease and death, and have known for most of that time that it is not the nicotine, but the smoke, that is killing consumers. Those who need to take action are not the health professionals who have already identified the simple idea of rethinking nicotine, but the lawyers who must craft regulatory interventions to put this idea into practice.

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enue and the Public" (2010) 19:15 Tobacco Control 423; and J Robert Branston & David Sweanor, "Big Tobacco, E-Cigarettes and the Road to the Smoking Endgame" (2016) 29 Int J Drug Policy 14 at 15.