

# Whither tobacco product regulation?

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## ABSTRACT

Despite decades of industry innovation and regulatory efforts, the harmfulness of conventional cigarettes has not changed. There are several pitfalls in this area, including the long time lag before health impacts of product regulatory changes become apparent, the danger of consumers deriving false reassurance of lesser harm in the interim period, the lack of relevant expertise and the lack of an internationally agreed and evidence-based strategic approach. Articles 9 and 10 of the Framework Convention on Tobacco Control provide the potential for such a global strategy, and knowledge and research has increased significantly over recent years. However, there are huge opportunity costs in implementing product disclosure and regulatory strategies: most national regulators have very limited human and financial resources, which should be focused on other evidence-based tobacco control interventions. We believe therefore that it is now time to abandon the notion of safe or safer cigarettes while moving consumers towards cleaner nicotine products as soon as possible. In parallel to this, we recommend a number of other strategies be implemented including: reducing the appeal of all tobacco products, forbidding new tobacco products or brand variants being marketed without evidence of reduced harm, appeal or addictiveness, and developing a tobacco industry resourced, but industry independent, Framework Convention on Tobacco Control global repository to assist national regulators in understanding and regulating the products on their markets.

## INTRODUCTION

Product regulation is the most complex and under-developed area of tobacco control, yet with 1 billion tobacco users worldwide, it could hold the key to rapid reductions in the mortality and morbidity wreaked by continuing tobacco use. The complexity arises because little is known outside the tobacco industry about the technologies and formulae involved in making individual products. What is established is that cigarettes are highly engineered and sophisticated products designed to give fingertip control of nicotine intake while masking unpleasant tastes and aromas; however, even crudely manufactured tobacco products, such as hand-rolled cigarettes, are widely used and highly addictive. All tobacco products are deadly but their harmfulness ranges dramatically. Nicotine is the key dependence-inducing component, but other attributes of tobacco and tobacco smoke play an important role in continued use<sup>1</sup>; indeed many tobacco users have not shown much willingness to switch to much less harmful nicotine products (although a policy to encourage such switching has not yet been rigorously pursued by any government).

The key form of product regulation adopted for cigarettes in the last 50 years was the reduction of machine-based emission yields of smoke constituents (the 'tar reduction' strategy) achieved through filter ventilation. Despite evidence that machine yields of 'light' cigarettes did not reflect smokers' exposure,<sup>2</sup> regulations to reduce machine-based yields and associated information on packs remain stubbornly in place in many areas of the world. This inertia may reflect, among other things, difficulties in overturning ineffective legislation, the lack of an agreed alternative strategy and/or the tobacco industry's influence on policymakers to maintain ineffective regulations. However, the WHO's Framework Convention on Tobacco Control (FCTC) has given cause for renewed optimism. Articles 9 and 10 of the FCTC focus on product testing, measurement, regulation and disclosure<sup>3</sup> and in November 2010 partial guidelines for these Articles were adopted at the Fourth Conference of the Parties.<sup>4</sup> A new regulatory framework has also emerged in the USA, one of the few countries with the technical capacity and resources to undertake comprehensive regulation. In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the US Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution and marketing of tobacco products to protect public health and this has already led to a number of actions being taken.

This paper critiques past and present efforts to regulate tobacco products and makes recommendations for the future. Although tobacco product regulations are inextricably linked to product packaging and promotion, these aspects are covered in other papers in this issue and will not be discussed in detail here, although the implications of these important linkages will be briefly highlighted.

## TYPES OF REGULATION

Table 1 summarises extant product regulatory strategies for tobacco products, and we outline below a brief summary of the key strategies.

### Combustible tobacco products

No clear differences in risk have yet been demonstrated across the range of popular combustible products, but the harmfulness of pipes and cigars appears to vary according to the degree of inhalation (eg, Rodriguez *et al*<sup>5</sup>). Most regulatory strategies in this area have focused on manufactured cigarettes, given that they are the most prevalent form of tobacco use worldwide and responsible for most of the deaths caused by tobacco use, rather than other combustible products, some of which are growing in popularity (such as hand-rolled cigarettes, cigars, pipes, waterpipes, kreteks, bidis, etc).

**Table 1** Key extant product regulatory strategies

Type of regulation	Countries implementing regulations	Example of regulation	Reference
<b>Regulation of harm and toxicity</b>			
Emission limits	For example, European Union countries, Australia, Singapore	European Union: since January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than 10 mg per cigarette for tar, 1 mg per cigarette for nicotine, 10 mg per cigarette for carbon monoxide under the ISO smoking regimen. These tar limits represent further reductions of 15 mg per cigarette implemented in 1992 and 12 mg per cigarette implemented in 1997.	Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001. <a href="http://europa.eu/legislation_summaries/public_health/health_determinants_lifestyle/c11567_en.htm">http://europa.eu/legislation_summaries/public_health/health_determinants_lifestyle/c11567_en.htm</a> (accessed 23 April 2011).
Reduced ignition propensity	For example Canada, US States, Australia	Australia: 23 March 2010: the date from which the mandatory standard applied to all cigarettes manufactured in, or imported into, Australia; 23 September 2010: the date from which the mandatory standard applied to all cigarettes supplied in Australia, no matter when or where they were manufactured or when they were imported into Australia	Australian Competition and Consumer Commission. Product Safety Australia: Mandatory standard—Reduced fire risk cigarettes. <a href="http://www.productsafety.gov.au/content/index.phtml/itemId/974720/fromItemId/974709">http://www.productsafety.gov.au/content/index.phtml/itemId/974720/fromItemId/974709</a> (accessed 23 April 2011).
Product bans	For example Australia, New Zealand, European Union	New Zealand: chewing tobacco imported for sale that is labelled or otherwise described as suitable for chewing or for any other oral use (other than smoking)	Smoke Free Environments Act 1990. <a href="http://www.legislation.govt.nz/act/public/1990/0108/latest/DLM223191.html">http://www.legislation.govt.nz/act/public/1990/0108/latest/DLM223191.html</a> (accessed 23 April 2011).
Product toxin controls	For example Sweden	Sweden: the tobacco company, Swedish Match, has developed limits for certain toxins in tobacco products, and this is referred to as the Gothiatek Standards	Gothiatek standards. <a href="http://www.swedishmatch.com/en/Snus-and-health/Our-quality-standard-GothiaTek/GothiaTek-standards/">http://www.swedishmatch.com/en/Snus-and-health/Our-quality-standard-GothiaTek/GothiaTek-standards/</a> (accessed 23 April 2011).
<b>Regulation of attractiveness</b>			
Restrictions/bans on additives and ingredients	For example Canada, US, Australia, Thailand, France, Singapore, Lithuania	Canada: as of July 2010, Canada prohibited additives with flavouring properties or that enhance flavour, with the exception of menthol. Other additives, including caffeine and vitamins, are also prohibited.	Department of Justice, Canada. Cracking Down on Tobacco Marketing Aimed at Youth Act. <a href="http://laws-lois.justice.gc.ca/PDF/2009_27.pdf">http://laws-lois.justice.gc.ca/PDF/2009_27.pdf</a>
<b>Regulation of addictiveness</b>			
Testing and disclosure	No countries have yet implemented laws in this area For example, Canada, Brazil, Australia, Thailand, USA, Venezuela, New Zealand	Canada: disclosure of 26 chemical constituents in whole tobacco, tobacco weight, pH and 41 smoke emissions using the ISO and Health Canada smoking regimens for every brand sold in Canada with more than 1% market share. Manufacturers and importers must also conduct and report on three toxicity tests. Finally, every manufacturer of a consumer tobacco product shall report annually on each research activity that was undertaken, continued or completed during a year by or on behalf of the manufacturer in respect of that consumer tobacco product, including, but not limited to, research regarding: (a) toxicity, (b) health effects, (c) ingredients, (d) taste and flavour, (e) modification, (f) marketing and (g) the manner in which it is used by consumers.	Health Canada. Tobacco reporting regulations: <a href="http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/reg/indust/index-eng.php">http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/reg/indust/index-eng.php</a> (accessed 18 April 2010).

ISO, International Organization for Standardization.

### Reducing harm and toxicity

The tar reduction strategy arose in the 1960s and 1970s in the UK and USA when knowledge of smoking behaviour and the chemical characteristics of smoke was in its infancy. Initially through voluntary agreements with the tobacco industry, and later through legislative approaches in a number of different countries, maximum yields were set for tar emissions from cigarettes and, subsequently, nicotine and carbon monoxide. The failure of this approach and its manipulation by the tobacco industry has been widely documented elsewhere (eg, the report by the Royal College of Physicians<sup>6</sup>) so will not be covered in

detail here. In short, the maximum yields were set using cigarette smoking machines and products were altered, predominantly by putting ventilation holes in the filter, to dilute the smoke. Humans compensated for the reduced delivery of the cigarettes by changing the way they smoked, including covering the holes.<sup>2</sup> Levels of human exposure were therefore very similar across different yields of cigarettes and studies have failed to show any health benefits of smoking lower-yielding cigarettes.<sup>6,7</sup> Nevertheless, the tar reduction strategy was a marketing success in that the market share of lower-yielding cigarettes increased markedly in most jurisdictions worldwide. This was partly due

to very high-yielding products being taken off the market but also due to a very successful marketing strategy by the tobacco industry, using branding such as 'light' and 'mild' and colours to mislead consumers that there was a genuine advantage to health in smoking the lower-tar-yield products.

Other industry innovations to reduce harm include charcoal filters, which are common in markets such as Japan, Venezuela and South Korea. These significantly reduce some toxic gas-phase emissions in cigarette smoke, and have been postulated as one of the reasons for the lower lung cancer rates of Japanese smokers (eg, Muscat *et al*<sup>8</sup>). Such filters also affect the flavour of cigarette smoke, which may explain why they have not become more prevalent. It is not yet known whether the emission reductions translate into reduced human exposure and disease risk.

The tobacco market is a dynamic one with new products and brands being introduced regularly; for example, in the UK the number of new brands of manufactured cigarettes increased by 168% over a 10-year period between 1998 and 2008<sup>9</sup> and in the USA, an estimated 233 new products were introduced in 2008.<sup>10</sup> In the USA, manufacturers of new or modified tobacco products are now required to submit a premarket application and obtain a market authorisation order before they can market new products.<sup>11</sup> This is a useful attempt at regulation, primarily because it would allow for regulatory scrutiny prior to the product being introduced to the market and prior to consumer use. To some extent, this system also compels the regulatory agency to establish criteria for review and regulatory approval. A potential weakness of this approach is that nothing is required of manufacturers of products for which they can claim 'substantial equivalence' to ones that are already on the market. This would appear to allow further expansion of product variants and be a disincentive against producing reduced risk products. In addition, premarket regulatory approval might be perceived as regulatory 'approval' for tobacco products and may even have implications for regulatory liability.

The tobacco industry has also developed a number of putatively reduced harm cigarettes and cigarette-like devices, such as those that heat rather than burn tobacco, some of which have been referred to as potential reduced exposure products (PREPs).<sup>12</sup> Although some can result in reduced levels of key biomarkers, (eg, Breland *et al*<sup>13</sup>) they have not been demonstrated to significantly reduce the disease burden or addictive potential in comparison to usual cigarettes. Overall, these products have been market failures,<sup>14</sup> with low levels of public awareness.<sup>15</sup>

### Reduced ignition propensity cigarettes

A strategy gaining momentum worldwide at the behest of regulators is the development of reduced ignition propensity (RIP) cigarettes designed to reduce the fire hazard caused by smouldering cigarettes. In 2005, Canada became the first country to require RIP cigarettes following the adoption of a minimal fire safety standard in the state of New York in the USA. Ignition propensity can be reduced in a number of ways and tests have shown that RIP cigarettes are significantly less likely to cause fires if left unattended.<sup>16</sup> No formal evaluation has yet been undertaken but preliminary data from New York and other states indicated a reduction in the incidence of fires.<sup>17</sup> While the tobacco industry protested for many years that RIP cigarettes could either not be developed or be acceptable to consumers,<sup>18</sup> compliance has been high. The WHO Tobacco Product Regulation Study Group (WHO TobReg) has recommended that RIP cigarettes be made mandatory.<sup>18</sup>

### Performance standards for cigarettes

WHO TobReg has also recommended that a new machine smoking regimen be agreed for cigarettes which would give a better characterisation of cigarette smoke and that this should be used to set product performance standards for cigarettes.<sup>18</sup> The group has suggested setting limits for eight constituents per mg of nicotine in tobacco smoke emissions<sup>18</sup>; these compounds were selected based on known toxicity, variation in concentration across brands, the potential for the toxin to be reduced in cigarette smoke using existing methodologies, and the need to have constituents that represented gas and particulate phases of smoke and different chemical and disease families. While tying the emission reductions to nicotine delivery should reduce compensation, it is unknown whether reducing or removing individual known toxins in cigarettes will produce marked reductions in smoking related diseases.<sup>19</sup>

### Reducing attractiveness

Attractiveness has been defined simply as the stimulation to use a product<sup>20</sup> and hence the public health rationale for this approach is to reduce the consumer appeal of tobacco products which in turn could reduce youth uptake, repeat usage or facilitate cessation. In the last few years, steps have been taken to remove some types of flavoured cigarettes (table 1), but menthol is currently excluded from such laws. An expert scientific advisory committee in the USA has reported that removing menthol cigarettes from the market would benefit public health<sup>21</sup> and the FDA is currently considering what action, if any, to take in response to this report. The partial guidelines for Articles 9 and 10 recommend the prohibition or restriction of several types of ingredients (table 1). The introduction of plain packaging, given the appeal of branded cigarettes, is also likely to have an impact on reducing the attractiveness of cigarettes, particularly to children.

### Reducing nicotine dependence/abuse liability

Relatively little focus has been given to this area of regulation. There are criteria for assessing addictiveness (or misuse liability) in animals, but not currently in humans<sup>20</sup> although recent reviews have identified processes for doing this.<sup>22–23</sup> The addictiveness of tobacco products is linked to the dose and speed of nicotine delivery and it has been suggested that tobacco products can be made less addictive and possibly 'non-addictive' by reducing the nicotine content of cigarettes (ie, the amount of nicotine contained in the tobacco itself).<sup>24</sup> This strategy merits further research as tobacco companies have explored nicotine thresholds,<sup>25</sup> and it may be an easier strategy to adopt than one aimed at reducing harm. However, we believe that there is currently insufficient evidence and experience with this approach given the substantial risks of adopting such a strategy: concerns remain about compensatory smoking; nicotine has been shown to exert effects at relatively low levels and there is likely to be individual variability in any nicotine 'threshold' level of addictiveness; and the lure of black market cigarettes having higher nicotine levels.<sup>24–26–27</sup> Notably, cigarettes such as Vector Tobacco's QUEST that have used genetically modified tobacco which is nicotine free, have not proved to be popular.

Regulating substances in tobacco other than nicotine could also reduce the addictiveness of cigarettes.<sup>1</sup> Whereas individual additives have not yet been identified as addictive, additives could give rise to other addictive substances, or impact on pH or ease of inhalation and thereby indirectly enhance addiction.<sup>20</sup> Some cigarettes are already marketed by the industry as 100%

additive free, but there is no evidence to suggest that these are less harmful or addictive than traditional cigarettes.

### Non-combustible tobacco products

The regulation of non-combustible tobacco products is more variable between countries than combustibles, including outright bans for some product categories and voluntary controls on toxin constituents (table 1). The FCTC partial guidelines for Articles 9 and 10, governing the regulation of ingredients and flavours, apply to all tobacco products and so include smokeless tobacco.

Non-combustible tobacco covers a heterogeneous array of products, such as chewing tobacco and oral snuff. Product innovation is also common in the non-combustible tobacco market, with a plethora of new brands and products being recently launched, often bearing well known cigarette brand names, such as Camel Orbs, sticks and strips. Non-combustible tobacco products vary greatly in their manufacture and content and there is good evidence of differences in health outcomes resulting from the use of different products.<sup>28</sup> It is believed that quantities of two main carcinogens, tobacco specific *N*-nitrosamines (TSNAs) and polycyclic aromatic hydrocarbons (PAHs) are responsible for the differences in health outcomes across smokeless tobacco products.<sup>29–30</sup> WHO TobReg has proposed specific limits for the concentration of three toxins in the dry weight of tobacco in smokeless products<sup>31</sup> and suggested that regulatory efforts be focused initially on the larger manufacturers, but with a parallel process to educate smaller cottage industries how to manufacture and store compliant products. We support this strategy.

Regulating non-combustible tobacco to reduce the concentrations of the most harmful toxins could also improve the potential for harm reduction if smokers can be encouraged to switch from cigarettes to smokeless products. Evidence from Sweden clearly shows how the use of snus (a low nitrosamine oral snuff product) instead of cigarettes can lead to lower overall harm, reduced initiation and increased cessation of cigarettes.<sup>32</sup>

### LESSONS LEARNT AND ISSUES UNDER DEBATE

Overall, the above examples illustrate different approaches to tobacco product regulation being adopted worldwide, often driven by the tobacco industry with no regulatory oversight. The lack of a clear, regulator-led internationally agreed and articulated strategy is apparent, unlike in other areas of tobacco control, but the adoption of partial guidelines for Articles 9 and 10 of the FCTC now paves the way for the development of such a global strategy.

### Misrepresentation of risks

A key lesson from early product regulatory efforts is the potential dangers of any tobacco marketing and communications of altered tobacco products that can falsely reassure and lead to continued tobacco use. A clear distinction therefore needs to be made between any changes made to products and communicating these changes to consumers. To enable this to happen, all marketing of tobacco products should be prohibited to ensure that only regulators communicate with tobacco users about differential risks and avoid the industry misusing regulation to promote their products. Given the evidence that pack imagery, colours and design suggest differential risks to consumers, and can increase appeal of tobacco products and smoking (eg, Hammond *et al*<sup>33</sup>), we also believe that plain packaging should be urgently introduced across all tobacco products.

### Measuring impact

Another key lesson from the 'tar reduction' strategy was that the public health community was slow to recognise the limitations of the approach despite early evidence that filter venting was an ineffective method of reducing exposure to smokers.<sup>2</sup> Hence, it took some time to realise that the health benefits were not forthcoming. This underscores the dangers involved in all product regulatory approaches aimed at reducing harm to users, as diseases caused by tobacco use can take up to two decades to develop, an issue not affecting other tobacco control strategies that are aimed at either reducing initiation or increasing cessation (and hence have more easily measureable outcomes over relatively short timescales). Biomarkers are measures of exposure to different elements of tobacco or tobacco smoke, or precursors of disease, and these can be tracked over time or compared across different tobacco products, hence offering quicker feedback as indicators of reduced harm. A recent review<sup>34</sup> concluded that biomarker testing in large studies of smokers is now feasible and should be prioritised, enabling, over a few decades, the identification of the best biomarkers to use as interim measures to predict tobacco-related disease. Ultimately, the selected biomarkers could then be used to test the introduction of PREPs or modified tobacco products. Given the costs of introducing such biomarker testing and the large numbers of tobacco users needed, this approach is likely to exceed the resources available in most countries.

### Measurement, monitoring and evaluation

An adequate surveillance and feedback system is required to enable regulators to monitor the impact of tobacco products on prevalence, initiation, harm and particularly unintended outcomes.<sup>35</sup> Before such a system can function, mandatory reporting regulations for all nicotine and tobacco products on the market are necessary as adopted by Canada (table 1) and set out in Articles 9 and 10. Mandatory reporting should include design components (eg, filter ventilation level, paper porosity, etc), tobacco constituents, emissions for combustible products, as well as measures of abuse liability.

Such regulations, however, require substantial investment of human and financial resources even where the financial costs are borne by the tobacco industry (as recommended in the guidelines for Articles 9 and 10). As regulatory capacity for tobacco is very limited in the vast majority of countries worldwide, we are concerned that tobacco product regulation has enormous opportunity costs and could detract from implementing other evidence-based tobacco control strategies. Regulatory capture by the tobacco industry is also a risk. The complexity of tobacco products also requires knowledge and skills ranging across toxicology, pharmacology, biochemistry, psychology and behaviour change; the long history of denial and deception by the tobacco industry indicates that regulators cannot rely on industry information alone and will need to validate information provided to them. The working group set up for Articles 9 and 10 was asked to consider the development of an independent Global Data Repository to facilitate tobacco product regulation worldwide<sup>36</sup> but it is not clear how or if this will be taken forward. We believe that such a repository is a prerequisite for implementing Articles 9 and 10 and while initially focusing on product data (eg, content, design and emissions), it could be expanded to include other data (such as toxicity and sales data) and underpin other FCTC Articles. The repository would ease the burden on regulators as data would be collected and analysed, enabling comparisons to be made globally; information would then be relayed to national regulators with



recommendations in an easily understandable form. This could build on existing research and templates<sup>37–39</sup> and incorporate the comprehensive testing programme set out in a recent review.<sup>40</sup>

### The challenge of reducing the risk of cigarettes

Making combustible tobacco products less harmful is not straightforward because the relationships among unburnt content, the products of pyrolysis and toxicant exposure are not well established. Given that tobacco smoke consists of over 4000 constituents, with 60 of these known carcinogens, care needs to be taken to ensure that decreasing the content of 1 or more carcinogens does not increase the concentration of other carcinogens in the smoke. For these reasons, we are cautious about strategies to limit specific toxic emissions for cigarette smoke.

Instead, some strategies to reduce the attractiveness of cigarettes could have a more marked effect on public health and be introduced relatively easily, the most obvious one being the introduction of generic packaging. Strategies to reduce the addictiveness of cigarettes are currently in their infancy.

### The importance of coregulation

Focusing on the much greater differential risks among classes of tobacco and nicotine products, such as among smoked tobacco, smokeless tobacco and medicinal nicotine products, is likely to be a more promising strategy.<sup>41–43</sup> However, the wide range of harms across the non-combustible tobacco products and the long history of deception and aggressive marketing strategies of the tobacco industry have led to deep distrust by many in the tobacco control movement. There has therefore been reluctance to acknowledge the differential health risks<sup>44</sup> and the role that regulated smokeless tobacco products could play in a harm reduction strategy.<sup>45</sup> This has been an area of much divisive debate among tobacco control advocates and as a result regulatory strategies have rarely looked across all tobacco products and developed regulations commensurate to differential harmfulness.

The plethora of nicotine and tobacco products now being marketed does, however, suggest that serious consideration could now be given to prohibiting combustible tobacco over a specified time period,<sup>27</sup> perhaps by capping smoked tobacco<sup>46–47</sup> while incentivising cleaner nicotine products<sup>42–43</sup> (and possibly highly regulated smokeless tobacco products<sup>47</sup>). Premarket applications should therefore only be given to tobacco products that demonstrate reduced risk, appeal, or addictiveness for which global standards should ultimately be set through the FCTC processes. While non-tobacco products are outside the scope of this paper, we believe that they hold much greater potential for harm reduction than those involving tobacco, as witnessed by the rapid increase in public interest in electronic cigarettes.<sup>48</sup> Regulators in the UK and New Zealand are beginning to look at nicotine products and appropriate regulations for them.<sup>49</sup> Such a strategy raises ethical dilemmas including whether the use of clean but addictive nicotine products would be an acceptable end point. Tobacco control advocates need to engage actively with consumers as the voice of the consumer has often been appropriated by the tobacco and other industries (eg, FOREST<sup>50</sup>).

In addition to product regulation, regulation of the whole tobacco and nicotine industry should be considered (eg, Sugarman, Hall and Gartner and Borland<sup>46–47–51</sup>). However, as yet no country has seriously considered this. Following examples from other areas, such as the use of leaded petrol or medicines,

manufacturers are unlikely to introduce meaningful steps to make their products less harmful without goals and targets being set for the whole industry.

### CONCLUSIONS AND NEXT STEPS

Cigarettes are the most prevalent and deadly form of tobacco use worldwide and it is not yet known if and how they can be made significantly less harmful. Any reductions in health risk from regulating cigarettes are likely to be small and will take a long time to achieve. We believe that the time has come to abandon the notion of safe or safer cigarettes. Tobacco product regulation has huge opportunity costs and given the range of harms across the nicotine and tobacco product spectrum, we believe a better strategy for regulators is to assess the feasibility of setting a goal to end the sale of combustible tobacco use over a given period of time<sup>24</sup> and move customers towards less harmful nicotine products as soon as possible. While smokeless tobacco products could be used for those who will not stop smoking or switch to clean nicotine products, we believe that there is no appetite for any sort of promotion of smokeless tobacco products currently in the public health community given the divisions in opinion on this issue, but research and debate on this should continue. Regulations that would remove or dramatically alter conventional cigarettes or other widely used tobacco products may also have implications for contraband tobacco, although this would largely depend upon the jurisdiction and the scope of the regulatory change.

The removal of combustible tobacco products should be done in parallel with efforts to: restrict attractiveness of all tobacco products (eg, introducing generic packaging); forbid all marketing of tobacco products to ensure that only regulators communicate with tobacco users about relative risks; introduce toxin limits for smokeless tobacco products; forbid the introduction of any new, or changes to existing, products without prior notification and demonstrable reduction in harm, attractiveness and/or addictiveness; forbid the introduction of new combustible products which are 'substantially equivalent'; and introduce a global, tobacco industry resourced but industry

### What this paper adds

- There are many pitfalls involved in tobacco product regulation including the long time lag before health impacts become apparent, the danger of consumers deriving false health reassurances and the opportunity costs of implementing resource-intensive product regulatory strategies.
- The goal of producing safer cigarettes should be abandoned and instead regulators should set a goal over a period of time to end the sale of combustible tobacco and consider a comprehensive nicotine regulation strategy that moves smokers who cannot or will not quit towards less harmful nicotine products as quickly as possible.
- Product regulation should reduce the appeal of tobacco products and prevent new tobacco products/brand variants from being marketed without evidence of reduced harm, appeal or addictiveness.
- An independent, but industry resourced, global repository should be set up to assist national regulators in understanding and regulating the products on their markets.

independent, FCTC data repository to guide international strategy in this area.

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## REFERENCES

- Balfour DJ. The neuronal pathways mediating the behavioural and addictive properties of nicotine. *Handb Exp Pharmacol* 2009;**192**:209–33.
- Kozłowski LT, Frecker RC, Khoury V, et al. The misuse of 'less-hazardous' cigarettes and its detection: hole-blocking of ventilated filters. *Am J Public Health* 1980;**70**:1202–3.
- WHO Framework Convention on Tobacco Control. Geneva: World Health Organization, 2005.
- Conference of the Parties to the WHO Framework Convention on Tobacco Control. Draft guidelines for the implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control. Agenda Item 5.2. FCTC/COP/4/6Rev.1. Uruguay, 2010.
- Rodriguez J, Jiang R, Johnson WC, et al. The association of pipe and cigar use with cotinine levels, lung function, and airflow obstruction: a cross-sectional study. *Ann Intern Med* 2010;**152**:201–10.
- Royal College of Physicians of London. Nicotine Addiction in Britain. A report of the Tobacco Advisory Group of the Royal College of Physicians. London: Royal College of Physicians of London, 2000.
- National Cancer Institute. Risks associated with smoking cigarettes with low machine-measured yields of tar and nicotine. *Smoking and Tobacco Control Monograph 13*. Bethesda, MD: National Cancer Institute, 2001.
- Muscat JE, Takezaki T, Tajima K, et al. Charcoal cigarette filters and lung cancer risk in Aichi Prefecture, Japan. *Cancer Sci* 2005;**96**:283–7.
- Action on Smoking or Health. Briefing on Plain Packaging. 2010. [http://www.ash.org.uk/files/documents/ASH\\_699.pdf](http://www.ash.org.uk/files/documents/ASH_699.pdf) (accessed 22 Apr 2010).
- US Department of Health and Human Services, Food and Drug Administration. AFR Parts 16 and 1107. Docket No. FDA-2010-N-0646. Document issued on 5 January 2011. <http://www.fda.gov/downloads/TobaccoProducts/ResourcessforYou/ForIndustry/UCM238885.pdf> (accessed 23 Apr 2011).
- US Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Control Products. Guidance for Industry and FDA Staff. Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products. Document issued on 5 January 2011. <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf> (accessed 23 Apr 2011).
- Stratton K, Shetty P, Wallace R, et al, eds. *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*. Washington DC: National Academy Press, 2001.
- Breland AB, Kleykamp BA, Eissenberg T. Clinical laboratory evaluation of potential reduced exposure products for smokers. *Nicotine Tob Res* 2006;**8**:727–38.
- Wayne GF. Potential reduced exposure products (PREPs) in industry trial testimony. *Tobacco Control* 2006;**15**(Suppl 4):iv90–7.
- Bogen K, Biener L, Garrett CA, et al. Surveillance indicators for potential reduced exposure products (PREPs): developing survey items to measure awareness. *Harm Reduct J* 2009;**6**:27.
- American Society for Testing and Materials International ASTM E2187-09. Standard test method for measuring the ignition strength of cigarettes. West Conshohocken, Pennsylvania: ASTM International, revised 2009.
- National Fire Protection Association. *The Smoking-Material Fire Problem*. Massachusetts, 2010. <http://www.nfpa.org/assets/files/PDF/OS.Smoking.pdf> (accessed 22 Apr 2011).
- World Health Organization. *The Scientific Basis of Tobacco Product Regulation: second report of a WHO Study Group*. WHO Technical Report Series, No.951. Switzerland: WHO, 2008.
- Pankow JF, Watanabe KH, Tocalino PL, et al. Calculated cancer risk for conventional and 'potentially reduced exposure product' cigarettes. *Cancer Epidemiol Biomarkers Prev* 2007;**16**:584–92.
- Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). *Addictiveness and Attractiveness of Tobacco Additives*. Brussels: Belgium, Directorate-General for Health and Consumers, European Commission, 2010.
- Tobacco Products Scientific Advisory Committee (TPSAC) of the Centre for Tobacco Products of the Food and Drug Administration. *Report and Recommendations on the Impact of the Use of Menthol in Cigarettes on the Public Health*. 2011. <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf> (accessed 22 Apr 2011).
- Carter LP, Stitzer ML, Henningfield JE, et al. Abuse liability assessment of tobacco products including Potential Reduced Exposure Products (PREPs). *Cancer Epidemiol Biomarkers Prev* 2009;**18**:3241–62.
- Henningfield JE, Hatsukami DK, Zeller M, et al. Conference on abuse liability and appeal of tobacco products: conclusions and recommendations. *Drug Alcohol Depend* 2011;**116**:1–7.
- Hatsukami DK, Perkins KA, Lesage MG, et al. Nicotine reduction revisited: science and future directions. *Tob Control* 2010;**19**:e1–10.
- Panzano VC, Wayne GF, Pickworth WB, et al. Human electroencephalography and the tobacco industry: a review of internal documents. *Tob Control* 2010;**19**:153–9.
- Hatsukami DK, Kotlyar M, Hertsigaard LA, et al. Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation. *Addiction* 2010;**105**:343–55.
- Hall WD, West R. Thinking about the unthinkable: a de facto prohibition on smoked tobacco products. *Addiction* 2008;**103**:873–4.
- International Agency for Research on Cancer (IARC). *Smokeless Tobacco and Some Tobacco-Specific N-Nitrosamines*. Lyon, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Lyon: WHO IAC, Vol 89, 2007.
- Stepanov I, Jensen J, Hatsukami D, et al. New and traditional smokeless tobacco: comparison of toxicant and carcinogen levels. *Nicotine Tob Res* 2008;**10**:1773–82.
- Stepanov I, Villalta PW, Knezevich A, et al. Analysis of 23 polycyclic aromatic hydrocarbons in smokeless tobacco by gas chromatography-mass spectrometry. *Chem Res Toxicol* 2010;**23**:66–73.
- World Health Organization. *The Scientific Basis of Tobacco Product Regulation: third report of a WHO Study Group*. WHO Technical Report Series, No.955. Switzerland: WHO, 2009.
- Foulds JL, Ramstrom L, Burke M, et al. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tob Control* 2003;**12**:349–59.
- Hammond D, Dockrell M, Arnott D, et al. Cigarette pack design and perceptions of risk among UK adults and children. *Eur J Pub Health* 2009;**19**:631–7.
- Hecht SS, Yuan JM, Hatsukami D. Applying tobacco carcinogen and toxicant biomarkers in product regulation and cancer prevention. *Chem Res Toxicol* 2010;**23**:1001–8.
- O'Connor RJ. Postmarketing surveillance for 'modified-risk' tobacco products. *Nicotine Tob Res*. Published Online First: 20 January 2011. doi:10.1093/ntr/ntq243.
- WHO Framework Convention on Tobacco Control. *Elaboration of guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control. Progress report of the working group*. FCTC/COP/3/6. Third Session of the Conference of the Parties. 2008. [http://apps.who.int/gb/fctc/PDF/cop3/FCTC\\_COP3\\_6-en.pdf](http://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_6-en.pdf) (accessed 22 Apr 2011).
- Electronic Model Tobacco Control. *Project by RIVM funded by European Commission*. Rijksinstituut voor Volksgezondheid en Milieu: RIVM. <http://ec.europa.eu/eahc/projects/database.html?prjno=2007312> (accessed 23 Apr 2011).
- O'Connor RJ, Wilkins KJ, Caruso RV, et al. Cigarette characteristic and emission variations across high-, middle- and low-income countries. *Public Health* 2010;**124**:667–74.
- WHO Framework Convention on Tobacco Control. Work in progress in relation to Articles 9 and 10 of the WHO Framework Convention on Tobacco Control. FCTC/COP/4/INF.DOC/2. Fourth Session of the Conference of the Parties. 2010. [http://apps.who.int/gb/fctc/PDF/cop4/FCTC\\_COP4\\_ID2-en.pdf](http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_ID2-en.pdf) (accessed 23 Apr 2011).
- Hatsukami DK, Biener L, Leischow SJ, et al. Tobacco and nicotine product testing. *Nicotine Tob Res*. Published Online First: 6 April 2011. doi:10.1093/ntr/ntq027.
- Kozłowski LT, Strasser AA, Giovino GA, et al. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. *Tob Control* 2001;**10**:201–3.
- Le Houezec J, McNeill A, Britton J. Tobacco, nicotine and harm reduction. *Drug Alcohol Rev* 2011;**30**:119–23.
- Gartner C, Hall W, McNeill A. Harm reduction policies for tobacco. In: Rhodes T, Hedrick D (eds) *Harm Reduction: Evidence, Impacts and Challenges*. Portugal: EMCDDA, 2010.
- Kozłowski LT, O'Connor RJ, Edwards BQ. Some practical points on harm reduction: what to tell your lawmaker and what to tell your brother about Swedish snus. *Tob Control* 2003;**12**:372–3.
- Gartner CE, Hall WD, Chapman S, et al. Should the health community promote smokeless tobacco (snus) as a harm reduction measure? *PLoS Med* 2007;**4**:1703–4.
- Sugarman S. No more business as usual: enticing companies to sharply lower the public health costs of the products they sell. *Public Health* 2009;**123**:275–9.
- Hall W, Gartner C. Supping with the Devil? The role of law in promoting tobacco harm reduction using low nitrosamine smokeless tobacco products. *Public Health* 2009;**123**:287–91.
- Yamin CK, Bittan A, Bates DW. E-Cigarettes: a rapidly growing internet phenomenon. *Ann Intern Med* 2010;**153**:607–9.
- Medicines and Healthcare Products Regulatory Authority (MHRA). *The Regulation of Nicotine Containing Products*. 2011. <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617> (accessed 23 Apr 2011).
- Freedom Organisation for the Right to Enjoy Smoking Tobacco (FOREST). <http://www.forestonline.org/> (accessed 23 Apr 2011).
- Borland R. A strategy for controlling the marketing of tobacco products: a regulated market model. *Tob Control* 2003;**12**:374–82.